

Comparison of Baska Mask Versus I-Gel in Short Gynaecological Laparoscopic Surgeries Under General Anaesthesia in Adult Female: A Randomized Interventional Study

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ABSTRACT

Background: Various newer generations of Supraglottic Airway Devices (SAD) with improved designs and performance are available for use by anaesthesiologist. We conducted the present study to compare 3rd generation SAD Baska Mask with 2nd generation SAD I-gel with the aim of comparing their clinical performance in terms of insertion parameters and oropharyngeal leak pressure in short laparoscopic gynaecological surgeries in adult females.

Methods: 80 adult female patients were randomly allocated to either Baska Mask (n=40) or I-gel (n=40) groups. Insertion characteristics that included number of attempts, mean insertion time and manipulation frequency were recorded and compared. Oropharyngeal leak pressure was measured just after insertion of device and after 5 min of creating pneumoperitoneum in both devices and were compared.

Results: Baska Mask insertion was successfully achieved in first attempt in 38/40 patients in Baska group vs 35/40 patients in I-gel group. Mean oropharyngeal leak pressure (OLP) in Baska Mask versus I-gel just after insertion was (29.24±4.20cm H₂O vs 26.33±2.51cm H₂O, P=0.003) whereas it was (29.42±2.70 vs 26.18±2.54 cm H₂O) after 5 min of creating pneumoperitoneum. Both groups were comparable in terms of removal characteristics and postoperative laryngopharyngeal airway morbidities.

Conclusion: Baska Mask provided more effective ventilation in terms of greater oropharyngeal leak pressure as compared to I-gel. However Baska Mask was more difficult to insert and the incidence of postoperative laryngopharyngeal morbidity was higher in case of Baska Mask.

Introduction

Supraglottic airway devices (SADs) are suitable alternatives to endotracheal intubation during general anaesthesia until unless contraindicated [1]. SADs are useful in anticipated and unanticipated difficult airway scenarios and also provide a rapid access to the airway in emergency and can't intubate can't ventilate situation [2]. Various generations of SADs with

variable characteristics are available to the anesthesiologists. With this background we planned to conduct our study to compare 3rd generation SAD Baska Mask and 2nd generation SAD I-gel with the primary objective to compare oropharyngeal leak pressure after insertion and 5minutes after creating pneumoperitoneum and with the secondary objectives to compare in their insertion and postop characteristics.

We hypothesized that Baska Mask offers comparatively higher perilaryngeal seal as compared to I-

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gel by creating higher oropharyngeal leak pressure in short laparoscopic gynaecological studies lasting upto 60 min.

Methods

After getting approval from the institutional ethics committee and informed written consent from the patients this hospital based randomized interventional study was conducted on 80 adult female patients ASA grade I or II of 25-40 yrs age and weight between 30-60 kgs scheduled for elective diagnostic laparoscopic surgery of short duration. The included patients were randomly allocated to either of the two groups (Baska mask vs I gel) by sealed envelope technique. Patients with known/ predicted difficult airway congenital malformations involving respiratory tract, cervical spine disorder, with increased risk of aspiration of gastric contents (NBM status unknown, nonfasted, gastrointestinal stricture or stenosis) or surgery time more than 1hr were excluded from our study. Standard general anesthesia as per our institute protocol with routine monitoring (ECG, NIBP, HR, pulse oximetry and EtCO₂) was received by both the groups. In supine, neutral head position and after achieving induction of anesthesia and adequate muscle relaxation either of the two SADs were inserted in each patient.

Baska Mask or I-gel were properly checked for their function and integrity before insertion. The size 3 for both devices was selected for the patients with weight 30-60 kgs. After lubrication the Baska Mask was introduced into the mouth toward the hard palate and advanced downward until resistance felt. The “tab” which is a unique feature of Baska Mask was used in manipulation to negotiate the palatopharyngeal curve in case of any difficulty while insertion. Similarly, I-gel was introduced after lubrication into the oral cavity of the patient against the hard palate, avoiding the tongue, and going downward and backward until a resistance was felt. Correct placement and effective ventilation was confirmed by square form ETCO₂ waveforms and bilateral equal thoracic movements. In cases where effective ventilation was not achieved after insertion of the device, pushing and pulling of the device, neck extension and flexion, jaw thrust, and chin lift manipulations were done. After these maneuvers if leak was still present, the device was removed and reinserted with endotracheal intubation done after insertion failure, which was defined as three or more attempted SADs insertions. Oropharyngeal leak pressure (OLP) was assessed immediately after insertion and 5 mins after

creating pneumoperitoneum in both the groups. After closure of APL valve and fresh gas flow set at 6 l/min, the pressure at which audible gas leakage was detected with the stethoscope in front of neck was taken as OLP in both the groups. After completion of surgery and complete reversal of neuromuscular blockade the Baska Mask or I-gel was removed. Removal characteristics of the device was observed and recorded in the form of any trauma to the teeth, lips, and tongue, cough and blood staining on the device. Laryngopharyngeal morbidity after 1 hour of surgery in the form of sore throat, dysphagia, dysphonia was also noted in both the groups. The device was also checked for its integrity and shape at time of removal.

Results

A sample size of 39 cases were required in each group required at 95% confidence and 80% power to verify the expected difference of 2.9 [+4.5] cmH₂O in mean oropharyngeal leak pressure in both groups³ as per seed article. The sample size was rounded off to 40 cases in each group.

80 patients were randomly divided into the Baska Mask or I-gel groups. Two patients were excluded in the Baska Mask group, because in them, more than 3 attempts were needed hence they were intubated. Demographic parameters like age, mallampati score, ASA grading, Anaesthesia time and pneumoperitoneum time were comparable in both groups (Table1).

(Table 2) showing the data regarding insertion characteristics of both Baska Mask and I-gel groups. First attempt successful insertion was achieved in 35 patients in Baska Mask group and 38 patients in i-gel group. Three patients in Baska Mask and two patients in I-gel group required second attempt (p=0.785) for successful insertion.

OLP was significantly higher in Baska Mask group after insertion (29.24±4.20 vs 26.33±2.51, p=0.003) as well after 5 min of creating pneumoperitoneum (29.42±2.70 vs 26.18±2.54, p<0.001) as compared to I-gel group (Figure 1). After creating pneumoperitoneum, an audible air leak was present in 4 patients in Baska Mask and 3 patients in I-gel group so manipulations were done in these cases but reintubation was not required.

(Table 3-4) showing removal characteristics and postop morbidities after 1 hour of surgery in both groups. There was no statistical difference between the two groups with regards to change in the heart rate, mean arterial pressure, ETCO₂, SPO₂ at each measured time (Figure 2-3).

Table1- Patients' Characteristics and Anesthetic Data

Variable	Baska Mask (n=38)	i-gel (n=40)	P value
Age (yrs)	29.73±4.93	30.30±5.37	1.00 (NS)
Mallampatti score (1/2/3/4)	3/35/0/0	10/30/0/0	0.085 (NS)
ASA (1/2)	15/23	13/27	0.685 (NS)
Duration of surgery (min)	57.50±9.06	55.00±8.16	0.198 (NS)
Pneumoperitoneum time (min)	20.45±3.23	20.08±2.14	0.541 (NS)

Values are presented as mean±SD or number. ASA: American Society of Anesthesiologists.

Table 2- Insertion characteristics of Baska Mask and I-gel

Characteristics	Baska Mask (n=38)	i-gel (n=40)	P value
No of attempts(1/2/3/4)	35/3/0	38/2/0	0.953(NS)
Ease of insertion(I/II/III/IV)*	30/8/0/2	34/6/0/0	0.281(NS)
Insertion time(min)	19.47±3.32	17.45±3.66	0.012(S)
Manipulation frequency(0/1/2)	34/4/0	37/3/0	0.943(NS)
OLP (T1)	29.24±4.20	26.33±2.51	0.003(s)
OLP(T2)	29.42±2.70	26.18±2.54	<0.001

Values are presented as mean±SD or number.

*I:easy, II:moderate, III:difficult, IV:impossible.

T1(at the time of insertion) T2 (after 5 minutes of creating pneumoperitoneum).

Table3- Removal Characteristics

	Baska Mask(n=38)	i-gel(n=40)	P value
Blood staining on device	7(18.42%)	2(5%)	0.134(NS)
Coughing	5(13.16%)	2(5%)	0.388(NS)
Bronchospasm/Laryngospasm	0	0	

Table4- Postoperative morbidity after 1hr of surgery

	Baska Mask(n=38)	i-gel(n=40)	P variable
Sore throat	11(28.95%)	6(15%)	0.224(NS)
Dysphagia	0	0	

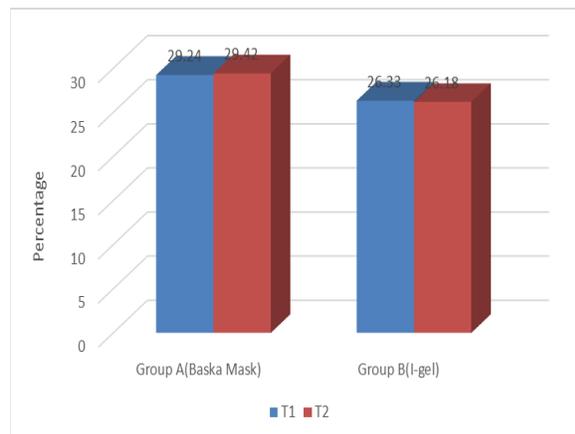


Figure1- Oropharyngeal leak pressure between Baska Mask and I-gel measured just after insertion (T1) and after 5 min of creating pneumoperitoneum

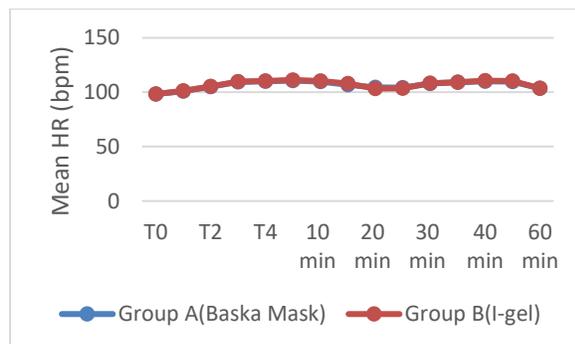


Figure 2- Comparison of mean heart rate between the two groups

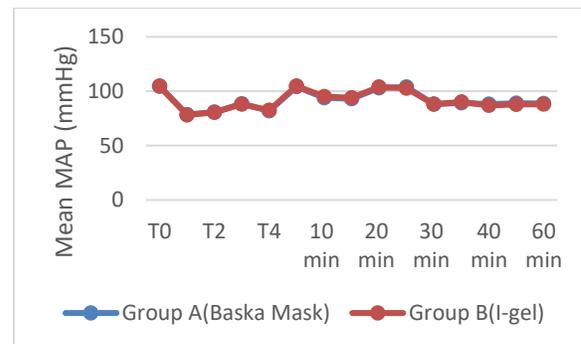


Figure 3- comparison of mean arterial pressure (MAP) between the two groups

Discussion

In our study we compared 3rd generation SAD Baska Mask with 2nd generation SAD I-gel in terms of oropharyngeal leak pressure and other clinical performance characteristics. The first/second attempt successful insertion rate seen was 35/3 vs 38/2 in Baska mask and I gel mask groups respectively. In Baska group, we were unable to insert mask in 2 patients, they were intubated and excluded from the study. The reason behind failed device insertion could be attributed to bigger cuff size of Baska Mask. In contrast to our study, Aziz et al reported better first attempt successful insertion with Baska Mask than I-gel. (90% with Baska Mask vs 83.3% with I-gel) [4].

The ease of insertion was comparable between the two groups in the present study. We could insert Baska Mask in mean duration of 19.47 ± 3.32 seconds and I-gel in 17.45 ± 3.66 seconds and the difference was statistically significant with not much clinical significance. A longer insertion time was observed by Ozlem Sezen et al with Baska group (27.97 ± 12.97 sec) as compared to I-gel group (12.73 ± 2.01) in their study [5].

In our study, during pneumoperitoneum, an audible air leak developed in (5/38) patients in Baska Mask group and (2/40) patients in I-gel group so they required airway manipulations but none of them required endotracheal intubation. Suhelya et al observed similar results [6].

We observed a higher mean OLP with Baska Mask than I-gel group after insertion of device and after 5 minutes of creating pneumoperitoneum with significant p value. Our results were in agreement to the study by Anil Kumar et al. The relatively higher mean OLP of Baska Mask could be attributed to the fact that it gets "inflated" with increasing pressure of positive pressure ventilation after creation of pneumoperitoneum, thereby improving its seal with the glottis aperture. Singh et al in their study also reported a significantly higher mean seal pressure with Baska mask as compared to LMA Proseal.

In our study in [7] out of 38 patients blood staining on the device was seen upon removal in case of Baska Mask group where in case of I-gel in 2 out of 40 patients was seen which could be related to either manipulation or to the second attempt on insertion. Sachidananda et al in their study found blood staining in 1 patient in both groups, being statis. G. Shanmugavelu observed 6.66% (2/30) patients recruited in Baska mask group had blood staining on device in comparison to I-gel (10 %; 3/30) [8]. Coughing was seen in (5 /38) 13.16% patients in case of Baska Mask group and in (2/40) 5% in case of I-gel group on extubation in our study. In study by Ranjith kumar et al where he compared Baska Mask and Proseal-laryngeal mask airway found coughing in (5/50) 10% patients in Baska group where (9/50) 18% in PLMA group. In our study we observed sore throat in 28.95 % cases.

(11/38) in Baska Mask group and (6/40) 15.00% in case of I-gel group attributed to either manipulation or second attempt on insertion. None of the patients in our study complained of dysphagia after 1 hr of removal of device and after discharge from ward. Dysphonia was noted in (2/38) 5% patients in case of Baska Mask group and (1/40) 2.50% patients in case of I-gel group with p value of 0.964 (NS).

Anil Kumar et al in their observational study observed sore throat in 15% cases in immediate post-operative period, which settled at the end of 2 hours. This was noted in initial part of the study where enough priority was not given to specified areas of lubrication. None of patients complained of dysphagia or dysphonia [9-10]

One of the major advantages of the SAD is that there is less hemodynamic instability when inserting the device compared with inserting the tracheal tube [11-12]. In our study, there was no significant difference in the heart rate and mean arterial pressure due to device insertion between the two groups. Baska Mask provided hemodynamic stability similar to that provided by I-gel. Fotedar et al [13] demonstrated that the I-gel and the Baska devices provided similar intraoperative hemodynamics. Whereas, in study by Ozlem Sezen et al hemodynamics revealed a significant difference in favor of the I-gel group in heart rate and mean arterial pressure.

Conclusion

On the basis of observations from this study, we conclude that though I-gel is easier to insert with lesser insertion time, Baska Mask is more effective in providing higher OLP as compared to I-gel explaining its safer use in laparoscopic surgeries creating pneumoperitoneum because of Baska's unique morphological design which offers the advantage of securing the airway rapidly with an efficient seal thus providing efficient ventilation.

Both Baska Mask and I-gel can be safely used in laparoscopic surgeries though Baska Mask may have a slight clinical advantage by providing a better oropharyngeal seal.

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