

Comparative study between Baska and I-gel in spontaneously ventilated females undergoing minor gynecological procedures

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Abstract : *Background*: Several Supraglottic airway devices are used in anesthesia and emergency medicine, with different designs and safety issues.

Objectives : To compare insertion characteristics, oropharyngeal leak pressure, fitting on the larynx (detected by fiber-optic) & any associated complications of two different supraglottic airway devices (Baska® mask and I-gel) in females during minor gynecological procedures under general anesthesia whilst spontaneous breathing.

Design : Prospective, randomized, interventional study approved by institutional ethical committee.

Setting: Operating room of Kasr-Al-Ainy Hospital, Cairo (Egypt).

Methods : Sixty adult female patients were randomized into group A Baska® mask (n=30) and group B I-gel (n=30). Patients BMI >35, expected upper airway problems, gastrointestinal tract diseases, pregnancy & high risk of aspiration excluded. Patients were induced intravenously with fentanyl plus propofol and maintained spontaneous ventilation with sevoflurane in oxygen. Primary outcome measures were sealing pressure and laryngeal fitting by fiberoptic verification. Secondary outcome measures included insertion time, number of attempts, and complications.

Results : Mean insertion time in seconds was significantly shorter in I-gel group compared to Baska group (13.87±3.082 vs. 31.67±2.916 respectively) (P=0.000). Mean oropharyngeal leak pressure was significantly higher in Baska group than I-gel group (38.83±4.044 vs. 26.50±2.389 cmH₂O respectively) (P=0.000). Mean end-tidal CO₂ was significantly lower in I-gel group than Baska group (31.90±2.591 vs. 33.67 ± 2.523 mmHg respectively) (P=0.010).

Conclusions : Baska® mask provides significantly higher seal pressure than I-gel. Baska mask is efficient for spontaneous ventilation of females during minor gynecological procedures under general anesthesia with minimum postoperative complications

Keywords : Anesthesia, General; Laryngeal Masks; Gynecological Surgical Procedure.

INTRODUCTION

Aim of the work: The study aim was to compare the safety of the Baska® supraglottic airway device to the safety of the I-gel regarding oropharyngeal

leak pressure, fitting on the larynx detected by fiberoptic and related complications in spontaneously ventilated females.

Several Supra -glottic devices are used in anesthesia and emergency medicine, with different designs and safety issues, that were categorized according to several classifications including Brimacombe, Miller, and Cook classifications (1-3). However, Miller has published a new classification according to the sealing mechanism and anatomic site of sealing (4). Finally, it was agreed upon that the eminent need to new classifications (5, 6).

Baska® mask (Proact Medical Systems, Frenchs Forest NS, Australia) is displayed in Fig.1. It has 3 unique features; high seal pressure to facilitate ventilation, gastric access port providing airway protection and a bite block that minimizes airway obstruction (8, 9). Baska incorporates high flow suction clearance system consisting of a large distal aperture opposite the oesophagus and opens into a sump cavity behind the mask. The sump cavity is aspirated using two cylindrical tube vents. One of these tube vents is connected to high pressure, high flow suction, while the other is left open to ambient to equilibrate the pressure in the sump cavity to atmospheric (10). Baska® mask could be inserted with the patient's head in neutral position, while flexing the device using the extended hand tab attached to the cuff. This insertion method may reduce the need for neck manipulation. So, it was suggested that Baska mask is a suitable airway device for short procedures or when endotracheal intubation is not mandatory (11).

I-gel airway (Intersurgical Ltd, Workingham, Berkshire, United Kingdom) is second generation

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Fig. 1. — Baska Mask.

supraglottic airway devices (SAD_s), that integrates a non-inflatable cuff with a gel-like thermoplastic elastomer surface which is soft and conforms to the larynx, and a wide, flat shaft with integral bite block to resist rotation and mal-position. It also has a port for gastric tube insertion (12). Compared to LMA, I-gel was proved to be inserted as fast as LMA with adequate ventilation and no major airway complications. Therefore, I-gel can be used in emergency airway management or general anesthesia (13, 14).

Primary outcome measures are oropharyngeal leak pressure and fitting of the chosen device against the laryngeal aperture that could be detected by fiber-optic while secondary outcome measures are insertion time, number of attempts, easiness of insertion of both of the chosen device and the gastric tube, duration of surgery during which the device used, and complications.

METHODS

We obtained approval from Cairo University Hospitals Research Ethics Committee (Cairo, Egypt) (N-22-2016), and written informed patient consent. Then the study was registered on the clinical trial prior to the start of the trial and any patient enrollment undertaken. This study

was submitted in Clinical Trials.gov. in January 8, 2016 by the principal investigator Nesrine Abdelrahman El-Refai, the registration number is : NCT03140215. Then the study was conducted in obstetrics and gynecology department, Kasr Al Ainy Hospitals, Cairo University. Sixty female patients ASA I&II, BMI<35, ranging from 18-55 years old, underwent elective minor gynecological procedure (e.g. hysteroscopy, dilatation and curettage, repair of secondary sutures, drainage of vesicular mole, insertion or removal of IUD) in the supine position with SAD placement of ≤ 1 hour duration were randomly allocated into two equal groups; group A (Baska® Mask, n = 30) and group B (I-gel, n = 30).

This manuscript adhered to the applicable CONSORT guidelines. Patients BMI >35, suspected upper airway problems, gastrointestinal tract diseases, pregnancy and high risk of aspiration were excluded. All patients received a standard general anesthesia. Standard monitoring (including ECG, non-invasive blood pressure, pulse oximetry and end-tidal CO₂) was applied before induction of anesthesia. Anesthesia was induced with the head of patient in neutral position and resting on a donut head ring about 5 cm in height. All patients were induced intravenously with iv fentanyl 1-2 µg/kg and iv propofol (1.5-2.5 mg/kg) that were titrated to induce anesthesia, then all patients were maintained by manual ventilation with sevoflurane (2-4%) in oxygen. Adequacy of depth of anesthesia was detected when the patient has loss of eyelash reflex and no response to jaw thrust. When coughing, gagging or movement occurred during insertion, anesthesia was deepened with further boluses of iv propofol 0.5 mg/kg. Successful ventilation was confirmed by the presence of bilateral chest expansion and satisfactory end-tidal CO₂ tracing with plateau. The entire mask was lubricated liberally with a water soluble lubricant and with the tip of the mask mildly lubricated both upper and lower lips of the patient. The head and neck of the patient were put in a slightly extended position. All devices insertions were performed by one of the two investigators. A maximum of three attempts for placement of each examined device were permitted per patient. The size of Baska Mask and I-gel used for the first attempt was chosen according to the manufacturer instructions for each device. If the device did not function effectively, we inserted the device more deep, rotated it and withdrew it slightly out, then the device was moved up & down with the assistant performing jaw thrust. If these maneuvers failed to achieve adequate airway position, the device was removed. Then we assessed the size of the device

to decide whether to use one size smaller or larger. Failure of three attempts of insertion was followed by insertion of laryngeal mask airway (LMA). If LMA failed, the patient would be intubated. After successful insertion of the examined device, the lungs were kept on mechanical ventilation until spontaneous ventilation established. At the end of operation, Baska Mask or I-gel was removed after confirming adequate respiration and patient's response to verbal command. Data were collected by a physician who was unaware of the study. Postoperative scoring of LPM (Laryngo-Pharyngeal Morbidity scoring) was done by a recovery unit nurse who was unaware of the study groups. The following parameters were recorded:

1. Primary Outcome Measures including

- Oropharyngeal leak pressure in cmH₂O, 5 minutes after placement. The airway sealing pressure was defined as the pressure at which leak starts. This leak pressure was calculated by the following steps : the adjustable pressure limit valve was set at 70 cmH₂O, the fresh gas flow was set at 6 l.min⁻¹, and the airway pressure was measured on the breathing system pressure gauge. Leak pressure is considered as the achieved plateau airway pressure when the patient was apneic (15, 16).
- Fitting of SAD against laryngeal aperture detected by Fiber -optic. A flexible bronchoscope was passed down the airway tube and the placement of the Baska Mask (BM) and I-gel was scored using the fiber-optic scoring system of Brimacombe (4 = only vocal cords visible, 3 = vocal cords plus

posterior epiglottis visible, 2 = vocal cords plus anterior epiglottis visible, 1 = vocal cords not seen, but function adequate, 0 = vocal cords not seen and failure to function.). Brimacombe scores of 4 or 3 were considered favorable and 2, 1 or 0 were considered unfavorable placement (17, 18). If the bronchoscopic view showed the oesophageal opening, the device (either BM or I-gel) was reinserted and it was considered as an unfavorable view.

2. Secondary Outcome Measures including

- Insertion time that's needed for the placement of the SAD was calculated in seconds, from SAD touching the teeth to the first recorded near rectangular capnogram curve in the presence of satisfactory bilateral chest expansion. Only the successful attempt was counted (19, 20).
- Number of insertion attempts needed to correctly place the SAD.
- Difficulty of SAD placement was classified according to insertion SAD score ; (3 = insertion at first attempt without any tactile resistance, 2 = insertion at first attempt with tactile resistance, 1 = insertion successful at second attempt, 0 = insertion failed at second attempt).
- After the placement of the SAD, lubricant gel was applied 1 cm proximal to the gastric tube outlet, then the suprasternal notch test was performed by monitoring the pulsatile movement of the gel in the gastric outlet proximally when continuous pressure is applied at the cricoid cartilage level. The nasogastric tube was placed after correct placement of SAD. The number of attempts at gastric tube insertion and the success of the gastric discharge tube placement was evaluated using a three-point scale (1 = easy, 2 = difficult, and 3 = impossible) (21).
- The duration of device remaining in the oropharynx in minutes was expressed as duration of surgical procedure.
- LPM Score = Sum of sore throat, dysphagia and hoarseness scores.

Statistical analysis : Data were statistically described in terms of mean ± standard deviation

Table 1.

Miller's new classifications with examples of SGD (7)

	Location of sealing	
	Peri-laryngeal	Base-of-tongue
1 st generation-inflatable cuff	cLMA, PLMA*	Combitude*
2 nd generation-pre-shaped	I-gel**	SLIPA*
3 rd generation-self-energizing	Baska mask	

*Device has draining channel. **Device has draining channel and can be used as a conduit for blind intubation. cLMA : Classic laryngeal mask airway, PLMA : Proseal laryngeal mask airway, SLIPA : streamlined liner of the pharynx airway.

Table 2

LPM Score: Laryngopharyngeal morbidity parameter with scores (22)

Scores	0	1	2	3
Sore throat	none	minimal	moderate	Severe ; never an SAD again
Dysphagia	none	minimal	moderate	Severe ; cannot eat
Hoarseness	none	minimal	moderate	Severe ; cannot speak

LPM score was evaluated 1 and 4 hour postoperatively

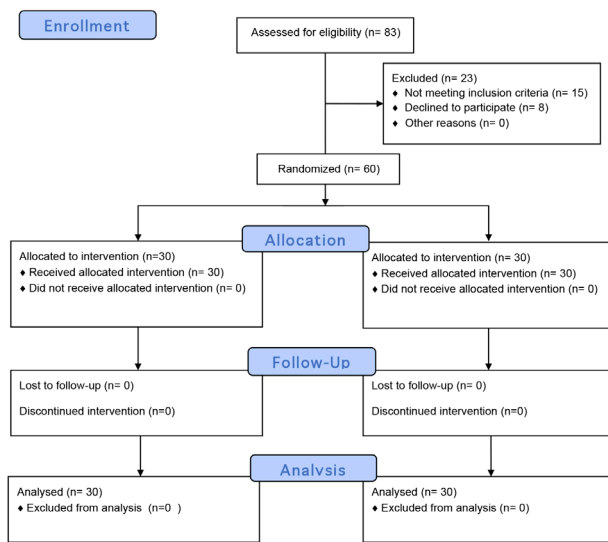


Fig.2 — Consolidated Standards of Reporting Trials flow diagram showing recruitment and flow of patients.

were expressed as number (%) or mean \pm SD and p -value < 0.05 considered significant.

There was no statistically significant difference between Baska Mask group and I-gel group regarding confounding factors including : age, weight, height, BMI, mouth opening, thyromental distance and duration of surgical procedures (Table 3).

Table 4 shows: Comparison between Baska® Mask group and I –gel group regarding their placement parameters of the used device including: SAD insertion attempts, ease of insertion, manipulations & maneuvers used to insert the device, Brimacombe Score to assess the anatomical fitting of the SAD against the glottic region, ease and attempts of gastric tube insertion, insertion time of SAD, end-tidal CO₂, and oropharyngeal leak pressure.

Table 3

Comparison between Baska® Mask group and I- gel group as regards the possible confounding factors

	Baska Mask (n = 30) Mean \pm SD	I-Gel (n = 30) Mean \pm SD	p-value
Age (years)	30.47 \pm 7.811	30.47 \pm 5.178	1.000
Weight (Kg)	57.63 \pm 7.889	59.60 \pm 10.159	0.406
Height (cm)	159.70 \pm 6.193	160.03 \pm 7.504	0.852
BMI (Kg/m ²)	22.57 \pm 2.144	23.33 \pm 2.952	0.254
Mouth opening(cm)	4.57 \pm 0.469	4.53 \pm 0.472	0.785
Thyromental distance(cm)	6.35 \pm 0.993	6.52 \pm 0.987	0.517
Duration of surgical procedure (min.)	25.00 \pm 7.656	23.50 \pm 7.21	0.438

SD : standard deviation, $p < 0.05$ is considered statistically significant.

(\pm SD). Comparison between study groups was done using student t-test for independent samples. $P < 0.05$ was considered statistically significant. Statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

Sample size : Sample size was calculated using EpiCalc program using the following data: mean seal pressure for I-gel: 25.62 (23) mean seal pressure for Baska: 29.98 (24). SD: 4.9, study power 80% confidence interval, p value < 0.05 , the calculated sample size was found to be 19 for each group (overall 38), so we allocated 30 patients in each group to avoid drop out.

RESULTS

Patients recruitment and flow were summarized in figure 2. Sixty patients divided into two groups: group A (Baska Mask) and group B (I-gel). Data

Tables 5 and 6 show LPM score at 1 and 4 hour postoperatively that expressed data in both groups as numbers (%).

Anatomical fitting of the SAD against the glottic region is shown in figures 3 and 4.

DISCUSSION

In this trial, most of the confusing factors which could influence the results e.g. age, weight, height, BMI, mouth opening, thyromental distance and duration of surgery were similar in both groups (Table 3).

We recorded that the insertion of Baska and I-gel occurred from the first attempt with significant easy insertion of I-gel in comparison to Baska mask with adequate fitting of both devices against the larynx confirmed by fiber-optic, in addition to the easy placement of their orogastric tube to the same extent (Table 4), beside insignificant differences

Table 4

Comparison between Baska ® Mask group and I-gel group regarding their placement parameters

	Baska Mask (n = 30)	I-Gel (n = 30)	p-value
SAD insertion attempts:			
1	22 (74.3%)	28 (94.3%)	
2	7 (22.9%)	2 (5.7%)	
3	1 (2.8%)	0 (0%)	
Ease of insertion:			0.0004
3	19 (62.5%)	24 (80%)	
2	11 (37.5%)	6 (20%)	
1	0	0	
0	0	0	
Manipulations:			0.0001
Yes	13 (42.5%)	2 (7.5%)	
No	17 (57.5%)	28 (92.5%)	
Maneuvers:			0.0001
No	20 (67.5%)	28 (92.5%)	
1	6 (20%)	2 (7.5%)	
2 or more	4 (12.5%)	0 (0%)	
Brimacombe Score:			
4	29 (97.5%)	28 (94.2%)	
3	1 (2.5%)	2 (5.8%)	
2	0	0	
1	0	0	
0	0	0	
Ease of gastric tube insertion:			0.195
1: easy	23 (77.1%)	27 (91.4%)	
2: difficult	7 (22.9%)	3 (8.6%)	0.208
3: impossible	0 (0%)	0 (0%)	
Attempts at gastric tube insertion:			
1	28 (93.33%)	29 (96.67%)	
2	2 (6.67%)	1 (3.33%)	
Insertion time (seconds)	31.67±2.916	13.87±3.082	0.000
End-tidal CO ₂ (mmHg)	33.67±2.523	31.90±2.591	0.010
Oropharyngeal leak pressure (cmH ₂ O)	38.83±4.044	26.50±2.389	0.000

Data are expressed as numbers (%) or mean (±SD). p<0.05 is considered significant.

Table 5

Laryngopharyngeal morbidity parameters
at 1 hour postoperatively

Parameter	Baska Mask (n=30)	I-Gel (n=30)
Sore throat	12(41.3%)	13(43.5%)
Dysphagia	5 (18.1%)	6 (20%)
Hoarseness	0	0

Data are expressed as numbers (%).

Table 6

Laryngopharyngeal morbidity parameters
at 4 hour postoperatively

Parameter	Baska Mask (no=30)	I-Gel (n=30)
Sore throat	7 (23.3%)	8 (26.67%)
Dysphagia	2 (6.67%)	3 (10%)
Hoarseness	0	0

Data are expressed as numbers (%).

in LPM score in both groups (Tables 5, 6). All insertions were done by the same investigator.

In our study mean insertion time (in seconds) of I-gel was significantly shorter than Baska (13.87 vs. 31.67 respectively) and mean oropharyngeal leak pressure (in cmH₂O) of Baska was significantly higher than I-gel (38.83 vs. 26.50 respectively) (Table 4).

I-gel had significantly shorter time of insertion than cLMA (classic Laryngeal Mask Airway), different key components of I-gel worked together to provide easy and short duration of I-gel insertion and high stability after insertion as it has non-inflatable cuff; thus there is no change in position with cuff inflation as occurs with other supraglottic airway devices with inflatable cuffs (23). Our study revealed difficult insertion of Baska that was previously documented when Baska compared with cLMA(24), while in the contrary it was proved that Baska was easier in insertion than proseal LMA(25)

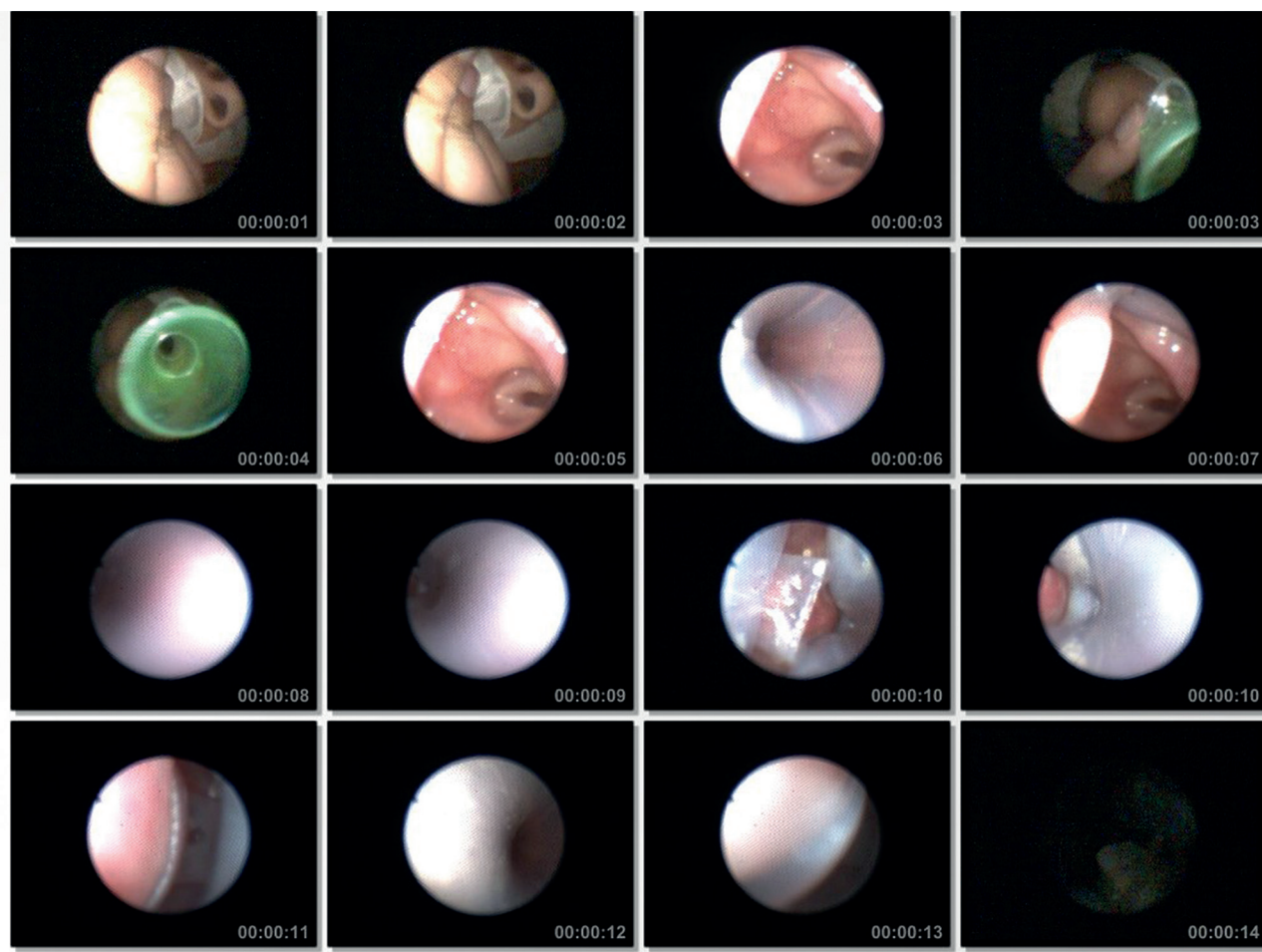


Fig. 3. — Fiber-optic laryngeal view through Baska.



Fig. 4. — Fiber-optic laryngeal view through I-Gel.

When I-gel and cLMA were compared together, they showed that insertion time of I-gel was less than that of cLMA and oropharyngeal leak pressure of I-gel was higher than that of cLMA (26).

In study comparing I-gel™, cLMA™ and proseal LMA™ showed successful insertion of the three devices from first attempt with I-gel had the highest seal and required the least insertion time (27).

It was shown that mean duration of insertion attempts was significantly less in I-gel than cLMA and proseal LMA (28). Another study comparing I-gel with cLMA demonstrated that I-gel required less insertion time than cLMA and seal pressure was significantly higher among patients of I-gel group than cLMA group with statistically significant fewer postoperative complications in I-gel group that showed better fiber-optic view of vocal cords (29). In spite of Baska was difficult to insert when compared to single used LMA, but it provided a better seal with favorable placement at the laryngeal aperture (30-32).

Regarding the higher oropharyngeal leak pressure of Baska than I-gel as proved by our study and at the same time in the previous studies. It was recommended that to ventilate safely with SAD, it should have high seal pressure during positive pressure ventilation (33). This makes Baska ideal for positive pressure ventilation especially in conditions expected to have high peak inspiratory pressure (e.g. obesity, laparoscopic surgeries, various positions of patients during surgery such as: prone, lateral, Trendelenburg, lithotomy positions, asthmatic patients, etc..) as mean peak airway

pressure of more than 20 cmH₂O increased risk of leakage resulting in insufficient ventilation and increased risk of aspiration (34-39).

In our study mean end-tidal CO₂ was significantly lower in I-gel group than in Baska group (31.90 vs. 33.67, respectively) (Table 4) in spite of adequate pre-oxygenation in both groups, this is coincided with a study compared easiness of placement of LMA and I-gel as end-tidal CO₂ measurement was used to assess easiness of supraglottic airway devices placement (40). It was also documented by another study comparing the two techniques for insertion of LMA ; classic technique [one-person LMA insertion] with new technique [two-persons LMA insertion], the new technique was associated with higher rate of success as confirmed by enhancement of O₂ saturation and reduction of ET CO₂ with significant difference between the two techniques [ET CO₂ and saturation of O₂ were 31.68 mmHg and 98.87% in the classic method and 30.47 mmHg and 99.42% in the two-persons method respectively] (41). One study compared I-gel to Baska in paralyzed anesthetized patients undergone positive pressure ventilation, it was found that both devices were suitable for PPV; however Baska mask gave a better laryngeal seal than I-gel and that coincided with our results (42).

Limitation of this study : this study was restricted to non-obese adult females to reduce variability in size of Baska and I-gel, so facilitating the analysis of performance parameters of both devices with greater confidence. However, further studies are recommended including great clinical and operative variability.

CONCLUSIONS

I-gel is easier in insertion than Baska mask, but Baska provides higher seal preventing leakage and aspiration, furthermore progressive cuff inflation of Baska limits possible injury risk in airway. Hence, Baska is efficient in airway control in spontaneously ventilated patients during minor gynecological procedures with minimum airway trauma.

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