

A PROSPECTIVE COMPARATIVE STUDY OF BASKA MASK Vs I-GEL IN SHORT ELECTIVE SURGERIES UNDER GENERAL ANAESTHESIA

ABSTRACT

Introduction: General anesthetic procedure requires a safe and open airway. Endotracheal intubation is the gold standard for airway management; it is being replaced by supraglottic airway devices because they are easy to introduce, better tolerated and results in a lesser haemodynamic response. As both the Baska mask and I-gel have a non-inflatable self-sealing mechanism, these two devices were compared in our study in terms of time taken for insertion, airway sealing pressure, the number of attempts, hemodynamic changes, and complications.

Methods: A Prospective comparative study was conducted on 90 patients (45 in each group), aged 18-60 years, undergoing elective surgeries under general anesthesia at Tertiary care Hospital, Madurai. Patients were randomized into two groups: **Group B:** Airway was secured by insertion of Baska mask. **Group I:** Airway was secured by insertion of I-Gel. Following assessments were done to evaluate the SAD: Time taken to insert the device, airway sealing pressure, rate of successful insertion, number of attempts, Haemodynamic parameters, laryngopharyngeal morbidity. Data were analyzed using Student t-tests and chi-square tests, with $p < 0.05$ considered significant.

Results: The mean airway sealing pressure of the Baska mask (26.1 ± 6.1 cmH₂O) was significantly higher than that of the I-gel (23.1 ± 5.9 cmH₂O) with a P value of 0.019 which was statistically significant. In our study the time taken to insert the device, for Baska mask it was 18.9 ± 4.1 seconds and for the I-gel it was 17.2 ± 5.1 seconds with a P value of 0.089 which was statistically insignificant. In our study there was no statistical difference between Baska mask and I-gel groups in regard to hemodynamic changes (Heart rate and Mean arterial pressure). This may be due to the same stress response produced by the both devices.

Conclusion: Baska mask is superior to I-gel in positive pressure ventilation under general anaesthesia for short surgical procedures with statistically significant higher airway sealing pressure though it has comparable time of insertion, haemodynamic changes and laryngopharyngeal morbidity.

Keywords: supraglottic airway devices, I-gel, Baska mask, general anaesthesia

1. INTRODUCTION

General anesthetic procedure requires a safe and open airway. Two groups of devices, namely tracheal tube guides and supraglottic airway devices (SADs)

are recurrently used. Endotracheal intubation is the gold standard for airway management; it is being replaced by supraglottic airway devices because they are easy to introduce, better tolerated and results in a lesser haemodynamic response.⁽¹⁾

Supraglottic Airway Devices (SADs) comprise a vast group of tools designed to provide a means for ventilation, oxygenation and administration of anaesthetic gases during situations of respiratory arrest or in a patient who is submitted to a surgical procedure under general anaesthesia. They are used as an alternative to the traditional methods of airway management: the face mask (FM) and the endotracheal tube (ET). This is a field that has witnessed rapid growth lately, becoming central to everyday anaesthetic practice, which warrants continued learning by practitioners (anaesthetists) to provide the safest care to their patients.⁽²⁾

Three generations of SADs exist. The location of sealing can be either peri-laryngeal or at the base of tongue.

1st generation (inflatable cuff): Classic LMA, Proseal LMA (PLMA), Combitube

2nd generation (pre-shaped): I-gel and SLIPA (streamlined liner of the pharynx airway)

3rd generation (self-energizing): BASKA mask⁽³⁾.

I-gel™ (Intersurgical Ltd, Wokingham, U.K.) is a novel supraglottic airway device with a non-inflatable mask, which is soft, gel-like and transparent, made of thermoplastic elastomer, designed anatomically to seal the hypopharyngeal and perilaryngeal framework. The I-gel cuff moulds to body temperature to fit the supraglottic region and produces a good airway sealing pressure.⁽⁴⁾ The Baska Mask (PROACT Medical Systems, Frenchs Forest NSW, Australia), designed by Australian anaesthetists Kanag and Meena Baska is a supraglottic airway device without inflatable cuff that inflates during inspiration and deflates during expiration and has an esophageal drainage inlet and side channels for aspiration of gastric contents as well as an integrated bite-block. An inbuilt tab facilitates insertion of the device.^(5,6)

AbdelRaof AbdelAziz et al⁽¹³⁾ in his study showed that Oropharyngeal sealing pressure (OSP) was significantly higher following Baska mask insertion than I-gel, intra and postoperative airway morbidity rates were not significantly different between both groups. **Shivani Fotedar**⁽¹⁴⁾ in a study showed that I-gel takes a lesser amount of time for insertion as compared to the Baska which was statistically significant (P value of 0.001) and incidence of sore throat as a post-operative complication is found to be higher in the Baska group concluding that the I-gel appears to be a better supraglottic airway device as compared to the Baska. **Shanmugavelu Getal**⁽¹⁷⁾ in a study showed that insertion time was shorter for I-gel than Baska mask (P value of 0.124) which is statistically non-significant. Oropharyngeal leak pressure was significantly higher for Baska mask than I-gel which was statistically significant (P value of 0.0008). Oropharyngeal airway morbidity was not significantly different between the two groups.

To date, there are not many studies comparing the efficacy of Baska mask vs I-gel. Even, a few above stated studies had conflicting conclusions regarding their comparative efficacies. As both the Baska mask and I-gel have a non-inflatable self-sealing mechanism, these two devices were compared in our study in terms of time taken for insertion, airway sealing pressure, the number of attempts, hemodynamic changes, and complications.

The aims of the study are to Compare the efficacy of Baska mask vs I-Gel in patients undergoing surgery under general anaesthesia. **PRIMARY OBJECTIVES:** 1) Time taken to insert the device. 2) Airway sealing pressure. **SECONDARY OBJECTIVES:** 1) Rate of successful insertion of the device. 2) Number of attempts. 3) Changes in haemodynamics (HR, MAP). 4) Laryngopharyngeal morbidity- Sore throat, Dysphagia, Hoarseness of voice.

2. MATERIAL AND METHODS

2.1 Study design and setting:

This is a prospective, randomized double blinded comparative study. After obtaining ethical committee clearance for the research, patients were chosen based on the inclusion and exclusion criteria. **INCLUSION CRITERIA: 1)** Patients aged between 18-60 years of either gender. 2) Patients belonging to ASA Class I or II (American Society of Anesthesiologists). 3) Patients with BMI < 30 Kg/m². 4)

Patients undergoing elective surgeries of short duration < 2 hours
Patients coming for emergency surgeries. **EXCLUSION CRITERIA**
1) Patients belonging to ASA III and IV. **2)** Patients with a history of hiatus hernia or full stomach or GERD (Gastro esophageal reflux disease). **3)** Patients with a history of obstructive sleep apnoea, asthma, mental retardation, congenital heart disease. **4)** Patients with a history of obstructive sleep apnoea, asthma, mental retardation, congenital heart disease. **5)** Recent history of upper respiratory tract infection (< 7 days). **6)** Patients requiring rapid sequence induction. **7)** Patients with anticipated difficult airway

2.2 Sample size:

Sample size was estimated from previous study done **AbdelRaof AbdelAziz et al**⁽¹³⁾ assuming power at 80% and confidence limit 95%. The sample size was calculated to be 90 cases. (45 cases in each group).

After obtaining Institutional Ethics Committee approval (IEC), patients were selected based on inclusion and exclusion criteria and informed consent was obtained after explaining the study. Demographic data such as weight, height, body mass index (BMI) and gender were recorded in the proforma. The enrolled patients were allocated to one of the two groups based on a computer-generated random number. The random numbers were generated using a statistical software STATA Version 14 (Texas, USA).

Group B: Airway was secured by insertion of Baskamask.

Group I: Airway was secured by insertion of Gel

2.3 Study procedure:

On previous day of surgery pre anaesthetic assessment was done, patients were selected based on inclusion and exclusion criteria. Anaesthetic plan and study was explained and consent was obtained. Continuation or discontinuation of drugs and NPO (Nil per oral) orders were given as per accepted routine ASA guidelines.

On the day of surgery patient was identified, NPO was confirmed, and consent for anaesthesia and participation in the study was checked. The patient was shifted to operation theatre intravenous (IV) access secured, standard monitoring including ECG, NIBP, SpO₂ were connected, pre oxygenated with 100% oxygen for 3 minutes and induced with IV Glycopyrrolate 0.2mg, IV Midazolam 1mg, IV Fentanyl (2mcg/kg) and IV Propofol (2-3mg/kg) in titrated doses. After checking for the ease of manual ventilation, the patient was paralysed with IV Vecuronium (0.1mg/kg) and bag mask ventilation done for 3min with 100% O₂.

After 3min of manual ventilation, either Baskamask or I-Gel of adequate size as per manufacturer's guidelines was placed with the patient's head in the sniffing position. All the devices were placed by the same experienced anaesthesiologist with at least 15 placements previously.

Adequate placement and ventilation was determined by auscultation of breath sounds, chest wall movement, and square wave capnography. Then, once position and adequacy of ventilation were confirmed, SAD was fixed with an adhesive tape. After successful placement, a well lubricated nasogastric tube was inserted into the drainage channel to facilitate gastric drainage.

Then the patients were mechanically ventilated using volume controlled ventilation maintained with 1-1.5% Isoflurane, oxygen and air (FiO₂ 50%) and neuromuscular blockade maintained with boluses of Vecuronium as and when required. At the end of the surgery, patients were reversed with IV Glycopyrrolate (0.01mg/kg) and IV Neostigmine (0.05mg/kg) once patients had spontaneous efforts. Anaesthetic gas mixture was replaced with 100% O₂ to facilitate patient's recovery. The SAD was removed after the patient regained consciousness and responded to oral commands.

Following assessments were done to evaluate the SAD:

- 1. Time taken to insert the device:** Insertion time needed for placement of the SAD was defined as time in seconds from picking up SAD to the first recorded near rectangular capnogram curve.
- 2. Airway sealing pressure**
Determination of sealing pressure: The pressure at which leak starts. This leak pressure was calculated as the plateau airway pressure reached with fresh gas flow 6l/min, and pressure adjustment valve set at 70 cmH₂O.

3. **Rate of successful insertion:** Defined as presence of EtCO₂ and chest rise after placing the SAD in either one or two attempts.
4. **Number of attempts** required for successful insertion of the device was noted. An attempt is defined as the placing of the supraglottic airway device within the oropharynx to secure the airway. If the first two attempts of insertion failed then it would be considered as failure of insertion and patient would be intubated with endotracheal tube to proceed with the surgery. That patient would be excluded from the study.
5. **Haemodynamic parameters** (Heart rate, Mean arterial pressure pre-insertion (0Min), post-insertion 1 Min 5 Min and 10Min).
6. **Laryngopharyngeal morbidity** Incidence of sore throat, dysphagia, and hoarseness were noted 1 hour after extubation and 24 hrs postoperative.

2.4 Statistical analysis:

Data analysis was done with the help of computer using SPSS Statistics 20.0 software (SPSS Inc. Bengaluru India). Chi-square test and Fisher's exact test were used to find out association between the categorical variables. Independent 't'-test was used to find the significance difference between groups. $P < 0.05$ was considered as statistically significant

2.5 Ethical clearance:

The patient and attendees were explained about the procedure and the expected complications. They were informed about the present study and their eligibility for participating in the study. Only patients who were willing to participate were included and informed consent was obtained. The study was approved by the Institutional Ethical Committee [NBE/CNS/DNB PDCET/41159]

3. RESULTS AND DISCUSSION

We finally recruited around 90 patients [45 in each group] who fulfilled the inclusion criteria [0% non-response rate]. The mean age in B and I group was 40.7 ± 10.7 years and 40.5 ± 11.0 years respectively. The percentage of male patients in group B and I are 57.8% and 55.6% respectively. The percentage of female patients in group B and I are 42.2% and 44.4% respectively. The average weight of patients in group B and I was 63 ± 9.5 Kgs and 62.7 ± 13 Kgs respectively with a P value of 0.892. The average height of patients in Group B and I is 160.2 ± 8.7 cms and 159.4 ± 11.1 cms respectively with a P value of 0.712. The average BMI of patients in Group B and Group I is 24.4 ± 2.6 kg/m² and 24.5 ± 3.0 kg/m² respectively with a P value of 0.887. The percentage of patients belonging to ASA 1 and 2 in Group B was 60% and 40% respectively. The percentage of patients belonging to ASA 1 and 2 in Group I was 64.4% and 35.6% respectively. The percentage of patients belonging to Mallampati classification 1 and 2 in Group B was 55.6% and 44.4% respectively. The percentage of patients belonging to Mallampati classification grade 1 and 2 in Group I was 66.7% and 33.3% respectively. There was no statistically significant difference in the sociodemographic variables in the two groups ($p = 0.05$) and they were comparable.

Table 1: Comparison of sociodemographic parameters (age) across the study groups, N=90

Parameter	Group				P-Value
	B		I		
	Mean	SD	Mean	SD	

Age(In years)	40.7	10.7	40.5	11.0	0.961
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Table 2: Comparison of sociodemographic parameters (sex) across the study groups, N=90

Sex	Group				P-Value
	B		I		
	Number of patients	%	Number of patients	%	
Male	26	57.8	25	55.6	0.832
Female	19	42.2	20	44.4	

Table 3: Comparison of sociodemographic parameters (weight, height, BMI) across the study groups, N=90

Parameter	Group				P-Value
	B		I		
	Mean	SD	Mean	SD	

Weight (inKgs)	63.0	9.5	62.7	13.0	0.892
Height (incms)	160.2	8.7	159.4	11.1	0.712
BMI (inKg/m2)	24.4	2.6	24.5	3.0	0.887

Table 4: Comparison of ASA classification across the study groups, N=90

ASA	Group				P-Value
	B		I		
	Number of patients	%	Number of patients	%	
ClassI	27	60.0	29	64.4	0.664
ClassII	18	40.0	16	35.6	

Table 5: Comparison of Mallampati classification across the study groups, N=90

Mallampati	Group	
	B	I

Classification	Number of patients	%	Number of patients	%	P-Value
	Grade1	25	55.6	30	
Grade2	20	44.4	15	33.3	0.280

The mean duration of surgery in group B and I were 89.9 ± 20.7 minutes and 88.2 ± 17.8 minutes respectively. Both the groups B and I are comparable in terms of types of surgeries. Statistically there was no significant difference between two groups (P value > 0.05) and they were comparable.

Table 6: Comparison of duration of surgery across the study groups, N=90

Parameter	Group				P-Value
	B		I		
	Mean	SD	Mean	SD	
Duration (In Minutes)	89.9	20.7	88.2	17.8	0.691

Table 7: Comparison of type of surgery across the study groups, N=90

SURGERY	Group		P-Value
	B	I	

Debridement	18	20	0.778
	40.0%	44.4%	
Lap Appendicectomy	13	14	
	28.9%	31.1%	
Lap Cholecystectomy	14	11	
	31.1%	24.4%	

First attempt success rate in group B and I was 84.4% and 93.3% respectively. Second attempt success rate was 15.6% and 6.7% respectively. Statistically there was no significant difference between two groups in terms of number of attempts (P value 0.180) and they were comparable. Time taken to insert device in group B was 18.9 ± 4.1 seconds and in group I was 17.2 ± 5.1 seconds. Statistically there was no significant difference between two groups in terms of time taken to insert device (P value 0.019) and they were comparable. Airway sealing pressure in group B was 26.1 ± 6.1 cmH₂O and in group I was 23.1 ± 5.9 cmH₂O. Statistically there was significant difference between two groups in terms of airway sealing pressure (P value 0.019).

Table 8: Comparison of Number of attempts across the study groups, N=90

Number of Attempts.	Group				P-Value
	B		I		
	Number of patients	%	Number of patients	%	
1	38	84.4	42	93.3	0.180
2	7	15.6	3	6.7	

Table 9: Comparison of time taken to insert the device across the study groups, N=90

Parameter	Group		P-Value
	B	I	

	Mean	SD	Mean	SD	
Time(In seconds)	18.9	4.1	17.2	5.1	0.089

Table 10: Comparison of airway sealing pressure across the study groups, N=90

Parameter	Group				P-Value
	B		I		
	Mean	SD	Mean	SD	
Airway sealing pressure(In cmH ₂ O)	26.1	6.1	23.1	5.9	0.019

The change in Heart Rate at 0,1,5,10 minutes in Group B was 80.5 ± 17.4 mins, 85.9 ± 17.7 mins, 83.6 ± 17.1 mins, 80.7 ± 16.2 mins respectively. The change in Heart Rate at 0,1,5,10 minutes in Group I was 83.4 ± 16.1 mins, 88.4 ± 17.6 mins, 83.8 ± 15.8 mins, 81.3 ± 15.1 mins respectively. Statistically there was no significant difference between two groups in terms of change in heart rate at 0,1,5,10 minutes (P values were 0.405, 0.505, 0.959 and 0.869) and the results were comparable. The Average of MAP at 0,1,5,10 minutes in Group B was 81.1 ± 10.7 mmHg, 90.5 ± 13.4 mmHg, 82.0 ± 11.3 mmHg, 78.5 ± 10.0 mmHg respectively. The Average of MAP at 0,1,5,10 minutes in Group I was 79 ± 8.6 mmHg, 86.8 ± 12.3 mmHg, 78.7 ± 9.6 mmHg, 75.2 ± 8.2 mmHg respectively. Statistically there was no significant difference between two groups in terms of change in MAP at 0,1,5,10 minutes (P values were 0.309, 0.169, 0.140, 0.084) respectively and they were comparable.

Table 11: Comparison of hemodynamic parameters [Heart rate and mean arterial pressure during the time intervals across the study groups, N=90

	Group		
	B	I	

Heart rate at n th minute	Mean (inbeats per minute)	SD	Mean (inbeats per minute)	SD	P-Value
0	80.5	17.4	83.4	16.1	0.405
1	85.9	17.7	88.4	17.6	0.505
5	83.6	17.1	83.8	15.8	0.959
10	80.7	16.2	81.3	15.1	0.867

MAP At n th minute	Group				P-Value
	B		I		
	Mean (InmmHg)	SD	Mean (InmmHg)	SD	
0	81.1	10.7	79.0	8.6	0.309
1	90.5	13.4	86.8	12.3	0.169
5	82.0	11.3	78.7	9.6	0.140
10	78.5	10.0	75.2	8.2	0.084

57.8% of patients in group B and 60% of patients in group I had sore throat after 1 hour of extubation. 42.2% of patients in group B and 40% of patients in group I had no sore throat after 1 hour of extubation. There was statistically no difference between two groups in terms of presence or absence of sore throat after 1 hour of extubation (P value 0.830) and they were comparable. 6.7% and 11.1% of patients had sore throat after 24 hours of extubation in group B and I respectively. 93.3% and 88.9% of patients had no sore throat after 24 hours of extubation in group B and I respectively. The results were statistically insignificant (P value 0.459) and the results were comparable. 2.2% of patients in group B had dysphagia after 1 hour of extubation and none in the group I had similar complaints. 97.8% of patients in group B and 100% of patients in group I had no dysphagia after 1 hour of extubation. There was statistically no difference between two groups (P value 0.315) and they were comparable. None of the patients in either group B or I had dysphagia after 24 hours of extubation. None of the patients in either of the group B or I had hoarseness of voice after 1 hour and 24 hours of extubation.

Table 12: Comparison of complications (sore throat after 1 hour of extubation, after 24 hours of extubation, dysphagia after 1 hour of extubation) across the study groups, N=80

Group	
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Sorethroat after1hour of extubation	Group				P-Value
	B		I		
	Number of patients	%	Number of patients	%	
Present	26	57.8	27	60.0	0.830
Absent	19	42.2	18	40.0	

Sorethroat after 24 hours of extubation	Group				P-Value
	B		I		
	Number of patients	%	Number of patients	%	
Present	3	6.7	5	11.1	0.459
Absent	42	93.3	40	88.9	

Dysphagia after1hour of extubation	Group				P-Value
	B		I		
	Number of patients	%	Numberof patients	%	

Present	1	2.2	0	0.0	0.315
Absent	44	97.8	45	100	

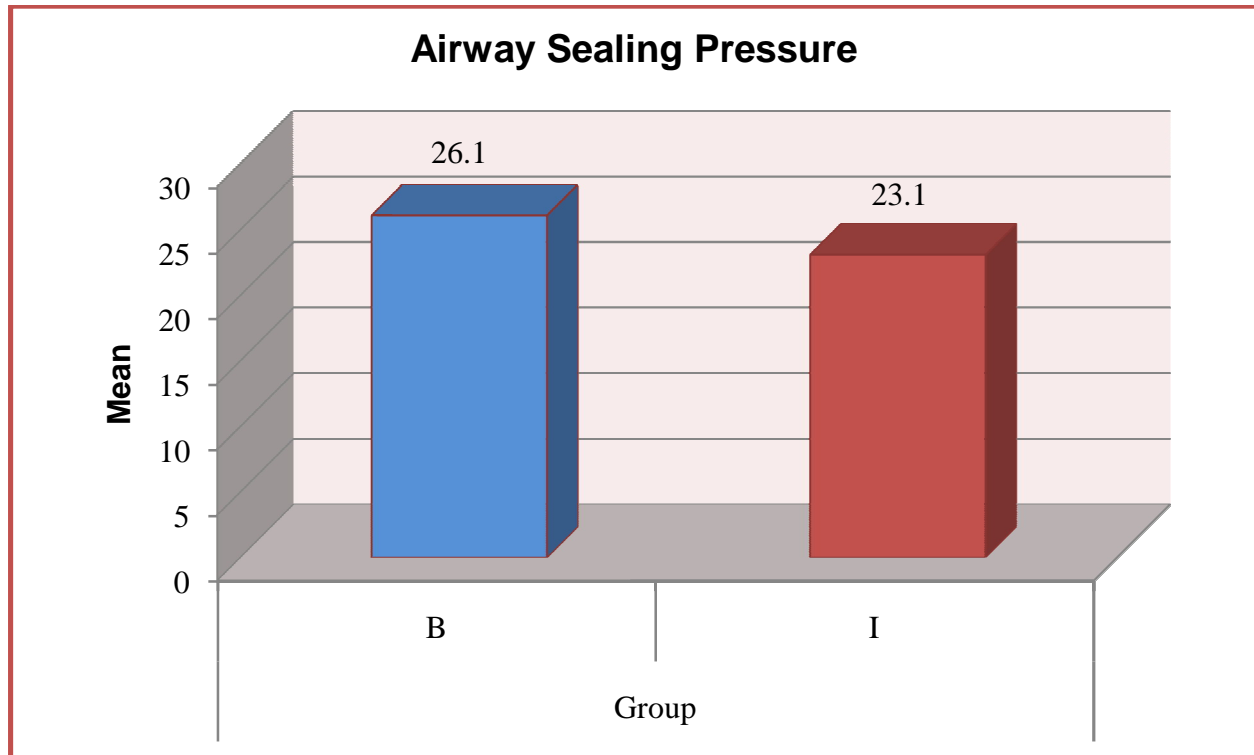


Fig 1: Comparison of airway sealing pressure within the study groups, N=90

UNDER REVIEW

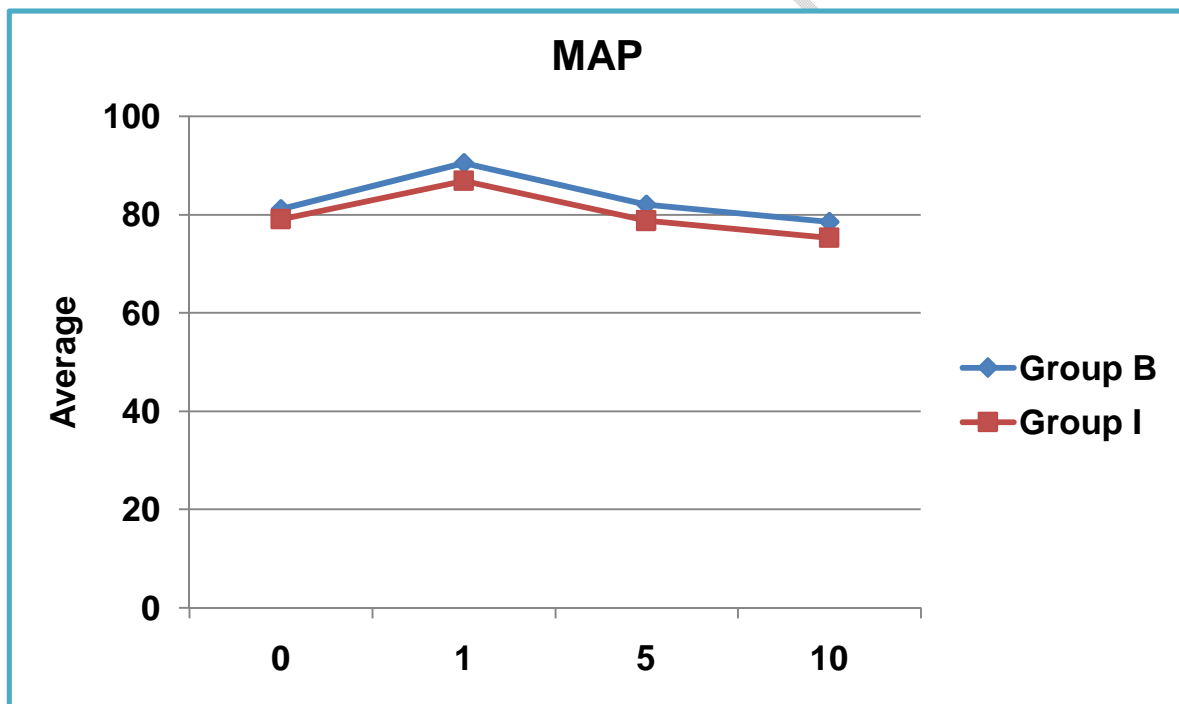
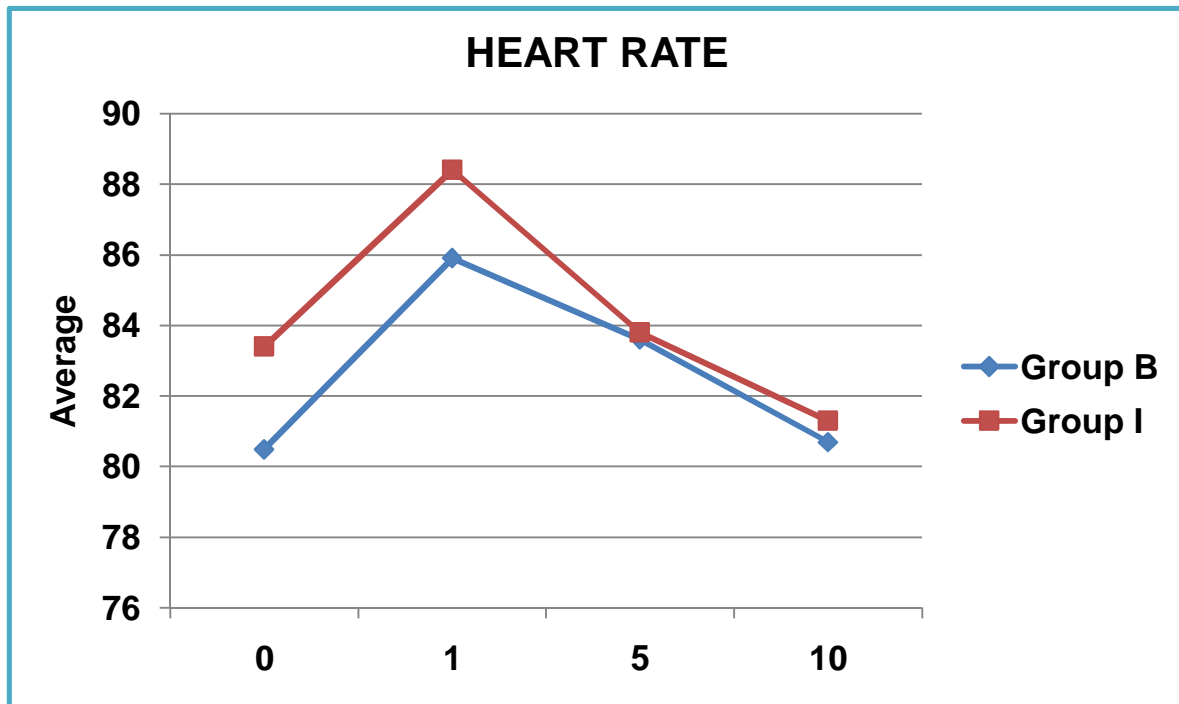


Fig 2: Comparison of hemodynamic parameters [Heart rate and mean arterial pressure] during the time intervals within the study groups, N=90

4. Discussion:

The usage of SADs has been growing rapidly especially for outpatient procedures avoiding tracheal intubation which needs laryngoscopy and sometimes muscle relaxants. Their usage also decreases the risk of dental lesion, sore throat, myalgia, muscle weakness, post operative nausea and vomiting. Inserting SADs is generally less stimulating for the autonomic nervous system, resulting in lesser cardiovascular events.

The main shortcoming of SADs is the risk of pulmonary aspiration. Proper oesophageal sealing constitutes a barrier to the entry of regurgitated gastric fluid into the pharynx similarly perilyngeal sealing stops fluid from entering the airway. These minimize the risk, but depend on the shape and size of the device and the material which it is made out of. The SADs with less risk of aspiration are those which show high pharyngeal and oesophageal sealing pressures, appropriate pharyngeal size, malleable material (regardless of being cuffed or not), and a draining channel.⁽²⁾

Over the years SADs have become indicated for a growing number of scenarios including extremely invasive and prolonged surgeries. This is especially true for the newer SADs, which have specific features for added safety.⁽²⁾ An ideal SAD should be easy to insert and has less insertion time, good airway seal pressure, and minimum laryngopharyngeal morbidity.

The Baska mask is a recently introduced device with unique improvements over other supraglottic airway devices to enhance patient safety and ease of insertion. The device has been stated to serve an additional advantage of higher sealing pressures compared with other non-inflatable devices such as I gel. As both Baska mask and I-Gel are uncuffed supraglottic airway devices we have compared them in our study in the following characteristics.

- Time taken to insert the device
- Airway sealing pressure
- Rate of successful insertion of device
- Number of attempts
- Changes in haemodynamics (HR, MAP)
- Laryngopharyngeal morbidity
-

TIME TAKEN TO INSERT THE DEVICE

In our study the **time taken to insert the device**, for Baska mask it was 18.9 ± 4.1 seconds and for the I gel it was 17.2 ± 5.1 seconds with a P value of 0.089 which was statistically insignificant. In a study by **Abdel Raof Abdel Aziz et al**⁽¹³⁾ where the utility of I-Gel with Baska Mask in obese patients undergoing elective ambulatory surgeries was compared, the time taken to insert Baska mask was 19.6 ± 8.4 seconds and I gel was 15.6 ± 4.6 seconds with a P value of 0.024 which was significant. A sample size of 30 in each group might be the cause for their significant difference in time taken for insertion of device. Our results are comparable with this study in terms of similar time taken for insertion. In a study by **Shanmugavelu G et al**⁽¹⁷⁾ the mean insertion time of I-gel was shorter when compared to Baska mask (12.3 ± 3.8 sec Vs 20.1 ± 8.1 sec) with a P value of 0.124 which was statistically insignificant similar to our results. Our study results are also consistent with the results of **Abita•ao•luetal**⁽¹⁶⁾, **Sachidananda Retal**⁽¹⁾.

In a study by **Shivani Fotedar**⁽¹⁴⁾ done in 2018 where I-Gel and the Baska mask were compared, the mean time for insertion in I gel was 5 seconds and for Baska mask was 23.0 seconds. This disparity might be because of author's attempt to secure baska mask in spontaneously ventilating anaesthetized patients.

AIRWAY SEALING PRESSURE (ASP)

In our study, the mean airway sealing pressure of the Baska mask (26.1 ± 6.1 cmH₂O) was significantly higher than that of the I-gel (23.1 ± 5.9 cmH₂O) with a P value of 0.019. **Abdel Raof Abdel Aziz et al**⁽¹³⁾ in a study showed that mean airway sealing pressure was significantly higher in baska group (28.6 ± 2.9 cm H₂O) than I gel group (23.6 ± 3.07 cmH₂O) with a P value of 0.0008. Our study results are comparable to this study. **Shanmugavelu G et al**⁽¹⁷⁾ in a study showed that mean airway pressure of baska

mask ($26 \pm 5.8 \text{ cmH}_2\text{O}$) was significantly higher than I-gel group ($22 \pm 4.1 \text{ cmH}_2\text{O}$) with a P value of 0.0008. Our study results are comparable to this study. Our study findings are also consistent with findings observed by other authors **Shivani Fotedar**⁽¹⁴⁾, **Chaudhary et al**⁽¹⁵⁾, **Sachidananda R et al**⁽¹⁾. **Abita• ao• lu et al**⁽¹⁶⁾ in their study showed that there was statistically no difference between Baska mask and I-gel in terms of airway sealing pressures (32 ± 2 Vs $30 \pm 4 \text{ cmH}_2\text{O}$); This study is the first study in the literature done in 2016-2017 to compare Baska mask and I-gel, lack of expertise and a low sample size of 15 patients in each group might be the cause for disparity in results compared to our study. The better maintenance of ASP with Baska mask is due to the cuff of the Baska mask, a recoilable membrane that inflates and deflates with the respiratory cycle, so the pressure on the surrounding tissues is never more than the peak airway pressure. This decreases the laryngopharyngeal morbidity and also increases the oropharyngeal seal with IPPV (Intermittent positive Pressure Ventilation).⁽¹⁵⁾

RATE OF SUCCESSFUL INSERTION OF DEVICE

The first insertion attempt success rate with Baska mask and I-gel were comparable in our study. In our study, success rate of Baska mask in the first insertion attempt was 84.4% and second attempt success rate was 15.6%. In I-gel group, first insertion attempt success rate was 93.3% and second attempt success rate was 6.7%. Overall success rate (in two attempts) was 100% in both Baska mask and I-gel group.

In a study by **Sachidananda R et al**⁽¹⁾ the first-time insertion success rate of the Baska mask was 88% when compared with the I-gel, which was 92%. Our study results are comparable to this study. **Abdel Raof Abdel Aziz et al**⁽¹³⁾ in their study results showed that first attempt success rate of insertion in I-gel group was 83.3% and Baska group was 90% with an overall success rate of 90% in I-gel group and 96.67% in Baska mask group. Probable cause for lower overall success rate in this study might be because of the study done in obese patients with BMI $25-40 \text{ Kg/m}^2$ whereas our study excluded patients with BMI $>30 \text{ Kg/m}^2$. **Abita• ao• lu et al**⁽¹⁶⁾ in a study, showed that success rate in the first insertion attempt was 40%. Such a long insertion duration and a low ratio of success rate in the first attempt in their study was attributed to the necessity to position the cuff opening in the glottis due to the specific nature of Baska mask, leading to a potential insertion difficulty to a particular extent and also, the leaflet structure of non-inflating cuff of Baska Mask that can contact to teeth during insertion might be creating difficulty in the course of oral passage. This study is the first study in the literature done in 2016-2017 to compare Baska mask to I-gel, lack of expertise might also be the cause for low first attempt success rate. Studies^(1,14,15,17) done later to **Abita• ao• lu et al**⁽¹⁶⁾, showed higher first attempt success rates showing that lack of expertise was the probable cause in their study for lower success rate.

In our study, both Baska mask and I-gel devices were inserted with high success rates on the first attempt 84.4% and 93.3% respectively and 100% overall success rate in both groups. This finding is in agreement with the results of **Shivani Fotedar**⁽¹⁴⁾, **Chaudhary et al**⁽¹⁵⁾, **Sachidananda R et al**⁽¹⁾, **Shanmugavelu Getal**⁽¹⁷⁾.

LARYNGOPHARYNGEAL MORBIDITY

Postoperative laryngopharyngeal morbidity in the form of postoperative sore throat, dysphagia and hoarseness of voice 1 hour and 24 hours post extubation is comparable between the two groups in our study. 57.8% of patients in Baska group and 60% of patients in I-gel group had sore throat after 1 hour of extubation. 6.7% and 11.1% of patients had sore throat after 24 hours of extubation in Baska and I-gel group respectively. Postoperative complications are comparable between two groups in studies done by **Abdel Raof Abdel Aziz et al**⁽¹³⁾, **Shivani Fotedar**⁽¹⁴⁾, **Chaudhary et al**⁽¹⁵⁾, **Abita• ao• lu et al**⁽¹⁶⁾, **Sachidananda R et al**⁽¹⁾, **Shanmugavelu Getal**⁽¹⁷⁾. Higher incidence in our study may be due to mean duration of surgeries being longer (89.9 ± 20.7 minutes in Baska group & 88.2 ± 17.8 minutes in I-Gel group) than other studies discussed previously.

HAEMODYNAMICS

In our study mean heart rate (in beats per minute) at various time intervals of 0, 1, 5, 10 minutes after intubation in Baska group was 80.5 ± 17.4 , 85.9 ± 17.7 , 83.6 ± 17.1 , 80.7 ± 16.2 respectively. In our study mean heart rate (in beats per minute) at various time intervals of 0, 1, 5, 10 minutes after intubation in I-gel group was 83.4 ± 16.1 , 88.4 ± 17.6 , 83.8 ± 15.8 , 81.3 ± 15.1 respectively. In our study mean arterial pressure (in mmHg) at various time intervals of 0, 1, 5, 10 minutes after intubation in Baska group was 81.1 ± 10.7 , 90.5 ± 13.4 , 82 ± 11.3 , 78.5 ± 10.0 respectively. In our study mean art

erial pressure (in mmHg) at various time intervals of

0, 1, 5, 10 minutes after intubation in I-gel group was 79 ± 8.6 , 86.8 ± 12.3 , 78.7 ± 9.6 , 75.2 ± 8.2 respectively.

There was no statistical difference between Baska mask and I-gel groups in regards to hemodynamic changes. This may be due to the same stress response produced by the both devices. These results are consistent with previous studies by **Sachidananda R et al**⁽¹⁾, **Shivani Fotedar**⁽¹⁴⁾, **Abitağaoğlu et al**⁽¹⁶⁾

5. SUMMARY

This is a study comparing efficacy of Baska mask and I-gel in short elective surgeries. The study was conducted in Department of Anaesthesia, Meenakshi Mission Hospital and Research Institute, Madurai between April to October 2019. The aim of this study to compare the efficacy of Baska mask vs I-Gel in patients undergoing surgery under general anaesthesia. Till date there are not many studies comparing the efficacy of Baska mask vs I-gel. Even studies done previously had conflicting conclusions regarding their comparative efficacies.

As both the Baska mask and I-gel have a non-inflatable self-sealing mechanism, these two devices were compared in our study. In our study 90 patients of either gender satisfying inclusion or exclusion criteria undergoing short elective surgery were included in the study. The study population was randomly divided into two groups namely Group B and Group I. In group B airway was secured with Baska mask and in group I airway was secured by I-gel.

The primary objectives of the study were to insert the device and airway sealing pressure, secondary objectives being rate of successful insertion of device, number of attempts, changes in haemodynamics and laryngo-pharyngeal morbidity - sore throat, dysphagia, hoarseness of voice.

In our study both the groups (B&I) were comparable with no statistical significant difference in terms of demographic data (Age, sex, weight, height and BMI).

In our study, the mean airway sealing pressure of the Baska mask (26.1 ± 6.1 cmH₂O) was significantly higher than that of the I-gel (23.1 ± 5.9 cmH₂O) with a P value of 0.019 which was statistically significant similar to studies by Abdel Raof Abdel Aziz et al (13), Shivani Fotedar (14), Chaudhary et al (15), Sachidananda R et al (1), Shanmugavelu G et al (17).

In our study, success rate of Baska mask in the first insertion attempt was 84.4% and second attempt success rate was 15.6%. In I-gel group, first insertion attempt success rate was 93.3% and second attempt success rate was 6.7%. Overall success rate was 100% in both Baska mask and I-gel group. This finding was in agreement with the results of Shivani Fotedar (14), Chaudhary et al (15), Sachidananda R et al (1), Shanmugavelu G et al (17).

Post operative complications (sore throat, dysphagia, hoarseness of throat 1 and 24 hours post extubation) though comparable between two groups which was in agreement with other authors by Abdel Raof Abdel Aziz et al (13), Shivani Fotedar (14), Chaudhary et al (15), Abitağaoğlu et al (16), Sachidananda R et al (1), Shanmugavelu G et al (17), relatively higher incidence in our study may be due to mean duration of surgeries being longer (89.9 ± 20.7 minutes in Baska group & 88.2 ± 17.8 minutes in I-Gel group) than other studies.

In our study there was no statistical difference between Baska mask and I-gel groups in regards to hemodynamic changes (Heart rate and Mean arterial pressure). This may be due to the same stress response produced by the both devices. These results were in consistence with previous studies by Sachidananda R et al (1), Shivani Fotedar (14), Abitağaoğlu et al (16)

6. Conclusion:

Baska mask is superior to I-gel in positive pressure ventilation under general anaesthesia for short surgical procedures with statistically significant higher airway sealing pressure though it has comparable time of insertion, haemodynamic changes and laryngo-pharyngeal morbidity

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Nil

COMPETING INTERESTS

Nil

CONSENT (WHEREEVER APPLICABLE)

Informed written consent taken

ETHICAL APPROVAL (WHEREEVER APPLICABLE)

The patient and attendees were explained about the procedure and the expected complications. They were informed about the present study and their eligibility for participating in the study. Only patients who were willing to participate were included and informed consent was obtained. The study was approved by the Institutional Ethical Committee [NBE/CNS/DNB PDCET/41159]

REFERENCES

1. SachidanandaR, ShaikhSI, MitragotriMV, JoshiV, LadhadaDA, MallappaM, Bhat VK. Comparison between the Baska Mask® and I-Gel for Minor Surgical Procedures Under General Anaesthesia. *Turkish Journal of Anesthesia & Reanimation*. 2019 Jan 1;47(1).
2. Almeida G, Costa AC, Machado HS. Supraglottic airway devices: a review in a new era of airway management. *J Anesth Clin Res*. 2016;7(647):2.
3. Miller DM. A proposed classification and scoring system for supraglottic sealing airways: a brief review. *Anesthesia & Analgesia*. 2004 Nov 1;99(5):1553-9.
4. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. *Anaesthesia*. 2005 Oct;60(10):1022-6.
5. van Zundert T, Gatt S. The Baska Mask®-A new concept in Self-sealing membranecuffextraglotticairwaydevices, usingasumpandtwo gastricdrains: A critical evaluation. *Journal of Obstetric Anaesthesia and Critical Care*. 2012 Jan 1;2(1):23.
6. Alexiev V, Salim A, Kevin LG, Laffey JG. An observational study of the Baska® mask: a novel supraglottic airway. *Anaesthesia*. 2012 Jun;67(6):640-5.
7. Miller RD. *Miller's Anesthesia*. 8th ed. Elsevier Saunders. Chapter 55. Philadelphia: Churchill Livingstone-Elsevier; pp. 1648-1651
8. Hagberg CA, Artime CA. Airway Management in the Adult. In: Miller RD, editors. *Miller's Anesthesia*. 8th ed. Philadelphia: Saunders; 2015. p. 1661.
9. Cook T, Howes B. Supraglottic airway devices: Recent advances. *Contin Educ Anaesth Crit Care Pain*. 2011;11:56-61.
10. Kannaujia A, Srivastava U, Saraswat N, Mishra A, Kumar A, Saxena S. A preliminary study of i-gel: a new supraglottic airway device. *Indian journal of anaesthesia*. 2009 Feb;53(1):52.
11. I-gel for use in anaesthesia [Internet]. Berkshire; Intersurgical Ltd:2018. Available from: <https://www.intersurgical.com/info/igel-anaesthesia>
12. Cook T. Airway management equipment. In: Davey A, Diba A, Ward C, editors. *Ward's anaesthetic equipment*. 6th ed. Edinburgh: Elsevier; 2012. p. 156.
13. Aziz RA, Osman YM. Comparison of I-gel with Baska Mask Airway for Controlled Ventilation in Obese Patients Undergoing Ambulatory Surgery: A Prospective Randomized Trial. *International Journal of Anesthesia and Clinical Medicine*. 2017 Nov 20;5(4):29.
14. Fotedar S, Taneja D, Sarangi S. *INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH*. Age.;38(36.85):0-528.
15. Chaudhary UK, Mahajan SR, Mahajan M, Sharma C, Sharma M. A comparative analysis of the baska mask versus i-gel for general anesthesia in surgical patients undergoing laparoscopic cholecystectomy. *Acta Medica International*. 2018 Jul 1;5(2):69.
16. Abitağaoğlu S, Köksal C, Turan G, Akgün AY, Arı DE. Comparison of the clinical performances of i-gel and baska mask. *Medical Science*. 2019;23(95):100-7.
17. Shanmugavelu G, Kanagarajan T. Comparing the functional analysis of I-gel with Baska mask in laparoscopic surgeries: An observational study. *Int J Res Med Sci*. 2018;6:1440-3.

18. Al-Rawahi SA, Aziz H, Malik AM, Khan RM, Kaul N. A comparative analysis of the Baska mask vs Proseal laryngeal mask for general anesthesia with IPPV. *Anaesthesia, Pain & Intensive Care*. 2013 Sep 1;17(3):233-6.
19. López AM, Muñoz-Rojas G, Fontanals M, de San José I, Hermoso A, Valero R. Clinical evaluation of the Baska Mask® laryngeal mask in adult patients in ambulatory surgery. *Revista Española de Anestesiología y Reanimación (English Edition)*. 2015 Dec 1;62(10):551-6.
20. Jawe N, Dhumal P, Rathi P, Padmanabha DV, Kumbhar A. Comparative study of clinical performance of I-Gel with classic LMA in adult patients. *Journal of Evolution of Medical and Dental Sciences*. 2016 Oct 13;5(82):6121-5.
21. Beleña JM, Núñez M, Vidal A, Gasco C, Yuste J, Kahn A. Comparison of the i-gel™ and the LMA Proseal™ in anesthetized patients undergoing laparoscopic cholecystectomy: a prospective, randomized clinical trial. *Anaesthesia, Pain & Intensive Care*. 2019 Jan 26;135-40.
22. Lai CJ, Liu CM, Wu CY, Tsai FF, Tseng PH, Fan SZ. I-Gel is a suitable alternative to endotracheal tubes in the laparoscopic pneumoperitoneum and trendelenburg position. *BMC anesthesiology*. 2017 Dec;17(1):3.
23. Dhanda A, Singh S, Bhalotra AR, Chavali S. Clinical comparison of I-gel supraglottic airway device and cuffed endotracheal tube for pressure-controlled ventilation during routine surgical procedures. *Turkish journal of anaesthesiology and reanimation*. 2017 Oct;45(5):270.
24. De Montblanc J, Ruscio L, Mazoit JX, Benhamou D. A systematic review and meta-analysis of the i-gel® laryngeal mask airway in adults. *Anaesthesia*. 2014 Oct;69(10):1151-62.

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