Original Article

Comparison of LMA Supreme, i-gel, and Baska Mask for Airway Management during Laparoscopic Cholecystectomy: A Prospective Randomized Comparative Study from North India

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Abstract

Background: The supraglottic airway device (SAD) has proved to be an appropriate alternative to endotracheal intubation in laparoscopic surgeries owing to various advantages, namely, decreased airway manipulation and stable hemodynamics. **Aims:** We compared the efficacy in terms of oropharyngeal leak pressure (OLP) and safety of laryngeal mask airway (LMA)-Supreme (LMA-S), i-gel, and Baska mask in patients undergoing laparoscopic cholecystectomy. **Settings and Design:** Ninety patients posted for elective laparoscopic cholecystectomy were selected for a prospective randomized comparative study in a tertiary care center. **Materials and Methods:** The study comprised three groups of 30 each based on the different SADs used Group-LS with LMA-Supreme, Group-IG with i-gel, and Group-BM with Baska mask. The secondary objectives were device insertion time, ease of insertion, changes in the peak airway pressure (PAP), heart rate, mean arterial pressure, and airway complications (sore throat, dysphagia. dysphonia, lip/tongue or dental injury, etc.) between three groups. **Statistical Analysis:** The quantitative data were analyzed using the one-way analysis of variance test and Bonferroni *post hoc* multiple comparison test. Qualitative data were compared using Chi-squared test. **Results:** OLP was significantly higher ($P = 0.005$) in the Baska mask than i-gel and LMA-S groups just after insertion and during carboperitonium. There was no significant difference in time for device insertion, number of attempts, ease of insertion, and use of manipulation ($P > 0.05$). However, the gastric tube insertion time was significantly lower in Group BM (9.59 ± 2.78) than Group IG with 12.79 ± 3.47 and Group LS with 10.84 ± 3.68 ($P < 0.05$). There were no significant differences between the groups with regard to changes in the PAP, heart rate, mean arterial pressure at different time intervals, and complications. **Conclusion:** Baska mask provided a significantly higher OLP compared to i-gel and LMA-S without significant airway morbidity in laparoscopic surgeries.

Keywords: Airway management, laparoscopic cholecystectomy, laryngeal masks

Introduction

Laparoscopic resection of gallbladder has become a standard technique for cholecystectomy due to its less invasive nature.[1] Tracheal intubation, though considered as the ideal mode of ventilation, has various disadvantages such as increased sympathetic response during intubation, pneumoperitoneum and extubation,[2] situations of failed intubation, and damage to the oropharyngeal structures at insertion with added concerns about postoperative laryngopharyngeal complications.

Trends in airway management has nowadays progressed from the use of endotracheal tube (ETT) to supraglottic airway (SGA) devices (SADs) because of its quick placement in the airway, decreased airway manipulation and stable hemodynamics decreased requirement of neuromuscular blockade, along with lower incidence of postoperative complications such as sore throat, dysphagia, and dysphonia.[3] In laparoscopic surgeries with increased airway pressures, it also helps maintain peak airway pressure (PAP).[4] Laryngeal mask airway Supreme (LMA S) is

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an innovative, sterile, and single use second generation SAD that provides access and functional separation of respiratory and digestive tracts in laparoscopic abdominal procedures.[5] They have improved pharyngeal seal enabling controlled ventilation at higher airway pressures and increased esophageal seal which lessens the likelihood of regurgitated fluids entering the pharynx, leading to aspiration. Similarly, the i-gel (Intersurgical Ltd. UK) is a noninflatable, anatomically designed SAD, made up of thermoplastic elastomer, offering high sealing pressure and less trauma and being widely used for such laparoscopic surgeries;[6] however, the routine use of SAD in laparoscopic surgeries remains controversial. The introduction of third-generation SADs such as Baska mask with a noninflatable cuff and better sealing pressure has shown to provide more efficient ventilation and also overcome the disadvantages of lower generation SAD like risk of pulmonary aspiration.[7] Early experience with Baska mask has demonstrated it to be a suitable device,[8] so the present study was undertaken to compare the efficacy and safety of LMA-S, i-gel, and Baska mask in patients undergoing laparoscopic cholecystectomy in general anesthesia using neuromuscular blockage with positive pressure ventilation.

Materials and Methods

The sample size was calculated by considering at least 20% difference in the oropharyngeal leak pressure (OLP) relative to the expected mean between the devices with an α error of 0.05 and power of 80% which required 28 patients in each group.[9] Considering the possibility of dropouts from the study, we decided to include 90 patients in the study.

The patients of either sex belonging to American Society of Anesthesiologists (ASA) Physical Status Grade 1 and 2 aged 20–65 years and weighing 40–70 kg were included in the study. Patients with anticipated difficult airway, obesity (body mass index [BMI] more than 30 kg. m^{-2}), oropharyngeal pathology, cardiopulmonary disease, cervical spine fracture, or instability or at increased risk of aspiration (gastroesophageal reflux disease, hiatus hernia, pregnant patients, etc.) were excluded from the study.

After obtaining the institutional ethics committee approval, written informed consent was taken from the patient and their attendants. This prospective randomized study was conducted on 90 patients who underwent laparoscopic cholecystectomy under general anesthesia with neuromuscular blockage and positive pressure ventilation. Patients were randomly assigned for airway management with any of the three devices, using closed sealed envelopes in three groups of 30 patients each inside the operation theater [Figure 1].

Group LS

LMA-S (sizes 3 and 4 for patients weighing 30–50 kg and 50–70 kg) was used.

Group IG

i-gel (sizes 3 and 4 for patients weighing 30–60 kg and 60–90 kg) was used.

Group BM

Baska mask (sizes 3 and 4 for patients weighing 30–60 kg and >60 kg) was used.

After preanesthetic checkup, patients were fasted after midnight. Patients were given oral alprazolam 0.5 mg and ranitidine 150 mg night before surgery. In the preoperative room, after intravenous (i.v.) access was obtained, ranitidine 150 mg i.v. and metoclopramide 10 mg i.v. were administered 30 min before surgery. In the operation theater, standard monitors such as pulse oximetry (SPO_2), electrocardiography, noninvasive blood pressure monitoring, and capnography were attached and baseline parameters were recorded.

The airway device to be used was prepared for insertion with the cuff completely deflated and shaped if applicable, and its dorsal/external surface lubricated with a water-soluble jelly. The manufacturer's recommended insertion technique was strictly adhered for all the airway devices.

Injections of midazolam 0.02 mg. kg^{-1}, glycopyrrolate 0.2 mg, and fentanyl 2 μg. kg^{-1} were administered as a part of premedication in operation theater. After preoxygenation with 100% oxygen for 3 min, propofol 1–2.5 mg. kg^{-1} was administered slowly until adequate depth of anesthesia was obtained (loss of verbal command, jaw relaxation, and no movement) with adequate facemask ventilation followed by administration of vecuronium bromide 0.1 mg. kg^{-1} to facilitate device placement.

After adequate paralysis, LMA-S was inserted in Group LS with patient's head positioned in neutral or "slight sniffing" position, and then, lubricated LMA-S was grasped along the integral bite block and was introduced into the mouth (without using fingers in the patient's mouth to facilitate insertion) in the direction toward the hard palate and was glided downward and backward along the hard palate until definite resistance was felt. In Group IG and Group BM 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 palatopharyngeal curve. The i-gel and Baska mask were pushed until a definitive resistance was felt.

The time interval between holding the airway device to placement with confirmation of correct placement by bilateral air entry in chest auscultation was noted. Correct placement of device was confirmed by adequate chest movement on manual ventilation, capnography, and no audible leak from the drain tube with PAP <20 cm of water.

A well-lubricated gastric tube (16 Fr) was passed through DT in all the groups. Correct placement was confirmed by air injection and epigastric stethoscopy. Anesthesia was maintained with oxygen 40%, air, isoflurane, and vecuronium bromide. Pneumoperitoneum was established with the introduction of Veress needle in the abdominal cavity and

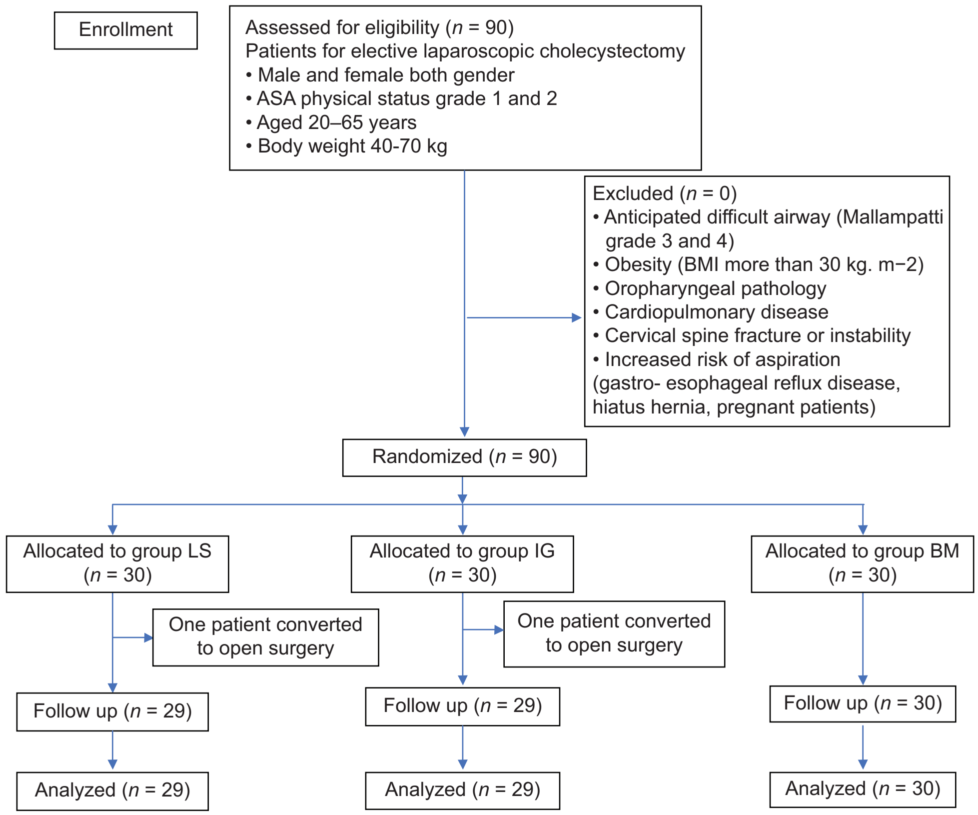

Figure 1: Consort flowchart

the desired intra-abdominal pressure (12–16 mmHg) was set manually on the electronic variable flow insufflators, which terminates flow automatically when a preset intra-abdominal pressure is reached. Neuromuscular blockade was antagonized with neostigmine and glycopyrrolate at the end of surgery. The device was removed when patient was able to open mouth on command.

We had assessed and recorded OLP (as primary outcome) just after and 30 min after insertion of the device. It was determined by closing the expiratory valve at a fixed gas flow of 5 L/min and recording the airway pressure at which equilibrium was reached. The airway pressure was not allowed to exceed 40 cm of water. We also assessed the time taken for insertion of device, i.e., ease of insertion, i.e., easy insertion – insertion at first attempt with no resistance; difficult insertion – insertion with resistance or at second attempt; and failed insertion – insertion not possible even after two attempts. Manipulations were done in the form of increasing the depth of insertion; giving jaw thrust or changing size of the device. For standardization, intra-abdominal pressure (IAP) was maintained at 12–16 mmHg. We also assessed gastric tube insertion time. The PAP, leak fraction, hemodynamic responses (heart rate and mean arterial blood pressure), SPO_2 and end tidal carbon dioxide ($EtCO_2$) were also recorded at 1 min after induction (T1), 5 min before carboperitonium (T2), 5 min after carboperitonium (T3), 5 min before removal of carboperitonium (T4), and 5 min after removal of carboperitonium (T5) along with the baseline (T0) value. The aim was to maintain target SPO_2 (>95%) and $EtCO_2$ (<45 mm Hg) by adjusting the fraction of inspired oxygen, respiratory rate, and tidal volume. When SPO_2 was 94%–90%, the oxygenation was graded as suboptimal, and the oxygenation was graded as failed if SPO_2 was <90%. The leak fraction was calculated by the formula: tidal volume inspires − tidal volume expired/tidal volume inspired (Vinsp − Vexp/Vinsp) × 100 to assess the device stability. Incidence of gastric distension/desaturation/aspiration/cough/any lip, tongue, and dental injury was recorded. Postoperative laryngo-pharyngeal morbidity (pain in throat/change of voice/difficulty in swallowing) was assessed after 2 h of removal of the device.

All data were statistically analyzed using SPSS statistical software, Version 18 (Chicago, Illinois, Inc., USA). The quantitative data (OLP, times for insertion of SGA and gastric tube) were analyzed using the one-way analysis of variance test and Bonferroni *post hoc* multiple comparison test. Qualitative data (ease of insertion of SGA and gastric tube, first attempt insertion success rate, number of insertion attempts, and any complications) were compared using Chi-squared or Fisher's exact test. A $P < 0.05$ was considered significant.

Results

A total of 90 patients scheduled to undergo laparoscopic cholecystectomy and fulfilling the inclusion criteria were enrolled in the study and were randomly divided into one of the three groups LS, IG, and BM (*n* = 30). One patient each in LS and IG group was excluded due to conversion of laparoscopic cholecystectomy to open one [Figure 1] Demographic and baseline general characteristics of patients in all the three groups such as age, sex, weight, BMI, Mallampatti grading, and ASA status of patients in all the three groups were matched and showed no significant statistical difference between two groups [Table 1]. All the groups were also matched for duration of anesthesia and did not show a statistically significant difference between them ($P > 0.05$) [Table 1].

Table 2 shows the data regarding OLP in the LMA-S, i-gel and Baska mask groups just after insertion and 30 min after insertion, i.e., during carboperitonium. OLP, just after insertion of the device, was significantly higher in the Baska mask group (31.61 ± 0.4.3 cmH_2O) than in the i-gel group (28.27 ± 0.3.4 cm H_2O) and LMA-S group (29.42 ± 0.3.9 cm H_2O) ($P = 0.005$), but *P* value obtained for Group IG and Group LS was not statistically significant. The OLP was also significantly higher after 30 min of insertion, i.e., during carboperitonium in BM group (36.32 ± 0.5.8 cm H_2O) than IG group (32.37 ± 6.3 cm H_2O) and LS group (33.54 ± 5.1 cm H_2O).

The device insertion time for Group BM was 14.51±0.5.2 s; Group IG was 15.54 ± 0.4.1 s; and for Group LS was 17.33 ± 0.6.3 s. Intergroup difference as for insertion time was not statistically significant. Most of the devices were inserted in first attempt in all the groups except 2 in Group LS, 1 in Group IG and 2 in Group BM. Ease of device insertion in all the groups was mostly easy except a few. Intergroup difference as for ease of device insertion was not statistically significant. The only manipulation required is jaw thrust, more in IG group but the intergroup difference was not significant. Gastric tube insertion time was significantly different between the groups with 9.59 ± 2.78 in Group BM, 12.79 ± 3.47 in Group IG, and 10.84 ± 3.68 in Group LS [Table 3].

The intergroup difference with regard to changes in PAP at each measured time (i.e., T1, T2, T3, T4, and T5) was not statistically significant [Table 4]. Changes in leak fraction also showed no significant differences between all the groups. There were no statistically significant differences between the groups with regard to changes in the heart rate and mean arterial pressure at baseline (T0) and different measured time (i.e., T1, T2, T3, T4, and T5) [Figures 2 and 3]. In all the groups, mean oxygen saturation at different measured times did not show significant difference either intergroup or from the baseline. The $EtCO_2$ at all measured times also show no significant intergroup difference.

As per the complications are concerned, none of the patients, in any of the three groups, had desaturation, bronchospasm, distension, aspiration, change of voice, and lip/tongue or dental injury. Pain in throat was observed in 5 (16.6%) patients in Group BM, 7 (23.1%) patients in Group IG, and 9 (29.7%) patients in Group LS. In Group BM, difficulty in swallowing was seen in 1 (3.3%) patient, cough in 3 (10%), and blood on device in 1 (3.3%). The same was in 1 (3.3%), 4 (13.2%), and 3 (10%) patients in Group IG and 2 (6.6%), 1 (3.3%), and 2 (6.6%) patients in Group LS, respectively. However, for

Table 1: Demographic data

Characters	Group LS (*n*=29)	Group IG (*n*=29)	Group BM (*n*=30)	*P*
Age (years)	47.47±7.6	51.67±7.9	48.46±8.1	0.111
Sex				
Male	7	8	6	>0.05
Female	22	21	24	
Weight (kg)	63.46±11.3	61.53±9.8	59.37±10.7	0.339
BMI ($kg.m^{-2}$)	24.46±2.6	25.42±2.3	23.89±3.1	0.095
ASA grade				
1	25	23	22	>0.05
2	4	6	8	
Mallampatti grading				
1	9	8	10	>0.05
2	20	21	20	
Duration of anaesthesia	81.73±13.6	75.54±11.1	78.61±14.5	0.207

Data are presented as mean±SD or numbers. SD=Standard deviation, ASA=American Society of Anesthesiologist, BMI=Body mass index

Table 2: Inter group comparison of oropharyngeal leak pressure at different time intervals

OLP (cmH_2O)	Group LS (*n*=29)	Group IG (*n*=29)	Group BM (*n*=30)	*P*
Just after insertion	29.42±3.9	28.27±3.4	31.61±4.3	0.005
30 min after insertion	33.54±5.1	32.37±6.3	36.32±5.8	0.029

Data are presented as mean±SD. SD=Standard deviation, OLP=Oropharyngeal leak pressure

Table 3: Insertion parameters of laryngeal mask airway-supreme, I-gel and Baska mask

Parameters	Group LS (*n*=29)	Group IG (*n*=29)	Group BM (*n*=30)	*P*
Device insertion time (s)	17.33±6.3	15.54±4.1	14.51±5.2	0.123
Number of attempts				
1	27	28	28	>0.05
2	2	1	2	
Ease of device insertion				
Easy	27	28	28	>0.05
Difficult	2	1	2	
Failed	0	0	0	
Use of manipulation (jaw thrust)	5	8	5	>0.05
Gastric tube insertion time (s)	10.84±3.68	12.79±3.47	9.59±2.78	0.002

Data are presented as mean±SD or numbers. SD=Standard deviation none of the complications, the difference between any of the three groups was significant statistically ($P > 0.05$) [Table 5].

Discussion

The ideal choice of airway management in laparoscopic surgeries under general anesthesia is endotracheal intubation, but the widespread use of SADs has changed the clinical scenarios in modern anesthetic practice. The reason behind this change is exaggerated hemodynamic stress response during endotracheal intubation in contrast to quick and easy placement of the SAD for laparoscopic surgeries under general anesthesia.[10] The main concern with these supraglottic devices has been the risk of aspiration, more so in laparoscopic procedures due to its structural characteristics. Thus, the OLP is a critical factor when deciding to use the SAD. OL*P* values that are higher than PAP values ensure airway maintenance without leakage.[11] During laparoscopic surgery, the intra-abdominal pressure is known to increase, and with this rise of IAP, the PAP increases and the lung compliance decreases,[12] so the ventilatory conditions during laparoscopic surgeries are more unfavorable.

The primary objective of this study is to assess the OLP among the three supraglottic devices used in the study and SAD with a higher OLP may be recommended for laparoscopic surgeries. OLP was assessed just after insertion and at 30 min during surgery in all the subjects. The OLP of the Baska Mask was 31.16 ± 4.3 cmH_2O, at insertion time and 36.32 ± 5.8 cmH_2O at 30 min after insertion, i.e., during laparoscopy was significantly higher in comparison to i-gel (28.27±0.3.4 and 32.37 ± 6.3) and LMA-S (29.42±0.3.9 and 33.54±.5.1). Al-Rawahi *et al.*[13] compared the Baska mask with the ProSeal LMA and found that the sealing pressure was significantly higher in the Baska group (30 ± 9 vs. 24 ± 6 cm of H_2O). A previous study reported that inflatable SADs, such as LMA-S and LMA-ProSeal, have higher OLPs than that of the i-gel.[14] Higher sealing pressure achieved with Baska mask over PLMA was also shown in other studies.[8,15] In this study, LMA-S and i-gel were comparable in terms of OLP. The cuff of the Baska Mask is connected to the central channel

Table 4: Comparison of peak airway pressure at different time intervals (cmH_2O)

Time interval	Group LS (*n*=29)	Group IG (*n*=29)	Group BM (*n*=30)	*P*
1 min after induction (T1)	17.1±2.0	17.3±2.1	16.5±1.9	0.283
5 min before carboperitonium (T2)	17.4±2.0	17.7±2.1	17.2±2.2	0.657
5 min after carboperitonium (T3)	24.3±3.2	24.6±2.9	24.5±3.0	0.929
5 min before removal of carboperitonium (T4)	24.9±3.3	25.1±3.2	25.0±3.1	0.972
5 min after removal of carboperitonium (T5)	17.6±2.1	18.3±2.0	17.3±1.9	0.151

Data are presented as mean±SD. SD=Standard deviation

Table 5: Complications

Parameter	Group LS (*n*=29), *n* (%)	Group IG (*n*=29), *n* (%)	Group BM (*n*=30), *n* (%)	*P*
Desaturation	0	0	0	-
Bronchospasm	0	0	0	-
Distension	0	0	0	-
Aspiration	0	0	0	-
Change of voice	0	0	0	-
Pain in throat	9 (29.7)	7 (23.1)	5 (16.6)	0.475
Difficulty in swallowing	2 (6.6)	1 (3.3)	1 (3.3)	0.759
Cough	1 (3.3)	4 (13.2)	3 (10)	0.382
Blood on device	2 (6.6)	3 (9.9)	1 (3.3)	0.565
Lip/tongue or dental injury	0	0	0	-

Data are presented as *n* (%)

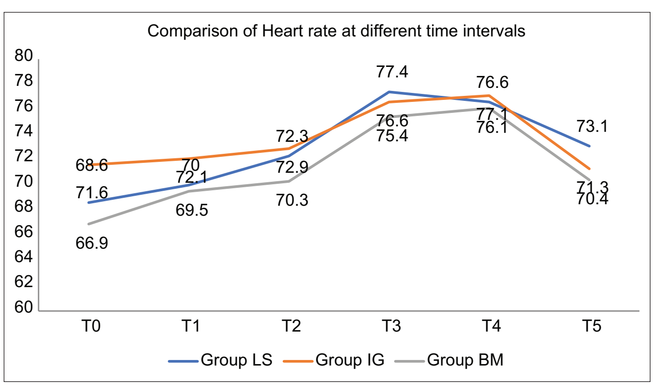

Figure 2: Values are presented as mean ± SD. There was no significant difference in the heart rate between the groups. T0: Baseline, T1: 1 min after induction, T2: 5 min before CO_2 pneumoperitoneum, T3: 5 min after start of CO_2 pneumoperitoneum, T4: 5 min before removal of pneumoperitoneum, T5: 5 min after removal of pneumoperitoneum, SD: Standard deviation

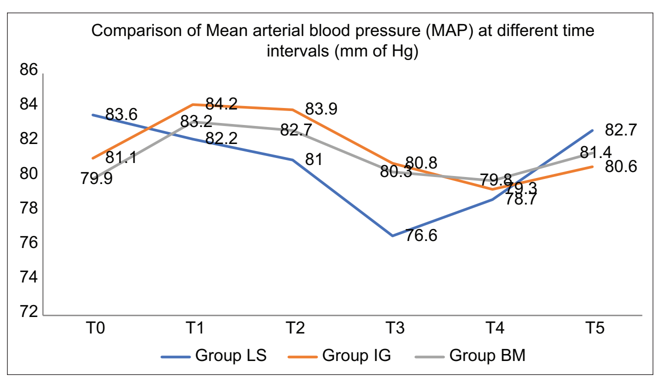

Figure 3: Values are presented as mean ± SD. There was no significant difference in the mean arterial pressure between the groups. T0: Baseline, T1: 1 min after induction, T2: 5 min before CO_2 pneumoperitoneum, T3: 5 min after start of CO_2 pneumoperitoneum, T4: 5 min before removal of pneumoperitoneum, T5: 5 min after removal of pneumoperitoneum, SD: Standard deviation

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[11] and provides a good degree of airway protection and feasibility for using in positive pressure ventilation. In addition, the Baska mask group also showed no significant difference in leak fraction with the i-gel and LMA-S groups. Lai *et al*.[16] reported that the i-gel group did not show a significant difference in leak fraction compared with the ETT, so Baska mask with higher OLP can replace of i-gel in laparoscopic surgeries.

In our study, the ease of insertion, number of first insertion attempts, use of manipulation, and insertion time, which reflect the difficulty of insertion, were not significantly different between these three groups. Baska mask had the quickest insertion time (13.54 ± 5.2 s) when compared to the i-gel (15.54 ± 4.1 s) and LMA-S (17.34 ± 6.3 s) [Table 3] which is in contrast with the result by Alexiev *et al*.,[17] who showed that the Baska mask was more difficult to insert than the classical laryngeal mask. We used the extended hand-tab of the Baska mask to control the flexion to adjust the angle.[11] Therefore, ease of insertion was possibly similar to that of i-gel and LMA-S. Teoh *et al*.[18] also found similar insertion times for i-gel (15.4 ± 7.3 s) and SLMA (14.3 ± 4.7 s).

This study also showed that PAP increased during pneumoperitoneum[12] in all the groups with similar changing pattern between the groups, without any significant difference [Table 4]. More hemodynamic stability is one of the advantages of the SAD during insertion in comparison with inserting the tracheal tube.[19,20] All the three groups showed almost no difference in the heart rate and mean arterial pressure due to device insertion between them in our study. The changes in heart rate and mean arterial pressure between all the groups were similar, without a statistically significant difference; hence, the hemodynamic stability provided by Baska mask was similar to that provided by I-gel and LMA-S.

In our study, complications encountered such as pain in throat and difficulty in swallowing were observed more in the LMA-S group without significant difference between the three groups. It may be attributed to the artificially pressurized inflatable cuff of LMA-S.[16] Brimacombe *et al*.,[21] 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. Cough and blood on device after removal were found more in i-gel group without significant difference between all the three groups, maybe due to hardness of the cuff material. In our study, there was no incidence of desaturation, bronchospasm, change in voice, gastric distension, aspiration, and lip/tongue or dental injury in any of the groups. One of the major limitations of our study was that the insertion and removal of the airway device along with data collection done by unblinded investigator, thus there may be a potential for bias. Obese and patients with anticipated difficult airway were not included in this study, which may be evaluated in future studies for the role of these devices in them.

Conclusion

This study concludes that Baska mask provided a significantly higher OLP compared to i-gel and LMA-S without significant airway morbidity. Hence, Baska mask can be considered as a superior alternative to I-gel and LMA-S in patients with normal airway for laparoscopic cholecystectomy.

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The manuscript has been read and approved by all the authors and the requirements for authorship as stated earlier in this document have been met.

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Conflicts of interest

There are no conflicts of interest.

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