



Original Research Article

Comparative evaluation of the clinical performance of supraglottic airways- Supreme laryngeal mask airway, I gel and baska mask

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ABSTRACT

Introduction: There are no studies comparing Supreme laryngeal mask airway (LMA), I gel and Baska mask in Indian population. A comparison of the clinical performance of Supreme LMA, I gel and Baska mask was undertaken in this randomized controlled study.

Materials and Methods: The present research was undertaken in 75 patients aged 18 to 60 years who underwent elective surgery for less than 3-hour duration under general anaesthesia. The patients were randomly divided into three groups; Supreme LMA, I gel, and Baska mask. The oropharyngeal leak pressure (OLP) after 30 minutes to loss of spontaneous respiration was the primary objective, whereas the secondary objectives were attempts required for insertion of LMA, ease of gastric tube insertion, time required for gastric tube insertion and post-operative morbidity.

Results: The mean OLP of Baska mask group was (28.2 cm H₂O) as compared to Supreme LMA (25.3 cm H₂O) and I-gel (24.1 cm H₂O) groups (p-value = 0.0001). The mean gastric tube insertion time of Baska mask group was (20.7 s) as compared to Supreme LMA (6.7 s) and I-gel (9.6 s) groups (p-value = 0.0001). The three groups were comparable with regards to the number of attempts required, ease of gastric tube insertion and post-operative morbidity.

Conclusion: A higher OLP was observed in Baska mass group as compared to Supreme LMA and I-gel. The three devices were similar in terms of attempts required for insertion, ease of gastric tube insertion and post-operative morbidity.

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1. Introduction

The gold standard for airway management is an endotracheal intubation. The endotracheal intubation is a speedy, simple, harmless and non-surgical technique. The aim of the endotracheal intubation is airway management, preserving airway patency, and protecting lungs from aspiration. Endotracheal intubation can cause complications because of the necessity to visualize and its passage through the laryngeal opening.¹

The supraglottic airway devices (SADs) can be blindly inserted into the pharynx and provide a patent channel for ventilation, oxygenation and delivery of anaesthetic gases without the need of tracheal intubation. SADs are less invasive than tracheal intubation and can also provide more definitive airway than a face mask. These can be used for providing spontaneous ventilation or positive pressure ventilation.¹ The laryngeal mask airway (LMA) is an SAD developed by British anaesthesiologist Dr. Archi Brain in 1981.² LMA can be classified based on sealing mechanism-Miller classification, which is useful from a research and device design perspective and also can be classified by generations - Cook classification.²

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The Supreme LMA is a second-generation SAD. It has a soft, elongated cuff which form an effective first seal with the oropharynx. This allows higher glottic seal pressures. It has an advanced second seal with the upper oesophageal sphincter. The patency of the drain tube is preserved and this reduces the risk of insufflation during ventilation and the risk of regurgitated gastric contents leaking around the tip of the mask.³ The I-gel is a latex-free SAD. It has a non-inflatable cuff and medical-grade thermoplastic elastomer. The design creates a closer interface for interacting with supraglottic tissue.⁴ In I-gel, the precise aeration and spontaneous breathing can be achieved because of a good seal during anaesthesia.^{5–7} The Baska mask is as second-generation SAD with numerous innovative features.⁸ It has an innovative self-sealing adjustable pressure cuff. This pressure cuff produces an oropharyngeal seal. As air pressure increases, the seal also increases. The mask inflates with positive pressure ventilation. This increases the pharyngeal seal. The mask partly deflates to its resting state when the pressure is released. The Baska mask has a gastric reflux drainage system. There is a soft, elliptical airway opening at the distal end which provides patency of seal against gastric overflow.^{8,9}

There are no studies comparing Supreme LMA, I gel and Baska mask in the Indian population. Therefore, this randomized controlled study was aimed to compare the clinical performance of Supreme LMA, I gel and Baska mask.

2. Materials and Methods

The present randomised controlled study was conducted between May 2021 and July 2022 in the major and minor operation theatres of a tertiary care hospital, India. An institutional ethics committee approval was obtained before the commencement of the study. The patients were explained regarding the risks and benefits of the procedure. A written informed consent was obtained from all the patients. The patients aged between 18 and 60 years, elective surgery for less than 3-hour duration under general anaesthesia, and American Society of Anaesthesiologist (ASA) grades I-II were included. Patients who had mouth opening < 2.5 cm, diseases of neck and upper respiratory tract, and body mass index (BMI) > 30Kg/m² were excluded.

In all 84 patients were assessed for eligibility. Six patients were excluded. Seventy-eight patients were randomly divided into three groups; Supreme LMA (Group A), I gel (Group B), and Baska mask (Group C). The standard pre-anaesthetic and anaesthetic procedures were followed. Supreme LMA /I gel /Baska mask were lubricated with lignocaine jelly over the cuff before they were introduced. An appropriate size for supreme LMA, I-gel and Baska mask were used as per the body weight. LMAs were inserted without any introducer. Neck flexion,

head extension and midline approach were used for the insertion of the devices. Number of attempts for insertion of LMAs were noted. A total three attempts were allowed for the introduction of devices. If still not achievable, then endotracheal tube was inserted and the case was then considered as a failure. Three failures were noted in Supreme LMA group. They were excluded from the study.

Oropharyngeal leak pressure (OLP) was measured after 30 minutes to loss of spontaneous respiration. It was defined as plateau airway pressure reached with fresh gas flow at a rate of 6L/min and pressure adjustment valve was set to 70 cm of H₂O. A higher OLP is a marker of efficacy and safety when using LMA devices. A gastric tube of size F14 was placed into the LMA's drainage canal. The ease of inserting a gastric tube was graded as 1 (easy), and 2 (difficult, requiring effort to overcome resistance). The time required to insert the gastric tube was noted. Post-operative morbidity was evaluated by observing any trauma to teeth, lips and tongue, blood staining on the device. Patients were asked about any sore throat, coughing or dysphagia after one hour of admission to the recovery room.

The primary outcome measure was OLP after 30 minutes to loss of spontaneous respiration. The secondary outcome measures were attempts required for insertion of LMA, ease of gastric tube insertion, time required for gastric tube insertion and post-operative morbidity. The sample size was calculated from a previous similar study conducted by Mukadder S et al.¹⁰ The formula used for sample size was $N^{11} = \{2SD^2(Z\alpha + Z\beta)^2\} / \Delta^2$, N is the number of subjects in each group, where SD can come from previous data, Δ is the minimum difference between means of previous study. The term $(Z\alpha + Z\beta)^2$ is sometimes referred to as power index. The required sample size was 17 in each group. Twenty-five patients were included in each group to authenticate the results.

3. Results

In all 84 patients were assessed. Six patients who refused were omitted. Seventy-eight patients were randomized into three groups. Of 28 patients in Supreme LMA group, 3 were omitted because of failure of insertion (Chart 1). The mean age, BMI and ASA grades were comparable between the three groups. The proportion of male patients was notably higher in Supreme LMA group, and the proportion of female patients was notably higher in Baska mask group (Table 1). The mean OLP and the mean gastric tube insertion time was notably higher in Baska mask group as compared to two other groups. The number of attempts required for insertion of LMAs and ease of gastric tube insertion were comparable between the three groups (Table 2). The post-operative morbidity was comparable between the three groups (Table 3).

Table 1: Demographic characteristics

Characteristics	Supreme Laryngeal mask airway Group A	I gel Group B	Baska mask Group C	p- value
Mean age (in years) ± standard deviation	43.4 ± 12.8	39.7 ± 12.8	38.2 ± 9.6	0.282*
Gender n (%)				
Males	16 (64.0)	10 (40.0)	5 (20.0)	0.007**
Females	9 (36.0)	15 (60.0)	20 (80.0)	
Mean body mass index (Kg/m ²)	25.8 ± 2.9	24.3 ± 1.9	24.7 ± 2.3	0.09*
American Society of Anaesthesiologist Grades n (%)				
Grade I	15 (60.0)	20 (80.0)	19 (76.0)	0.249***
Grade II	10 (40.0)	5 (20.0)	6 (24.0)	

*Analysis of variance test was used

**Chi square test was used

Table 2: Comparison of outcome variables

Characteristics	Supreme LMA Group A	I gel Group B	Baska mask Group C	p- value
Mean OLP ± SD	25.3 ± 1.1	24.1 ± 1.5	28.2 ± 1.4	0.0001*
Number of attempts required for insertion of LMA n (%)				
One	19 (76.0)	21 (84.0)	20 (80.0)	0.788**
Two	5 (20.0)	3 (12.0)	5 (20.0)	
Three	1 (4.0)	1 (4.0)	0 (0.0)	
Mean gastric intubation time	6.7 ± 0.7	9.6 ± 1.6	20.7 ± 3.8	0.0001*
Ease of gastric tube insertion n (%)				
Easy	20 (80.0)	22 (88.0%)	20 (80.0)	0.689**
Difficult, requiring effort to overcome resistance	5 (20.0)	3 (12.0)	5 (20.0)	

*Analysis of variance test was used

** Fisher's exact test was used

OLP- Oropharyngeal leak pressure

SD- Standard deviation

LMA- Laryngeal mask airway

Table 3: Comparison of post-operative morbidity

Post-operative morbidity	Supreme LMA Group A n (%)	I gel Group B n (%)	Baska mask Group C n (%)	p- value
No	21 (84%)	24 (96%)	24 (96%)	0.159
Blood stain	0 (0.0)	2 (8%)	1 (4%)	
Sore throat	2 (8%)	0 (0.0)	0 (0.0)	
Sore throat and blood stain	2 (8%)	0 (0.0)	0 (0.0)	

Fisher's exact test was used

LMA- Laryngeal mask airway

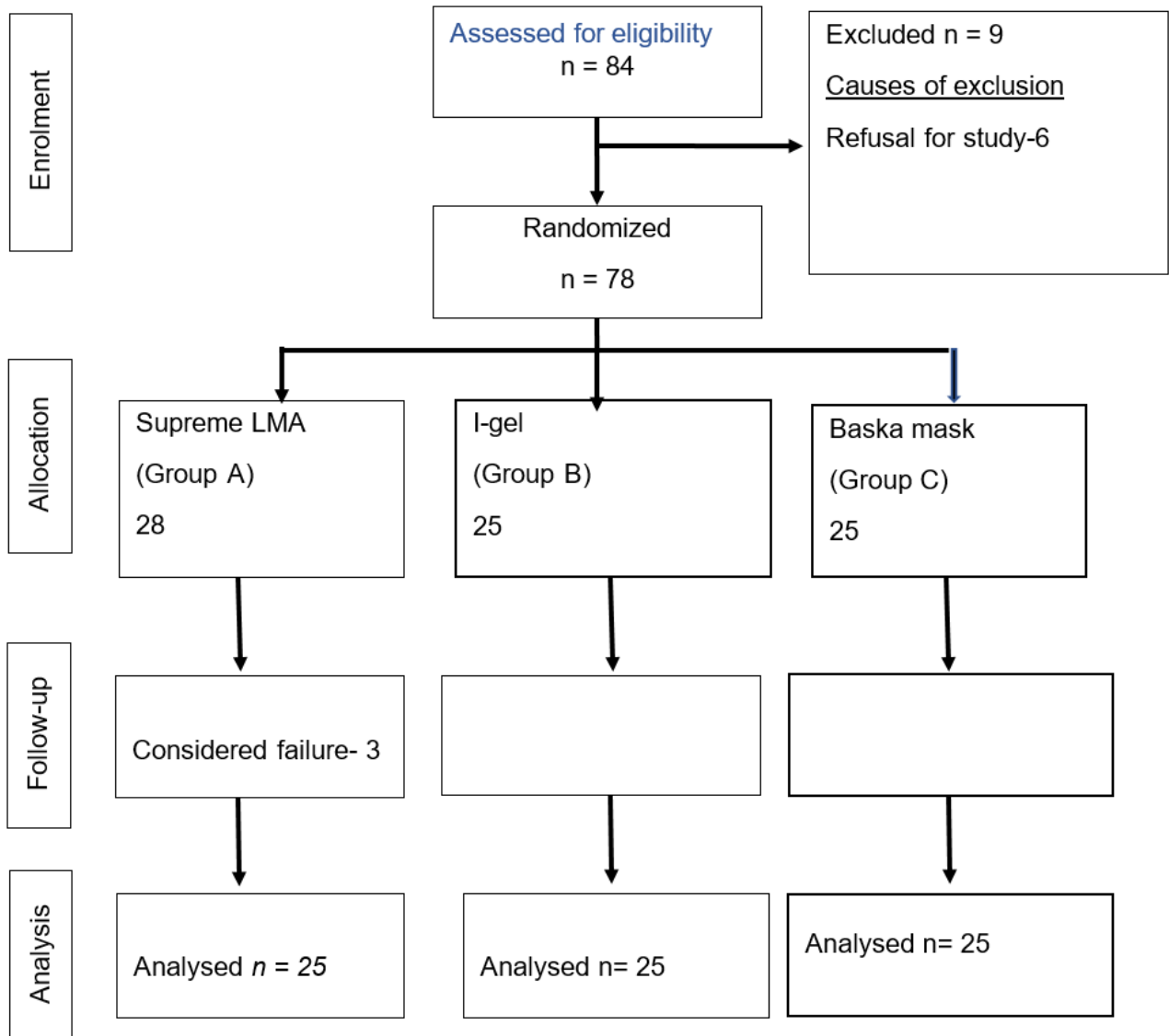


Chart 1: Consort Chart

4. Discussion

To secure a patent and unobstructed airway is a fundamental principle in anaesthesiology. The introduction of endotracheal tube with inflatable cuff in 1940's was a radical change in practice of anaesthesiology. The gold standard for airway management is an endotracheal intubation. The endotracheal intubation is a speedy, simple, harmless and non-surgical technique. The aim of the endotracheal intubation is airway management, preserving airway patency, and protecting lungs from aspiration. However, laryngoscopy and intubation are not innocuous and are associated with certain complications.

Discovery of LMA was a result of bioengineering and post-mortem studies of adult human larynx. Prototype mask

was invented in 1981 and was used in many studies with spontaneously breathing patients. Many modifications took place in the device till today. SAD has benefits such as easy insertion and less laryngopharyngeal morbidity as compared to the traditional tracheal intubation. SADs structural characteristics may lead to more leak than an endotracheal tube. Therefore, the OLP is an important factor when deciding to use the SAD. Airway maintenance without leakage is ensured when OLP values are higher than peak airway pressure values.

In this research, the mean OLP was 28.2 cm H₂O in the Bask Mask group as compared Supreme LMA (25.3 cm H₂O) and I gel (24.1 cm H₂O) group of patients (p-value = 0.0001). In a study conducted by Chaudhary UK

et al.¹² mean OLP was 33.54 cm H₂O among Baska Mask and 25.97 cm H₂O among I gel group (p-value = 0.001). Jayalekshmi S et al.¹³ observed that the mean OLP was 33.28 cm H₂O among Baska Mask and 27.47 cm H₂O among supreme LMA group (p value < 0.001). Choi SR et al.¹⁴ observed that OLP 29.6 cm H₂O and 26.7 cm H₂O in Baska Mask group and I gel groups respectively (p-value = 0.014). Liew GH et al. observed that OLP was 27.31 cm H₂O and 23.60 cm H₂O in I gel and Supreme groups respectively (p-value = 0.003).¹⁵ Mukkader S et al. stated that OLP at 30 minutes was 25.0 cm of H₂O cm and 28.3 cm of H₂O in Supreme and I gel groups respectively (0.001).¹⁰ Park SY et al. reported that the OLP was similar in any measurement period between the Supreme and I gel groups.¹⁶ The results of our research were consistent with the research conducted by Chaudhary UK et al.,¹² Jayalekshmi S et al.,¹³ Choi SR et al.,¹⁴ Liew GH et al.,¹⁵ and Mukkader S et al.¹⁰

In this research, number of attempts required for insertion of LMAs were comparable between the three groups. A study conducted by Chaudhary UK et al.¹² among Baska mask group, 43 (86.0%) and 7 (14.0%) patients required one and two attempts respectively, whereas among I gel group, 47 (94.0%) and 3 (6.0%) patients required one and two attempts respectively (p-value = 0.100). Jayalekshmi S et al.¹³ observed that the first attempt success rate was (97.1%) and (77.8%) in Supreme LMA and I gel groups respectively (p-value = 0.028). Liew GH et al. reported that the first attempt insertion rate was 44 (82.0%) and 44 (90.0%) in Supreme LMA and I-gel groups respectively (p-value = 0.105).¹⁵ Choi SR et al reported that among Baska mask group, 48 (100.0%) patients required one attempt, whereas among I gel group, 48 (98.0%) and 1 (2.0%) patients required one and two attempts respectively (p-value = 0.320).¹⁴ The findings in our study were consistent with study conducted by Chaudhary UK et al.,¹² Liew GH et al.,¹⁵ and Choi SR et al.¹⁴

In this research, the mean gastric tube insertion time was 6.7, 9.6 and 20.7 seconds in Supreme LMA, I gel and Baska mask groups respectively (p-value = 0.0001). Park SY et al. reported that gastric tube insertion time was 20.4 ± 3.9 s in the I-gel group and 16.7 ± 1.6 s in the Supreme LMA group (p-value < 0.001).¹⁶

In the current research, the ease of gastric tube insertion was 20 (80%), 22(88%), and 20(80%) in Supreme LMA, I gel and Baska mask groups respectively (p-value = 0.689). Chaudhary UK et al.¹² noted the ease to insert the gastric tube was similar in both the devices, I gel and Baska mask groups. In a study conducted by Jayalekshmi S et al.¹³ the nasogastric tube could effortlessly be put in supreme LMA and I gel group without any resistance. In a study done by Ke JD et al.¹⁷ among supreme LMA group, out of 30 study participants, 22, 7 and 1 had easy insertion, very difficult insertion and difficult insertion respectively.

The study further stated that among Oro Pharyngo Laryngo Airway Cap device (OPLAC) group, all 30 patients had easy insertion (p-value = 0.038). Mukkader S et al. reported that the ease of gastric tube insertion was 31 (88.6%) and 32 (91.4%) in Supreme and I-gel groups respectively (p-value = 0.195).¹⁰ Teoh WH et al.¹⁸ observed that the ease of gastric tube insertion was 50 (100.0%) and 38 (76.0%) in Supreme LMA and I-gel groups respectively (p-value < 0.001). The findings in our study were consistent with study conducted by Jayalekshmi S et al.,¹³ Mukkader S et al.¹⁰

In the present study post-operative morbidity was similar in the three groups. In a study conducted by Chaudhary UK et al.¹² among Baska mask group, none, and mild sore throat was observed in 46 (92.0%) and 4 (8.0%) patients respectively, whereas among I gel group none, and mild sore throat was observed in 47 (94.0%) and 3 (6.0%) patients respectively (p-value = 0.900). Jayalekshmi S et al.¹³ reported that sore throat was observed in 16.7% and 8.8% patients in Baska and Supreme LMA groups respectively. The findings were similar between the two groups. In a study conducted by Sinasmay TK et al.¹⁹ blood stain was observed in 2.5% patients in both the groups (Baska mask group and I gel group). The study further stated that mild throat pain was observed in 55.0% and 32.5% patients in Baska mask and I gel groups respectively (p-value = 0.042). Park SY et al.¹⁶ reported that out of 47 patients in I gel group, 3 had blood staining and 4 had sore throat and out of 46 patients in Supreme LMA group, 2 had blood staining and 1 had sore throat. The findings were similar between the two groups. Liew GH et al. observed that sore throat was notably higher in Supreme LMA group (28.0%) as compared to I gel group (4.0%). The study further stated that dysphagia was observed in 14.0% and 0% in Supreme LMA and I gel groups respectively (p-value = 0.020).¹⁵ In the present study, sore throat was observed in 8.0%, 0% and 0% in Supreme LMA, I-gel and the Baska mask groups respectively (p-value = 0.159).

5. Conclusions

The Baska mask was superior as compared to Supreme LMA and I-gel because the mean oropharyngeal leak pressure was notable higher in the Baska mask group of patients. The mean gastric tube insertion time of Baska mask group was higher as compared to Supreme LMA and I-gel groups. The Supreme LMA, Baska mask and I-gel groups were comparable with regards to the number of attempts required, ease of gastric tube insertion and post-operative morbidity.

6. Limitations

Only patients with ASA I and II were included in the study. High risk patients and obese patients were excluded. The present study was a single centre study with limited sample

size. Bronchoscopy was not performed to evaluate the appropriate placement of device. Insertion time of LMA was not measured. Laparoscopic surgeries were not included in the study. The duration of surgery was not compared between the three groups. The results may not be justifiable to patients with difficult airway. OLP was not observed in the dissimilar position of the patient.

7. Source of Funding

None.

8. Conflict of Interest

None.

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