Original research article

A comparison of clinical performance between the I-Gel and the Baska mask in spontaneously ventilating anaesthetised patients: A prospective randomized study

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Abstract

Supraglottic Airway devices (SAD) have now become a fundamental tool for ventilation, oxygenation and delivery of anaesthetic gases in modern anaesthesiology. The advent of newer generation of SADs has resulted in their extended use. Baska mask and I Gel being newer generation SADs are vastly being used due to their specific designs for ease of securing the airway, better ventilation and higher patient safety. After institutional ethical committee clearance, a prospective randomized comparative study was conducted. 60 patients of age group 18-60 years of ASA grade I and II undergoing elective surgeries under GA were included. Patients were randomized into 2 groups, Group B (Baska mask group) and Group I (I Gel group) with 30 patients in each group. The ease of insertion (p value 0.035), insertion attempts (p value 0.04) and the time taken for insertion (p value <0.001) were significantly better with I Gel compared to Baska mask. Both the groups were comparable in terms of postoperative pharyngolaryngeal morbidities.

Keywords: Baska mask, I Gel, general anaesthesia, spontaneous ventilation

Introduction

Securing airway during administration of Anaesthesia is of vital importance and significant urgency wherein lapses can lead to catastrophic outcomes [1]. Research is ongoing and relentless in field of airway management, to invent ideal device to secure the airway.
Endotracheal intubation is gold standard for securing the airway, however in many situations where endotracheal intubation becomes difficult, securing the airway becomes a challenge. Also, the process of endotracheal intubation carries many disadvantages due to manipulation of the airway, like haemodynamic perturbations and pharyngo-laryngeal morbidities like sore throat, hoarseness of voice, dysphagia, airway edema. These complications are not well tolerated in some critically ill patients.
Ventilation can also be provided by face-mask ventilation technique, but it can cause gaseous distension of stomach increasing the chances of regurgitation and risk of aspiration.

The invent of Laryngeal Mask Airway by Dr Archie Ian Jeremy Brain brought a revolution in field of anaesthesia in 1980s [2].

The LMA fits over the laryngeal inlet, secures the airway and provide ventilation. Since, there is less manipulation of airway involved during placement of LMAs, the extent of haemodynamic perturbations and postoperative laryngo-pharyngeal complications is reduced. Also, these LMAs are helpful in securing the airway in patients with difficult intubation. However, they also carry the risk of aspiration due to ventilatory air leak into the stomach, causing gastric distension and regurgitation either due to improper placement or inadequate seal pressure during intermittent positive pressure ventilation. To overcome these disadvantages, a relentless research had been going on resulting in development of various newer generation of Supraglottic Airway Devices.

One of the newer generation airway device is I Gel, a single-use non-inflatable supraglottic airway device made of soft, gel-like, transparent, thermoplastic elastomer. Introduced in market in 2007, I Gel is designed to achieve a mirrored impression of the pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. It also has integrated bite block and a drain tube which allows the insertion of a gastric tube [3].

Baska Mask is another newer generation airway device, designed by Australian anaesthetists Kanag and Meena Baska, has a non-inflatable, self-recoiling, thin membranous cuff which has the added advantage that its pressure fluctuates with maximum inspiratory pressure during IPPV. It is made of medical grade silicone and is integrated with a bite block. Baska mask obviates the need for an orogastric tube and replaces this with a sump and two drain tubes, which run along the airway stem of the device. One of these tube vents is connected to suction port, while the other is left open to ambient to equilibrate the pressure in the sump cavity to atmospheric pressure. Baska Mask is also integrated with 'Tab'- a unique feature, for manually curving the mask to facilitate insertion whenever required to overcome the palate-pharyngeal curve [4].

The current study is designed to compare the efficacy of Baska mask and I Gel in terms of ease of insertion, haemodynamic perturbations and post-operative complications like sore throat, dysphagia and hoarseness of voice in spontaneously ventilating anaesthetised patients.

Methodology

This was a prospective randomized study of patients satisfying all inclusion criteria.
An informed consent was obtained from all the patients participating in the study.
The study population was divided into 2 groups of 30 patients each.
1. Group B (N=30), was Baska mask group.
2. Group I (N=30), was I-GEL group.

All the patients of 2 groups, with their informed consent, were kept nil per oral for 6 hours. After careful pre-anaesthetic evaluation and airway assessment, patients were premedicated with Tab. Diazepam 5 mg and Tab. Ranitidine 150 mg the evening before the day of surgery.
After shifting the patients into Operation Theater, an intravenous line was secured, using 18 guage IV cannula, on non-dominant hand and infusion of ringer lactate was started. All the patients were connected with non-invasive monitors- pulse oximetry (SpO$_2$), Non-invasive blood pressure (NIBP) and Electrocardiography (ECG) using multiparameter monitor and baseline parameters were recorded. Preoxygenation for 3 minutes with 100% oxygen followed by premedication with injection midazolam 0.05 mg/kg, injection glycopyrrolate 0.01 mg/kg, injection fentanyl 2 mcg/kg and injection ondensetron 0.1 mg/kg was given intravenously. General anaesthesia was induced with injection propofol 2 mg/kg I.V slowly. The end point of induction was taken as no response to vocal commands and loss of eye lash reflex.

Decision of airway placement was done randomly, both the devices were lubricated on the posterior surface and the tip, using a water based gel prior to the insertion of the device. And the airway placement was done by experienced anaesthesiologist according to the manufacturer's instructions. Size selection was based on manufacturer's recommendation of weight-based estimate plus clinical judgement.

Anaesthesia was maintained with oxygen, nitrous oxide and sevoflurane under spontaneous ventilation.

Patients were observed in post-anaesthetic care unit for 6 hours for monitoring and look for complications like sore throat, dysphagia and hoarseness of voice.

Parameters observed
1. **Technique**
A. **Ease of insertion**
1. The ease of insertion is graded as:
2. Very easy (when assistant help is not required).
3. Easy (when jaw thrust is needed by assistant).
4. Difficult (when jaw thrust and deep rotation or second attempt is used for proper device insertion).

B. **Time taken for insertion**

Insertion time needed for placement of the SAD is defined as time in seconds from SAD touching the teeth to the first recorded near rectangular capnogram curve. Only the successful attempt time was counted.

2. **Post-operative pharyngo-laryngeal morbidity**
a) **Sore throat**

0 – None.
1 – Mild sore throat.
2 – Moderate sore throat.
3 – Severe sore throat; never an SAD again.

b) **Dysphagia**

0 – None
1 – Mild
2 – Moderate
3 – Severe; cannot eat

c) **Hoarseness of voice**

0 – None
1 – Mild
2 – Moderate
3 – Severe; cannot speak

Results

Table 1: Comparison of time for insertion between two groups (N=60)

	Baska mask group (N=30)	**I-GEL group (N=30)**	**p-value**
Mean (SD) Time for insertion (seconds)	11.9 (3.2)	5.9 (1.0)	<0.001*
Median (IQR) Time for insertion (seconds)	11.5 (10 - 14)	6 (5 - 7)	<0.001@

P value by: @ Mann Whitney U test, * independent samples t test

The above table and figure compares the mean time of insertion between the two groups. Statistical analysis using independent samples t test shows that the mean time for insertion of Baska mask was 11.9 seconds with SD of 3.2 seconds whereas I Gel group had a mean time of insertion of 5.9 seconds with a SD of 1 second. The p value between the two groups is <0.001, which was statistically significant. Therefore, the I Gel group proved to be superior to Baska mask group in terms of time taken for insertion. (Table 14, Chart 11)

Table 2: Comparison of ease of insertion between the two groups (N=60)

Ease of insertion	**Baska mask group (N=30)**	**I-GEL group (N=30)**	**p-value**
Grade 1	19 (63.3%)	27 (90.0%)	
Grade 2	8 (26.7%)	3 (10.0%)	0.035#
Grade 3	3 (10.0%)	0	

p value by Chi square test

The above table and figure compares the ease of insertion of the SAD between the two groups. Statistical analysis using chi square test shows that in the Baska mask group 63.3% were very easy insertions, 26.7% easy insertions and 10% were difficult insertions. In the I Gel group there were 90% were very easy insertions and 10% easy insertions and no difficult insertions. The p value between the two groups was 0.035 which is statistically significant. Therefore, the I Gel group proved to be superior to Baska mask group in terms of ease of insertion.

Table 3: Comparison of number of insertion attempts (N=60)

Number of insertion attempts	**Baska mask group (N=30)**	**I-GEL group (N=30)**	**p-value**
1	22 (73.3%)	28 (93.3%)	0.040#
2	8 (26.7%)	2 (6.7%)	

p value by Chi square test

The above table and figure compares the number of attempts taken for insertion of SAD between the two groups. Statistical analysis using chi square test shows that the Baska mask group had 73.3% first attempt insertions and 26.7% second attempt insertions. The I Gel group had 93.3% first attempt insertions and 6.7% second attempt insertions. The p value between the two groups was 0.04 which is statistically significant. Therefore, I Gel group proved to be superior to Baska mask group in terms of number of insertion attempts of SAD.

Table 4: Comparison of complications between two study groups (N=60)

Complications	**Baska mask group (N=30)**	**I-GEL group (N=30)**	**p-value**
Sore throat	6 (20.0%)	1 (3.3%)	0.103#
Dysphagia	4 (13.3%)	0	0.112#
Hoarseness of voice	0	0	-

p value by Chi square test

The above table and figure compares the incidence of sore throat, dysphagia and hoarseness

of voice between the two groups. Statistical analysis using chi square test shows that in the Baska mask group 20% patients had mild sore throat, compared to 1% in I Gel group (p value 0.103), none had moderate or severe degree of sore throat in both the groups. The incidence of mild dysphagia in Baska mask group was 13.3% compared to none in I Gel group (p value 0.112), none of the patients had developed moderate or severe degree of dysphagia in both the groups. However, none of the patients developed hoarseness of voice in both the groups. The analysis have shown that the difference in incidence and severity of complications as statistically insignificant.

Discussion

The parameters observed and compared between the two groups are duration of insertion of SAD, ease of insertion of SAD, number of attempts for SAD insertion, postoperative sore throat, dysphagia and hoarseness of voice.

The mean time for insertion of Baska mask was 11.9 ± 3.2 seconds whereas I Gel group had a mean time of insertion of 5.9 ± 1.0 seconds. The p value between the two groups was <0.001 which is statistically significant. Therefore, I Gel group proved to be superior to Baska mask in terms of time taken for insertion.

In support of our study, a study comparing Baska Mask and I Gel during laparoscopic cholecystectomy surgeries under general anaesthesia which was conducted by Usha Kumari Chaudhary *et al.* documented that the insertion time was shorter in I Gel group (11.31±1.84 secs) compared to baska mask group (12.33±2.61 secs) and was statistically significant with p value of 0.02 [5].

A randomized control study conducted by Duygu Kara and Cafer Mutlu Sarikas comparing Baska mask and I Gel in patients undergoing general anaesthesia for urological surgery showed similar results as our study and found that time taken for insertion of Baska mask is significantly higher compared to I Gel. This study found that median insertion was shorter in I-gel group [7 (5-12) seconds] compared to Baska group [14 (6-25) seconds] with p value of <0.001 [6].

Baska mask group had 19 (63.3%) very easy insertions, 8 (26.7%) easy insertions and 3 (10.0%) difficult insertions. I Gel group had 27 (90.0%) very easy insertions and 3 (10.0%) easy insertions and no difficult insertions. The p value between the two groups was <0.035 which is statistically significant. Therefore, the I Gel group proved to be superior to Baska mask in terms of ease of insertion.

N.A.R. El-Refai *et al.* conducted a prospective, randomized, interventional study comparing between Baska mask and I Gel in spontaneously ventilated females undergoing minor gynaecological procedures. This study found that in the Baska mask group (n=30) had 19 (62.5%) very easy insertions, 11 (37.5%) easy insertions and no difficult insertions. I Gel group (n=30) had 24 (80%) very easy insertions and 6 (20%) easy insertions and no difficult insertions. The p value between the two groups was <0.0004. Showing a statistically significant difference and proving I Gel is easier to insert compared to Baska mask, similar to our study [7].

The Baska mask group had 22 (73.3%) first attempt insertions and 8 (26.7%) second attempt insertions. The I Gel group had 28 (93.3%) first attempt insertions and 2 (6.7%) second attempt insertions. The p value between the two groups was 0.04 (p < 0.05) which is statistically significant. Therefore, I Gel group proved to be superior to Baska mask in terms of number of attempts for insertion of device in a statistically significant manner.

Our statistical data related to number of attempts taken to insert the device is consistent with findings of the study conducted by Shivani Fotedar which compared baska mask and I Gel in spontaneously ventilating anaesthetised patients. This study found that among Baska mask group (N=40), 32(80%) were inserted in 1st attempt, 7(17.5%) were inserted in 2 attempts and

1 (2.5%) in 3 attempts. Among I Gel group (N=40), 37 (92.5%) were inserted in 1st attempt, 3(7.5%) were inserted in 2 attempts and none required 3 attempts in this group. This difference was statistically significant, similar to our study [1].

In the Baska mask group 6 (20%) patients had sore throat compared to 1 (3.3%) patient in I Gel group. All the patients who had developed sore throat in both the groups had mild sore throat, none of the patients developed moderate or severe sore throat. The p value between the two groups was 0.103 (>0.05) which is statistically insignificant. Therefore, both groups proved to be statistically similar in terms of presence of incidence of sore throat.

In the Baska mask group 4 (13.3%) patients had developed mild dysphagia and none developed it in I Gel group. There was no incidence of moderate or severe dysphagia in both the groups. The p value between the two groups was 0.112 (>0.05) which is statistically insignificant. Therefore, both groups proved to be statistically similar in terms of presence of incidence of dysphagia.

There was no incidence of postoperative hoarseness of voice in both the groups.

A study conducted by Anurag Garg *et al.* found that the postoperative complications in patients of Baska mask group and I Gel group were comparable, showing similar results as in our study [8].

Our study is supported by the observations from Usha Kumari Chaudhary *et al.* who compared Baska mask and I Gel and found that laryngopharyngeal morbidity was comparable in the two groups, similar to our study [5].

Conclusion

We conclude that Baska mask and I Gel are equally efficacious in terms of effect on postoperative pharyngo-laryngeal morbidities. However, I Gel is quicker to insert compared to Baska mask.

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