



Comparison of clinical performance of i-gel[®] and Baska Mask[®] during laparoscopic cholecystectomy

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Background: The supraglottic airway device is an appropriate alternative to tracheal intubation in laparoscopic surgery. We compared the Baska Mask[®] with i-gel[®] by measuring the oropharyngeal leak pressure (OLP) and hemodynamic and respiratory parameters during laparoscopic cholecystectomy.

Methods: A total of 97 patients were randomly allocated to either i-gel group (n = 49) or Baska Mask group (n = 48). Insertion time, number of insertion attempts, fiber-optic view of the glottis, and OLP were recorded. Heart rate, mean arterial pressure, peak airway pressure (PAP), lung compliance, and perioperative complications were assessed before, during, and after pneumoperitoneum.

Results: There were no significant differences between the two groups regarding demographic data, insertion time, fiber-optic view of the glottis, and the use of airway manipulation. The OLP was higher in the Baska Mask group than in the i-gel group (29.6 ± 6.8 cmH₂O and 26.7 ± 4.5 cmH₂O, respectively; $P = 0.014$). Heart rate, mean arterial pressure, PAP, and lung compliance were not significantly different between the groups. The incidence of perioperative complications was small and not statistically significant.

Conclusions: Both the i-gel and Baska Mask provided a satisfactory airway during laparoscopic cholecystectomy. Compared with the i-gel, the Baska Mask demonstrated a higher OLP.

Keywords: Cholecystectomy; Hemodynamics; Laparoscopy; Laryngeal masks; Lung compliance; Pneumoperitoneum.

Introduction

The supraglottic airway device (SAD) is an appropriate alternative to tracheal intubation because of its advantages such as stable hemodynamics and decreased airway morbidity. It also helps to maintain adequate ventilation in laparoscopic surgery, with increased peak airway pressure (PAP) under general anesthesia [1,2].

The i-gel[®] (Intersurgical Ltd., UK) is widely used for laparoscopic surgeries [1,3–5]. However, the Baska Mask[®] (Logikal Health Products PTY Ltd., Australia), first introduced in 2012, provides more efficient ventilation by automatically inflating the cuff during positive pressure ventilation. The cuff differs from other non-inflatable cuffs in that it is continuous with the cen-

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tral channel of the device. As the pressure increases with positive pressure ventilation, the cuff automatically inflates and provides better oropharyngeal leak pressure (OLP) compared with that provided by existing SADs [6–8]. However, there are only a few studies assessing the effectiveness of the Baska Mask. Therefore, the aim of this prospective randomized study was to compare the Baska Mask with the i-gel for suitability for laparoscopic surgery under general anesthesia with elevated PAP.

We tested our hypothesis that the Baska Mask would have a higher sealing pressure than the i-gel by comparing OLP (the primary outcome measure) between the two SADs in patients undergoing laparoscopic cholecystectomy. Further, we compared respiratory and hemodynamic variables, SAD insertion-related characteristics, and the incidence of postoperative airway complications between the two SADs.

Materials and Methods

This study was conducted on 100 patients, with American Society of Anesthesiologists physical status classification I or II, who underwent elective laparoscopic cholecystectomy under general anesthesia. Patients with a body mass index ≥ 35 , pregnant women, patients with gastroesophageal reflux disease, and patients who were expected to have difficult intubation were excluded from the study. Informed consent was obtained from each patient. After receiving approval from the Institutional Review Board of our hospital (DAUHIRB-18-186), this prospective study was registered at the Korea Clinical Research Information Service (permit number: KCT 0003428).

All patients fasted for 8 h before surgery. Routine monitoring, including electrocardiography, pulse oximetry, and bispectral index (BIS) (Aspect Medical Systems, USA) was initiated upon each patient's arrival at the operating room.

Oxygen (flow rate, 8 L/min) was delivered via a mask to all patients in the supine position. After preoxygenation, target-controlled infusion (TCI) of propofol and remifentanyl, with an effect-site concentration (C_e) of 4 $\mu\text{g/ml}$ and 5 ng/ml, respectively, was started to induce anesthesia using an Orchestra[®] Base Primea device (Fresenius Kabi, France). After the loss of eyelid reflex and a BIS value < 50 were confirmed, a neuromuscular blockade was performed with rocuronium 0.8 mg/kg. The i-gel or Baska Mask was inserted when the train-of-four (TOF) count was zero.

During the operation, the C_e of TCI-propofol was adjusted to maintain a BIS value of 40–60 [9], and the C_e of TCI-remifentanyl was maintained to adjust the mean arterial pressure within the baseline value $\pm 20\%$. Rocuronium 0.15 mg/kg was also administered under peripheral neuromuscular monitoring. At the start of the operation, the following respiratory settings were used: inspired fresh gas at 3 L/min through the circle anesthesia

breathing system, inspired tidal volume preset at 8 ml/kg, and inspiratory/expiratory ratio of 1 : 2. The respiratory rate was adjusted to maintain the end-tidal carbon dioxide (EtCO_2) values at 30–40 cmH_2O [10]. At the end of the surgery, sugammadex was administered to counteract the effect of rocuronium as follows: if the TOF count was 0, sugammadex 4 mg/kg was administered; if the TOF count was 1–4, sugammadex 2 mg/kg was administered.

The sizes of the i-gel and Baska Mask were chosen according to the patient's weight, considering the manufacturer's recommendations. Sizes 3 and 4 i-gel were used for patients weighing 30–60 kg and 50–90 kg, respectively [3]. According to the manufacturer's recommendations, sizes 3 and 4 Baska Masks are suitable for females or small males and average adult males, respectively [11]. However, we judged these criteria to be unclear. Thus, we decided to apply sizes 3 and 4 Baska Masks in patients with 30–60 kg and > 60 kg body weights, respectively.

For inserting the i-gel and Baska Mask, the anesthesiologist opened the patient's mouth using the right thumb and index finger, held the bite block of the device with the left hand, and pushed it past the front teeth toward the hard palate, avoiding the tongue. Especially for the Baska Mask, the anesthesiologist used the extended hand-tab to control the flexion to help negotiate the palato-pharyngeal curve (Fig. 1A). The i-gel and Baska Mask were pushed until a definitive resistance was felt. At this point, the tip of the mask should be located at the upper esophageal opening.

All procedures were performed by a single anesthesiologist who had previously conducted similar studies with more than 30 insertions of the Baska Mask.

Effective ventilation was confirmed by EtCO_2 waveforms and bilateral thoracic movements. In the case of a critical leak because of the absence of effective ventilation after inserting the device, the following manipulations were performed first: pushing and pulling of the device, neck extension and flexion, jaw thrust, and chin lift. If the proper airway was not achieved after these maneuvers, the device was removed and a device with a different size was re-inserted. Endotracheal intubation was performed immediately after insertion failure, which was defined as three or more attempted insertions. The insertion time was defined as the time until the first EtCO_2 waveform appeared on the monitor after proper device insertion.

The OLP was measured before pneumoperitoneum and was determined by adjusting the expiratory valve of the breathing circle to 40 cmH_2O (fixed fresh gas flow, 3 L/min) and recording the pressure when equilibrium was reached [12]. The OLP was defined as the pressure at which audible gas leakage was detected with a stethoscope at the throat site. The flexible fiber-optic scope (external diameter, 3.1 mm; Olympus Optical, Tokyo, Japan) was inserted into the device to observe laryngeal structures

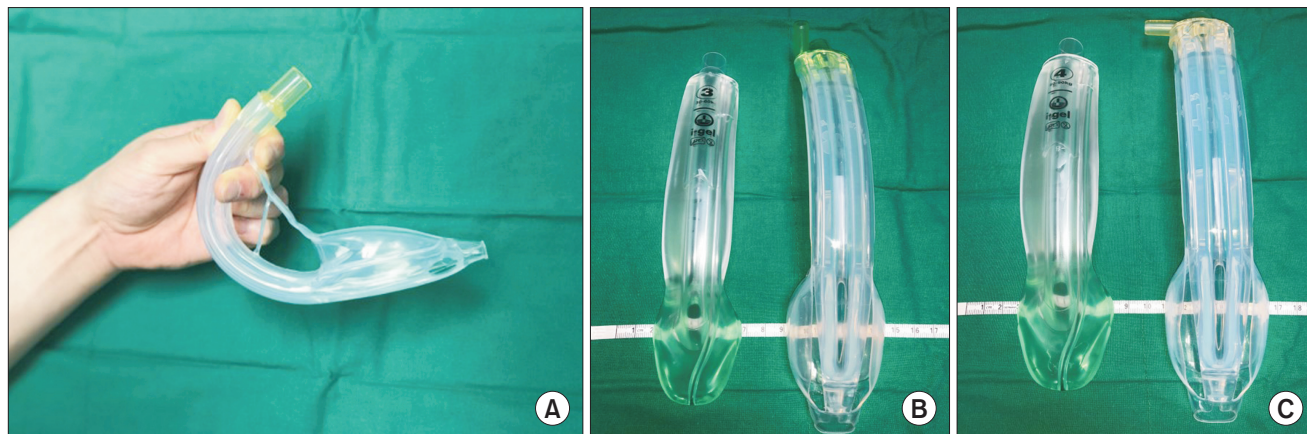


Fig. 1. Appearances of Baska Mask and i-gel. (A) Flexing the Baska Mask using the hand-tab. (B) Circumferences of size 3 of i-gel and Baska Mask were 11.7 cm and 13.8 cm, respectively. (C) Circumferences of size 4 of i-gel and Baska Mask were 13 cm and 14.8 cm, respectively.

such as vocal cords. The fiber-optic view of the glottis was graded according to the following scoring system: 1, vocal cord only; 2, vocal cords plus posterior epiglottis visible; 3, vocal cords plus anterior epiglottis visible; 4, vocal cords not seen [13]. PAP and pulmonary compliance were measured and compared at T0, T1, T2, T3, T4, and T5 (T0, baseline; T1, 1 min after induction; T2, 5 min before CO₂ pneumoperitoneum; T3, 5 min after start of CO₂ pneumoperitoneum; T4, 5 min before removal of pneumoperitoneum; T5, 5 min after removal of pneumoperitoneum) using a spirometer from Primus Dräger anesthesia ventilator (Dräger Medical GmbH, Germany). The leak fraction was calculated using the following formula:

$$\frac{\text{inspiratory tidal volume (VT)} - \text{expiratory VT}}{\text{inspiratory VT}}$$

. The peritoneal insufflation pressure was set at 15 mmHg, and the reverse Trendelenburg position was limited to approximately 30°.

The device was removed when the patient began to respond to verbal commands. Emergence from general anesthesia was performed by an unblinded investigator who was not involved with this study. Additionally, complications, such as bloodstains on the device, teeth or lip injury, coughing, vomiting, and bronchospasm, were confirmed immediately after device removal. Desaturation was defined as less than 90% oxygen saturation on pulse oximetry. Gastric distention was defined as the requirement of a gastric drain tube insertion by the surgeon, due to the inflated stomach that interfered with surgical exposure. Aspiration was defined as hypoxia after removal of the device with signs of chest infiltrate in postoperative chest radiography. Coughing was defined as at least four episodes of coughs, each lasting for more than 2 s, after device removal. Bronchospasm was defined as desaturation and laryngeal stridor after device removal [14–18].

In addition, the patients were assessed for sore throat, dysphonia, and dysphagia 1 h after the surgery. Sore throat was defined as complaints of throat discomfort on enquiry. Dysphonia was defined as hoarseness of voice noted by the patient. Dysphagia was defined as pain when swallowing saliva [19]. Data from these complications were collected by a blinded investigator.

Statistical analysis

The sample size was calculated based on the data from a pilot study of 30 patients in the i-gel and Baska Mask groups (15 patients each), in which the OLP was measured as 26.1 ± 4.3 cmH₂O and 29.3 ± 6.1 cmH₂O, respectively. The sample size calculation using the above data at a two-tailed $\alpha = 0.05$ and 80% power, determined that 44 subjects were needed to detect statistically significant differences between the groups. Fifty patients per group were recruited to allow for potential dropouts. Using a computer-generated random number list, the 100 participants were randomly allocated to the i-gel group (n = 50) or Baska Mask group (n = 50).

Data, presented as mean ± standard deviation or number of patients (%), were recorded using a data collection sheet and analyzed using SPSS version 18 software (IBM Corp., USA). Continuous variables were analyzed using the Student's *t*-test. Categorical data were analyzed using the chi-squared or Fisher's exact test. A P value of < 0.05 was considered statistically significant.

Results

In total, 50 patients each were assigned to the i-gel and Baska Mask groups. Three patients were excluded, one in the i-gel group and two in the Baska Mask group, because in them, laparoscopic cholecystectomy was converted to open cholecystec-

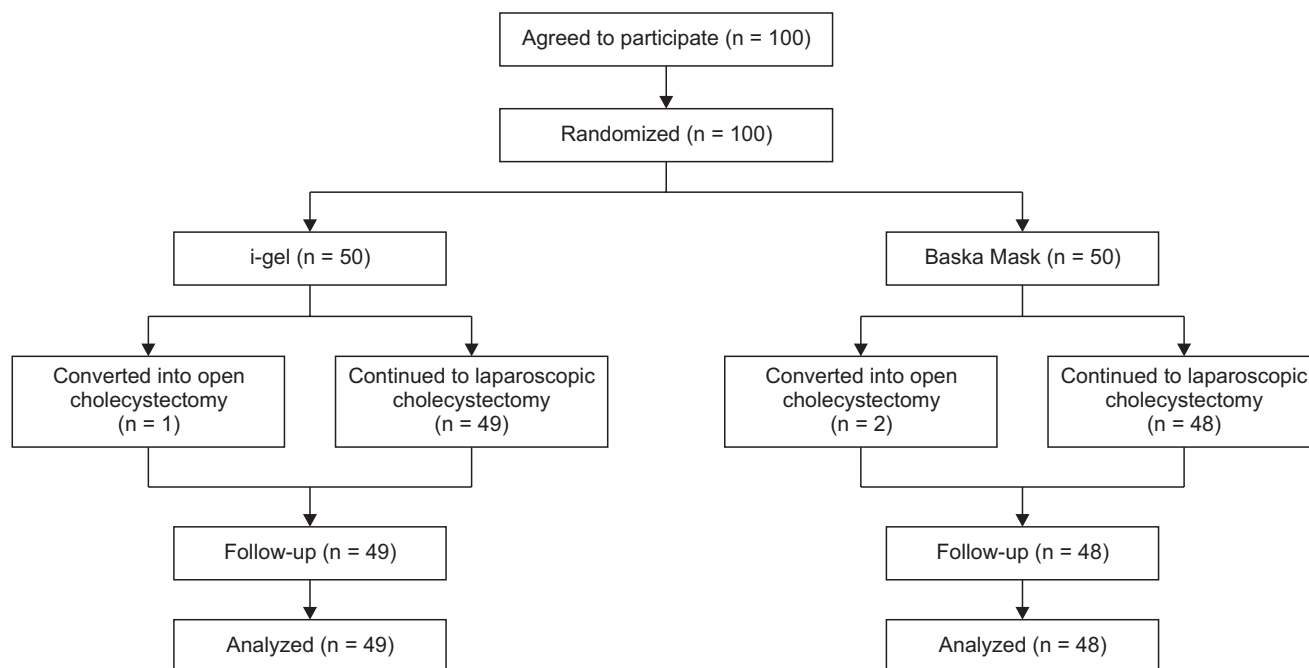


Fig. 2. CONSORT flow diagram for the study patients.

Table 1. Patients' Characteristics and Anesthetic Data

Variable	i-gel (n = 49)	Baska Mask (n = 48)	P value
Age (yr)	52.4 ± 13.3	48.2 ± 11.0	0.095
Sex (M/F)	18/31	21/27	0.538
ASA (1/2)	14/35	20/28	0.206
Height (cm)	160.9 ± 8.0	163.7 ± 8.0	0.094
Weight (kg)	64.6 ± 11.4	62.7 ± 10.9	0.416
Mallampati score (1/2/3/4)	19/28/2/0	11/33/4/0	0.202
Thyromental distance (cm)	7.5 ± 1.0	7.8 ± 0.7	0.058
Inter-incisor distance (cm)	4.5 ± 0.7	4.8 ± 0.5	0.093
Anesthetic time (min)	58.1 ± 16.2	59.2 ± 11.8	0.723
Pneumoperitoneum time (min)	25.7 ± 14.4	21.4 ± 11.3	0.109
Total propofol used (mg)	396.1 ± 127.3	382.8 ± 95.5	0.565
Total remifentanyl used (µg)	381.67 ± 151.0	394.1 ± 133.3	0.671
Analgesic method (0/1/2)*	20/28/1	21/20/7	0.054

Values are presented as mean ± SD or number. ASA: American Society of Anesthesiologists. *0: none, 1: local infiltration, 2: Transversus abdominis plane block. ASA: American Society of Anesthesiologists.

tomy during surgery (Fig. 2). The patients' characteristics and anesthetic data did not differ between the two groups (Table 1).

Table 2 summarizes the data regarding insertion in the i-gel and Baska Mask groups. Most of the devices were successfully inserted on the first attempt, except for one i-gel device, which was successfully inserted on the second attempt ($P = 0.320$). OLP was higher in the Baska Mask group (29.6 ± 6.8 cmH₂O) than in the i-gel group (26.7 ± 4.5 cmH₂O) ($P = 0.014$). There

Table 2. Insertion of i-gel and Baska Mask

Complications	i-gel (n = 49)	Baska Mask (n = 48)	P value
Size (3/4)	27/22	26/22	0.926
Attempt no. (1/2)	48/1	48/0	0.320
Insert time (min)	29.0 ± 10.3	31.4 ± 6.3	0.165
Insert resistance (1/2/3/4)*	42/7/0/0	44/4/0/0	0.355
Fiberoptic view (1/2/3/4) [†]	42/5/2/0	41/4/3/0	0.855
Manipulation frequency (0/1/2)	46/3/0	42/6/0	0.233
OLP (cmH ₂ O)	26.7 ± 4.5	29.6 ± 6.8	0.014

Values are presented as mean ± SD or number. *1: easy, 2: moderate, 3: difficult, 4: impossible. [†]1: vocal cord only, 2: vocal cords plus posterior epiglottis visible, 3: vocal cords plus anterior epiglottis visible, 4: vocal cords not seen. OLP: oropharyngeal leak pressure.

was no significant difference in the insertion time and fiber-optic view of the glottis between the two groups ($P = 0.165$ and $P = 0.855$, respectively). During pneumoperitoneum, an audible air leak developed in four patients in the i-gel group and three patients in the Baska Mask group ($P = 0.512$). Three patients in the i-gel group and six patients in the Baska Mask group required airway manipulations ($P = 0.233$).

There were no statistically significant differences between the two groups with regard to changes in the heart rate and mean arterial pressure at each measured time (i.e., T1, T2, T3, T4, and T5) (Fig. 3). There were no statistically significant differences between the two groups with regard to changes in PAP and lung compliance at each measured time (i.e., T1, T2, T3, T4, and T5)

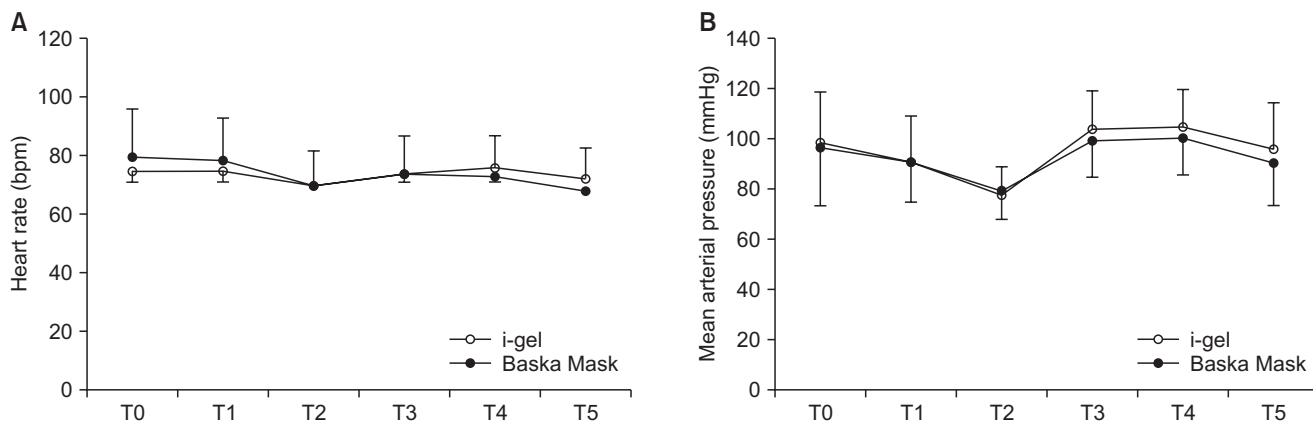


Fig. 3. Changes in the heart rate (A) and mean arterial pressure (B) between the i-gel group and Baska Mask group. Values are presented as mean ± SD. There was no significant difference in the heart rate and mean arterial pressure between the groups. T0: baseline, T1: 1 min after induction, T2: 5 min before CO₂ pneumoperitoneum, T3: 5 min after start of CO₂ pneumoperitoneum, T4: 5 min before removal of pneumoperitoneum, T5: 5 min after removal of pneumoperitoneum.

Table 3. Perioperative Complications

	i-gel (n = 49)	Baska Mask (n = 48)	P value
Audible air leakage	4 (8.2)	3 (6.3)	0.512
Desaturation	0 (0)	0 (0)	-
Gastric distention	0 (0)	0 (0)	-
Regurgitation/aspiration	0 (0)	0 (0)	-
Blood on device	3 (6.1)	2 (4.2)	0.510
Teeth or lip injury	0 (0)	0 (0)	-
Coughing	0 (0)	0 (0)	-
Vomiting	0 (0)	0 (0)	-
Bronchospasm	0 (0)	0 (0)	-
Sore throat	10 (20.4)	19 (39.6)	0.119
Dysphonia	2 (4.1)	1 (2.1)	0.566
Dysphagia	2 (4.1)	7 (14.3)	0.075

Values are presented as number (%).

(Supplementary Fig. 1). Changes in leak fraction showed no statistically significant differences between the two groups (Supplementary Fig. 2).

The incidence of perioperative complications was small and not statistically significant. The incidences of sore throat, dysphonia, and dysphagia were not significantly different between the two groups (Table 3).

Discussion

SAD offers an alternative airway to traditional tracheal intubation with potential benefits, including easy insertion and low laryngopharyngeal morbidity. However, it is more likely to leak than an endotracheal tube due to its structural characteristics. Thus, the OLP is a critical factor when deciding to use the SAD. OLP values that are higher than PAP values ensure airway main-

tenance without leakage. In general, intra-abdominal pressure is known to increase by an average of 15 mmHg during laparoscopic surgery [20]. As a result, PAP increases by approximately 50%, and lung compliance decreases by approximately 25% [21–23]. Thus, laparoscopic surgeries cause more unfavorable ventilatory conditions than general operations with lower PAPs. In this regard, investigating the function of SADs during laparoscopic surgeries with higher PAPs, which cause the aforementioned disadvantages, could be appropriate. In conclusion, SAD with a higher OLP value than PAP may be recommended for laparoscopic surgery.

In this study, the OLP of the Baska Mask was 29.6 ± 6.8 cmH₂O, which was higher than that measured with the i-gel (26.7 ± 4.5 cmH₂O). A previous study reported that inflatable SADs, such as LMA Supreme and LMA Proseal, have higher OLPs than that of the i-gel [24]. The cuff of the Baska Mask is connected to the central channel of the device. When the airway pressure increases during inspiration, the cuff inflates itself to ensure closer attachment to the surrounding surface. Therefore, the Baska Mask is considered to have a relatively high OLP, and it may be applicable in surgeries such as laparoscopic gynecology surgery, in which patients are in the Trendelenburg position, which can further increase PAP.

This study also showed that PAP increased and lung compliance decreased during pneumoperitoneum in both groups and that the changing pattern was similar between the two groups, with no statistically significant difference. In addition, the Baska Mask group also showed no statistically significant difference in leak fraction compared with the i-gel group. Lai et al. [4] reported that the i-gel group did not show a significant difference in leak fraction compared with the endotracheal tube. Although the OLP value of the Baska Mask group was not measured in

the pneumoperitoneum, effective ventilation may be possible in laparoscopic surgery as an aforementioned result of the leak fraction value. Therefore, we believe that the Baska Mask can be an alternative in patients who can tolerate the use of the i-gel device during laparoscopic cholecystectomy.

One of the advantages of the SAD is that there is less hemodynamic instability when inserting the device compared with inserting the tracheal tube [25,26]. In this study, there was almost no difference in the heart rate and mean arterial pressure due to device insertion between the two groups. The changes in heart rate and mean arterial pressure between the two groups were similar, without a statistically significant difference, and the Baska Mask provided hemodynamic stability similar to that provided by i-gel.

In this study, the cuff size of the Baska Mask was wider than those of the i-gel. Circumferences of size 3 of i-gel and Baska Mask were 11.7 cm and 13.8 cm, and those of size 4 were 13 cm and 14.8 cm, respectively (Figs. 1B and 1C). In addition, Alexiev et al. [7] showed that the Baska Mask was more difficult to insert than the classical laryngeal mask. Therefore, difficulty in insertion was anticipated before this study. However, the ease of insertion, number of first insertion attempts, and insertion time, which reflect the difficulty of insertion were not significantly different between the two groups. We used the extended hand-tab of the Baska Mask to control the flexion to adjust the angle. Therefore, ease of insertion was possibly similar to that of i-gel. However, there are only few studies related to the Baska Mask [7,8]; hence, further studies are needed.

The Baska Mask is characterized by a relatively large cuff and the process of cuff inflation at inspiration and cuff deflation at expiration during anesthesia. For this reason, it is expected that frequent stimulation on surrounding tissues in the Baska Mask group would lead to a higher incidence of complications such as postoperative sore throat compared with that in the i-gel group. However, there was no statistically significant difference in the incidence of postoperative complications between the two groups. Similarly, a study comparing the Baska Mask and LMA Supreme reported that complications such as mucosal injury were more frequent with the LMA Supreme [8]. Additionally, Brimacombe et al. [27], who compared the face mask and LMA, reported that the incidence of complications, such as sore throat, increased as the LMA cuff volume increased, with statistically significantly higher number of complications occurring with the use of larger cuff volumes. Hence, complications such as sore throat are thought to be caused by the volume of air inflated into the cuff rather than the size of the cuff. The cuff of the Baska Mask used in this study is not artificially pressurized but is self-inflated; thus, the cuff does not become bulky. Therefore, it is thought that the Baska Mask is less likely to damage or stimulate surrounding tissues compared with i-gel.

This study has some limitations. First, OLP was not compared in the presence of pneumoperitoneum. When a maneuver was performed for the measurement of OLP in the presence of increased PAP during pneumoperitoneum, the patient's airway maintenance during surgery was likely to be difficult because of the deviation of the fitted device. For safety, there was a limitation in measuring the OLP in the presence of pneumoperitoneum. Second, this study involved device insertion and removal by an unblinded investigator. Hence, the possibility of bias could not be excluded.

In conclusion, compared to the i-gel, the Baska Mask had a higher OLP. Additionally, there were no differences in complications in the setting of laparoscopic cholecystectomy. Therefore, the Baska Mask can be used as an alternative device to the i-gel, and its use can be extended to surgical situations wherein PAP can be further increased through a higher OLP.

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Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

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Sang Yoong Park (Formal analysis)

Chan Jong Chung (Conceptualization; Supervision; Writing—review & editing)

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Supplementary Materials

Further details are presented in the online version of this article (Available from <https://doi.org/10.4097/kja.19195>).

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