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Comparison of Baska Mask with I-GEL for Insertion Success Rate and Working Performance in Laparoscopic Pelvic Surgery

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Abstract

Aims: Study aimed at comparison of recent addition Supra Glottic Airway Devices I-gel and Baska mask during general anesthesia in patients undergoing elective laparoscopic pelvic surgery. *Settings and Design:* Prospective, randomized, single blind study. *Materials and Methods:* After institutional review board approval and written informed consent, 50 patients aged 18–60 years scheduled for elective laparoscopic pelvic surgery were randomly assigned into two groups either I-gel or Baska mask. After premedication and preoxygenation, patients were induced with Inj. fentanyl 2 mcg/kg and Inj. propofol 2- 2.5 mg/kg IV. Insertion of SGA was done according to group assigned. The insertion characteristics were recorded in form of number of attempt, time of insertion, manipulation required and failed insertions. Success of orogastric tube insertion was noted in both the groups. Working performance was compared in form of hemodynamic stability, oropharyngeal leak pressure, mean tidal expiratory volume and postoperative complications. *Statistical analysis used:* Data were analyzed by using unpaired *t*-test, Chi-square test. *Results:* Shorter insertion time was found with I-gel (16.80 ± 02.23) as compared to Baska mask (21.56 ± 04.20). Oropharyngeal leak pressure and mean tidal expiration volume were higher for Baska mask (25 ± 02.50;679 ± 98.17) as compared to I-gel (22.72 ± 02.13;600.08 ± 88.06). Hemodynamic parameters and postoperative complications were comparable among both the groups. *Conclusion:* Baska mask has a better working performance with higher oropharyngeal leak pressure and mean tidal expiratory volume while I-gel has lesser insertion time.

Keywords: Laparoscopic pelvic surgery; I-gel; Baska mask; Insertion time; Oropharyngeal leak pressure; Mean tidal expiratory volume.

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Introduction

The journey of the management of the airway has come a long-way since, the development of endotracheal intubation by Macewen in 1880, to the present-day usage of sophisticated supra glottic airway devices.[1] General anesthesia requires safe and open airway.[2] Till date, tracheal intubation is the gold standard method for maintaining a patent airway during anesthesia.[3] However, this maneuver requires skill, training and practice, usually requires direct laryngoscopy.[4] Laryngoscopy and endotracheal intubation produces reflex sympathetic stimulation which causes tachycardia, raised levels of plasma catecholamines, hypertension, myocardial ischemia, depression of

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myocardial contractility, ventricular arrhythmias and increase in intracranial pressure.[5] With advancement in anesthesia technique in airway management, it has been progressed from using an endotracheal tube to a supraglottic airway device because of ease and speed of insertion, improved hemodynamic stability, reduce anesthetic requirement and less postoperative complications.[6,7]

Wide variety of supraglottic airway devices available today which are employed to protect the airway in both elective as well as emergency situations.[8] A first-generation SADs is defined as being just a simple airway tube, with no specified design features for safety or performance, provide little protection from gastric regurgitation and aspiration. Second generation SADs, on the other hand, have been developed specifically for safety, with a gastric drain tube, improved pharyngeal seal and bite block. Miller, proposed in 2014 another system, based on the sealing mechanism (three generations) and on the anatomic location of sealing (base-of-tongue or perilaryngeal) (Table 1).

Laparoscopic surgery requires creation of pneumoperitoneum and appropriate positioning. The effectiveness of SAD use in gynecological surgery may be attributed to the short and elective nature of surgery, limitation of pneumoperitoneum and positioning to acceptable limits and the advantages offered by SAD in ambulatory surgery.

I-gel is a cuffless, single-use second generation supraglottic device.[9] I-gel is made up of a thermoplastic elastomer (styrene butadiene styrene ethylene)[10], a gel like material that is designed to more closely fit in the perilaryngeal anatomy without the need of inflatable cuff. I-gel has a gastric drainage tube that allow for passage of a nasogastric tube for stomach decompression, which significantly reduces risk of regurgitation and pulmonary aspiration.[11] I-gel has an intrinsic bite block to prevent compression of the airway tube and prevent misplacement and rotation.[12]

Baska mask is a novel 3rd generation SAD made up of medical grade silicon. It has noninflatable cuff, which is moulded to take shape of supraglottic airway, potentially reducing the risk of oropharyngeal tissue and nerve damage induce by cuff overinflation.[13] Baska mask has cuffless membranous bowl which inflates and deflates with each positive pressure inspiration and expiration respectively. Baska mask has an inbuilt tab that permits to increase its angulations for easy negotiation of oropharyngeal curve during placement. Baska mask has esophageal drainage inlet and side channel for aspiration of gastric content as well as integrated bite block.[14,15]

Materials and Methods

The study was done at tertiary care hospital, after obtaining approval from Institutional Review Board (IRB no.770/2018). It was registered with clinical trial registry-India under CTRI /2019/05/019242.

History of presenting complaint, past history, operative history, and drug history was taken. General examination of patients was done and vital parameters assessed. After preanesthetic check-up and necessary investigations, following patients were included and excluded from the study.

Inclusion Criteria

- Age of patient: 18–60 years.
- Gender: male/female.
- ASA Grade I–III.
- Laparoscopic Gynecological pelvic surgery for short-duration of 90–120 minutes.

Exclusion Criteria

- Age < 18 years and > 60 years.
- Risk of aspiration (nonadequately NBM, gastroesophageal reflux, BMI > 35 kg/m2, obstetrics' patient).
- Difficult Airway (mouth opening < 2 cm, mallampati class 4, limited neck extension, previous difficult intubation).
- Preoperative sore throat.
- Limited access to patient airway during surgery.

After taking written informed consent in the local language, patients were randomized using computer generated random number sequence methods in two groups:

Group A (I-gel Group).

Group B (Baska mask Group).

After shifting the patient to the preanesthetic care room, 20 G intravenous catheter is inserted on nondominant hand. Baseline parameters were recorded by multipara monitor, ECG for Heart Rate (HR), Noninvasive Blood Pressure (NIBP) for Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) and Pulse Oximetry for Oxygen Saturation (SpO_2). All patients were premedicated with Inj. ondansetron

0.08 mg/Kg IV, Inj. glycopyrrolate 0.004 mg/kg IV, Inj. midazolam 0.02 mg/kg IV and Inj. fentanyl 2 mcg/kg IV 20 minutes prior to surgery.

Patients were shifted to operation theater and were preoxygenated with 100% oxygen for 3 mins by face mask with Bains circuit. Patients were induced with Inj. propofol 2–2.5 mg/kg IV slowly till loss of eyelash reflex, jaw relaxation, absence of movements and apnea. Patients were ventilated with Bains circuit. Insertion of Supraglottic airway device was done according to group assigned to the patients either with I-gel or Baska mask. The size of supraglottic airway device was selected as per manufacturer recommendation.

Correct positioning of device was confirmed by bilateral chest movement and capnography. The time of insertion was counted from picking up the devices till establishment of manual ventilation *via* the Supraglottic airway device. If, ventilation was found to be inadequate, maneuver like neck flexion or extension, chin lift, gentle modification of the depth of the device will be applied. If, ventilation still remains inadequate device was then removed and inserted again. Maximum three failed insertion were permitted before it is considered as a failure. After insertion of device, appropriate sized of gastric tube was lubricated and placed into the stomach through the gastric channel. The correct placement of the gastric tube was confirmed by either aspiration of fluid or detection of injected air by auscultation over epigastrium. The ease of the device as well as gastric tube was graded as 1 (easy) and 2 (difficult).

Oropharyngeal leak pressure was measured by closing the adjustable pressure limiting valve against 5 l/min fresh gas flow and recording the airway pressure at equilibrium when air leak was heard in the oropharynx to a maximum airway pressure of 40 cm of H_2O. Supraglottic airway device was connected to ventilator with pressure controlled ventilation set as 17 cm H_2O[8] for 5 breaths to measure the mean tidal expire volume. Alveolar ventilation was set to maintain $EtCO_2$ in the range of 4–4.6 kpa (30 mm Hg).

Anesthesia was maintained with oxygen, nitrous oxide, IPPV, sevoflurane and intermittent dose of injection Atracurium. Hemodynamic parameters like heart rate, blood pressure as well as SpO_2 were recorded before, during and after induction with I-gel or Baska mask insertion at 1, 5, 10 (min) and after removal of the device.

At the end of surgery all the patients were ventilated with 100 % oxygen. After the fulfilment of the criteria of emergence, the SGA was removed and examined for traces of blood. Patients were asked for the pharyngolaryngeal pain and nausea before discharge from recovery.

Statistical analysis

Considering ease of insertion, attempts of I-gel and Baska mask insertion, oropharyngeal leak pressure, expired tidal volume, hemodynamic changes as the main outcome measure of interest in this study with at least 10% efficacy shown by the treatment group with permitted alpha error of 0.5 and beta error of 0.2 the power of study comes out to be 80%.

Data collected was analyzed as mean + SD and % which ever applied. Statistical analysis was done by graph pad instat 3.0 software. Intergroup comparison between two groups was done using the unpaired student *t*-test for quantitative data and Chi-square test for qualitative data ($p < 0.05$ was considered as statistical significant).

Results

The demographic and surgical data were comparable among both the groups, shown in Tables 2 and 3. I-gel was inserted successfully in 24 patients (96%) in first attempt and one patient (4%) in second attempt. Baska mask was inserted in successfully in 23 patients (92%) in first attempt and 2 patients (8%) in second attempt. There was no failure in insertion of airway in any group. One patient (4%) in I-gel Group and 2 patients (8%) in Baska mask Groups required airway manipulation for adequate ventilation (Table 4).

Table 1: Classification of SAD

Sealing mechanism	Location of sealing	
	Perilaryngeal	Base of tongue
1st generation-inflatable cuff	CLMA, PLMA	Combitube
2nd generation-preshaped	I-gel	SLIPA
3rd generation-self energizing	Baska mask	

Abbreviations: [CLMA - Classical Laryngeal Mask Airway, PLMA - ProSeal Laryngeal Mask Airway]

Table 2: Patient Characteristics

Patients characteristics	Group A Mean ± SD (*n* - 25)	Group B Mean ± SD (*n* - 25)	*p* - value
Age (years)	30.00 ± 07.20	30.00 ± 08.50	0.9293
Weight (kg)	57.28 ± 13.20	58.52 ± 11.66	0.7265
Height (cm)	157.48 ± 02.80	158.64 ± 02.70	0.1429

Table 3: Duration of surgery

Time	Group A Mean ± SD (*n* - 25)	Group B Mean ± SD (*n* - 25)	*p* - value
Duration (minutes)	75.40 ± 09.00	77.40 ± 09.02	0.4367

The mean insertion time was significantly less in I-gel as compared to Baska mask. ($p < 0.0001$), shown in Fig. 3. The Oropharyngeal leak pressure (p value 0.0017) and Mean tidal expiratory volume (p value 0.0041) were significantly higher in Baska mask group than I-gel, Figs. 4 and 5. Gastric tube could be inserted more easily and successfully in I-gel then Baska mask group but the difference was not statistically significant. (p value > 0.05). The heart rate and mean arterial pressure were comparable among both the groups, Figs. 7 and 8. Blood staining was observed in two and three cases each in the I-gel and Baska mask groups respectively. There was no incidence of Laryngobronchospasm in any of the groups, (Fig. 9).

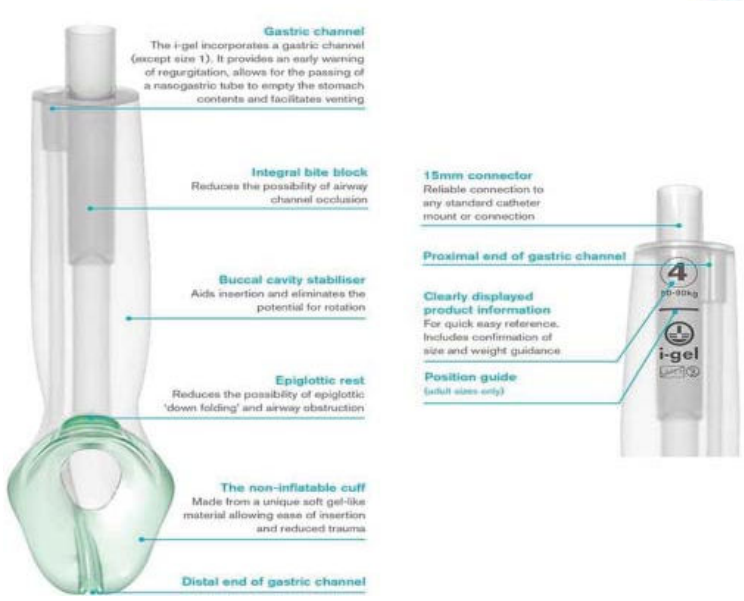

Fig. 1: I-GEL.

Table 4: Insertion characteristics of the device

Variable		Group A Mean ± SD (*n* - 25)		Group B Mean ± SD (*n* - 25)		*p* - value
		%	*N*	%	*N*	
Insertion attempts	First	24	96	23	92	0.5515
	Second	01	04	02	08	
Manipulation required after insertion to improve ventilation	Yes	01	04	02	08	0.5515
	No	24	96	23	92	
Failed insertion	Yes	00	00	00	00	
	No	25	100	25	100	

Table 5: Mean Insertion time of the device

Time	Group A Mean ± SD (*n* - 25)	Group B Mean ± SD (*n* - 25)	*p* - Value
Duration (sec)	16.80 ± 02.23	21.56 ± 04.20	< 0.0001

Table 6: Working performance of device

Variable	Group A Mean ± SD (*n* - 25)	Group B Mean ± SD (*n* - 25)	*p* - Value
Oropharyngeal leak pressure	22.72 ± 02.13	25.00 ± 02.50	0.0017
Expired tidal volume	600.08 ± 88.06	679.00 ± 98.17	0.0041
$EtCO_2$	31.84 ± 01.70	32.16 ± 01.79	0.5206

Abbreviation: [$EtCO_2$ - End Tidal CO_2]

Fig. 2: Baska Mask

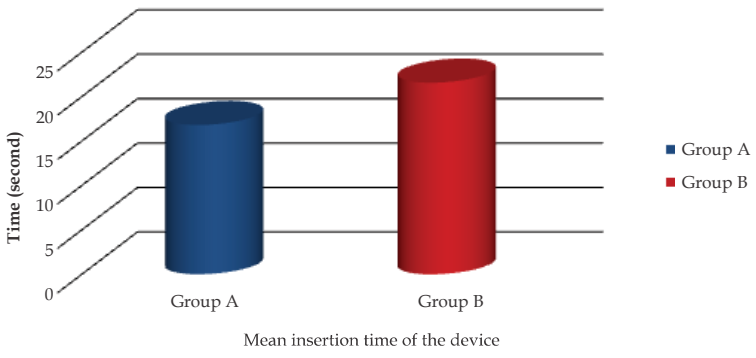

Fig. 3: Mean insertion time of device.

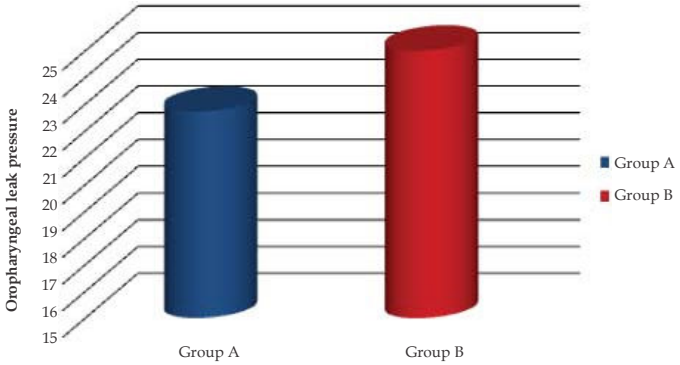

Fig. 4: Oropharyngeal Leak Pressure.

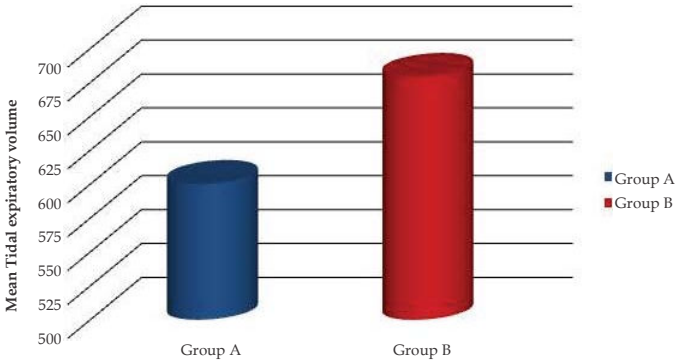

Fig. 5: Mean Tidal expiratory volume

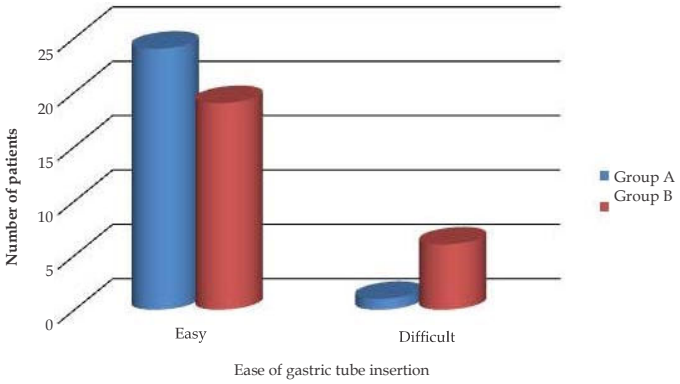

Fig. 6: Gastric tube insertion**.**

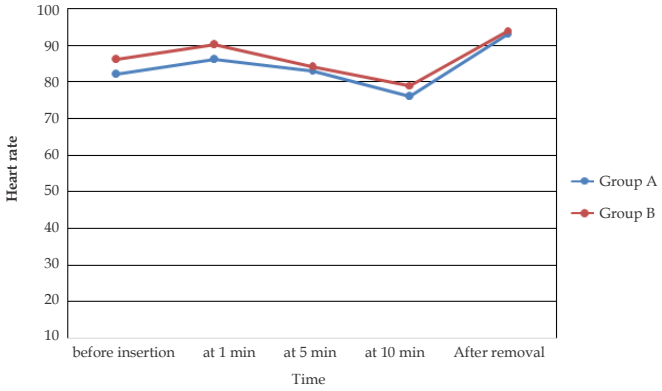

Fig. 7: Changes in Heart rate.

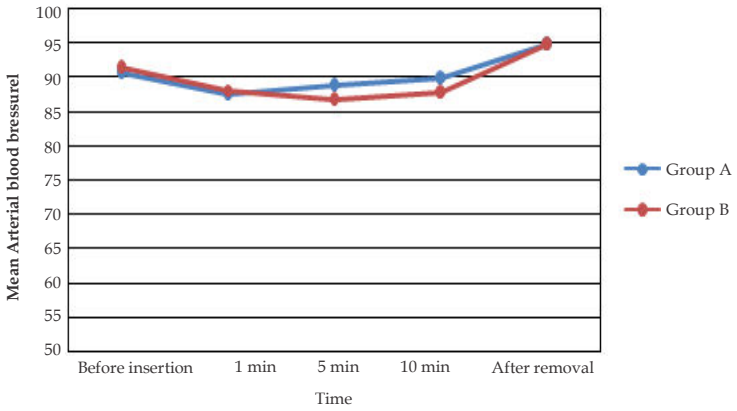

Fig. 8: Changes in mean arterial pressure.

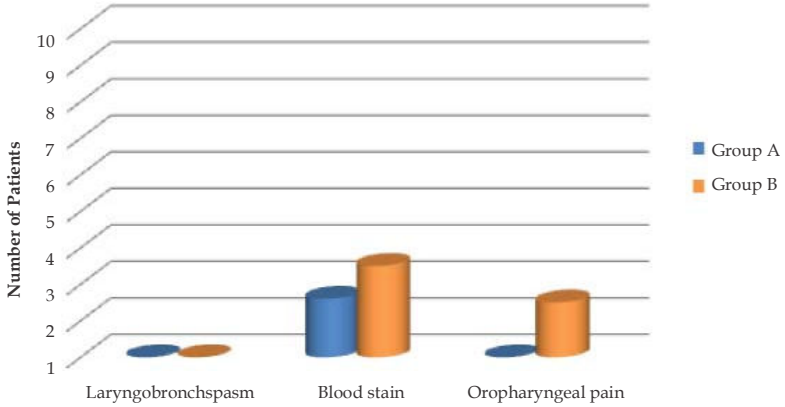

Fig. 9: Postoperative complications.

Discussion

Trend in airway management has recently been progressed from using an endotracheal tube to a supraglottic airway devices.[16] However, the use of supraglottic airway devices in laparoscopic surgery remain controversial because of increased risk of insufficient ventilation and pulmonary aspiration.[17,18] After introduction of airway devices with drainage system we can overcome many problems associated with its use.[19] Lu et al., have shown better suitability of supra glottic airway devices with drainage tube for securing airway in laparoscopic surgery.[20]

First generation supraglottic airway devices act as airway conduits whereas second generation devices have safety designs like integrated bite block, gastric drainage channel and act as airway conduit for endotracheal intubation.[21] Some of the cuffless devices like I-gel and Baska mask may reduce the risk of laryngopharyngeal trauma. First generation supraglottic airway devices develop air leak during positive pressure ventilation of 16–20 cm H_2O. But second-generation devices maintain seal pressure at 25–28 cm H_2O, which has permitted its use during complex surgeries including laparoscopic surgery, in which intraabdominal pressure is high. More recently, changes in surgical environment like shorter length of hospital stay, minimally invasive surgery and increased cost have all had some impact on the choice of airway management. Being less invasive supraglottic airway devices is good option for gynecological day care surgery. The Baska mask is a recently introduced device with self-energizing membranous cuff which provides high-oropharyngeal leak pressure which enhances the patient safety and ease of insertion when compared with the other noninflatable devices such as I-gel. Because both the Baska mask and I-gel have a noninflatable self-sealing mechanism, we decided to compare these two devices in laparoscopic surgery.

The present study shows, comparable demographic data (age, height and weight), shown in Table 2 and surgical details (type and duration of surgery) (Table 3).

In present study, first attempt insertion success rate was comparable between Group A and

Group B (Group A-96%; Group B-92% on first attempt) (p value > 0.05), this result was similar to a previously done study.[22,23] The lower success rate achieved with Baska mask may be attributed to the morphology of the device and unique expertise needed to insert the device. There was no failure after insertion and one patient in Group A and two patients in Group B required airway manipulation. (p value > 0.05), Table 4, which was similar to a previously done study.[24]

In present study, shorter insertion time was found with I-gel (16.80 ± 02.23) as compared to Baska mask (21.56 ± 04.20) (p value < 0.05), Table 5, this observation was correlated with previously done study.[22,23] This may be due to I-gel being less bulky as compared to Baska mask making it more handy device to insert and remove which is responsible for lesser insertion time.

The supraglottic airway device having separate gastric channel has the advantage of passing gastric tube through it which enable us for gastric decompression. In this study, ease of gastric tube placement was more with I-gel (24/25) then Baska mask (19/25), though the difference was not statistically significant (p value > 0.05), Fig. 6, which corelated with previously done study by El refai et al. in 2008.[25]

In present study, oropharyngeal leak pressure and mean tidal expiration volume were higher for Baska mask (25 ± 02.50;679 ± 98.17) as compared to I-gel (22.72 ± 02.13;600.08 ± 88.06) (p value < 0.05), Table 6, thereby providing greater airway protection during laparoscopic surgery. These findings were consistent with findings observed by other authors.[22,23,26] High oropharyngeal leak pressure of Baska mask may due to unique design of the cuff, a recoilable membrane that inflates and deflates with respiratory cycle. As pressure increases cuff inflates itself with positive pressure ventilation, which may improve the seal, thereby reducing the leak and provides high mean tidal expiratory volume making the ventilation more efficient.

Hemodynamic variables (heart rate and mean arterial pressure) were comparable between both the groups (p value > 0.05), Figs. 7–8. There was no statistically significant increase in heart rate and mean arterial pressure from baseline after insertion of device, this may be due to same stress response produced by both the devices, These results were comparable with previously done study.[26]

In the present study, Baska mask was associated with higher incidence of blood staining of the device (Group A-8% and Group B-12%) and oropharyngeal pain (Group A-4% and Group B-8%) in comparison to I-gel. But the difference was not statistically significant (p value > 0.05). These findings were correlated with previously done study.[26] The soft seal noninflatable supraglottic airway devices like I-gel or Baska mask has the potential advantage of minimal tissue compression which leads to lower incidence of laryngopharyngeal morbidity in form of Laryngobronchospasm, oropharyngeal pain and blood staining of device when compared to inflatable SADs.

There are several limitations to this study. First, findings may not be applicable to the patients with difficult airway. Second, we took single measurement of oropharyngeal leak pressure and did not observe it in the different positions of the patient. Third, it was an open label study as device blinding was not possible which could lead to bias. We recommend such more studies to compare the efficacy of both the devices and to support our study.

Conclusion

We conclude that, I-gel and Baska mask both are safe to use in laparoscopic pelvic surgery. Baska mask has a better working performance with higher oropharyngeal leak pressure and mean tidal expiratory volume while I-gel has lesser insertion time.

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