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ORIGINAL RESEARCH

Comparison of Efficacy of i-gel and Baska Mask as Ventilatory Device in Anaesthetised Patients

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ABSTRACT

Background:Supraglottic-airway devices (SAD) are divided into first-generation and second-generation devices. Baska Mask and i-gel device are the two commonly used second-generation SADs in anaesthetic practice. This study compares the i-gel and Baska Mask in terms of efficacy and safety as a ventilatory device in anaesthetized patients undergoing elective surgeries.

Materials and Methods: The study was carried out in Department of Anaesthesiology, Government Medical College and Dr.Sushila Tiwari Hospital, Haldwani. Patients were allocated into 2 groups: Group A (i-gel, n=35) and Group B (Baska Mask, n=35). All patients were pre-oxygenated for 3-minutes and anaesthesia was induced. Successful insertion of the device was confirmed by chest wall movement, auscultation of breath sounds and square wave capnographic tracing. At the end of the surgical procedure, anaesthesia was discontinued and patients were reversed with the standard dose of neostigmine and glycopyrrolate after proper suctioning. Complications, if any were noted after 2 hours and 24 hours period.

Results: The mean age of the study population was 35.83±9.50 years. Among i-gel group, there were 24 (68.6%) males and 11 (31.4%) females. Among Baska Mask group, there were 20 (57.1%) males and 15 (42.9%) females. The percentage of patients with easy insertion was 80% and 68.6% for i-gel and Baska Mask respectively. The mean time taken for SAD was significantly more among Baska Mask (24.49±4.39) in comparison to i-gel (16.19±2.38). Sore throat at 2 hours was seen in 3 (8.6%) and 2 (5.7%) patients of i-gel and Baska Mask group respectively. Dysphagia at 2 hours was seen in 2 (5.7%) and 1 (2.9%) patient of i-gel and Baska Mask group respectively, while dysphagia at 24 hours was seen in 1(2.9%) patient of i-gel group only, also hoarseness at 2 hours was seen in 1(2.9%) patient of i-gel group. Incidence of all the complications reported with i-gel and Baska Mask group were comparable.

Conclusion: This study demonstrated that both Baska Mask and i-gel provided a similar performance in airway management. In terms of the total time taken for insertion, i-gel has a lesser time of insertion than the Baska mask. The success rate of insertion of Baska Mask and i-gel was comparable and ease of insertion was also comparable. Complications observed in both devices were minimal.

Keywords: Anaesthesia, Baska mask, Complications, i-gel, Supraglottic-airway device.

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INTRODUCTION

Tracheal intubation is the "gold standard" for securement of the airway, because this allows the proper establishment of ventilation, and also offers protection against pulmonary aspiration. A considerable amount of training is required for a healthcare provider to be skilled in laryngoscopy and endotracheal intubation. Incidents relating to potential difficult airways not being identified or predicted are more than rare. As a result of an increasing number of equipments for airway management, there has been increasing advancement in airway management.[1]

The Supraglottic-airway devices (SAD) are considered to provide the bridge between the face mask and the endotracheal tube for ventilation.[2] SADs are of significant help in an emergency and difficult airway.[3] They are considered less invasive than endotracheal tubes, which may be due to their positioning outside of the larynx. A number of classifications of SADs have been proposed based on the absence or presence of a drainage channel, site and mechanism of sealing, or other features.[4,5] For those patients who are difficult to intubate or ventilate, the use of SADs as a means of rescue device has increased in the field of Anaesthesiology and emergency medicine. They are easily inserted, better tolerated, have favourable respiratory mechanics, and decreased airway morbidity.[6-8] They are broadly divided into the first generation devices having only breathing lumen and second-generation devices, provided with an additional lumen for aspiration of the gastric contents.[9] The concerns with the first-generation devices involve the increased risk of aspiration and inadequate ventilation. Baska Mask and i-gel device are the two commonly used second-generation SADs in anaesthetic practice, although some consider Baska Mask as third-generation.

The i-gel is a SAD with a gel-like, non-inflatable cuff made of thermoplastic elastometer, a stem with a rigid bite-block that acts as a buccal stabilizer and an esophageal vent through which a gastric tube can be inserted. It creates an anatomical seal with pharyngeal, laryngeal and perilaryngealstructures.[10] The buccal cavity stabilizer has a widened, elliptical, symmetrical and laterally flattened cross-sectional shape, which provides good vertical stability upon insertion providing an advantage over LMA with inflatable cuffs.

Dr. Kanag and Dr. MeenakshiBaska, have designed a Baska Mask which is a SAD without an inflatable cuff and has an esophageal drainage inlet, side channels for aspiration of gastric content and an integrated bite-block. It contains various features of other SADs (PLMA, LMA Supreme, i-Gel and SLIPA).[11] It is not provided with an inflatable cuff, but has a membrane which inflates on every breath during intermittent positive pressure ventilation (IPPV) to achieve a superior seal when opposed to the larynx, also with increase in IPPV the oropharyngeal seal also increases.

This study aims to compare the i-gel and Baska Mask in terms of efficacy and safety as a ventilatory device in anaesthetized patients undergoing elective surgeries. The research compares the time taken for placement of two devices, ease of insertion, the number of insertion attempts and overall success rate and complications noted if any.

MATERIALS & METHODS

The study was a hospital based Prospective Observational Study. The study was carried out in the Department of Anaesthesiology, Government Medical College and Dr.Sushila Tiwari Hospital, Haldwani (Uttarakhand).

The study population was calculated by using G-power software. Based on a previous study,[12]mean±sd insertion time of i-gel was 12.3±3.8 and Baska Mask was 20.1±8.1. The sample size was calculated by using an alpha error of 0.05, at 95% confidence interval and the power of study as 80%. The sample size calculated was 60. But in order to prevent the

dropout rate and to keep the sample population constant, we added 10% to the total sample population, making a total of 70, with 35 in each group. The study period was of 21 months from January 2019 to September 2020.

The inclusion criteria were American Society of Anesthesiologists (ASA) physical status I/II and age18-65 years. Exclusion criteria include patient refusal, patients with anticipated difficult airway (inter-incisor distance <2cm, Mallampati class 4, thyromental distance <6cm, limited neck extension, history of previous difficult intubation), pregnant females, BMI≥30kg/m2, patients with upper respiratory tract infections and laparoscopic surgeries.

The study was carried out in the Department of Anaesthesiology, Government Medical College and Dr.Sushila Tiwari Hospital, Haldwani. After taking approval from Institutional Ethical Committee, cases that fulfilled the inclusion criteria were taken up for study. Patients were allocated into 2 groups by Closed Envelope technique:

1. Group A (i-gel, n=35)
2. Group B (Baska Mask, n=35)

All the patients were advised to fast on the night before surgery for 8 hours. Inside the operation theatre, the patient's NPO status and identity were reconfirmed. After attaching the standard monitors (SpO2, NIBP, EtCO2, ECG) patients were pre-medicated with injection Midazolam 0.05mg/kg, Glycopyrrolate 0.02mg/kg, Dexamethasone 0.2mg/kg and Nalbuphine 0.2mg/kg intravenously.

All patients were pre-oxygenated for 3 minutes and anaesthesia was induced with an injection of Propofol 2mg/kg body weight. Neuromuscular blockade was achieved with Vecuronium bromide 0.1mg/kg. A Standard pre-use check was performed on i-gel and Baska Mask and the devices appropriate for weight and/or height were inserted after 3 minutes of giving muscle relaxant.

Successful insertion of the device was confirmed by chest wall movement, auscultation of breath sounds and square wave capnographic tracing. Patients were ventilated with 100% O2 for 1 minute before next attempt. Those patients who were unable to successfully ventilate even after two attempts were intubated by direct laryngoscopy and the case was included as a failed case. Anaesthesia was maintained with oxygen, nitrous oxide and isoflurane and ventilated with intermittent positive pressure ventilation. At the end of the surgical procedure, anaesthesia was discontinued and patients were reversed with the standard dose of neostigmine and glycopyrrolate after proper suctioning. Complications, if any were noted after 2 hours and 24 hours period.

The outcome measures were recorded in the form of following points.

1. Insertion time: The time interval (seconds) between the insertions of the device through the incisors to the first leak-free ventilation.
2. Ease of Insertion:

Based on resistance

1=easy
2=satisfactory
3=difficult

3. Number of insertion attempts: Attempt was defined as the insertion of the SAD between the teeth until it was deemed to be correctly placed. A maximum of two attempts were taken. After failure, intubation was performed using conventional rigid laryngoscopy and the case was recorded as failed.
4. Complications: Following complications were observed at 2-hrs and 24-hrs. Postoperative complications were assessed as:

0=Absent

1=Present

	At 2-hours	At 24-hours
Sore throat		
Laryngospasm		
Dysphagia		
Dysphonia		
Hoarseness of voice		

Statistical analysis

The data were entered into Microsoft excel and the statistical analysis was performed by statistical software SPSS version 21.0. The Quantitative (Numerical variables) were present in the form of mean and SD and the Qualitative (Categorical variables) were present in the form of frequency and percentage. The student t-test was used for comparing the mean values (continuous data) between the 2 groups whereas the chi-square test was applied for comparing the categorical data (frequency). The p-value was considered to be significant when <0.05.

RESULTS& DISCUSSION

An ideal SAD should be easy to insert and has less insertion time, good airway seal pressure, and minimum laryngopharyngeal morbidity. The use of SADs offers an alternative to traditional tracheal intubation with potential benefits, including easy insertion and low laryngopharyngeal morbidity.

Demographic Data

The mean age of the study population was 35.83±9.50 years. The mean age of the subjects in the i-gel group was 35.63±10.60 years and Baska Mask was 36.03±8.42. Among i-gel group, there were 24 (68.6%) males and 11 (31.4%) females. Among Baska Mask group, there were 20 (57.1%) males and 15 (42.9%) females. Males were predominant in our study, and no significant difference of male to female ratio was seen in both groups. Mean BMI of the subjects in the i-gel group was 23.66±2.66 and Baska Mask group was 23.03±2.53. Findings of our study were in concordance with study by Aziz et al.[13]

Table 1: Gender Distribution

	Groups		Total
	i-gel	Baska Mask	
Male	24	20	44
	68.6%	57.1%	62.9%
Female	11	15	26
	31.4%	42.9%	37.1%
Total	35	35	70
	100.0%	100.0%	100.0%
χ^2value=1.109, p-value=0.067#			

Table 2: Age Distribution

	AGE (years)			
Groups	Mean	Std. Deviation	t- test value	p-value
i-gel	37.43	12.55	1.125	0.813#
Baska Mask	36.66	14.56		
Over-all	37.04	13.50		

Table 3: BMI Distribution

	BMI (kg/m^2)		t- test value	p-value
Groups	**Mean**	**Std. Deviation**		
i-gel	23.66	2.66	0.959	0.319#
Baska Mask	23.03	2.53		
Over-all	23.35	2.59		

Table 4: ASA grade Distribution

ASA Grade	i-gel	Baska Mask	Total
I	27	25	52
	77.1%	71.4%	74.3%
II	8	10	18
	22.9%	28.6%	25.7%
χ^2value=1.587, p-value=0.242#			

Time Taken for Insertion

Mean time taken for SAD was significantly more among Baska Mask (24.49±4.39) in comparison to i-gel (16.19±2.38). A similar mean time of insertion of 11.28±2.9 seconds was reported by Badhekaet al.[14] with i-gel, whereas an insertion time of 16.43±4.54 was reported for Baska Mask by Al Rawahi et al,[15] and 16±6 seconds was reported with Baska Mask in another study by Zundert et al.[11]

Table 5: Comparison of Time taken for insertion of SADs

	i-gel		Baska Mask				
	Mean	**SD**	**Mean**	**SD**	**Mean Difference**	**t-test value**	**p-value**
Time taken (seconds)	16.19	2.38	24.49	4.39	-10.46	-12.389	0.001*

Number of Attempts

Number of Attempts for SAD insertion was not significant between Baska Mask group and i-gel group (80% and 88.6% on the first attempt, respectively, and 100% overall success rate for both) which was in line with the research by Chaudhary et al.[16] in which success rate of Baska Mask (58%) was lesser than i-gel (76%), but the overall successful insertion was comparable.

Baska Mask has wider sumps which allow the passage of larger orogastric tube insertion. It provides rapid and adequate sump clearance. Although i-gel is easier to insert with lesser insertion time, Baska Mask provides an advantage of greater OLP which increases with positive pressure ventilation. Simultaneously, it provides larger sump clearance with dual drainage system (one with elbow connector for suction) for pharyngeal contents along with a sump reservoir and a bigger fish mouth distal gastric opening.[16]

Table 6: Frequency distribution of number of Attempts for SADs

Number of Attempts	Groups	
	i-gel	**Baska Mask**
1	31	28
	88.6%	80.0%

2	4	7
	11.4%	20.0%
Total	35	35
	100.0%	100.0%
Chi-square value=2.135, p-value=0.102#		

Ease of Insertion

The percentage of patients with easy insertion was 80% and 68.6% for i-gel and Baska Mask respectively. Whereas moderate resistance was seen in 20% and 31.4% respectively for i-gel and Baska Mask. The comparison of ease for insertion for supra-glottic device insertion did not differ statistically between both groups, although it was better among the i-gel group.

In concordance with our study, Aziz et al,[13] reported that the ease of insertion was comparable in patients of both groups (73.3% for i-gel and 76.67% for Baska Mask group easy insertion). Another study done by Choi et al,[17] was in line with our study where easy insertion was seen in 42 patients and in 44 patients of i-gel and Baska Mask respectively. Whereas, moderate resistance was seen in 7 patients and in 4 patients respectively of i-gel and Baska Mask group.

Table 7: Comparison of frequency distribution of ease of insertion for SADs

Ease of insertion	**Groups**	
	i-gel	**Baska Mask**
1 (easy)	28	24
	80.0%	68.6%
2 (satisfactory)	7	11
	20.0%	31.4%
Total	35	35
	100.0%	100.0%
Chi-square value=2.185, p-value=0.173#		

Complications

In our study, sore throat at 2 hours was seen in 3(8.6%) and 2(5.7%) patients of i-gel and Baska Mask group respectively. Dysphagia at 2 hours was seen in 2(5.7%) and 1(2.9%) patient of i-gel and Baska Mask group respectively, while dysphagia at 24 hours was seen in 1(2.9%) patient of i-gel group only, also hoarseness at 2 hours was seen in 1(2.9%) patient of i-gel group. Incidence of all the complications reported with i-gel and Baska Mask group were comparable. No incidence of blood staining of device, and tongue, lip and gum trauma, dysphonia and laryngospasm were noted in our study.

Table 8: Comparison of frequency distribution of Complications

Complications		**i-gel**	**Baska Mask**	**Chi-square value**	**P-value**
Sore throat	At 2-hours	3	2	0.215	0.643#
		8.6%	5.7%		
	At 24-hours	0	0	0.000	1.000#
		0.0%	0.0%		
Dysphagia	At 2-hours	2	1	0.348	0.555#
		5.7%	2.9%		
	At 24-hours	1	0	1.014	0.314#
		2.9%	0.0%		
Dysphonia	At 2-hours	0	0	0.000	1.000#

		0.0%	0.0%		
	At 24-hours	0	0	0.000	1.000#
		0.0%	0.0%		
Hoarseness	At 2-hours	1	0	1.014	0.314#
		2.9%	0.0%		
	At 24-hours	0	0	0.000	1.000#
		0.0%	0.0%		

Alexiev et al,[18] noted that the severity of throat discomfort, dysphagia and dysphonia was minimal following use of Baska Mask. According to Aziz et al,[13] there was an increased number of cases with minor blood staining of the i-gel mask (20%) in comparison of Baska Mask (16%) after removal at the end of the surgery, but there were no differences in other complication rates, such as laryngospasm, or in the severity of sore throat, dysphagia, dysphonia or hoarseness on emergence or up to eight hours postoperatively.

Due to the need for extra manoeuvres, blood stains may be more common with the BaskaMask.[18] Kara and Sarikas,[19] reported that, blood was present in 5% of both Baska Mask and i-gel patients, both devices provided the similar seal pressures, but patients in the Baska Mask group had significantly less post-operative hoarseness or dysphagia, which can due to the structure of the mask.

The cuff of the Baska Mask does not rely on inflation of a cushion or balloon to retain its shape or maintain a seal during ventilation. The seal depends on the flexible membrane adapting to the patient's laryngopharynx. The pressure generated on the ventilator reflects the airway pressure, which is also the cuff pressure. As there is no inflated cuff in the Baska Mask, neither should it cause tissue or nerve damage,[11] nor should the intracuff pressure need monitoring. The unique gel-like material of the i-gel, conforms to the perilaryngealanatomy.[20] The i-gel has potential advantages over other supraglottic airways for use by non-anaesthetists during CPR.

CONCLUSION

This study demonstrated that both Baska Mask and i-gel provided a similar performance in airway management. The success rate of insertion of Baska Mask and i-gel was comparable and ease of insertion was also comparable. In terms of the total time taken for insertion, i-gel has a lesser time of insertion than the Baska mask. Complications observed in both devices were minimal. We concluded that both devices can be a good alternative to conventional endotracheal tube intubation.

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