Section: Anaesthesiology

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COMPARISON OF BASKA MASK WITH I-GEL IN ADULT PATIENTS UNDERGOING AMBULATORY SURGERY-A RANDOMIZED CONTROL STUDY

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Abstract

Background: Baska mask a novel supraglottic airway device has certain newer features like self inflating cuff which continues with two gastric channels unlike other devices. The cuff inflates with each positive pressure, improving the seal thus reduces leak and makes ventilation more efficient. I-gel is made of thermoplastic elastomer with non-inflatable cuff made from unique soft gel like material allowing easy insertion. The aim of my study was to compare the utility and advantages of Baska mask over I-gel in Indian patients and to add on to the limited studies that are done in India. Parameters like airway sealing pressures, ease of insertion, number of attempts of insertion, ease of gastric access and complications were assessed in both the groups. **Materials and Methods:** Following approval by institutional ethical clearance written and informed consent was taken from patients. The study was conducted on 80 patients with 40 in each Group(Group A- Baska mask, Group B-I-gel) aged 16-60 years, ASA status I, II ,Mallampatti score 1,2,3. **Result:** The mean airway sealing pressure of Baska mask was 35.0±2.6 compared to i gel 27.1±1.3 which was statistically significant (P value- 0.001).All other parameters were not statistically significant in both the groups. **Conclusion:** Both I-gel and Baska mask are suitable for airway management in patients undergoing general anaesthesia. Baska mask has better airway sealing pressure than I-gel. Both the devices are comparable in aspects of Ease of insertion, Number of attempts for insertion, Ease of gastric access and complications. Hence in a clinical situation where the seal with glottic aperture takes priority over ease, Baska mask may be useful alternative to I-gel.

INTRODUCTION

Most important responsibility of an anaesthetist is to provide adequate ventilation to the patient. A vital element in providing functional respiration is airway. Management of airway has come a long way since the development of endotracheal intubation to the emergence of supraglottic airway devices.

Supraglottic airway devices refers to broad set of medical devices capable of acting as a passage way for Ventillation, Oxygenation and administration of anaesthetic gases1. Over the past two decades various new supraglottic airway devices have come into practice. Due to several advantages of Supraglottic Airway Devices like less invasiveness, avoidance of laryngoscopy, ease of placement, hands-free airway, improved haemodynamic stability and less airway-related morbidity these devices are taking over the endotracheal intubation for general anaesthesia.2

Supraglottic airway devices are used both in spontaneous and controlled ventilation. They ventilate the patient by delivering gases above the level of vocal cords.2

In our study, we have compared the advantages and disadvantages of Baska mask(third generation device) with I-gel (second generation) in aspects of airway seal pressure , ease of insertion, attempts of

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insertion,ease of gastric access and complications. Hence this study was conducted to assess the Airway seal pressure of Baska Mask and I-gel.

MATERIALS AND METHODS

The present study was conducted in the Department of Anaesthesiology, S. Nijalingappa Medical College and Hanagal Shri Kumareshwar Hospital And Research Centre, Navnagar, Bagalkot during the period of December 2017-June 2019.

The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients. Eighty patients, scheduled for various elective surgical procedures undergoing general anaesthesia were grouped into two groups (Group A-Baska Mask, Group B- I-Gel).

INCLUSION CRITERIA

ASA physical status I and II.

Age between 16 to 60 years.

BMI <35 kg.m2 .

Surgery of planned duration 1- 2 hrs.

Mallampati score 1,2 and 3.

Exclusion Criteria

Patients refusal or inability to give consent.

Patients with increased risk of gastric aspiration.

Anticipated problems with upper airway.

Procedure: A detailed Pre-anaesthetic evaluation was done on the day before surgery. All patients included in the study were kept nill by mouth for 6 hours prior to surgery. On the day of surgery patient was shifted to operation theatre, wide bore iv cannula was secured. All patients received a standardized general anaesthetic 3,4. Standard monitoring including ECG, blood pressure, pulse oximetry and end tidal co2 was moniterd.17Before induction of anaesthesia all patients were given inj. Glycopyrrolate(0.01mg/kg),inj. midazolam(0.05 mg/kg),inj fentanyl (2 microgram/kg)intravenously. Induction was done with inj. propofol (2-4mg/kg)titrated to induce anaesthesia. Once the target anaesthesia was achieved group A patients were inserted with well lubricated Baska mask and Group B patients were inserted with i-gel by pushing against the hard palate till we get a definite resistance. The devices were inserted by the same anaesthesiologist in all patients who has extensive experience in the use and evaluation of supraglottic airway devices. The size of Baska mask and i-gel was chosen following inventor's indication and also based on characteristics of the patient's neck. During insertion of Baska mask if there was any resistance it was overcome by pulling the tab on the anterior side of the tube to increase the curvature of the device or by applying a lateral paramedian rotation and jaw thurst. If resistance still persisted the tip of the device was guided using contralateral finger to negotiate the palatopharyngeal curve .If insertion still not successful case was considered failed case .Thus number of insertion attempts and ease of insertion was assessed using the following scale5.1-Easy,no resistance;2-resistance,additional maneuvers required;3-unsuccessful at the third attempt .Airway seal pressure was measured with a manometer using standard technique while patient was apnoeic. Following confirmation of adequate ventilation, the adjustable pressure limit valve was closed to 70 cm H2o, the fresh gas flow was set at 6lit/min, and the airway pressure was measured using pressure guaze manometer.6 Insertion of gastric tube (lubricated with gastric jelly) was evaluated as:1-easy ,no resistance;2-moderate resistance;3-impossible.Patients were maintained with mixture of oxygen,nitrous oxide and sevoflurane and put on manual mode of ventilation.

At the end of surgery anaesthetic agents were cut off and only 100 % o2 was given. The device was removed after patient regains consciousness and responds to verbal commands to open the eye.

Statistical analysis: Data were entered in MS-Excel and analyzed in SPSS V22. Descriptive statistics were represented with percentages, Mean with SD. Chi-square test, Independent t-test were calculated to find significance. P<0.05 was considered as statistically significant.

RESULTS

The mean age in group A and group B is 31.3±12.5 and 34.0±13.1 respectively (P=0.35) showing no significant difference in both the groups. Sex distribution in both the groups with P value 0.76 showing no significant difference in both the groups.

The mean height in both Group A and Group B is 163.3±7.1 and 161.0±6.9 respectively (P value=0.015) showing no significant difference in both groups. [Table 1]

The mean weight in both Group A and Group B is 61.5±10 and 60.5±9.5 respectively. There is no statistical difference between two groups(P>0.05)

Mean BMI of Group A is 23.1±3.8 and Group B 23.3±3.3 with P value 0.78 showing no statistical difference between two groups. [Table 2]

The mean value of Group A 1.9±0.7 and group B 1.9±0.7 with P value =0.88 showing no significant difference in both the groups. [Table 3]

The mean size of device in Group A 3.6±0.5 and Group B 3.6±0.5(P=0.82) showing no significant difference in both the groups.

The mean airway seal pressure of Group A is 27.1±1.3 and Group B is 35.0±2.6 with P value P=0.001 showing significant difference in both the Groups.

The Mean value for number of attempts of insertion of Group A was 1.3±0.5 and Group B was 1.4±0.5(P =0.38) showing no significant difference in both the groups. In percentage in both the groups with P value 0.52 showing no significant difference in both the groups. [Table 4]

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Table and Graph showing ease of insertion of both the devices with P value 0.49 showing no significant difference in both the groups. [Table 5]

The mean value for ease of gastric tube insertion in Group A is 1.5±0.6 and Group B is 1.5±0.5 with p value 0.83 showing no significant difference in both the groups

The P value is 0.34 showing no significant difference in complications in both the groups. [Table 6]

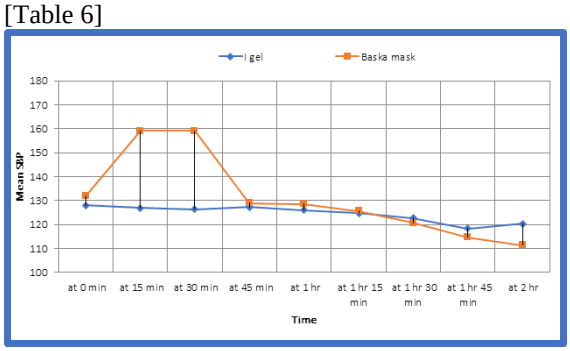

Figure 1: showing mean systolic blood pressure of both the groups for every 15 min interval with P values more than 0.005 showing no significant difference of both the groups.

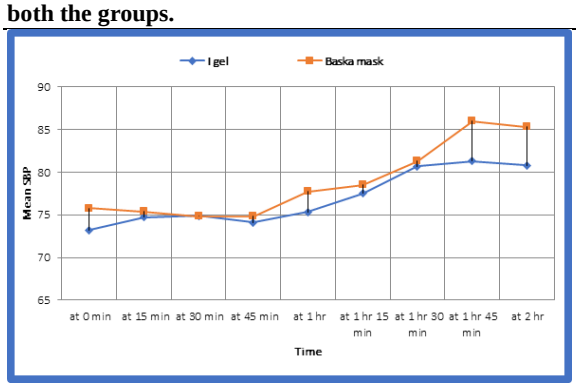

Figure 2: showing mean arterial pressure of both the groups at 15 min interval with P value >0.05 showing no significant difference in both the groups.

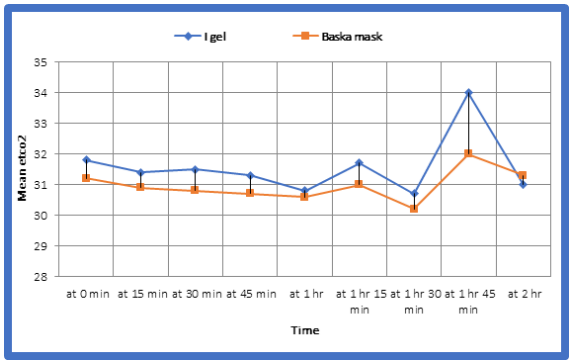

Figure 3: showing etco2 of both the groups with P values >0.05 showing no significant difference in both the groups.

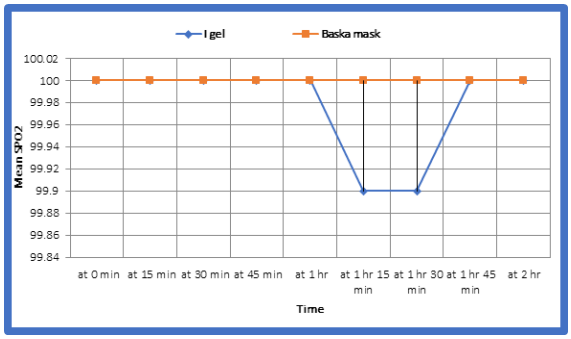

Figure 4: showing spo2 changes in both the groups with P values more than 0.05 showing no significant difference in both the groups.

Both the groups with P value 0.18 showing no significant difference in both the groups in types of surgeries.

Table 1: Height distribution between two groups

Group	Group	N	Minimum	Maximum	Mean	SD	P-value
Height in CM	I gel	40	146.0	178.0	163.3	7.1	0.15
	Baska mask	40	145.0	174.0	161.0	6.9	

Table 2:Weight in kg

Group	Group	N	Minimum	Maximum	Mean	SD	P-value
Weight in Kg	I gel	40	42.0	86.0	61.5	10.0	0.67
	Baska mask	40	45.0	78.0	60.5	9.5	

Table 3: Mallampatti classification

Group	Group	N	Minimum	Maximum	Mean	SD	P-value
Mallampatti classification	I gel	40	1.0	3.0	1.9	0.7	0.88
	Baska mask	40	1.0	3.0	1.9	0.7	

Table 4: Size of I-gel and Baska mask

Group	Group	N	Minimum	Maximum	Mean	SD	P-value
Size	I gel	40	3.0	4.0	3.6	0.5	0.82
	Baska mask	40	3.0	4.0	3.6	0.5	

Table 5: Ease of insertion

Ease of insertion	Baska mask		I gel	
	Count	%	Count	%
Easy, no resistance	23	57.5	27	67.5

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Resistance , additional manouver required	17	42.5	13	32.5
unsuccessfull	0	0	0	0
Total	40	100	40	100
	P=0.49			

Table 6: Ease of gastric tube insertion

Group	Group	N	Minimum	Maximum	Mean	SD	P-value
Ease of gastric tube insertion	I gel	40	1.0	3.0	1.5	0.6	0.83
	Baska mask	40	1.0	2.0	1.5	0.5	

DISCUSSION

Supraglottic airway devices (SAD) have been increasingly used for airway management.SAD fill the niche between facemask and endotracheal tube in terms of anatomical position, ease of insertion and degree of invasiveness.[7] The supraglottic airway device also plays a special role in the difficult airway algorithm in cases of anticipated and unanticipated difficult airway.SAD are a family of medical devices that facilitate ventilation and oxygenation with out need for endotracheal intubation.[9]So recently trend in airway management has progressed from using an endotracheal tube(ETT) to supraglottic airway device because of the advantages that these devices confer.[10]

Baska mask is a third generation supraglottic airway device having a non-inflatable cuff with better sealing pressure that increases with intermittent positive pressure ventilation (IPPV) without gastric inflation. It has a novel gastric drainage system that reduces the risk of gastric aspiration.[11]

The i-gel is a second generation SAD. It doesnot have an inflatable cuff.[12] I-gel is a device that mirrors the laryngeal anatomy in design. The cuff is made up of a thermoplastic elastomer (styrene ethylene butadiene). It has a rigid bite-block and an esophageal vent through which a gastric tube can be passed hence broadening its application to controlled ventilation in laparoscopic surgeries.[13]

The main purpose of this study was to compare third generation SAD Baska mask and second generation SAD I-gel as both devices are non-inflatable and self-sealing This study was designed to compare and evaluate airway leak pressure, number of insertion attempts,Ease of insertion of device, Ease of gastric tube insertion and any complications like throat discomfort,blood stains on device after removal in patients undergoing elective surgeries.

A total of 80 patients of ASA grade 1 and 2 aged 16-60 yrs were scheduled for surgery under general anaesthesia. These 80 patients were randomised into two groups with 40 patients in each group.

All the demographaic variables like age, sex, weight, height, BMI, size of devices, Mallampatti classification of both the groups are comparable. There was no statiscal difference between groups.

Airway seal pressure:

In our study conducted on 80 patients mean airway seal pressure of Baska mask (35 cm H20) was higher than I-Gel (27.1cm H20) indicating a better seal.

In the study conducted by Alexiev V et al,[6] a randomised comparative study of Baska mask with LMA in 150 females ,they found that median seal pressure was significantly higher with Baska mask(34-40 cm H20) compared with LMA(18-22 cm H20) indicating a better seal which is similar to our study.

In the study conducted by AlexievV , Salim A et al,[14] on 30 low risk female patients states that the mean airway leak pressure of Baska Mask was 35.7cm H20 indicating a better seal which is comparable to our study.

In the study conducted by Tom van Zundert et al5, on 50 patients oropharyngeal leak pressure was above 30 cm H20 in all patients and the maximum of 40 cm H20. Even in our study oropharyngeal leak pressure of Baska mask was above 30 in all patients and highest was 40 cm H20.

In the study conducted by Shanmugavelu G et al,[2] comparing the functional analysis of I-gel and Baska mask in laproscopic surgeries the mean oropharyngeal leak pressure of Baska mask was higher(26 cm H20) when compared to I-gel(22 cm H20) similar to our study.

In the study conducted by Rehab Abdel Raof Abdel Aziz et al,[15] on the utility of Baska mask with i-gel during General anaesthesia in obese patients. They concluded that mean oropharyngeal seal pressure of Baska mask was 28.6 and that of i-gel was 25.8 which is comparable to our study.

Number of attempts for insertion

In our study conducted on 80 patients we found that I-gel was inserted in first attempt in 70% patients, second attempt in 30% of patients whereas Baska mask was inserted on first attempt in 62.5% and 35% on second attempt and in one patient it was inserted on third attempt. Though I-gel took lesser number of attempts for insertion compared to Baska mask results were insignificant.

In the study conducted by Rehab Abdel Raof Abdel Aziz et al,[15] on the utility of Baska mask with i-gel during General anaesthesia in obese patients,they concluded that I-gel was successfully inserted in 25 patients(84.3%) on first attempt and in 2 patients(6.67%)on 2ndattempt and in three patients failed insertion. And in Baska mask insertion 27 patients(90%) required single attempt in insertion and in 2 patients(6.7%) required 2 attempts,one patient (3.3%)failed attempt.

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Alexiev V et al,[6] conducted a comparative study of Baska mask with LMA in 150 females in a randomised controll trial.They have concluded that first time success rate for insertion of Baska mask was lower (73%) than C-LMA(98%) .It was proved that Baska mask was more difficult to insert,requiring more attempts,taking longer to insert.

In the study conducted by Alexiev V, Salim A et al,[14] 23 out of 30 patients(76.7%)the Baska mask was successfully inserted on the first attempt ,four patients required two insertion attempts, while three patients required three insertion attempts. The overall success rate for the Baska mask was 96.7% and in the study conducted by Tom van Zundert et al,[5] found that first attempt to successfully insert Baska mask was high(88%),five patients needed second attempt(10%) and one patient(2%) a third attempt.

Ease of insertion

In our study conducted on 80 patients, we found that I-gel was easier to insert without any resistance in 67.5% patients and baska mask in 57.5% patients. Whereas with resistance, I-gel was inserted in 42.5% patients and baska mask in 32.5% patients. However results are not significant.

In the study conducted by Alexiev V, Salim A et al,[14] it was found that Baska mask insertion was relatively easy with a mean VAS insertion difficulty score of 0.9 (1.6) out of 10.

In the study conducted by Rehab Abdel Raof Abdel Aziz et al,[15] ease of insertion was comparable in patients of both groups.An easy insertion (score 1)and effective airway was achieved on the first attempt without performing adjustment maneuvers in 76.67% of baska mask group versus 73.3% of I-gel group similar to our study.

In the study conducted by Alexiev V et al,[6] on comparison of Baska mask with single use classic LMA in 150 females, concluded that Baska mask was proved to be difficult to insert without any additional manoeuvres in 35% of patient whereas cLMA in 96% of patients .

In the study conducted by Tom van Zundert et al,[5] concluded that compared to other SADs Baska mask cuff can easily be decreased in size by compressing the proximal, firmer part of the mask between thumb and fingers making insertion easier.

Ease of Gastric Tube Insertion

In our study, ease of gastric tube insertion was comparable in both the groups with p value of 0.83.

In the study conducted by Tom van Zundert et al5 on Baska mask –they evaluated the performance of Baska mask, a new extraglottic airway device for use in anesthesia in adult patients undergoing a variety of surgical interventions concluded that it was easy to insert an Oro gastric tube through one of the gastric drains in Baska mask.

Complications

In our study there were less complications with both the devices. In patients with Baska mask insertion out of 40 patients 38 patients did not have any complications, in one patient the device was blood stained after removal and one patient had throat discomfort post operatively.Whereas in I-gel insertion 36 patients did not have any complaints ,twopatients blood stained device after removal and 2 patients had throat discomfort postoperatively. However both the devices rae comparable.

In the study conducted by Alexiev V et al,[6] concluded that there was minor blood staining of the Baaska mask after removal but there were no differences in other complications.

In the study conducted by Shanmugavelu et al,[12] compared to baskamask(6.6%) I-gel(30%) had more blood staining on removal and sore throat was also common in I- gel (13%) compared to baska mask (3%).

And there are no significant changes in perioperative hemodynamics in both the study groups.

CONCLUSION

The Baska mask with its unique morphological design and air shaft has better sealing pressures than I-gel and can serve as an alternative airway device for short surgical procedures. Even though ease of insertion, number of attempts of insertion, ease of gastric tube insertion and complications are comparable in both the devices, in a clinical situation where the seal with glottic aperture takes priority over ease, Baska mask may be useful alternative to I-Gel.

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