Original Article

Comparative evaluation of airway dynamics in patients undergoing laparoscopic cholecystectomy under general anaesthesia with controlled ventilation using ProSeal laryngeal mask airway, I-Gel™ and Baska mask

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ABSTRACT

Background and Aims: TheProSeal™ laryngeal mask airway (PLMA) and I-Gel™ are second-generation supraglottic airway devices (SADs). The Baska mask is a SAD having a non-inflatable cuff with a tendency to increase the perilaryngeal seal with an increase in airway pressures. This study compared the efficacy of I-Gel™, PLMA and Baska mask with respect to airway dynamics in patients scheduled for laparoscopic surgeries under general anaesthesia (GA). **Methods:** Ninety patients, of American Society of Anesthesiologists physical status I and II, aged 20–65 years scheduled for laparoscopic cholecystectomy under GA were enroled. The patients were randomised into three groups: Group P (n = 30): airway secured using PLMA, Group I (n = 30): airway secured using I-Gel™ and Group B (n = 30): airway secured using Baska mask. The primary outcome was the change in dynamic compliance, and the secondary outcomes included insertion time, changes in peak inspiratory pressure (PIP) and oropharyngeal leak pressure (OLP) at different time intervals. **Results:** After insertion of the SADs, the dynamic compliance was highest in group B and least in the group I (p = 0.01). The maximum decrease in dynamic compliance was observed in group I. The insertion time for SAD placement was more in group P. The group B had least PIP as compared to groups P, I at insertion. After carboperitonium, groups P and B had comparable PIP, and group I had highest PIP (p = 0.001). OLP was highest in group B, whereas group I had least OLP. **Conclusion:** The airway dynamics are better maintained with Baska mask as compared to the PLMA and I-Gel™.

Key words: Airway management, cholecystectomy, laparoscopic, laryngeal masks

INTRODUCTION

Airway management is the cornerstone of anaesthesia practice in patients undergoing surgeries under general anaesthesia (GA).[1] Nonetheless, airway management in the recent years has been safer with the advent of newer supraglottic airway devices (SADs).[2,3] The second-generation SADs like I-Gel™ and ProSeal laryngeal mask airway (PLMA) have a cuff that provides higher sealing pressure and if required, allows aspiration of the gastric contents through a gastric drain tube. These SADs are being used safely during anaesthesia for procedures associated with a high peak airway pressure such as laparoscopic cholecystectomy.[4,5]

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The Baska mask is a SAD, having a non-inflatable self-sealing cuff and sump drainage system. It has been observed that with the increase in airway pressures, the perilaryngeal seal pressure increases with the Baska mask.[6]

As very few studies have compared the respiratory mechanics of Baska mask with other SADs, the present study compared respiratory mechanics, while securing the airway with PLMA, I-Gel™ and Baska mask in patients scheduled for laparoscopic cholecystectomy under GA. The primary outcome included change in the dynamic compliance and the secondary outcomes included peak inspiratory pressure (PIP) and oropharyngeal leak pressure (OLP) changes at various time intervals.

METHODS

After approval by the institutional ethics committee [IEC 54/2018] and written informed consent, a prospective, randomised study was carried out in ninety patients aged 20–65 years, of American Society of Anesthesiologists (ASA) physical status I/II having body mass index (BMI) of 18.5–29.9 kgm^{-2} and modified Mallampati class I or II scheduled for laparoscopic cholecystectomy under GA during the period June 2018 to June 2019 in a tertiary healthcare institute [Figure 1]. The trial was registered with the Clinical Trials Registry of India (2018/05/013923). The patients were excluded from the study if the mouth opening was less than 3 cm, thyromental distance less than 6.5 cm, and failure to insert the SAD. Additionally, patients were excluded if they met one of the contraindication criteria of the SADs placement including pregnancy, history of gastric regurgitation, features suggestive of low pulmonary compliance or high pulmonary resistance and an anticipated difficult airway.

A pre-anaesthetic check was conducted to evaluate the patient's eligibility one day prior to surgery before randomisation, and to record baseline data. The randomisation sequence was created with a computerised random-number generator, and patients were randomly allocated to have their airway secured with the PLMA (Group P), I-Gel™ (Group I) or Baska mask (Group B) in a ratio of 1:1:1. The details of the allocated SADs were contained in serially numbered sealed opaque envelopes. Another researcher (not involved in this trial and not blind to group assignment) opened the envelopes to view the patient's group assignment in the operation theatre.

All patients were kept nil per oral for 6 h for solid food and 2 h for water. The patients were premedicated with tablet ranitidine 150 mg and tablet metoclopramide 10 mg on the morning of surgery. In the operation theatre, the baseline parameters including peripheral oxygen saturation (SpO_2), five lead electrocardiogram and blood pressure (systolic, diastolic and mean) were noted and monitored throughout the procedure.

All the patients were premedicated with midazolam 0.05 $mgkg^{-1}$ intravenously in the operation theatre. After preoxygenation for three minutes, the patients were induced with intravenous fentanyl 2 μgkg^{-1} and propofol 2-2.5 $mgkg^{-1}$, and neuromuscular blockade was facilitated with injection atracurium 0.5 $mgkg^{-1}$. In group I patients, the airway was secured using an I-Gel™ of appropriate size (size 3 for patients weighing 30–60 kg, size 4 for 60–90 kg). In group B, the airway was secured with a Baska mask of appropriate size (size 3 for patients weighing 30–60 kg and size 4 for 60–90 kg). In group P patients, the airway was secured using a PLMA of appropriate size (size 3 for patients weighing 30–50 kg, size 4 for 50–70 kg). All the devices were inserted by an anaesthesiologist having sufficient experience in the use of all three devices.

The device was fixed by taping the tube over the chin, and a well-lubricated gastric tube was introduced into the stomach through the gastric port. An effective airway was confirmed by bilateral symmetrical chest movements on manual ventilation, square waveform on capnography, no audible leak of gases and lack of gastric insufflation. If the chest movement was not adequate or the capnography wave was not square-shaped after insertion, the ventilation was considered inadequate and manipulations were allowed in the following sequence: gentle pushing or pulling of device, changing head position and jaw thrust.

With the patient's head in the neutral position, the time to successful insertion was measured from the moment the facemask was removed until the first capnography upstroke after insertion of the device. Anaesthesia was maintained with oxygen 33%, nitrous oxide 67% and isoflurane 0.5-1%. Additional atracurium and fentanyl were given as deemed necessary by the attending anaesthesiologist. The ventilatory parameters were set as tidal volume 6–8 $mLkg^{-1}$ and respiratory rate 12–20 breaths per minute to maintain normocarbia.

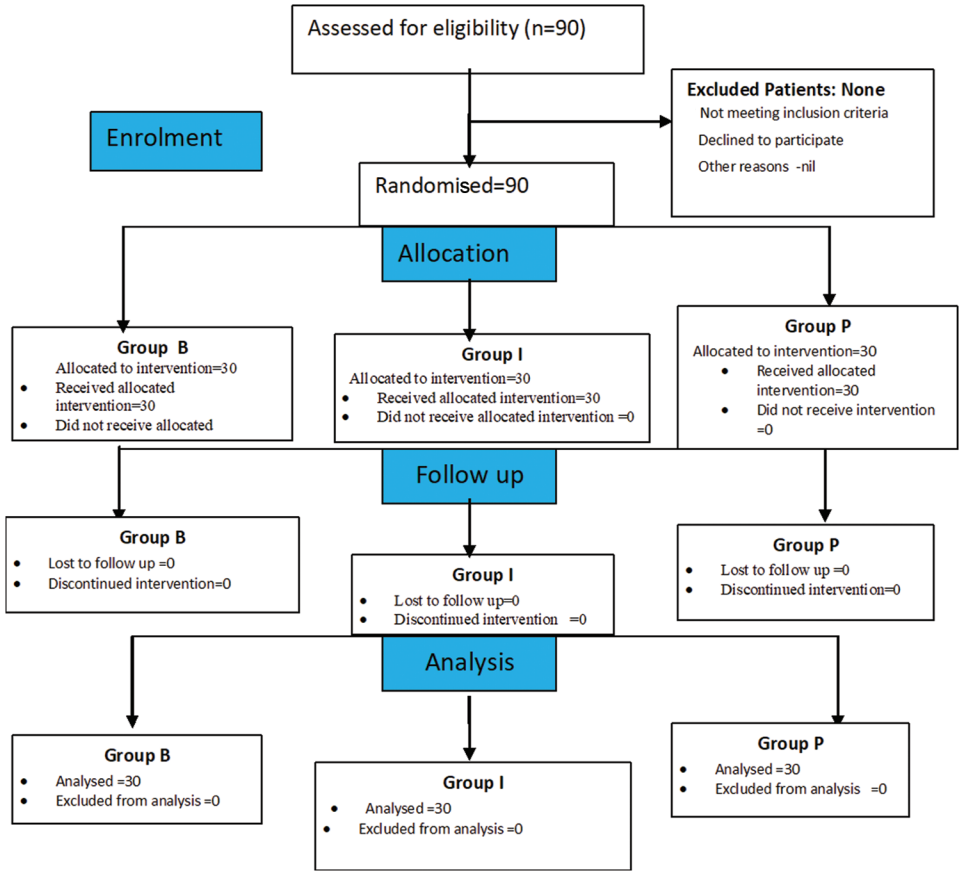

Figure 1: Consolidated standards of reporting trials (CONSORT) chart of patients

After confirming correct placement of the device, the following respiratory parameters were evaluated: PIP, dynamic compliance and OLP at the following time points: at the insertion of device, after 5 min, at carboperitoneum, reverse Trendelenburg position, left tilt with reverse Trendelenburg position and at release of the carboperitoneum utilising (Drager, Primus Medical GmbH, Germany) workstation ventilator.

The OLP was measured by adjusting the expiratory valve of the circle system to 40 cm H_2O at fixed fresh gas flow of 3 L/min and recording the pressure when equilibrium was reached. The pressure in the system at which the audible leak as assessed by auscultation over suprasternal notch was the OLP.

At the end of the procedure, intraperitoneal instillation of 20 mL levobupivacaine (0.25%) was done by the surgeons before releasing the carboperitoneum. The muscle relaxation was reversed with intravenous neostigmine 0.05 $mgkg^{-1}$ and glycopyrrolate 0.01 $mgkg^{-1}$, followed by device removal after ensuring adequate reversal. Blood staining of the device, tongue, lip and dental trauma were recorded. Patients were questioned after regaining full consciousness to assess sore throat, dysphagia and dysphonia immediately after surgery and after 24 hours. Postoperative nausea and vomiting were also noted.

Data were expressed as frequency/percentage, mean ± standard deviation (SD) and median [interquartile range (IQR)] as appropriate. The one-sample Kolmogorov–Smirnov test was employed to determine whether datasets differed from a normal distribution. Normally distributed data was compared between the three groups using one-way analysis of variance (ANOVA) followed by Bonferroni post-hoc analysis. Non-normally distributed data was compared using Kruskal–Wallis test followed by pairwise comparison. Chi-square test was used to compare categorical variables between the three groups. P value <0.05 was considered significant. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 21 (SPSS Inc., Chicago, IL, USA).

The sample size was based upon a pilot study having five patients in each group, and the dynamic

compliance was taken as the primary outcome. The dynamic compliance was 45 ± 11.5 in group B and 37 ± 9.7 in group I, whereas in group P, it was 38 ± 3. The calculated sample size was 84 patients [28 patients in each group] having an α error of 0.05 and 80% power, using the OpenEpi, version 3 software. We, therefore, recruited 30 patients in each group.

RESULTS

Patients in all the three groups were comparable in terms of general characteristics such as age, gender, BMI and ASA physical status [Table 1].

The insertion time for the device was significantly more in the group P (mean ± SD = 20.34 ± 3.65 s) as compared to group I (14.73 ± 5.30 s) and group B (13.78 ± 4.68 s, $p = 0.045$) with groups P versus groups I and B ($p < 0.05$). However, the insertion time was comparable in groups I and B [Figure 2]. The maximum dynamic compliance was observed in the group B throughout the procedure, whereas maximum decrease in compliance was noted in the group I at all time intervals [Figure 3]. The dynamic compliance after insertion in group B median 47.50 (IQR 39.07, 53.27) cm H_2O was highest as compared to group I 37.15 (33.5, 40.6) and group P 39.75 (IQR38.5, 44.9, $p = 0.001$) with groups B versus *P* and groups B versus I ($p = 0.011$, $p = 0.001$), respectively. After the carboperitoneum, the maximum decrease in compliance was observed in group I median 21.50 (IQR20.0, 33.32) as compared to group P 21.50 (IQR20.0, 26.17) and group B 30.40 (IQR 27.55, 34.1), respectively ($p = 0.001$, groups B versus I = 0.001 and groups B versus P, $p = 0.001$). After the release of carboperitoneum, the compliance was highest in the group B 30.20 (IQR 28.6, 36.55) as compared to *P* group 27.50 (IQR 25.0, 29.25) and group I 25.10 (IQR 23.0, 29.15, $p = 0.001$) [Figure 3].

Regarding PIP at insertion, the group B median 10.0 (IQR9.0, 11.0) cm H_2O had least PIP as compared to group I 12.0 (IQR 10.75, 13.0) and group P 11.0 (IQR 10.0,13.0, $p = 0.001$) with groups B versus P, groups B versus I ($p = 0.004$ and $p = 0.001$), respectively. After 5 minutes of insertion, group P 11.5 (IQR 10.0, 13.0) and group B 12.0 (IQR10.75,13.0) had comparable PIP and group I 14.5 (IQR 13.75, 16.0) had the highest PIP ($p = 0.00$). However, after the carboperitoneum, the group P had the least rise in PIP 13.0 (IQR 12.0, 14.0) as compared to the group B14.0 (IQR 13.0, 16.0, $p = 0.001$). The group I had higher PIP as compared to other two groups at all other time intervals ($p < 0.05$) [Figure 4]. After the release of carboperitoneum, the PIP was comparable in groups B and *P* 12.5 (IQR 12.0, 13.0) and 12.0 (11.0, 13.0); it was significantly higher in the group I 14.0 (IQR 13.75, 14.0, $p = 0.001$).

The OLP was highest in group B at all time intervals as compared to group P, whereas group I had least

Table 1: Demographic profile

Variables	Group B *n*=30	Group I *n*=30	Group P *n*=30
Age (years) (mean±SD)	42.6±12.25	45.37±10.50	40.40±7.31
Gender (number/percentage)			
Male	20 (67%)	25 (83%)	23 (77%)
Female	10 (33%)	5 (17%)	7 (23%)
BMI (kgm^{-2}) (mean±SD)	22.19±2.09	21.75±1.95	21.61±1.60
ASA (number/percentage)			
Grade 1	21 (70%)	27 (90%)	27 (90%)
Grade 11	9 (30%)	3 (10%)	3 (10%)

ASA:American Society of Anesthesiologists; SD:Standard deviation; BMI: Body mass index

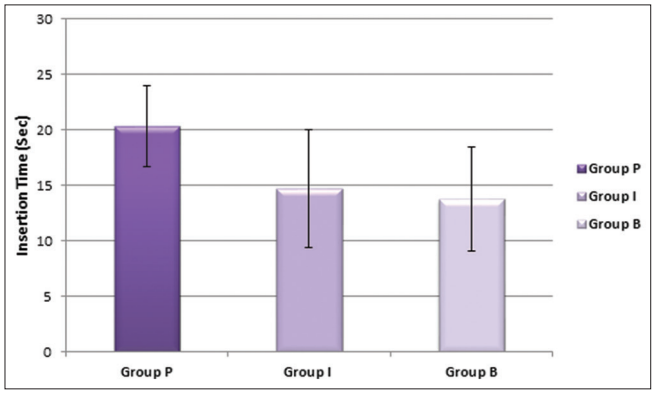

Figure 2: Insertion time for device placement in the three groups

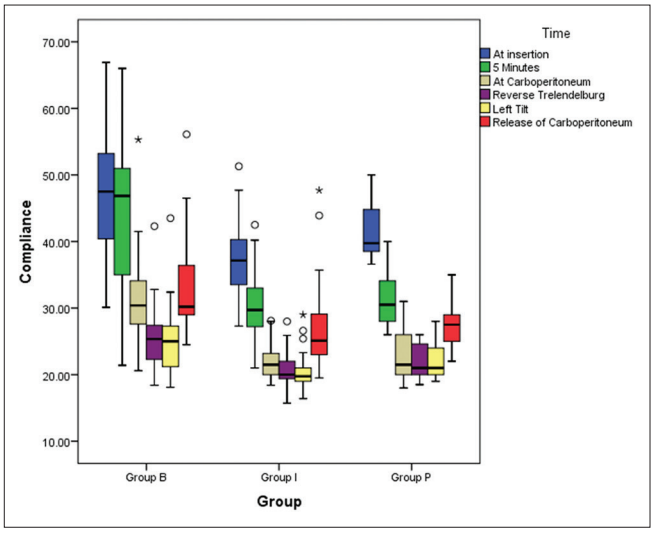

Figure 3: Comparative evaluation of the dynamic compliance in the three groups at different time intervals

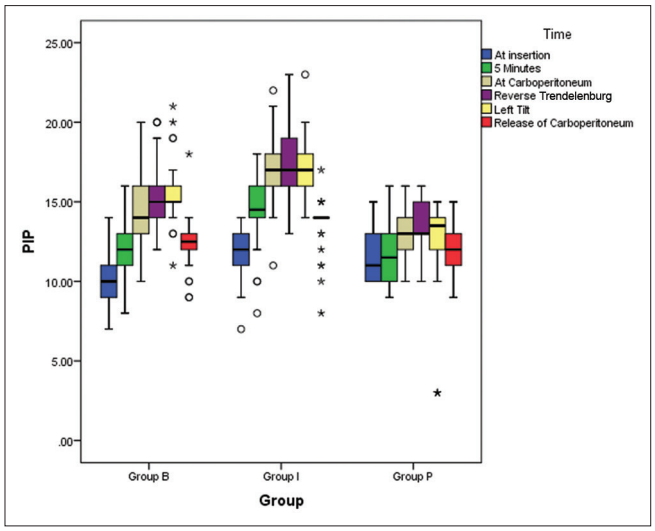

Figure 4: Peak inspiratory pressure changes at various study intervals in the three groups

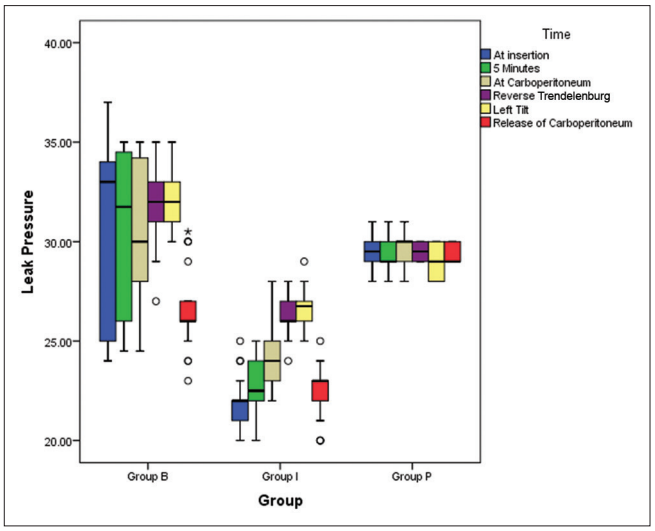

Figure 5: Changes in the oropharyngeal leak pressure in the three groups at various time intervals

OLP. The OLP after insertion was 33.0 (IQR 25.0, 34.0) cm H_2O in group B and group I 22.0 (20.75, 22.25), whereas group P had 29.5 (IQR 29.0,30.0, $p = 0.001$) with groups B, *P* versus I ($p = 0.001$). After the carboperitoneum, the OLP was 35.0 (27.87, 34.2) and 24.0 (23.0, 25.0) in groups B and I, respectively, whereas group P had 30.0 (29.0, 30.0, $p = 0.001$) groups B versus *P* and I ($p = 0.001$) [Figure 5].

Blood on the device was observed in three patients in group P as compared to none in group B and group I ($p = 0.04$). Five patients in group P and two patients in group I complained of sore throat 2 h after the surgery. However, after 24 h of surgery, none of the patients had sore throat. Dysphagia and dysphonia were not observed in any patient, and the incidence of post-operative nausea and vomiting was comparable in the three groups.

DISCUSSION

SADs, especially the second-generation SADs, are safer alternatives to endotracheal intubation during GA.[7,8] SADs which provide higher seal pressure are useful in laparoscopic surgery, as a higher OLP is required to compensate for increased peak airway pressures without the probability of gastric insufflation and resultant pulmonary aspiration.[9,10]

The characteristic feature of the Baska mask is that the airway pressure is transmitted intermittently to the membranous cuff so that it inflates and deflates with each positive pressure inspiration and expiration respectively, thus forming a perfect seal, reducing leaks and making intermittent positive pressure ventilation (IPPV) very efficient.[11]

In the present study, the highest dynamic compliance was observed in the group B. The pulmonary compliance decreased from insertion till the release of carboperitoneum in groups I and P. Moreover, the dynamic compliance was comparable in the groups I and P. In a study by Choi *et al.*,[12] though the dynamic compliance was more in the group B as compared to group I at all time intervals, it was statistically insignificant.

In our study, PIPs in groups B, I and *P* ranged from 10 to 15, 12 to 17.0 and 11.0 to 13.5 cm H_2O, respectively. The group I had the maximum rise in PIP at different time intervals compared to the groups P and B. Our results are in accordance to those of Banerjee *et al.*[13] who observed increased PIP with I-Gel™ in comparison to PLMA. After carboperitoneum, the increase in PIP was more in group B than in group P. In another study comparing the Baska mask and I-Gel™, the PIPs were insignificantly higher in group I (12-18 cm H_2O) as compared to group B at all time intervals.[12]

The median OLP in groups B, I and P ranged from 26 to 33, 22 to 26.8 and 29 to 30 cm of H_2O respectively. In our study, higher OLP was observed with Baska mask. Similarly, the OLP was higher in the group B (29.6 ± 6.8 cm H_2O) than in the group I (26.7 ± 4.5 cm H_2O, $p = 0.01$) as observed by the authors in patients scheduled for laparoscopic cholecystectomy.[12]

In another study, the leak pressure at insertion time was 38.33 ± 4.4 cm of H_2O for group B, 30.57 ± 2.2 cm of H_2O for group I, 29.36 ± 2.7 cm of H_2O for group P (p = 0.04).[14] The leak pressure was significantly more in the group B, and comparable amongst groups P and I. The leak pressure after 30 minutes of insertion was 40.00 ± 2.4 cm of H_2O for group B, 35.14 ± 3.2 cm of H_2O for group I and 34.36 ± 1.3 cm of H_2O for group P [p = 0.04]. Similar results were observed in a study comparing the Baska mask with the PLMA, wherein it was found that the sealing pressure was significantly higher in the group B (30 ± 9 versus 24 ± 6 cm of H_2O).[15]

In a meta-analysis, the authors concluded that the PLMA provides higher OLP than I-Gel™ (mean difference, 3.37 cm H_2O; 95% confidence interval, 1.80–4.95 cm H_2O; $p = 0.000$).[16]

In the present study, we observed that the OLP of I-Gel™ increased more with time as compared to PLMA. Nonetheless, the OLP of I-Gel™ has been reported to have improved with time in patients undergoing gynaecological surgeries.[17]

However, the maximum increase in OLP was observed in the group B in the present study following the carboperitoneum and is in direct relation to the increase in PIP with increase in intrabdominal pressure as compared to the other two groups. Similarly, in a study comparing seal pressures of Baska mask with that of PLMA, the authors observed that the OLP was 30.25 ± 3.34 cm H_2O in group B and 23.50 ± 4.05 cm H_2O in group P ($p < 0.05$).[18]

In the present study, sore throat was observed in five patients in the group P as compared to two patients in group I. In all the groups, the devices were successfully inserted in the first attempt without the need for any manipulation.

The I-Gel™ has been found to have fewer complications (blood staining, sore throat, dysphagia) than the PLMA in various studies.[19,20] Complications such as sore throat are primarily related to cuff inflation, and the cuff of the Baska mask self-inflates and deflates during inspiration and expiration, respectively. Therefore, compared to the ProSeal and I-Gel™, the Baska mask is less likely to damage the surrounding tissues.

The present study has some limitations. Firstly, only ASA physical status I and II patients were included. Secondly, the blinding to group allocation was not possible for the anaesthesiologist inserting the device. Moreover, the results are not applicable to the patients on spontaneous ventilation.

CONCLUSION

The Baska mask is a good alternative to the PLMA or I-Gel™ in laparoscopic cholecystectomy under GA, as maximum airway compliance is observed with the use of Baska mask. Moreover, by virtue of its ability to increase the OLP and maintain the PIPs with carboperitoneum as compared to other SADs, the Baska mask provides better airway protection during controlled ventilation.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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