Original Article

A Study to evaluate the efficacy and safety of I-GEL and Baska Mask in Adult patients posted for non-emergency surgeries under GA.

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Abstract

Background: Extraglottic airway devices (EADs) which are also known as supralaryngeal airways (SLA) or supraglottic airway devices (SADs, SGAs) are an integral part of modern anesthetic practice. After induction of anesthesia, SAD's are inserted into oral cavity which helps to maintain airway patency. The Baska mask which is the third generation SAD is introduced recently in the SAD market. When compared to second generation SAD, Baska mask has several novel features. **Objectives:** To evaluate the efficacy and safety of I-GEL and Baska Mask in Adult patients posted for non-emergency surgeries under GA (General anesthesia) regarding oropharyngeal Leak Pressure. **Materials and Methods:** The present prospective Randomized Single Blind Comparative study was undertaken from November 2018 to April 2020 from the Department of Anesthesia in JSS Medical College and Hospital Mysore Taking a difference of 10 cmH2O sealing pressure between Baska mask and I Gel as significant based on our pilot studies and previous studies considering alpha and beta values, we got our sample size as 63 in Baska group and 63 in I-gel group. We studied a total of 300 patients and into two groups of 150 in order to increase the power of the study. **Results:** OLP of Baska mask which is our primary objective was 40.45cmH2O which provided better sealing pressure than I-gel (30.29cmH20), with statistical significance (p value less than 0.0001). There was a statistical significance ($p < 0.001$) in the Brimacombe scoring of Glottic view. The increase in pulse rate soon after insertion was more with Baska than with I-gel (p=0.005), though it was not significant clinically. Similarly, though there was a rise in SBP (systolic blood pressure) after inserting the device in group Baska more than in the group I-Gel, it was not clinically significant(p=0.0001). **Conclusion:** The OLP for Baska mask which was our primary objective is superior to that of I-Gel. The ease of insertion was better with I-gel requiring lesser time for insertion but a significantly better fiber-optic view was provided by Baska mask. However, Baska mask may have clinical advantage by providing a favorable Brimacombe scoring, better OLP and hence an improved safety profile.

Keywords: I-GEL, BASKA MASK, EXTRA GLOTTIC, AIRWAY DEVICE, EMERGENCY

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Introduction:

Extraglottic airway devices (EADs) which are also known as supralaryngeal airways (SLA) or supraglottic airway devices (SADs, SGAs) are an integral part of modern anesthetic practice. After induction of anesthesia, SAD's are inserted into oral cavity which helps to maintain airway patency. The Baska mask which is the third generation SAD is introduced recently in the SAD market. When compared to second generation SAD, Baska mask has several novel features. Kanag Baska, who is an Australian anesthetist, designed and developed Baska mask over 11 years.[1]

I-gel is the second generation SAD which is single use, designed and developed by Mohammed Nasir. I-Gel is made of a different material which is gel like thermoplastic elastomer.[2] During difficult airway management, EAD may be of help as a rescue device during emergency. [3] Ease of insertion is one of the advantage of EAD and also has low incidence of post-operative complications. EAD's are less invasive devices when compared to endotracheal tube [4]. First attempt insertion success rate is high even with less experience in the field of anesthesia. [5] Presently there are multiple EAD's available in the market. Pharyngeal sealing devices, originally discovered by Leech in 1937 (and named as such), come with a proximal cuff to occlude the pharynx. The proximal cuff is also a feature of first line EADs, which were modelled after the original pharyngeal sealing devices. Modifications were made to prevent

aspiration, provide a more secure airway by Brain in 1983 by changing the cuff design, introducing a separate port for gastric content aspiration, and to prevent epiglottic down folding, a few internal mechanisms were added. These are changes made in the second line EAD's as well. [6]

The name supraglottic airway device implies that the tube sits above the glottis and allows gas to enter and exit the airway. However, the more appropriate term would be extra-glottic airway devices (EAD). [7]

A number of new devices have been introduced, without adequate testing for factors such as "ease of insertion, ease of intubation through the device, airway seal pressure, ability to protect against regurgitation, patient ease and charge per use". 8 The anesthesiologist may find it hard to choose the right device. Pros and cons of each EAD should be assessed and selected according to each situation. The Baska mask is the latest supraglottic airway device (SAD) and classified as third generation SAD[9].

In addition to the features of second generation, it also has a few additional features. It has been designed by an Australian anesthetist of Indian origin, Dr Kanag Baska. [10] In January 2007, Dr. Mohammad Aslam Nasir invented the I-Gel, a second generation SAD. It is a true anatomical device as it does not have a cuff for inflation. 11 The non-inflatable cuff exactly conforms to the upper airway structures like "epiglottis, aryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces." [11,12] Thus, this device can be used for patients under general anesthesia as the seal created is sufficient to prevent aspiration. There is also an additional drain port for passing Ryle's tube.[13]

Hence a prospective, single blinded, randomized controlled trail, comparing BASKA MASK and I-GEL was taken up in JSS hospital to evaluate efficacy and safety of both devices.

Objectives:

To evaluate the efficacy and safety of I-GEL and Baska Mask in Adult patients posted for non-emergency surgeries under GA (General anesthesia) regarding oropharyngeal Leak Pressure.

Materials and Methods:

The present prospective Randomized Single Blind Comparative study was undertaken from November 2018 to April 2020 from the Department of Anesthesia in JSS Medical College and Hospital Mysore.

Taking a difference of 10 cmH2O sealing pressure between Baska mask and I Gel as significant based on our pilot studies and previous studies [14] considering alpha and beta values, we got our sample size as 63 in Baska group and 63 in I-gel group. We studied a total of 300 patients and into two groups of 150 in order to increase the power of the study.

Inclusion criteria 1) Patients planned for an elective non head and neck surgical intervention under general anesthesia less than 2 hours duration 2) Age 18 to 60 years of both gender 3) American Society of Anesthesiologist Physical Status I-II 4) No silicon allergies 5) Body mass index of 20-30kg/m2 Exclusion criteria 41 1) Any Pathology related to Neck 2) Upper airway or upper GI tract diseases such as reflux, hiatus hernia, tumors of oropharynx and upper respiratory tract infection(URTI) 3) Difficult airway 4) Pregnancy 5) Gastric Aspiration risk 6) Surgical procedures under Non supine position Study population and source of data Following ethical committee approval (JSS/MC/PG/4623/2018-19), 300 patients posted for non-emergency surgical procedures under GA were included for our study. Randomization was done through sealed envelope technique. 300 Patients randomly selected an envelope containing the name of the EAD to be used. A thorough pre anesthetic evaluation was conducted 24 hours prior to the procedure and informed written consent was obtained. Standard ASA NPO guidelines were advised to all the patients. Pre-operative basal standard monitors including ECG, NIBP, and pulse oximetry was attached, and base line parameters noted. Patient was preoxygenated for 3 minutes with closed circuit. All patients were uniformly premeditated with intravenous midazolam (0.02mg/kg), Fentanyl (1mcg/kg). Induction of anesthesia was done using Injection Propofol (2mg/kg), Injection Vecuronium (0.1 mg/kg) and ventilated with oxygen and inhalational agent (Isoflurane). End tidal carbon dioxide levels were measured to confirm ventilation. After 5 minutes and following adequate relaxation of jaw, a well lubricated Baska mask sized 3 or 4 and I-GEL size 3 or 4 (according to the manufacturers' recommendations of weight based estimate plus clinical judgement) was placed and connected to Drager fabius plus work station. The I-Gel was well lubricated and introduced into the mouth with the cuff facing downwards and passed along the curvature of the hard palate until resistance was met. The Baska mask was held at the proximal end and was introduced into the mouth. When resistance was felt against hard palate, it indicated that the mask tip was at the upper part of the esophagus. 42 A clear airway was secured when $SpO_2 > 95\%$, $EtCO_2 \leq 40$ mmHg, bilateral equal chest rise, and End-tidal waveform traces with plateau were present. Suction apparatus was attached to gastric channel either continuously or intermittently as required. The other channel in BASKA MASK was left open to atmosphere.

Efficacy was assessed by noting the airway sealing pressure, insertion time, attempts taken, and finally ease of insertion and removal of both the devices. Safety was assessed by noting intraoperative complications, postoperative airway morbidity, Ryle's tube insertion time. Hemodynamic changes were noted soon after insertion and removal of both the devices.

All values were measured in terms of mean and/or SD (standard deviation). Non parametric data were measured as median, minimum and maximum values. Qualitative data was analyzed with Student t-test. Chi-square test for measuring proportions in Quantitative data. Other appropriate statistical tests were applied for the data collected. All statistical calculations were performed using SPSS version 24 software.

Results:

A total of 300 patients who met the inclusion criteria were recruited for the purpose of the study and 150 subjects were allotted in each group and further analyzed.

Table 1: Social Profile of the study subjects

		Baska Group		I Gel Group	
		N	%	N	%
Age Group	<20 years	11	7.3%	14	9.3%
	21-30 Years	42	28%	44	29.3%
	31-40 Years	44	29.3%	37	24.7%
	41-50 Years	20	13.3%	22	14.7%
	>50 Years	33	22%	33	22%
Gender	Male	74	49.3%	77	51.3%
	Female	76	50.6%	73	48.7%
Mean Age		37.65 ±12.5 years		36.91± 13.47 Years	

The age group and Gender were found to be almost uniform in both the groups with no significant difference between the groups with respect to age and gender.

Table 2: Comparison of Clinical Parameters between both the groups

		Baska Group		I Gel Group		P Value
		N	%	N	%	
Ease of insertion of Mask	Very Difficult	2	1.3%	0	0%	< 0.0001
	Difficult	22	14.7%	0	0%	
	Easy	116	77.3%	119	79.3%	
	Very Easy	10	6.7%	31	20.7%	
Anatomical position by Brimacombe grading	I	10	6.7%	10	6.7%	< 0.0001
	II	0	0%	54	36.0%	
	III	27	18.0%	59	39.3%	
	IV	113	75.3%	27	18.0%	
Number of Attempts	1	147	98..0%	140	93.3%	0.04
	2	3	2.0%	10	6.7%	
OLP/Airway sealing pressure		40.45±4.72		30.29±5.76		<0.0001
Insertion Time in seconds		14.84±1.85		11.25±1.76		<0.0001
Insertion time of Ryle's tube		8.67±1.54		15.42±2.02		<0.0001

OLP of Baska mask which is our primary objective was 40.45cmH2O which provided better sealing pressure than I-gel (30.29cmH20), with statistical significance (p value less than 0.0001). There was a statistical significance ($p < 0.001$) in the Brimacombe scoring of Glottic view. It was seen that Grade 4 was seen in 75.3% of patients in Baska group compared to 18% in the group I-Gel. Also, in the group I-Gel, Grade 2 and Grade 3 views were at 33% and 36.3% respectively compared to 18% and 0% in respective groups in the Baska group. Thus Baska mask provided with a better laryngoscopic view fiber optically. Insertion time too showed a statistically significant difference of $p< 0.0001$). The time required to pass a Ryles tube was less in Baska group (8.67 seconds) compared to 15.42 seconds in I-Gel group.

Table 3: Comparison of Vital Sings among study subjects in both the groups

	Baska Group		I Gel Group		P Value
	N	%	N	%	
PR/minute before insertion	77.54±10		76.63±8.66		0.4
PR/minute soon after insertion	85.25±8.22		82.57±8.26		0.005
SBP mm of Hg before insertion	127.09±10.06		124.91±10.45		0.07
SBP mm of Hg after insertion	133.16±7.00		129.68±7.88		0.0001
DBP mm of Hg before insertion	76.19±7.06		73.20±7.98		0.001
DBP mm of Hg after insertion	82.51±5.19		79.35± 7.48		0.0001

The increase in pulse rate soon after insertion was more with Baska than with I-gel (p=0.005), though it was not significant clinically. Similarly, though there was a rise in SBP (systolic blood pressure) after inserting the device in group Baska more than in the group I-Gel, it was not clinically significant(p=0.0001).
LPM assessment showed mild postoperative sore throat in 54.7% patients of group Baska and 23.3% in group I-Gel (p<0.0001). there was no post-operative dysphagia or dysphonia in both the groups. Only two patients in group I-Gel had stains of blood on the I-gel device and none in the group Baska.
No statistically significant intra-operative changes were there in either of the two groups.

Discussion:

Ideal characteristics of an Extraglottic airway device (EAD) are Easy to insert, short insertion time, adequate Oropharyngeal leak pressure (OLP) and decreased post-operative laryngopharyngeal morbidity. Baska Mask is the new entry into the market of EADs with more advantages compared to already existing airway devices. The device has been stated to have an additional advantage of higher sealing pressure compared to other non-inflatable devices such as I-Gel and SLIPA (Streamliner of the pharynx airway). There were limited literature in India that had been published comparing BASKA MASK and I-GEL in adult patients.
We found from our study that Baska mask provides statistically significant airway sealing pressure than I-gel. A sealing pressure of 41.45 cmH2O was provided by Baska Mask compared to 30.29 cmH2O with I-gel. This is in concordance with several other studies. Our study compares with the study conducted by R. Dhanasekaran et al [15] who compared Baska mask, I-Gel and Pro-seal LMA during Positive Pressure Ventilation in Laparoscopic Cholecystectomy with OLP of 38.33±4.353 cmH2O for group Baska, 30.57±2.174 cmH2O for group I-Gel, 29.36±2.706 cmH2O for group Pro seal respectively. The authors found statistically significant difference between Baska mask and I-Gel (p-0.04).
Refai N.A.R et al [16] conducted a study comparing both airways in spontaneously ventilated patients during minor gynecological procedures. "Mean OLP was significantly higher in group Baska than group I-Gel (38.83±4.044 vs. 26.50±2.389 cmH2O respectively)". These results are also similar in our study. Usha Kumari Chaudhary and colleague's compared both I-Gel and Baska mask among 100 patients posted for laparoscopic cholecystectomy. They found "the OLP was statistically significant with higher in group Baska than group I-Gel (29.54± 1.41cmH2O vs. 23.16 ± 3.07 cm H2O, P =0.02 respectively)".[17]
Shanmugavelu G et al, [18] found OLP was significantly greater for "Baska mask (26±5.8cmH2O) than I-Gel (22±4.1cmH2O) showing significant statistical difference (p value-0.0008)". This study compares with our study, though the OLP measured in their study of both the devices was less compared to our study. This is probably due to use of single method and use of 5L/min of FGF (our study 6L/min) for measuring OLP.
. In our study we noted a mean time of insertion of 11.25 seconds for Igel as compared with 14.84 seconds for Baska mask placement with high statistical significance (P<0.0001).
In studies comparing Baska mask and I-Gel, Aziz R.A.R et al, 26 Shanmugavelu G et al, [18] Chaudhary U.K et al [17] insertion time for I-Gel was less than Bask mask with statistical significance and it compares with our results. In a study by Son Ron Choi [19] there was no statistical significance among two SGA'S and insertion time being 29.0 ± 10.3 seconds with I-Gel, 31.4 ± 6.3 seconds with Baska mask respectively which is statistically not significant. This is the only study with insertion time being nearly 30 seconds for both airways. In a study conducted by Roopa Sachidananda et al, [20] "the mean insertion time of Baska mask was 14.9±6.2s, and that of the I-gel was 14.7±4.4 s (p=0.877) with no statistical significance. In another study conducted by Kara D et al, [21] "the median duration of insertion in the group Baska and group I-Gel was 14(6-25) and 7(5-12) seconds, respectively (z=-10.934; P<.001)."

In our study, a significant difference among two groups showed I-Gel had a better ease of insertion (p<0.0001). In I-Gel group out of 150 patients, it was very easy to insert in 31 patients and easy in 119 patients when compared to Baska mask it was "very easy" in 10 patients, "easy" (116), "difficult" (22) and "very difficult" (2). In a study

conducted by Chaudhary UK et al, [17] "insertion of the device was significantly very easy in 58% of patients in Baska mask group as compared to 76% patients in I-gel group." Thus I-Gel was easier to insert. Another study by N.A.R EL-Refai et al, [16] comparing Baska mask and I-Gel also showed I-Gel was easier to insert than Baska mask.
In our study, we noticed a greater first time success rate for Baska Mask (147/150) than for I-gel (140/150) with a statistical significance p value. In a study conducted by Son Ron Choi et al, [19] "there was no difference in the number of attempts between the I-Gel and Baska mask, though one patient in group I-Gel required more than one attempt." In their study the total number of patients were 100 when compared to 300 in our study. Hence probably is the difference compared to our study.
It is evident that a properly placed Baska mask provides positioning of the cuff against the glottis, as confirmed by fibreoptic view and thus helps to achieve good ventilation and also higher sealing pressures. Better the Brimocombe grading more is the sealing pressure.
There were no post-operative dysphagia and dysphonia noted in both groups. There were mild blood stains noted in two I-Gel patients, as they required second attempt for insertion. A study by Rehab Abdel Raof Abdel Aziz et al, [22] comparing I-Gel and Baska mask . Intra and postoperative airway morbidity were not significantly different among both groups. In a study by Al-Rawahi et al, [22] 43.3% patients had sore throat, and 20% of patients had hoarseness of voice with the use of Baska mask. Another randomized controlled trail was conducted by Chaudhary UK et al, [17] statistically there was no significance in post op sore throat, blood stained over the device or hoarseness of voice among two devices.

CONCLUSION:

The OLP for Baska mask which was our primary objective is superior to that of I-Gel. The ease of insertion was better with I-gel requiring lesser time for insertion but a significantly better fibre-optic view was provided by Baska mask. The hemodynamic changes, laryngopharyngeal morbidity were not significant 72 clinically. We conclude that both Baska and I-gel can be safely used in patients undergoing elective procedures of duration less than 2 hours. However, Baska mask may have clinical advantage by providing a favourable Brimacombe scoring, better OLP and hence an improved safety profile.

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