



Original Research Article

Comparison of baska mask with i-gel as ventilatory device in adult patients undergoing laparoscopic cholecystectomy

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ABSTRACT

Introduction: Oropharyngeal seal pressure of supraglottic device is an important parameter for safe use during laparoscopic surgeries.

Aim: To compare the oropharyngeal seal pressure and other insertion characteristics between baska mask and i-gel in adult patients undergoing laparoscopic cholecystectomy.

Materials and Methods: Sixty adult patients were randomly allocated into two groups of 30 each. Baska mask was inserted in group B and i-gel was inserted in group I. Primary outcome was oropharyngeal seal pressure. Secondary outcomes were insertion characteristics like first attempt success rate, insertion attempts, duration and maneuvers to achieve effective airway.

Results: Oropharyngeal seal pressure was significantly higher at insertion (31.70 ± 3.67 cmH₂O versus 27.3 ± 2.93 cmH₂O respectively, p value < 0.001) and after deflation of carboperitoneum (31.33 ± 3.51 cmH₂O and 28.20 ± 3.07 cmH₂O respectively, p value < 0.001) in group B than group I. Time for achieving effective airway in group B was comparable to that in group I (17.83 ± 2.05 seconds vs 17.86 ± 1.041 seconds respectively, p value = 0.937). Ease of insertion of device was comparable between the two groups (p value = 0.584). Upon fiberoptic assessment, anatomical alignment of the device to larynx was comparable between the two groups (p value = 0.655).

Conclusion: Baska mask, with a significantly higher oropharyngeal seal pressure, is a better ventilatory device as compared to i-gel in patients undergoing laparoscopic cholecystectomy.

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1. Introduction

Creation of pneumoperitoneum during laparoscopic surgeries raises intra-abdominal pressure, peak airway pressure (PAP) and decreases lung compliance. Second generation supraglottic airway devices (SGD) are reasonable alternatives to endotracheal intubation when performing anaesthesia for procedures accompanied by high PAP, such as laparoscopic surgery. Studies have been performed to establish safety of LMA-Proseal, LMA-Supreme and I-gel for laparoscopic procedures.¹⁻⁴

I-gel (intersurgical, Wokingham, Berkshire, UK) is a single use second generation SGD with noninflatable cuff made from medical grade thermoplastic elastomer and designed to anatomically fit perilaryngeal and hypopharyngeal structures and provide reliable perilaryngeal seal¹ with oropharyngeal seal pressure (OSP) of 23.58 ± 4.9 cmH₂O.⁴

Baska Mask (Baska Versatile Laryngeal Mask (BVLM) Pty Ltd, Strathfield NSW, Australia), is a new third generation SGD made of medical grade silicone with self-sealing membranous recoiling cuff that inflates and deflates proportionally with each positive pressure inspiration and expiration respectively⁵ Intermittent pressure on

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tissues reduces risk of their damage. Increase in airway pressure during positive pressure ventilation, increases oropharyngeal seal with Baska mask.⁵ It has a gastric reflux high flow suction clearance system consisting of large distal aperture located at upper end of esophagus which opens into sump cavity behind the mask. There are two lateral tubes located on each side of airway tube which join in a large distal sump for continuous drainage and suction of gastric and pharyngeal secretions. Baska Mask has been evaluated in few studies with limited number of patients⁵⁻⁸ with reported successful insertion rates of 96% to 100%, and OSP greater than 35cmH₂O.

We hypothesize that Baska mask will have higher OSP and better clinical efficacy as a ventilatory device in comparison to i-gel in adult patients undergoing laparoscopic cholecystectomy under general anaesthesia. This study was planned to compare clinical efficacy of Baska mask with i-gel as ventilatory device in adult patients undergoing laparoscopic cholecystectomy under general anaesthesia with OSP as primary objective. Secondary objectives were first attempt and overall success rate of insertion, time for achieving effective airway, ease of device insertion and anatomical alignment of device to glottis.

2. Materials and Methods

This prospective randomised comparative study was conducted for a period of 18 months (October 2019-March 2020) after obtaining approval from hospital Ethics Committee (IEC/VMMC/SJH/Thesis/October/2018-144) and written informed consent from all patients.

Sample size: Kini G et al observed mean value of oropharyngeal seal pressure (OSP) with I-gel as 23.58±4.9 cmH₂O.⁴ Taking this value as reference, and assuming that Baska mask had 20% higher OSP than i-gel, minimum sample size with 90% power of study and 5% level of significance was calculated as 23 patients per study group. To reduce margin of error, total sample size taken was 30 patients per group.

Sixty patients with American Society of Anesthesiologists physical status I and II, of either sex, aged 18-60 years, weighing 30-70 kgs, and undergoing elective laparoscopic cholecystectomy were included. Exclusion criteria were anticipated difficult airway (thyromental distance <6.5 cm, upper lip bite test more than grade 1, Modified Mallampati classes III and IV, restricted head and neck mobility, inter-incisor gap <3.5cm, BMI>30kg/m²), risk of regurgitation, edentulous patients, cervical spine pathology and pregnancy. Patients were kept fasting overnight. They received tablet alprazolam 0.25mg, tablet ranitidine 150mg and tablet metoclopramide 10mg, orally night before and two hours prior to surgery. Block randomization in series of blocks of 10 was done using sealed envelope method to allocate patients into two groups: group B: Baska mask was inserted (n= 30) and group I:

i-gel was inserted (n= 30).

Inside operation theatre, standard monitors (non-invasive blood pressure, electrocardiography and pulse oximeter) were attached and intravenous line was established. After preoxygenation with 100% oxygen for three minutes, general anaesthesia was induced using intravenous fentanyl 2µg/kg, propofol 2-2.5mg/kg and vecuronium bromide 0.1mg/kg. Mask ventilation was done with oxygen (FiO₂ 0.5) and nitrous oxide (N₂O) in isoflurane (1-1.5%) for three minutes followed by insertion of lubricated and appropriately sized (30-50 kg: i-gel size 3, Baska mask size 3; 50-70 kg: i-gel size 4, Baska Mask size 4) supraglottic airway device (SGD) as per group allocation by an experienced anaesthesiologist (successfully inserted the device atleast 30 times before), with patient's head and neck in sniffing position.^{9,10}

In group B, after opening the mouth, the proximal, firmer part of Baska mask was compressed between thumb and two fingers. It was pushed past the front teeth towards hard palate, avoiding the tongue and tab used only when required to negotiate the palato-pharyngeal curve. Mask was advanced until resistance was encountered.⁹ In group I, i-gel was grasped firmly along integral bite block. The leading soft tip was inserted into patient's mouth directed towards hard palate and then glided downwards and backwards along hard palate with continuous but gentle push until a definitive resistance was felt and incisors were resting on the integral bite-block.¹⁰

Airway tube of SGD was connected to closed circuit. Effective airway was said to be present if there was bilateral symmetrical chest expansion, bilateral equal air entry on auscultation, square wave form capnography tracing, lack of gastric insufflation and no audible leak at peak airway pressure of 20 cmH₂O during manual ventilation. Airway manipulations like jaw thrust, head and neck flexion or extension, chin lift and change in depth of device needed for achieving effective airway were noted. Lubricated gastric catheter kept preloaded into gastric vent tube of device (till just inside the distal opening of gastric vent tube) was then inserted and its placement confirmed by detection of injected air on epigastric auscultation. Achieving both effective airway and successful gastric tube insertion were considered as criteria for successful insertion of SGD. In event of insertion failure (either failure to achieve effective airway or inability to pass gastric catheter), device was removed and reinsertion attempted. Removal of SGD from mouth after insertion was counted as failed attempt. Reason for failure and any change in size of SGD in subsequent attempts was noted. Three failed attempts were labelled as failure of device in which case endotracheal intubation was done. Insertion time (time from holding SGD at teeth for insertion until obtaining first square wave capnograph tracing) and ease of insertion were recorded (Score 1 easy-insertion successful at first attempt

without tactile resistance, score 2 slightly difficult- insertion successful at first attempt with tactile resistance, score 3 difficult- insertion successful at second attempt, score 4 very difficult - insertion successful at third attempt and score 5 impossible- insertion failed at third attempt). Fiberoptic bronchoscopy scoring of device alignment with respect to glottic opening was done as follows: score 4: full view of vocal cords, score 3: part of vocal cords and posterior surface of epiglottis seen, score 2: part of vocal cords and anterior surface of epiglottis seen, score 1: vocal cords not visible.¹¹ Insertion was terminated and patient mask ventilated with 100% oxygen if SpO₂ fell below 95% at any time during SGD insertion.

Oropharyngeal seal pressure (OSP) was measured by closing circle system's expiratory valve at fixed gas flow of 3l/min with ventilator at bag mode (manual) and noting airway pressure (maximum 40cmH₂O) at which equilibrium was reached. Audible air leak at mouth and presence or absence of gastric insufflation by epigastric auscultation was also checked during leak pressure testing¹². Patient was ventilated using volume control ventilation (tidal volume 8ml/kg, respiratory rate 12-14/minute, inspiratory:expiratory ratio 1:2) using closed circle breathing system with soda lime at flow rate of 3L/minute, maintaining EtCO₂ of 30–35mmHg. Anaesthesia was maintained with N₂O, O₂ (FiO₂ 0.33) with isoflurane (0.6-0.8%) with vecuronium bromide intravenous top-ups. Intra-abdominal pressure was maintained constant at 12mmHg by automatic high flow carbon dioxide insufflation unit. Patient received injection diclofenac 1.5mg/kg intramuscular and injection ondansetron 75µg/kg intravenous. OSP was again measured five minutes after deflation of carboperitoneum. Hemodynamic and respiratory monitoring was done at regular intervals. Upon completion of surgery, 100% oxygen was given and residual neuromuscular blockade reversed with intravenous neostigmine 0.05mg/kg and glycopyrrolate 0.01mg/kg. Gastric catheter was removed after applying suction through it and device removed when patient was awake with return of full reflexes.

Intraoperative and postoperative adverse events such as desaturation (SpO₂<92%), aspiration (gastric fluid in airway port or hypo-pharynx), bronchospasm, laryngospasm, airway obstruction, airway manipulations for maintaining patent airway, failure to maintain effective airway and need for replacement of device with tracheal tube were recorded. Tissue trauma and blood staining of device was noted post removal. Postoperatively, patient was interviewed (interviewer blinded to group allocation) at one and four hours for sore throat, dysphagia and hoarseness of voice.

2.1. Statistical analysis

Categorical variables were presented in number and percentage whereas continuous variables were presented

as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If normality was rejected then non parametric test was used. Quantitative variables were compared using unpaired t-test/Mann-Whitney test and qualitative variables were compared using Chi-Square test /Fisher's exact test. P value of <0.05 was considered statistically significant. Data was entered in MS EXCEL spreadsheet and analysed using latest version of Statistical Package for Social Sciences.

3. Results

65 patients were enrolled in study of whom five got excluded after applying exclusion criteria. Remaining 60 patients consented and were randomly allocated into group B (Baska mask inserted, n=30) and group I (i-gel inserted, n=30) whose results were analysed (figure 1). Demographic characteristics (Table 1) and airway examination findings were comparable between the groups (Table 2).

Baska mask was successfully inserted in 27 patients (90%) and i-gel in 29 patients (96.67%) in first attempt leading to comparable first attempt success rate (p value 0.604). Rolling up of tongue during insertion was responsible for unsuccessful attempts. Overall insertion success rate in both groups was 100%. Incidence of patients needing manipulation for successful insertion of device was comparable (p value 1.000) in both groups. Jaw thrust was required for insertion in one (3.3%) patient in group B whereas increase in depth of insertion was required to achieve effective airway in one (3.3%) patient in group I. Time for achieving effective airway in group B was comparable with group I (17.83±2.05 seconds vs 17.86±1.041 seconds respectively, p value=0.937). Ease of device insertion was comparable between the two groups (p value= 0.584) (Table 4) Upon fiberoptic assessment, anatomical alignment of the device to larynx was comparable between the two groups (p value =0.655). The insertion characteristics are depicted in Table 3.

The mean oropharyngeal seal pressure (OSP) (Table 4) in group B after device insertion was 31.70±3.67cmH₂O which was significantly higher (p value <0.001) than OSP in group I (27.30±2.93cmH₂O). OSP after deflation of carboperitoneum was significantly higher (p<0.001) in group B than in group I (31.33±3.51cmH₂O vs 28.20±3.07cmH₂O respectively).

No intraoperative and postoperative adverse events occurred in any group. Postoperative pharyngolaryngeal morbidity was comparable between the groups (p value=0.237). (Table 5)

4. Discussion

This study compared the clinical efficacy of Baska mask with i-gel as a ventilatory device with oropharyngeal seal pressure (OSP) as primary objective in adult patients

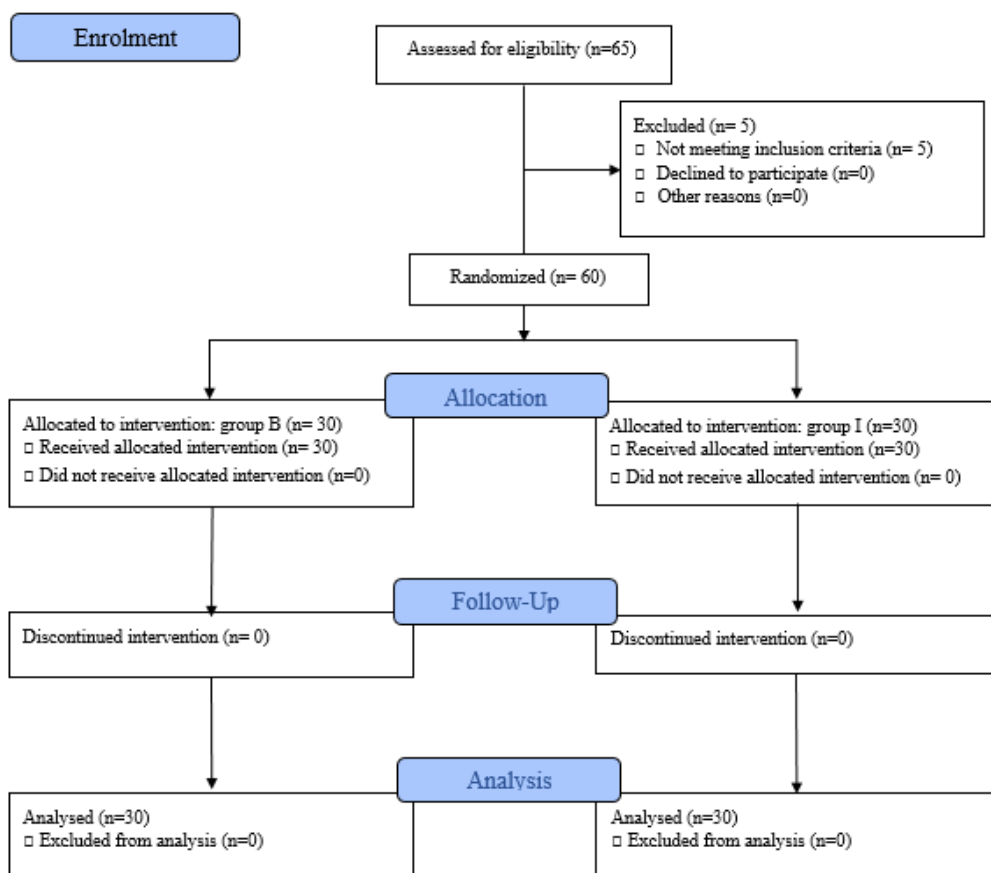


Fig. 1: CONSORT Flow Diagram

Table 1: Demographic profile of the patients

Variable	Baska mask	i-gel	p-value
Age (years)	29 (25.25-42)	32 (24.25-42)	0.929**
Sex (M/F) n(%)	10/20 (33.33/66.67)	7/23	0.390*
Weight (kg)	56 (50-62)	53.5 (49.25-63.75)	0.177**
Height (cm)	155 (151.25-163.5)	153 (150-156)	0.097**
BMI (kg/m ²)	22.76 (22.21-24.17)	22.95 (22-24.08)	0.523**
ASA (I/II) n(%)	28/2 (93.33/6.67)	26/4	0.671*
Duration of surgery (minutes)	80 (75.25-85.75)	75.5 (71.25-83.5)	0.288**
Size of device 3/4 n(%)	11/19 (36.7/63.3)	13/17 (43.3/56.7)	0.598*

**Mann-Whitney U; *Chi-square test; M: male; F: female; p-value<0.05 considered statistically significant

Table 2: Airway Parameters of the patients

Variable	Baska mask	i-gel	p-value
Inter-incisor gap (cm)	4.5 (4-5)	4.5 (4-5)	0.616**
Thyromental Distance (cm)	8.5 (8-9)	8.5 (8-9)	0.374**
Upper lip bite test class (I/II/III)(n)	28/2/0	29/1/0	1.000*
Neck mobility (Normal/ Restricted)	30/0	30/0	-
Mallampati class (I/II) n (%)	14/16 (46.7/53.3)	13/17 (43.3/56.7)	0.795*

**Mann-Whitney; *Chi-square test; p-value <0.05 considered statistically significant

Table 3: Insertion characteristics of baska mask and i-gel

Variable		Baska mask	i-GEL	p-value
Total time for achieving effective airway (seconds)		17.83 ± 2.05	17.86 ± 1.041	0.937**
Mean±SD				
No. of Attempts for device insertion n (%)	1	27(90.0%)	29 (96.67%)	0.604***
	2	3(10.0%)	1(3.33%)	
	3	0 (0.0%)	0 (0.0%)	
	4	0 (0.0%)	0 (0.0%)	
Manipulation Required (Yes / No) n (%)		1(3.3%)/29(96.7%)	1(3.3%)/29(96.7%)	1.000*
Ease of Insertion Score n (%)	1	26 (86.67%)	28 (93.3%)	0.584***
	2	1(3.3%)	1(3.3%)	
	3	3(10.00%)	1(3.3%)	
	4	0(0.00%)	0(0.00%)	
	5	0(0.00%)	0(0.00%)	
Fiberoptic Bronchoscopic Score n (%)	1	2 (6.7%)	0 (0.0%)	0.655***
	2	1 (3.3%)	2 (6.7%)	
	3	8 (26.7%)	7 (23.3%)	
	4	19 (63.3%)	21 (70.0%)	

Mann-Whitney; *Chi-square test; * Fischer Exact test; p-value <0.05 considered statistically significant

Table 4: Oropharyngeal seal pressure of baska mask and i-gel

		Baska mask	i-gel	P value
OSP at insertion (cm H ₂ O)	Mean± S.D	31.70 ± 3.67	27.30 ± 2.93	<0.001**
	Median (IQR)	32.5 (30-34)	27 (25-29.75)	
OSP after deflation of carboperitoneum (cm H ₂ O)	Mean± S.D	31.33 ±3.51	28.20 ±3.07	<0.001**
	Median (IQR)	32 (30-33.75)	29 (26-30)	

OSP-Oropharyngeal seal pressure; **Mann-Whitney; p-value <0.05 considered statistically significant

Table 5: Complications of baska mask and i-gel

Variable		Baska mask	i-gel	p-Value
Tissue Trauma / Blood Staining of Device n (%)		0 (0.0%)	0 (0.0%)	1.000***
Sore Throat (Present) n(%)	1 hour	7 (23.3%)	7 (23.3%)	1.000***
	4 hours	0 (0.0%)	0 (0.0%)	
Hoarseness of Voice (Present) n (%)	1 hour	1 (3.3%)	1 (3.3%)	1.000***
	4 hours	0 (0.0%)	0 (0.0%)	
Dysphagia (present) n (%)	1 hour	0 (0.00%)	3 (10.0%)	1.000***
	4 hours	0 (0.0%)	0 (0.0%)	

Mann-Whitney; *Chi-square test; * Fischer Exact test; p-value <0.05 considered statistically significant

undergoing laparoscopic cholecystectomy under general anaesthesia. Secondary objectives were first attempt and overall success rate of insertion, time for achieving effective airway, ease of insertion of device and fibreoptic assessment of anatomical alignment of device to glottis.

OSP after insertion of device in group B was significantly higher than in group I (31.70±3.67 cmH₂O versus 27.3±2.93 cmH₂O respectively, p value<0.001). OSP five minutes after deflation of carboperitoneum in group B was 31.33±3.51 cmH₂O whereas in group I it was 28.20±3.07 cmH₂O (p value<0.001). Similar results were found in other studies comparing Baska mask with i-gel in adult patients undergoing laparoscopic cholecystectomy.^{13–16} In a study with 100 subjects, OSP of Baska mask was significantly higher than i-gel at insertion (29.54±1.41

cmH₂O and 23.16±3.07 cmH₂O respectively, p value=0.02) and at 30 minutes after insertion (33.54±1.16 cmH₂O versus 25.97±2.25 cmH₂O respectively, p value=0.001).¹³ Another study with 97 patients reported significantly higher OSP with Baska mask than i-gel (29.6±6.8 cmH₂O and 26.7±4.5 cmH₂O respectively; p=0.014).¹⁴ Baska mask resulted in significantly higher OSP than i-gel when used in obese population, during minor surgical procedures and during spontaneous ventilation.^{17–19} Other studies evaluating Baska mask have reported its high OSP.^{20,21} I-gel has an integrated non-inflatable cuff made of gel-like thermoplastic elastomer, which conforms to the shape of laryngeal and perilaryngeal structures, providing a seal with these structures. Baska mask has a self-sealing membranous, non-inflatable, recoiling cuff made of medical

grade silicon. This variable pressure cuff inflates with each positive pressure inspiration and deflates during expiration. During intermittent positive pressure ventilation (IPPV), as airway pressure increases, the membranous seal apposes to glottis incrementally with time increasing the OSP thereby resulting in better seal with glottic structures, better airway protection and feasibility for using with IPPV.⁸ Hence, Baska mask will be superior to i-gel in patients who have high intrathoracic airway pressure due to pneumoperitoneum during laparoscopic surgery, poor thoracic compliance and high risk of gastric regurgitation.

Number of insertion attempts were comparable between groups (p value 0.604). First attempt success rate with Baska mask was 90.0% (27/30 patients) and with i-gel was 96.67% (29/30 patients). Second attempt was successful the remaining patients of both groups yielding 100% overall insertion success rate with both devices. Comparable first attempt success rates between Baska mask and i-gel have been reported in various studies.^{13,14,19} Presence of slightly bulkier cuff in Baska mask than i-gel could explain the slightly lower first attempt success rate though statistically insignificant. Gastric catheter, already preloaded in gastric vent of device could be passed successfully in all patients. Preloading of gastric catheter in Baska mask prevents its misdirection to pharynx from pharyngeal opening of sump cavity. Time taken for achieving effective airway was comparable between Baska mask and i-gel groups (17.83 ± 2.05 vs 17.86 ± 1.041 seconds respectively, p value=0.937) in current study. This was in accordance with Choi et al.¹⁴ Significantly longer insertion times with Baska mask as compared with i-gel have been reported.^{13,14,22} Presence of a larger and bulkier cuff in Baska mask and insertion during spontaneous ventilation could be possible causes of prolonged insertion times in these studies. Insertion of SGDs after administration of muscle relaxants could have facilitated SGD insertion resulting in shorter insertion durations in present study. Ease of insertion scores were comparable (p value 0.584) between group B and group I in present study. Insertion was easy in majority patients (group B 86.67%, group I 93.3%). Insertion of Baska Mask was reported easy in 91.66% patients by Choi et al.¹⁴ Similar results were obtained in a study on obese population. However, Chaudhary et al found insertion with i-gel significantly easier than Baska mask. This different result could be because of bulkier cuff of Baska mask and more experience with use of i-gel.¹³ In present study, jaw thrust was required for Baska mask insertion in one (3.33%) patient. One (3.33%) patient in i-gel group required increase in depth of insertion of the i-gel to achieve effective airway. Choi SR et al reported using airway manipulation after insertion during pneumoperitoneum in six (12.5%) patients with Baska mask and three (6.1%) patients with i-gel.¹⁴

Assessment of anatomical alignment of SGD in relation to glottic opening revealed full view of vocal cords (grade

4) in majority patients {19 (63.3%) in group B and 21 (70%) in group I}. Grade 1 view (worst) was present in two (6.7%) patients with Baska mask and none with i-gel. The two groups were comparable for anatomic alignment of device with glottic opening (p value 0.655). Choi S R et al also obtained grade 4 views in majority patients with Baska Mask and i-gel (p value=0.855).¹⁴ Similar anatomical alignment of both devices with glottic opening and good score on fibreoptic view implies that both devices have good anatomic fit and will be suitable for SGD guided fibreoptic bronchoscopic intubation.

No adverse events were recorded during intraoperative and postoperative periods. After device removal, there was no patient with visible trauma to oral tissues and no blood staining of SGD. This could be attributed to gentle insertion of SGD with adequate muscle relaxation without using any undue force. Incidence of pharyngolaryngeal morbidity in the postoperative period was comparable. At one hour postoperatively, incidence of sore throat was 23.3% (seven patients each) in group B and also group I, hoarseness of voice was 3.3% (one patient each) in both group B and group I, dysphagia occurred in three patients (10%) in Group I and in no patient in group B. These results are in accordance with previous studies.^{13,14,23} Cuff of Baska mask is soft, self-sealing, pliable membranous structure not requiring inflation to provide adequate seal with glottis. It inflates and deflates during inspiration and expiration respectively exerting intermittent pressure on tracheal mucosa. This is an advantage over most other inflatable cuffed SGDs whose continuously over-inflated cuffs can exert excess pressure and injure surrounding tissue or cause nerve damage causing dysphonia.⁸ I-gel has a non-inflatable cuff made of soft gel like thermoplastic elastomer that reduces perilaryngeal tissue trauma.

Limitations of this study were that some degree of observer's bias could have occurred as operator inserting device could not be blinded. Sample size was calculated for OSP, so; study could be underpowered for other endpoints such as postoperative pharyngolaryngeal morbidity. Results of this study cannot be extrapolated to patients with difficult airway or those with spontaneous respiration as this study was conducted in paralyzed patients with normal airway.

Baska mask and i-gel have comparable insertion success rates, durations to achieve effective airway, need for manoeuvres for achieving effective airway, ease of insertion, anatomical alignment to glottic opening and postoperative pharyngolaryngeal morbidity. Hence, both i-gel and Baska mask can be used as ventilatory devices in anaesthetised and paralysed patients. However, Baska mask provides higher OSP than i-gel after device insertion and after deflation of carboperitoneum and hence could be superior to i-gel for IPPV at higher peak airway pressures such as during laparoscopic cholecystectomy with creation of pneumoperitoneum.

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No financial support was received for the work within this manuscript.

6. Conflicts of Interest

No conflicts of interest.

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