

A COMPARATIVE STUDY OF BASKA MASK[®]
AND I-GEL[®] IN PATIENTS UNDERGOING ELECTIVE
GYNECOLOGICAL SURGERY

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Abstract

Background: Supraglottic airway devices (SAD) are placed above the larynx forming a niche between the facemask and the tracheal tube to facilitate airway management. Baska mask[®] and i-gel[®] have been developed that provide better oropharyngeal seal pressure (OSP) during positive pressure ventilation (PPV) than the first generation SAD. We therefore, evaluated the clinical performance of newly developed Baska mask[®] with that of i-gel[®] in terms of OSP.

Methods: Thirty patients were randomly divided into two groups (Group I and Group II). Baska mask[®] and i-gel[®] were introduced as the airway device in Group I and Group II respectively, after institution of general anesthesia. OSP of both the devices was compared as a primary objective of the study. Time to insertion, rate of first time successful placement of the device, number of attempts and ease of insertion, pharyngolaryngeal morbidity and other adverse effects were also evaluated.

Results: The OSP in both the groups was comparable. Time to insertion was longer in Group I but did not attain statistical significance. First time successful placement of airway device was achieved in 66.66% patients in Group I and 86.66% patients in Group II. However, overall insertion success rate was 100% with both the devices. Mean number of attempts was 1.4 for Group I and 1.13 for Group II. Difficult insertion was noted in 33.33% patients of Group I and 13.33% patients of Group II. Pharyngolaryngeal morbidity and other adverse effects were comparable between the groups.

Conclusions: Clinical performance of Baska mask[®] and i-gel[®] as airway devices is comparable in terms of OSP and time taken for insertion in patients undergoing elective gynecological surgery.

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Introduction

Supraglottic airway devices (SAD) are placed above the larynx and form a niche between the facemask and the tracheal tube. The recently introduced Baska Mask[®] (Proact Medical Ltd, Northants, UK) is a newly approved and internationally patented second generation SAD made of medical grade silicone, designed by Australian anesthetists Kanag and Meena Baska (Figure 1).¹ Baska mask[®] is currently available in 4 sizes (3, 4, 5 and 6) for patients weighing between 30kg and 100 kg.

Fig. 1. Baska mask[®]



It has a non-inflatable variable pressure membranous cuff, an anatomically curved airway tube, two side channels within the large sump cavity and an integrated bite block over the full length of the airway.¹ It has certain special features such as a 'tab' to manually curve the mask to ease insertion and an interchangeable swivel suction elbow attached to either the suction or air inflow ports. The oval shaped airway tube matches the shape of the mouth and reduces the rotation within the pharynx. The two drain tubes allow gastric decompression. These features reduce the risk of pulmonary aspiration of gastric contents accumulating in the supraglottic area. The self-recoiling membrane inflates during positive pressure ventilation (PPV) to improve the seal when opposed to the larynx and provides higher oropharyngeal seal pressure (OSP) with PPV. It is inserted in the neutral head position, which reduces the need for neck manipulation. The Baska mask has an insertion success rate of about 96%.²

The i-gel[®] (Inter surgical Ltd, Wokingham, England), a newly developed SGD developed by

Dr. Mohd Aslam Nasir, is a truly anatomical device (Figure 2). It has a semi rigid stem for easy insertion and less chances of kinking, an intrinsic bite block to prevent compression of an airway tube and avoid axial rotation.^{3,4} The soft non-inflatable cuff fits snugly on the perilaryngeal frame work, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossa, perithyroid, pericricoid, and posterior cartilages. The cuff is made of thermoplastic elastomer (styrene butadiene styrene ethylene).⁵ The seal created is sufficient for both spontaneous and positive pressure ventilation.⁵

Fig. 2. i-gel[®]



The present study was conducted to compare the Baska mask[®] with the i-gel[®] in terms of OSP, duration, success rate and ease of insertion, pharyngolaryngeal morbidity (sore throat, nausea, vomiting, dysphagia and dysphonia) and other adverse effects in patients undergoing elective gynecological surgery.

Methods

This prospective double blind, randomized, comparative study was conducted after obtaining ethics committee clearance (EC/08/16/1047) and written informed consent from thirty patients, scheduled for gynecological surgery. The study was registered at the Clinical Trials Registry-India (CTRI/2018/03/012563).

All patients with ASA physical status II-III, above the age of 18 years and BMI <35 kg.m⁻² with a fasting period of more than 6 hours and surgical duration of less than two hours were included in the study. Patients who refused to consent, had anticipated difficult airway, risk of aspiration of gastric contents (i.e. pregnancy, full stomach, hiatus hernia) and those requiring tracheal intubation for the surgical procedure

were excluded from the study. Patients with mouth opening ≤ 2.5 cm, Modified Mallampati classification 3 or 4, thyromental distance ≤ 6.5 cm and sternomental distance ≤ 12.5 cm were considered as having difficult airway.

Patients were randomly divided into two groups by computer generated random allocation method. Group I and Group II received Baska mask® and i-gel® respectively as an airway device. Detailed pre-anesthetic checkup was done with special emphasis on airway examination to rule out difficult airway.

Standard monitoring was established following which general anesthesia was given to all the patients with intravenous midazolam (1 mg), fentanyl ($1.5 \mu\text{g kg}^{-1}$) and propofol ($2-4 \text{ mg kg}^{-1}$). The lungs were manually ventilated using a face mask and sevoflurane (1-1.5%) in oxygen. An airway device of appropriate size was then inserted by a trained anesthesiologist. Subsequent monitoring was performed by another anesthesiologist not involved in the study. The size of the Baska mask® and the i-gel® was selected according to the manufacturer's recommendations based on the patient's weight. Any resistance encountered during insertion of the Baska mask® was taken care off by pulling the 'tab' to help negotiate the palato-pharyngeal curve.

The primary objective of the study was to compare the OSP achieved with both the airway devices. Secondary objectives were to evaluate the two devices with respect to the insertion time, rate of first time successful placement of the device, number of attempts and ease of insertion, pharyngolaryngeal morbidity and other adverse effects (fall in $\text{SpO}_2 < 95\%$ during device insertion, trauma to lips, tongue, teeth, blood or bile staining of SAD).

Manipulations in terms of head tilt, jaw thrust, rotation of the device or adjustment of depth of insertion were done to position the device properly. If the device had a leak, a device one size larger was re-inserted. In absence of proper insertion, the device was removed (defined as failed attempt). An insertion attempt was considered each time the device was taken in and out of the mouth. The number of attempts were recorded. After three failed attempts, tracheal intubation was planned after giving appropriate neuromuscular blocking agent and the patient was then excluded from

the study.

The insertion time was taken as the time interval from holding the device in hand till confirmation of end tidal carbon dioxide on the monitor screen. In case of multiple attempts for insertion, the individual insertion times were summed up to give the final insertion time.

A suction catheter was inserted through the device to confirm the esophageal patency and proper positioning of the device. OSP and any fall in oxygen saturation below 95% during device placement were noted. To measure OSP, the expiratory valve of the circle system was closed and keeping the flow rate of oxygen at 3 L min^{-1} , the airway pressure was noted at which equilibration was achieved (maximum allowed was $40 \text{ cm H}_2\text{O}$).⁶ Anesthesia was maintained with sevoflurane (1-2%), nitrous oxide and oxygen (40%:60%) mixture.

A note was made of the time of successful placement of the device, number of attempts at insertion and ease of insertion graded by the operator as easy or difficult. Difficult insertion meant the requirement of maneuverability during device placement. At the end of surgery, the airway device was removed. The patient's mouth was carefully inspected for trauma to lips, tongue and teeth after removal of respective device while the cuff of the device was examined for the presence of blood or bile.

The patient was then transferred to the post-anesthesia care unit (PACU), where they were questioned about the presence of sore throat, dysphagia, dysphonia, nausea and vomiting at arrival and at discharge from the PACU and four hours later. Assessment of pharyngolaryngeal morbidity was done on a two point scale (1 = present, 2 = absent).

Statistical Analysis

The data was analyzed using SPSS software (version 17.0 Chicago, IL, USA). Continuous variables were presented as mean \pm SD while categorical variable were expressed as frequencies. Differences between groups were assessed with Chi Square or Fisher's exact test for comparison of categorical variables. Unpaired t tests were used for continuous variables between the two groups. Data was considered statistically significant with $P < 0.05$.

Table 1
Physical characteristics

	Group I (n = 15)	Group II (n = 15)	p-value
Age (yr)	39.47 ± 11.47	38.00 ± 10.53	0.718
Weight (kg)	64.67 ± 15.82	64.27 ± 11.01	0.062
Height (cms)	152.93 ± 5.20	156.23 ± 4.01	0.937
ASA I/II	13/2	9/6	0.099
Mask size used (3/4)	10/5	9/6	0.705

Data are number (n), mean ± standard deviation; Group I-Baska mask®, Group II-i-gel®

In a previous study,⁷ which demonstrated a mean OSP of 35.6 ± 4.84 cmH₂O in the i-gel® group, a sample size of 12 patients per group provided a 90% power for detecting a 20% difference between the groups for a mean difference in OSP at an alpha level of 0.05. The difference of 20% was taken from clinical experience. We included 15 patients per group to accommodate for the dropout cases.

Results

Thirty patients were included in the study. Demographic data and mask size used in both groups were found to be comparable (Table 1).

OSP in Group I and Group II was 34.80 ± 2.90 cmH₂O and 34.53 ± 2.44 cmH₂O respectively and the difference was statistically insignificant. The time taken for insertion of the device was slightly longer in Group I (27.73 ± 10.87 sec) than in Group II (23 ± 8.29 sec) but did not achieve statistical significance (Table 2). The airway device was successfully placed on the

first attempt in 10 patients (66.66%) in Group I and 13 patients (86.66%) in Group II (Table 2). Successful insertion on the second attempt occurred in 4 patients (26.66%) of Group I and 2 patients (13.33%) of Group II. Only 1 patient (6.7%) of Group 1 needed a third attempt for successful insertion. Insertion success rate was 100% with both devices and none of the patients required tracheal intubation. The mean number of attempts was 1.4 for Group I and 1.13 for Group II. The device was easy to insert in Group II patients (93.33%) as opposed to Group I patients (66.66%). Difficulty was encountered in device insertion in 5 patients (33.33%) of Group I and 2 patients (13.33%) of Group II.

Fall in oxygen saturation below 95% during device placement was not observed in either of the groups. On arrival at the PACU, sore throat was observed in 5 patients of Group I and 2 patients of Group II. Four hours post surgery, only 2 patients of Group I and 1 patient of Group II had sore throat (Table 3).

Table 2
Clinical performance of SAD

	Group I (n = 15)	Group II (n = 15)	p-value
OSP (cmH ₂ O)	34.8 ± 2.90	34.53 ± 2.44	0.788
Insertion time (s)	27.73 ± 10.87	23.00 ± 8.29	0.191
Number of insertion attempts (1/2/3)	10/4/1	13/2/0	0.357
Difficulty of insertion (easy/difficult)	10/5	14/1	0.068

Data are number (n), mean ± standard deviation; Group I-Baska mask®, Group II-i-gel®

One patient from each group complained of nausea upon arrival to the PACU but it settled by the time of discharge from the PACU. One patient in Group I had vomiting on arrival at the PACU and one patient in Group II vomited at the time of discharge. Four hours post surgery, none of the patients had nausea or vomiting.

Dysphagia and dysphonia were not observed in any patient in either group upon arrival at the PACU but one patient from each group had dysphagia and one patient in Group I had dysphonia at the time of discharge from PACU. Four hours post-surgery, one

patient in Group I complained of dysphagia but none of the patients had dysphonia (Table 3).

Trauma to lips occurred in 1 patient in Group I. Blood staining of the device was noted in 4 patients from Group I and 2 patients from Group II. There was no trauma to tongue or teeth. Bile fluid staining of device was not observed in either of the groups.

Discussion

Our study evaluates the performance of two non-inflatable SADs. Our results showed that there was no

Table 3
Post operative complications and adverse effects in both the groups

	Group I (n = 15)	Group II (n = 15)	p-value
Sore throat			
Arrival in PACU	5 (33%)	2 (13.3%)	
Discharge from PACU	4 (26.7%)	2 (13.3%)	
4 h postop	2 (13.3%)	1 (6.7%)	0.534
Dysphagia			
Arrival in PACU	0 (0%)	0 (0%)	
Discharge from PACU	1 (6.7%)	1 (6.7%)	
4 h postop	1 (6.7%)	0 (0%)	1.000
Dysphonia			
Arrival in PACU	0 (0%)	0 (0%)	
Discharge from PACU	1 (6.7%)	0 (0%)	
4 h postop	0 (0%)	0 (0%)	1.000
Nausea			
Arrival in PACU	1 (6.7%)	1 (6.7%)	
Discharge from PACU	0 (0%)	0 (0%)	
4 h postop	0 (0%)	0 (0%)	1.000
Vomiting			
Arrival in PACU	1 (6.7%)	0 (0%)	
Discharge from PACU	0 (0%)	1 (6.7%)	
4 h postop	0 (0%)	0 (0%)	1.000
Trauma to lip	1 (6.7%)	0 (0%)	1.000
Trauma to tongue	0 (0%)	0 (0%)	0
Trauma to teeth	0 (0%)	0 (0%)	0
Blood staining of mask	4 (26.7%)	1 (6.7%)	0.330
Bile fluid staining of mask	0 (0%)	0 (0%)	0

Values are numbers (%), PACU: Post anesthesia care unit
Group I-Baska mask®, Group II-i-gel®

statistically significant variation in the oropharyngeal pressure (OSP) between the two groups. OSP achieved with Baska mask[®] (34.82cmH₂O) in the current study was higher than that noted by Al Rawahi et al (29.98cmH₂O).⁸ Similarly, we observed a higher OSP with i-gel[®] (34.53 cmH₂O) than that observed by Jeon et al (24.3cmH₂O).⁵ The secondary objectives of the study were also comparable between the two groups. The longer time for insertion of Baska mask[®] (27.23 s) in comparison to that of i-gel[®] (23 s) could be attributed to the time taken for manipulation of the tab of the Baska mask[®] to increase its distal curvature for adequate positioning. Time to insertion of Baska mask[®] was longer in our study in comparison to 16.43 reported by Al Rawahi et al⁵ and Van Zundert et al (16 ± 6 s).¹ Time to insertion varied due to the difference in the way it was recorded.^{1,8} However, time to insertion in our study is similar to the effective airway time (32 ± 12 s) recorded by Van Zundert et al.¹ The time to insertion of i-gel[®] was shorter than that reported in other data.^{3,5,9} In comparing the first time successful insertion rate, i-gel[®] had a slight edge over the Baska mask[®], but this was statistically insignificant. The first time successful placement of Baska mask[®] in our study (66.66%) was less than in other studies,^{1,2} but that of i-gel[®] (86.66%) was comparable.¹⁰ The number of attempts needed to insert both the SADs were comparable. Even though the number of difficult insertion of the SAD were more in the Baska[®] group compared to i-gel[®] group, the difference was statistically insignificant.

One would assume that the presence of variable pressure recoiling membrane would lead to a decreased chance of sore throat but there was a higher incidence

of sore throat in patients with the Baska mask[®] although this difference was not statistically significant.

Blood staining on the Baska mask[®] was more than the i-gel[®], contrary to that observed by RARA Aziz,¹¹ but statistically insignificant. There was no relationship between blood staining and the incidence of sore throat and dysphagia. Similar to other studies, the postoperative incidence of dysphagia, dysphonia, nausea, vomiting and trauma to lips, tongue or teeth were low.^{1,8,11,12} Both of these devices being non inflatable do not need monitoring of intra-cuff pressure and should not cause tissue or nerve damage as evident in our study.

There were certain limitations in our study. Participants with difficult airway were excluded from the study so, the authenticity of these devices in difficult airway cannot be predicted. The study was conducted in patients with positive pressure ventilation and not those on spontaneous ventilation.

Conclusion

Both of the Baska Mask and i-gel devices were comparable in terms of OSP and time taken for insertion, although a higher OSP was expected by the unique self recoiling membrane present in Baska mask[®]. Hence, our study concludes that both Baska mask[®] and i-gel[®] show comparable performance in patients undergoing elective gynecological surgery. Further studies should be conducted in other types of surgical procedures and in patients with difficult airways to have a more comprehensive outlook.

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