

Original Article

COMPARISON BETWEEN BASKA MASK AND I-GeI INSERTION IN MINOR SURGERIES UNDER GENERAL ANAESTHESIA IN PATIENT AGED 18-50 Y:-A RANDOMIZED INTERVENTIONAL STUDY

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ABSTRACT

Objective: The supraglottic airway (SAD) is considered a viable alternative to endotracheal intubation, particularly in cases where SAD is not contraindicated. SAD plays a crucial role in difficult airway algorithms, offering unobstructed oxygenation and ventilation, as well as providing hemodynamic stability with minimal laryngopharyngeal morbidity. The LMA-classic, introduced by Archie Brain in 1983, was the first second-generation SAD used in clinical practice. Over time, numerous advancements have led to the development of improved second-generation SADs.

Methods: This study aims to compare the efficacy and advantages of different supraglottic airway devices. Two types of second-generation SADs were evaluated: I-gel (Intersurgical, Wokingham, UK) and a novel device called Baska Mask, which belongs to the third generation of SADs. The evaluation criteria included ease of insertion, oropharyngeal sealing pressure, ability to drain gastric fluid, prevention of malposition, sealing pressure during controlled ventilation and spontaneous breathing, and reduction of respiratory complications.

Results: The second-generation SADs, including the I-gel, are easy to insert and offer high oropharyngeal sealing pressure. They have a gastric channel to drain gastric fluid, reducing aspiration risk. The I-gel, a new latex-free SAD with a noninflatable cuff made of medical-grade thermoplastic elastomer, provides a superior seal, resulting in lower respiratory complications compared to earlier SADs. It ensures effective sealing during controlled ventilation and spontaneous breathing. The third-generation Baska Mask combines the advantages of second-generation LMAs and provides higher seal pressure during IPPV by apposing to the glottis, distinguishing it from non-inflatable cuff devices like the I-gel.

Conclusion: Supraglottic airway devices, particularly second-generation SADs like I-gel, offer effective airway management alternatives to endotracheal intubation. These devices provide ease of insertion, high oropharyngeal sealing pressure, and the ability to drain gastric fluid, reducing the risk of complications. The third-generation device, Baska Mask, exhibits enhanced seal pressure during IPPV, making it a promising advancement in airway management.

Keywords: Supraglottic airway device, Endotracheal intubation, Difficult airway algorithms

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INTRODUCTION

The supraglottic airway (SAD) is the good alternative device of endotracheal intubation until unless SAD is contraindicated. SAD plays a special role in difficult airway algorithms. SAD Provides unobstructed oxygenation and ventilation, provide hemodynamic stability with minimal laryngopharyngeal morbidity [1]. The LMA-classic was first SGAD Introduced into clinical practice in 1983 by Archie Brain. Over the years, numerous enhancements have resulted in the creation of improved second-generation SGAD [2].

Second-generation SAD being as easy to insert with high oropharyngeal sealing pressure. They having a gastric channel to drain the gastric fluid, thereby reducing the chance of aspiration. A second-generation device, like I-gel (Intersurgical, Wokingham, UK) is a new second-generation latex-free SAD with a noninflatable cuff, medical-grade thermoplastic elastomer with a buccal stabilizer to prevent malposition. It provides higher sealing pressure and lower respiratory complications as compare to earlier SAD. The i-gel offers a good seal during anesthesia for both controlled ventilation and spontaneous breathing [3].

The Third generation supraglottic airway device, including-Baska Mask is novel SDA that incorporates all the beneficial features of 2nd generation LMA with an additional feature that it provides a higher seal pressure than other LMAs as during IPPV the seal apposes to the glottis to augment seal pressure with increasing airway pressure, thus making it different from other non-inflatable cuff devices like I-gel [4].

MATERIALS AND METHODS

Study design: Hospital-based Prospective Randomized Interventional study.

Study period: After the approval of the plan by the Institutional Ethics Committee till the completion of desired sample size. (1/10/2022 to 10/12/2022).

Sample size: A sample size of 30 case in each group are adequate at 95% confidence interval and power of 80% to verify the expected difference of 3 cm H₂O in mean and SD 35 for sealing pressure in between two study groups [group B or Baska mask group and group I or i gel group] To compare baska mask and i-gel for minor surgical procedures under general anaesthesia.

Eligibility criteria inclusion criteria

1. Adult patients of 18-50 y age group
2. Weight of 30-60 kgs
3. ASA grade I and II
4. Undergoing minor surgical procedure under general anesthesia.

Exclusion criteria

1. Anticipate difficult airway
2. With the recent history of upper respiratory tract infection, any obvious scar or mass or ulcer in neck, cleft lip/palate, adenotonsillar hypertrophy or lingual tonsil.)
3. Mouth opening <2.5 cm
4. With an increased risk of aspiration of gastric contents 5. Surgery time more than 1 h
6. Obesity [BMI>30 kg/m²].

7. Negative patient consent.

Methods

In this study, 60 participants were randomly assigned to either Group A (n=30) receiving the Baska Mask or Group B (n=30) receiving the I-Gel supraglottic airway device. Anesthesia was induced with preoxygenation and the administration of medications. The size of the device was chosen based on the patient's weight. Insertion of the Baska Mask involved manipulation of the tab to negotiate the palatopharyngeal curve, while the I-Gel was inserted with the cuff directed toward the patient's chin. Successful device placement was confirmed using capnography and chest movement. Insertion time and ease of insertion were assessed. If the device did not provide effective ventilation, manipulations were performed, and reinsertion attempts were allowed up to a maximum of three. Oropharyngeal leak pressure tests were conducted. Gastric tubes were inserted, and insertion ease was graded. Vital signs were monitored throughout the procedure, and postoperative morbidity, including trauma, coughing, regurgitation, and blood staining, was evaluated. Laryngopharyngeal morbidity, such as sore throat, dysphagia, and dysphonia, was assessed after device removal. Anesthesia was maintained, and postoperative pain management was administered. The device was removed when the patient exhibited adequate spontaneous breathing and responsiveness. Morbidity and device integrity were assessed during removal.

Statistical analysis

Statistical data was performed with the SPSS (Statistical Package for the Social Science), version 21 for Windows statistical software package (SPSS inc., Chicago, I, USA). The sample size was calculated based on the data from a pilot study of 60 patients in the I-gel and Baska mask (30 patients each) required 95% confidence interval

and power of 80% to verify the expected difference of 3 cm H₂O in mean and SD 35 for sealing pressure in between two study groups. Continuous data (Quantitative data) would be summarized in form of mean and standard deviation. Difference in mean of two groups would be analysed using a student t-test. Categorical variable (Qualitative data) would be expressed in form of proportions and difference in proportions would be analysed using chi-square test. A P value of <0.05 was considered statistically significant.

RESULTS

A total of 60 patients were included in the study. Demographic and airway characteristics are given in table 1. Both parameters are comparable in both groups. Insertion characteristics in terms of number of attempts, ease of insertion, manipulation frequency, grading of gastric tube insertion was also comparable in both groups. Mean insertion time of Baska mask group slightly higher as compare to I gel group but the difference was statistically non-significant (p value=0.749). Oropharyngeal leak pressure just after insertion in baska group (T1) was 28.8±5.12 cm H₂O and in I gel group was 25.07±4.27 cm H₂O with a significant p value of 0.003 (significant). Whereas OLP after 5 min (T2) of insertion in baska group 29.33±3.47 cm H₂O and in I gel group was 25.97±3.7 cm H₂O with p value of <0.001 (significant). P value <0.05 was considered to be significant. The oropharyngeal leak pressure was significantly higher in Baska group just after insertion and 5 min later as compare to I gel group with a statistically significant p value. No significant difference was found between both the groups in terms of blood stain on devices, trauma to lip/tongue/teeth, sign of regurgitation, coughing, and bronchospasm/laryngospasm. No significant differences were found in post-operative morbidity in terms of sore throat, dysphagia, and dysphonia. There was no significant haemodynamic difference among the groups.

Table 1: Demographic data and airway characteristics

Parameters	Group BM (n=30)	Group I-gel (n=30)	p-value
Age (years)	33±10.20	32.1±7.91	0.546(NS)
Weight(kg)	50.63±5.01	51.63±6.18	0.494(NS)
Height(cm)	162.03±11.28	165.6±14.25	0.287(NS)
Body Mass Index	19.3±0.91	19.3±0.91	0.088(NS)
Gender			
Female	29(96.7%)	26(86.7%)	0.350(NS)
Male	1(3.3%)	4(13.3%)	
Mallampati Score			
1	19(63.3%)	18(60%)	1.000(NS)
2	11(36.7%)	12(40%)	
Thyromental distance(cm)	6.81±0.19	6.76±0.15	0.253(NS)
Inter incisor gap	4.37±0.49	4.57±0.50	0.125(NS)
Mouth Opening			
2.5 finger	16(53.3%)	15(50%)	1.000(NS)
3 finger	14(46.7%)	15(50%)	

The comparison between Group BM (n=30) and Group I-gel (n=30) showed no significant differences (p>0.05) in various parameters. These included age (33±10.20 vs. 32.1±7.91 y), weight (50.63±5.01 vs. 51.63±6.18 kg), height (162.03±11.28 vs. 165.6±14.25 cm), body mass

index (19.3±0.91 vs. 19.3±0.91), gender distribution, Mallampati score, thyromental distance (6.81±0.19 vs. 6.76±0.15 cm), inter-incisor gap (4.37±0.49 vs. 4.57±0.50 cm), and mouth opening (2.5 fingers: 53.3% vs. 50% and 3 fingers: 46.7% vs. 50%). All p-values were non-significant.

Table 2: Insertion characteristics and oropharyngeal leak pressure

Parameters	Group BM (n=30)	Group I gel (n=30)	P-VALUE
No. of attempts (%)			
1	26(86.7%)	27(90%)	0.606(NS)
2	3(10%)	3(10%)	
3	1(3.3%)	0	
Ease of insertion of SGA			
Grade I	20(66.7%)	24(80%)	0.266(NS)
Grade II	8(26.6%)	6(20%)	
Grade III	2(6.7%)	0	
Grade IV	0	0	
Mean insertion Time	14.87±5.39	14.43±5.05	0.749(NS)
Manipulation frequency			

Parameters	Group BM (n=30)	Group I gel (n=30)	P-VALUE
0	26(86.7%)	27(90%)	1.000(NS)
1	4(13.3%)	3(10%)	
2	0	0	
Grading of gastric tube insertion			
1(easy)	29(96.7%)	29(96.7%)	0.368(NS)
2(difficult)	0	1(3.3%)	
3(Impossible)	1(3.3%)	0	
Oropharyngeal leak pressure			
Just after insertion	28.8±5.12	25.07±4.27	0.003(S) 0.001(S)
5 min after insertion	29.33±3.47	25.97±3.7	

In both Group BM (n=30) and Group I-gel (n=30), there were no significant differences observed in parameters such as blood staining on the device, trauma to lip/tongue/teeth, signs of regurgitation, coughing, bronchospasm/laryngospasm, dysphagia, and dysphonia (p>0.05). The incidence of sore throat was similar in both groups, with 3 cases (10%) reported in each group (p=0.667).

Table 3: Frequency of complications among study groups

Parameters	Group BM(=30)	Group I gel (n=30)	P value
Blood staining on device	1(3.3%)	1(3.3%)	0.472(NS)
Trauma to lip/tongue/teeth	0	0	
Sign of Regurgitation	0	0	
Coughing	1(3.3%)	1(3.3%)	0.472(NS)
Bronchospasm/laryngospasm	0	0	
Sore Throat	3(10)	3(10)	0.667(NS)
Dysphagia	0	0	0
Dysphonia	0	0	0

The comparison between Group BM (n=30) and Group I-gel (n=30) showed no significant differences (p>0.05) in parameters such as blood staining on the device, trauma to lip/tongue/teeth, signs of regurgitation, coughing, bronchospasm/laryngospasm, dysphagia, and dysphonia. The incidence of sore throat was similar in both groups, with 3 cases (10%) reported in each group (p=0.667).

DISCUSSION

Baska mask is the latest SAD for airway management, overcoming the limitations with the existing SADs. Baska mask provide high sealing pressure as compare to second-generation LMA. There is a gradual improvement in the Baska mask seal against the glottis over the first 2-3 min, which might be due to the thermolability of the membranous mask, making it more adaptable to the shape of the laryngeal outlet over time [5].

In our study the success rate of insertion of the baska mask was comparable to that of the I-gel [6]. In Baska Group the first attempt success rate was seen in 26/30 patients (86.7%), second attempt was in 3/30 patients (10%), and third attempt was in 1/30 patient (3.3%). Whereas in I gel Group first attempt success rate was seen in 27/30 patients (90%), second attempt in 3/30 patients (10%). P value for number of attempts was 0.601 which was statistically non-significant. In study of Sachidananda R *et al.* compared Baska mask and I-gel in minor surgical procedure under general anaesthesia [7]. They also found first-time success rate of the Baska Mask was 21/24(87.5%) when compared to that of the I-gel, which was 23/25(92%). The lower success rates achieved for baska mask may be attributable to morphology of the device and unique expertise needed to insert the device.

In our study Mean insertion time required to successfully placement of device was 14.87±5.39 seconds in Baska Group 14.43±5.05 seconds was taken in I gel Group with p value 0.749(NS). In our study mean OLP at the time of insertion in Baska Group (28.8±5.12) cm of H2O and in I gel Group (25.07±4.27) cm H2O which was higher in baska group than I gel group and statistically significant (p value 0.003). After 5 min of insertion mean OLP in baska group (29.33±3.47) cm of H2O and in I gel group (25.97±3.7) cm of H2O which was also higher in baska group than I gel group and statistically significant (p value<0.001) [8]. Similar result also found in study conducted by Garg A *et al.* compared Baska Mask with I-gel device for short gynaecological procedures. They also found that airway sealing pressure was higher with the Baska Mask than I-gel device (35.8±10.3 vs 26.9±7.5 cm H2O, p=<0.0001 [9].

Multiple studies that compared baska mask and I gel in laparoscopic surgeries like Ron Choi *et al.*, Hussain D *et al.*, Patel V *et al.*, Agarwal N *et al.*, Choudharyket *al.* they all found higher OLP with baska

mask than I gel. They also found statistically significant differences in both groups. Other parameters like ease of insertion of SGAD, manipulation frequency, grading of gastric tube insertion, Hemodynamic parameters are comparable in both groups.

Removal characteristics in terms of blood stained on devices, trauma to tongue/lip/mouth, sign of regurgitation and aspiration, coughing, Bronchospasm and laryngospasm are comparable in both the groups. Post-operative complications like sore throat seen in 10% (3/30) patients in Baska Group and 10% (3/30) in I gel Group with a statistically non-significant p value 0.66. No sign of dysphasia and dysphonia seen in both the groups. Our results are also comparable with the study conducted by Sachidananda R *et al.* observed sore throat in 3 (12.5%) patients only in baska group and None of patients complained of dysphagia or dysphonia in both groups [10].

STUDY LIMITATIONS

Our study was a single-centered and smaller sample size study. In our study we were not noted intraoperative ventilation parameters like inspiratory and expiratory tidal volume, peak airway pressure which is required to known about adequate ventilation with SADs. So further knowledge required large sample size multicentric study with ventilation parameters observations.

CONCLUSION

On the basis of observations from this study, we concluded that though I-gel was easier to insert with lesser insertion time, as compare to baska mask. The sealing pressures of the Baska mask@ are superior to those of the I-gel and both devices can serve as an exemplary, alternative airway device for short surgical procedures with minimum complications.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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