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Original Research Article

Comparative Analysis between I-Gel and Baska Mask in Elective Short Duration Surgeries

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Abstract

Background and Aim: The newer spraglottic airway devices (SADs) are designed to decrease the risk of aspirations and to improve the airway seal, at higher airway pressures during intermittent positive pressure ventilation. This study was done to evaluate the efficacy of supraglottic airway devices BASKA MASK and I-GEL by comparing ease of insertion, first time insertion success rate, number of insertion attempts, insertion time and possible complications in elective short procedures under general anaesthesia.

Methods: After obtaining Institutional Ethical committee approval, 90 adult female patients of ASA physical status I and II, aged 18-50 yrs. were randomly assigned into two groups: Group B: BASKA MASK and Group I: I GEL. The technique of anaesthesia was standardised in both the groups. The following parameters were compared. Ease of insertion, first time insertion success rate, number of insertion attempts, time taken for device insertion, Ease of gastric tube placement, $EtCO_2$, manipulation, Occurrence of complications like laryngospasm, cough, hoarseness, sore throat, blood staining on the device, soft tissue damage.

Results: Ease of insertion was significantly($p=0.006$) less ease in Baska group 65.8%,4.8%,29.2% than I‑gel group 81.3%,13.9%,4.65%. The mean insertion time for Baska group (24.58±4.15s) was significantly($p<0.001$) longer than I-Gel group(14.16±2.55s). The first-time insertion success rate of Baska group was only 29/41 (70.73%), compared to I-gel group which was 41/43 (95.34%)($p=.002$). The number of attempts required for the placement of the device in Baska mask is more than I gel ($p=0.009$). Complications like hoarseness, blood stained device, sore throat, were high in Baska mask group.

Conclusion: Based on the results of our study, we conclude that I-Gel aids easy and rapid insertion with an acceptable airway seal pressure.

Keywords: Supraglottic airway devices(SAD), I-GEL, Baska mask(BM), Ease of insertion.(EOI).

Introduction

The newer supraglottic airway devices (SADs) are designed to decrease the risk of aspiration and to increase the sealing pressure, improving the airway seal at higher airway pressures during intermittent positive pressure ventilation without significant gastric inflation. I-Gel, a novel supraglottic airway device with a non-inflatable cuff [1] is composed of transparent, soft gel like, thermoplastic elastomer. The shape and contour of the cuff accurately mirrors the peri-laryngeal structures to attain a perfect seal [2].Airway seal tend to improve with time likely due to the warming of the thermoplastic cuff to body temperature [3]. It also has gastric channel and possess greater stability. I Gel is a useful device for MRI suite [4] has been used as a rescue device in difficult, failed intubation situation [5] and resuscitation [6-7].

BASKA MASK is the latest addition to the SADs, with a cuffless dynamic self-inflating membranous bowl and a dual drainage tube system for effective drainage of gastric contents providing option for continuous suctioning of gastric contents. As there is no inflated cuff in the Baska mask, neither does it cause tissue or nerve damage nor does it require intracuff pressure monitoring. The newer Baska mask has many novel features which improves safety when used during controlled ventilation or in spontaneously breathing patients [8-9].

The I-gel has been used in our clinical practice for long time but the Baska mask was a new device for us. In this study we have compared the BASKA MASK (with its proven efficacy in reducing aspiration and withstanding higher sealing pressure) with I GEL in terms of ease of insertion, first attempt insertion success rate, insertion time, perioperative and postoperative complications.

Methods

After approval of our ethical committee VIREC-ECR/861/Inst/OR/2016 (Approval No- 093/19-I-S-094/Dt.25.01.2019) the observational cross-sectional study was carried out at O&G OT and SURGERY OT of VSSIMSAR, Burla, Sambalpur, during the period from February 2019-November 2020.

Based on the results of previous study [10], the first insertion success rate for the Baska Mask was significantly lower (73%) than that for the LMA (98%). Applying the formula of sample size for comparing two proprotions: n= [p1 × (100−p_1) + p_2 × (100−p_2)] ($Z_{1-}\alpha/2$ + $Z_{1-\beta}$)^2 / (p_2−p_1)^2 Where p_1 and p_2 are the percent of success in two groups respectively. Z1-α / 2 = Two - sided Z value (Z = 1.96 for 95 % confidence interval), Z1-β = Power of 80 %=0.84. The calculated minimum sample size was 28 for each group. We enrolled 45 patients in each group.

The study population consists of 90 female patients, aged between 18-50 years, ASA grade I &II, BMI <30kg/m^2, Mallampatti class I, II air way anatomy, posted for various elective minor (<60 min) gynecological and surgical procedures (hysteroscopy, dilatation and curettage, drainage of vesicular mole, excision of fibroadenoma, incision and drainage of breast abscess, excision of lipoma in axila) under General Anesthesia.

The exclusion criteria were Patient refusal, Patients with a history of allergic reaction to drug that being used, ASA grade III and IV, Patients with restricted mouth opening(<2.5cm), difficult airway, Increased risk of aspiration (Pregnancy, BMI > 30kg/m^2, GERD, hiatus hernia), Patients with increased airway resistance and decreased lung compliance (obstructive and restrictive lung diseases) , Requiring surgery in the non-supine position ,Patients with neck swelling/ thyroid, Patients with post burns contracture neck.

Informed and written consent was obtained after explaining the procedure to the patients. The patients were randomized using sealed envelopes into two groups Group I (I GEL) and Group B (BASKA MASK).

A thorough pre-anaesthetic assessment was done prior to the day of surgery. All patients were premedicated with Tab. Alprazolam 0.5 mg and Tab. Ranitidine 150 mg orally at night on the day before surgery and were kept nil per orally for a minimum duration of 8 hours. After arrival of the patient to the operation theatre, patients were connected to routine monitor showing heart rate (HR),non-invasive blood pressure (NIBP), electrocardiogram (ECG), oxygen saturation (SPO_2), and end tidal carbon dioxide ($EtCO_2$). All patients were preoxygenated with 100% oxygen and pre-medicated with inj glycopyrrolate 0.004 mg/ kg iv, inj midazolam 0.03mg/kg iv, inj. nalbuphine 0.2mg/kg iv, inj Ondansetron 0.1 mg/kg iv. Inj dexmedetomidine infusion with a loading dose of 1 μg kg^{-1} over 10 minutes then in a maintenance dose of 0.2μg kg^{-1} h^{-1}.The size of the airway device was selected based on patient's body weight. In Baska mask group Size 3 was used for weight between 30 to 50kg and Size 4 was used for weight between 50 to 70 kg. In I-gel group Size 3 was used for weight between 30 to 50kg and Size 4 was used for weight between 50 to 70 kg. I-Gel and Baska mask were lubricated and prepared. Anaesthetic induction was initiated with inj. Propofol 2mg/kg iv. Patient were then be given bag and mask ventilation till the loss of eyelash reflex and no response to jaw thrust. The SAD was inserted as per the standard recommendations issued by the manufacturer. For insertion of the devices, the patient's head was placed in neutral position resting on a ring. Patient's mouth was opened using right thumb and index finger. The lubricated device was introduced into the mouth of the patient against the hard palate, avoiding the tongue, and glided downward and backward until a definitive resistance was felt. In Baska mask, when felt necessary, the tab, which is a unique feature of this device, was manipulated to negotiate the palatopharyngeal curve. During insertion coughing, and laryngospasm was noted and if required IV inj propofol 0.5mg/kg was given. The Baska mask or I-gel were inserted by the same experienced senior anaesthesiologist.

Successful device placement was concurred by the appearance of a square wave Capnograph trace and bilateral chest movements on ventilation, no audible oropharyngeal leak and stable oxygen saturation. If airway obstruction (abnormal chest/abdominal movement, occlusion sound) or if an obvious leak was observed manipulations were done (jaw thrust, chin lift, head extension or flexion, in/out movements). If proper airway was not achieved after manipulations, the device was removed and another size was reinserted up to three times. If there was failure in the third attempt, an alternative device was used and the patient was excluded from the study. After confirming the correct placement anaesthesia was maintained with Sevoflurane 1-2%vol in a mixture of 66% N2O and 33% oxygen, and inj dexmedetomidine infusion in a maintenance dose of 0.2μg kg^{-1} h^{-1}. Ventilation was assisted if patient was in apnoea or allowed to breathe spontaneously. No muscle relaxant was used.

12F gastric tubes were selected for size 3 and size 4 I gel and Baska mask.The gastric tube was lubricated and inserted through the drain tube channel of I-gel or Baska mask. The gastric tube was left open. Correct placement of the gastric tube into the stomach was confirmed by insufflation of air heard on auscultation over the epigastrium or aspiration of gastric contents.

All the patients were received inj paracetamol1gm iv and 75mg diclofenac

aqua iv for postoperative analgesia. At the end of operation, the anaesthetic gas mixture was discontinued, inj dexmedetomidine stopped and 100% O2 allowed. Once the patient was awake and breathing adequate tidal volume, with thorough oral suctioning, the Baska mask or I-Gel was removed. On removal of the device, the integrity of the device and the presence of blood stains were noted and the patient was inspected for any injury to the soft tissue and teeth. The patient was observed for 30 min in the recovery room for any postoperative undesirable responses and then shifted to postoperative ward for observation. After 2hrs sign and symptoms of sorethroat, dysphagia, hoarseness were observed.

The primary outcome was to measure the ease of insertion of device and the first-time insertion success rate. The secondary outcome was to measure the number of attempts required for successful placement of the device, insertion time, the ease of insertion of gastric tube and perioperative and postoperative complications.

The time to successful SAD insertion was measured from time taking SAD in hand to obtaining first rectangular capnogram. Easy of SAD placement was classified according to insertion SAD score; Easy (1)- single pass without manipulations or significant resistance. Slight difficulty (2)- single pass with upto 2 manipulations. Difficult (3)- ≥2 attempts or >2 manipulations. Impossible- three failures. Manipulations done were - jaw thrust, chin lift, head extension or flexion, in/out movements. The gastric tube placement was evaluated using a three-point scale (1= easy, 2= difficult, and 3= impossible). The duration of device remaining in the oropharynx in minutes was expressed as duration of surgical procedure. Complications observed were soft tissue damage, dental damage, bleeding, hypoxia (SpO2<90%), regurgitation, aspiration, laryngospasm, gagging, coughing.

Statistical analysis

The data was entered in Microsoft excel. Continuous variables were presented as means with Standard deviation (SD) and categorical variables were presented as frequency and percentages. Association between two qualitative data will be done using chi-square test. Comparison of mean data between two groups was done using independent t-test. P-value less than 0.05 was considered as statistically significant. The data was analysed using SPSS version 23 and Microsoft Excel 2016.

Results

90 patients were enrolled in the study and the consort flow diagram is shown in figure 1. There were no significant differences in age, BMI, ASA grade, Mallampatti scores, mouth opening and thyromental distances. There was no significant difference in overall duration of surgery.

The easy of insertion was significantly less in Baska group 27:2:12 (65.8% : 4.8% : 29.2%) than I-Gel group 35 :6 :2 (81.3% :13.9%:4.65%) p=0.006. First attempt success rate was significantly less in baska group 70.7% than I-Gel 95.3% (p=0.002). The number of successful insertion attempts were significantly less in Baska group 29 : 9 :3(70.7% :22% :7.3%) than I-Gel 41:2:0 (95.3% :4.7% :0) p=0.009. The mean insertion time for Baska group 24.58 ± 4.15s was significantly longer than I-Gel group 14.16 ±2.55s p=0.002. $EtCO_2$ in Baska group was higher in comparison to I gel which signifies that Baska mask has the better seal.

We did not observe hypoxemia, laryngospasm or bronchospasm intra-operatively. Complications like hoarseness, blood stained on device, cough, sorethroat, were high in Baska mask group. No incidence of dysphagia, vomiting, was seen in each group.

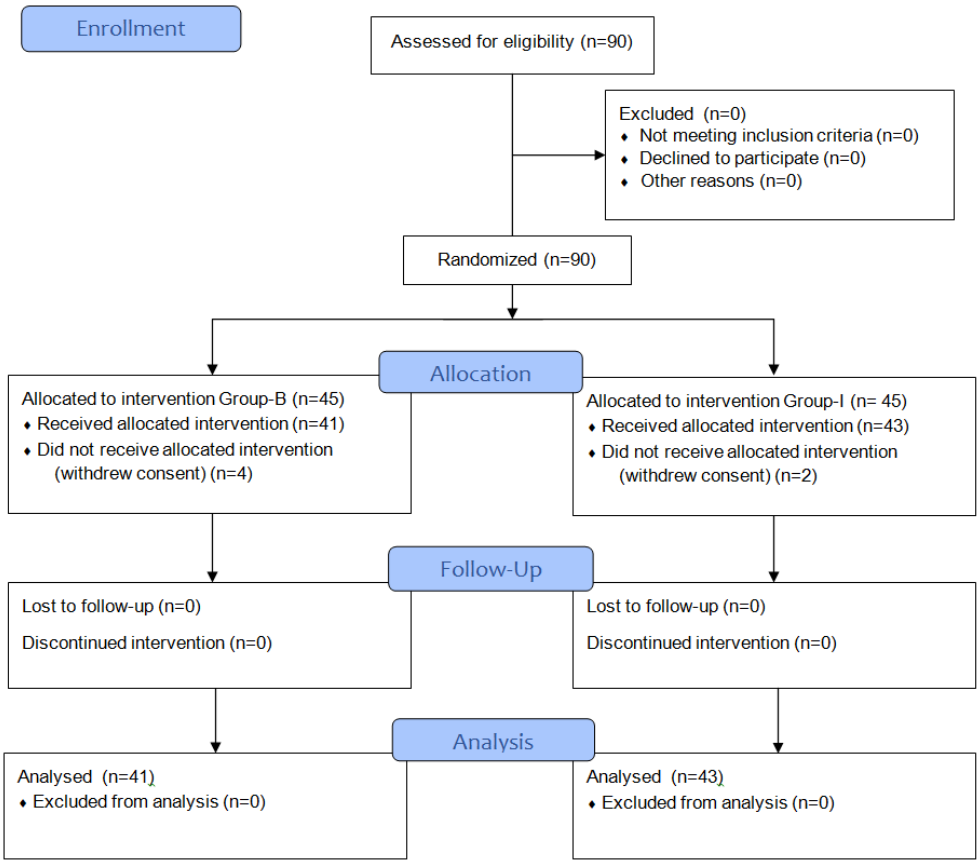

Figure 1

Table 1: Base line characteristics of patients

Variables		Group-B Baska(n=41)	Group-I I-Gel (n=43)	p-value
Age(years)		39.56 ± 13.75	39.48 ± 14.33	0.981*
BMI(kg/m^2)		24.34 ± 2.20	23.57 ± 2.01	0.098*
Mouth opening(cm)		4.43 ± 0.34	4.41 ± 0.34	0.79*
Thyromental distance(cm)		6.32 ± 0.54	6.44 ± 0.55	0.318*
Mallmpatti score no(%)	**1**	33 (80.48%)	30 (69.76%)	
	2	8 (19.51%)	13 (30.23%)	0.257**
ASA Gradingno(%)	**1**	36 (87.8%)	39 (90.69%)	0.668**
	2	5(12.19%)	4(9.3%)	
Duration of surgery(mins)		24.02 ± 4.61	25.14 ± 4.47	0.264*

Data are presented as mean± SD or numbers(percentages). * independent t-test, ** Pearson chi-square test.

Table 2 : Perioperative and postoperative complications

Variables		Group-B Baska (n=41)	Group-I I-Gel (43)	p-value
Intraoperative desaturation	yes	0	0	-
	no	41	43	
Laryngospasm.	yes	0	0	-
	no	41	43	
Cough.	yes	5(12.2%)	1(2.3%)	0.079**
	no	36(87.8%)	42(97.3%)	
Vomiting	yes	0	0	-

	no	41	43	
Blood on device	yes	7(17%)	0	0.005**
	no	34(83%)	43(100%)	
Trauma to soft tissue and tooth	yes	0	0	-
	no	41	43	
Sore throat at 2hrs.	yes	11(26.8%)	0	<0.001**
	no	30(73.18%)	43	
Hoarseness at 2hrs.	yes	6(14.63%)	1(2.32%)	0.045**
	no	35(85.36%)	42(97.67%)	
Dysphagia at 2hrs.	yes	0	0	-
	no	41	43	

** Pearson chi-square test.

Table 3: Comparative data regarding device placement

Varibles		**Group-B Baska (n=41)**	**Group-I I-Gel (n=43)**	**p-value**
Ease of insertion. no(%)	Easy	27(65.8%)	35 (81.3%)	0.006**
	Slight difficult	2(4.8%)	6(13.9%)	
	Difficult	12(29.2%)	2(4.65%)	
First attempt success rate. no%	yes	29(70.7%)	41(95.3%)	0.002**
	no	12(29.3%)	2(4.7%)	
Successful insertion attempts.no(%)	1	29(70.7%)	41(95.3%)	0.009**
	2	9(22%)	2(4.7%)	
	3	3(7.3%)	0	
Insertion time (sec)		24.58 ± 4.15	14.16 ± 2.55	<0.001*
Manipulations required.no(%)	yes	14 (34.14%)	8 (18.6%)	0.105**
	no	27(65.85%)	35(81.39%)	
Ease of Gastric tube insertion. no(%)	Easy	30(73.2%)	38(88.4%)	0.076**
	Difficult	11(26.8%)	5(11%)	
	Impossible	0	0	
EtCO2 (mmHg)		33.26 ± 2.53	31.0 ± 1.58	<0.001*

Data are presented as mean± SD or numbers(percentages). * independent t-test, ** Pearson chi-square test

Discussion

In our study it was found that only 65.8% (27/41) of patients had easy insertion in Baska group while 81.3% (35/43) patients had easy insertion in I-Gel group. The incidence of slight difficult insertion was 4.8% (2/41) in Baska group and 13.9% (6/43) in I-Gel group. The difficult insertion was 29.2% (12/41) were higher in Baska group compared to I-Gel group where difficult insertion was found only in 4.65% (2/43) of patients. There is a statistical difference (p=0.006) between both the groups in terms of ease of insertion grading. This was in similarity to a study conducted by N.A.R. Refai *et al* [11]. In their study there was significance ease of insertion in the I Gel group 24/30 (80%), 6/30 (20%),0,0. Compared to BM group 19/30 (62.5%), 11/30 (37.5%),0,0. In a study by Chaudhary, et al [12] insertion of the device was significantly very easy in 76% patients in I-gel group as compared to 58% of patients in Baska mask group.

We found that most of our patients in I-Gel group 95.3% (41/43) had SAD inserted in single attempt while only 70.7%(29/41) had successful single attempt SAD insertion in Baska maska group(p=0.002). Second attempt of insertion was seen in 4.7% (2/43) of patients in I-Gel group and 22% (9/41) of patients in Baska mask group. Third attempt of insertion was seen only in patients of Baska mask group 7.3% (3/41). There was statistical significance (p=0.009) between both the groups with respect to the number of attempts required for supraglottic device insertion. This was in similarity to a study conducted by N.A.R. Refai *et al* [11]. In their study the success rate of insertion of the BM was 22/30 (74.3%), 7/30 (22.9%), 1/30(2.8%) compared to I Gel 28/30 (94.3%), 2/30 (5.7%), 0/30 (0%). In a study by Alexiev et al [10] , the first-time success rate of the Baska mask was 52/71 (73%) when compared to that of the laryngeal mask airway, which was 77/79 (98%). In the study by Schidanand et al [13], there was no significance difference in the first-time success rate of the Baska mask 21/24 (87.5%) and I-gel 23/25 (92%).

Patients in Baska mask group had required higher number of manipulations 14/41(34.14%) than in I-Gel group 8/43(18.6%) while inserting devices. However there was no statistical significance (p=0.105) in terms of number of manipulations between both the groups.

In our study the mean insertion time for Baska mask group was 24.58±4.15s which was significantly more (p=<0.001) than I-Gel group 14.16±2.55s. The insertion time of the Baska mask in N.A.R. Refai *et al* [11] was 31.67±2.916s and that of the I-gel was 13.87±3.082s. In the study conducted by Sachidananda et al [13] there was no significance difference in mean insertion time of Baska group 14.9±6.2 s and I-gel group 14.7±4.4 s. In the study conducted by G. Shanmugavelu et al [14] the insertion time was shorter for I-gel (12.3±3.8secs) than Baska mask (20.1±8.1secs). In the study by Chaudhary, et al[12] the insertion time was 12.33 ± 2.61 s with Baska mask and 11.31 ± 1.84 s with I‑gel (*P* = 0.02). In the study by Al-Rawahi et al[15], the Baska mask was compared with the proseal laryngeal mask; the mean insertion time of the Baska mask was significantly shorter when compared with the proseal laryngeal mask (16.43±4.54 s vs. 21.45±6.13s). They implicated their results to the non-inflatable cuff and the use of tab for insertion of the device.

In our study in Baska group $EtCO_2$ is 33.26±2.53mmHg and in I-Gel group is 31.0±1.58mmHg, which is stastically significant (P=0.001). In N.A.R. Refai *et al* [11] mean end-tidal CO_2 was significantly lower in I-gel group than in BM group (31.90 vs. 33.67, respectively). This shows may lesser leak in Baska mask group than I-Gel and contribute to a better seal with less operative room pollution.

In our study, there was no statistically significant(p=0.076) difference found in ease of gastric tube insertion. In Baska group there was easy in 30(73.2%) and difficult in 11(26.8%) while in I-Gel group easy in 38(88.4%) and difficult in 5(11.6%). This was similar to the study conducted by In N.A.R. Refai *et al* [11] where ease of gastric tube insertion in BM group was 23 (77.1%), 7 (22.9%),0 and in I-Gel group was 27 (91.4%), 3 (8.6%),0 respectively.

In our study there were no intraoperative complications in both the groups and no untoward hemodynamic changes occurred in either of the groups.

In our study the incidence of cough in I Gel was 2.3% (1/43) and in Baska mask was 12.2% (5/41), which was insignificant(p=0.079). There was significant (p<0.001) incidence of sorethroat in Baska group 26.82% (11/41). The incidence of hoarseness is significantly more (p=0.045) in Baska group14.63%(6/41) than I-Gel group

2.32%(1/43). In the study by Al-Rawahi et al. [15], 43.3% of patients had sore throat, and 20% of patients had hoarseness of voice with the use of the Baska mask. In the study by Schidanand et al [13] 3 patients (12.5%) in group B had sore throat during the post-operative period, including one patient who had history of dry cough.

In our study there was an increased rate of blood staining, on the Baska mask following removal 17% (7/41) which was significant(p=0.005). This was similar to a study by Alexiev, V et al [10] where there was increased blood staining on Baska mask after removal. In Chaudhary et al [12] 1 patient had blood staining in Baska mask group on removal. In our study there was no laryngospasm, vomiting and dysphagia was observed.

In our study the limitations are we only included ASA I-II and non-obese patients, the device blinding was not possible, there was absence of fiberoptic confirmation of correct position of devices and oropharyngeal sealing pressure was not calculated as patients were not paralyzed.

Conclusion

Based on the results of our study, we conclude that I-Gel aids easy and rapid insertion with an acceptable airway seal pressure. I-Gel scores well than Baska mask in terms of number of attempts and lesser incidence of postoperative complications.

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