

COMPARATIVE EVALUATION OF SUPRAGLOTTIC AIRWAY DEVICES I-GEL VERSUS LMA-SUPREME IN PATIENTS UNDERGOING SURGERY UNDER GENERAL ANAESTHESIA

Vikas Gupta¹, Nandita Mehta², Sunana Gupta^{3,*}, Kulbhushan Mahotra⁴

¹Resident, ²Professor & Head, ³Assistant Professor, ⁴Professor, Department of Anaesthesia, Acharya Shri Chander College of Medical Sciences and Hospital, Jammu

*Corresponding Author:

Email: sunaynaarnav@yahoo.com

ABSTRACT

Background and Aim: Supraglottic airway devices are increasingly being used as an excellent alternative to mask ventilation and tracheal intubation with least complications. The present randomized, prospective study was conducted to compare the I-Gel with LMA-Supreme with respect to time taken for insertion, insertion success rate, ease of insertion of gastric tube, hemodynamic changes before and after insertion and post-operative airway morbidity.

Materials and Methods: Sixty American Society of Anaesthesiologist (ASA) grade-I and II patients between 18-60 years age, of either sex, were randomly assigned to two groups of 30 patients each. Group A: I-gel was inserted and Group B: LMA- supreme was inserted by grasping firmly along the integral bite block (Digital Technique). Hemodynamic responses were recorded before induction and at the intervals after insertion of LMA Supreme/I-Gel. Time taken for insertion, insertion success rate and ease of insertion of gastric tube was noted. Patients were inspected for any trauma to mouth, lip and tongue in the immediate postoperative period and asked about sore throat, hoarseness and dysphonia 24 hours after the surgery. Statistical analysis was carried out with student's t-test and chi-square test and value of $P < 0.05$ was considered statistically significant.

Results: Insertion time of I-Gel (11.07 ± 1.93 seconds) was faster than the LMA-Supreme (12.50 ± 2.35 seconds) and the results were statistically significant ($P = 0.01$). Ease of insertion of gastric tube was more in LMA Supreme (28/30) as compared to I Gel (26/30) but statistically this difference came out to be non-significant ($P = 0.157$). The two groups were comparable as far as the insertion success rate, hemodynamics and post-operative airway morbidity were concerned.

Conclusion: I-Gel is better than LMA-Supreme in terms of faster insertion time. Insertion success rate, ease of insertion of gastric tube, hemodynamics and post-operative airway morbidity is comparable in both the groups.

Keywords: Supraglottic airway devices, I-Gel, LMA-Supreme, General Anaesthesia

INTRODUCTION

Airway management forms an important part of anaesthesia and for previous years it has been dominated by use of face mask and tracheal tubes. Endotracheal intubation is the most widely accepted technique of maintaining airway in day to day anaesthesia practice. Endotracheal tube has some shortcomings in the form of hypertensive response to laryngoscopy, endobronchial or oesophageal intubation, laryngospasm, increased incidence of sore throat.^[1] Supraglottic airway devices provides ample advantages over face mask and tracheal tube and these devices are now routinely used in clinical anaesthesia. These airway devices with gastric access tubes are increasingly being used in surgery requiring general anaesthesia and positive pressure ventilation. Recently, two new supraglottic devices have been developed the LMA Supreme and the I-Gel. The I-Gel is designed as a single patient use, disposable device to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures while avoiding the compression trauma that can occur with inflatable supraglottic airway devices.^[2] LMA supreme is an inflatable device with an oesophageal drainage tube for suctioning gastric

contents. The present study was conducted to compare the I-Gel with LMA supreme with respect to insertion success rate, ease of insertion of gastric tube, time taken for insertion, hemodynamic changes before and after insertion and post-operative airway morbidity.

MATERIALS AND METHODS

After taking the Institute's Ethics Committee approval, and informed written consent, 60 patients between 18-60 years age, of either sex, with ASA physical status I & II and MPG I & II, undergoing elective surgery under general anaesthesia were enrolled for the prospective, randomized study. Patients with limited mouth opening, reduced mobility of cervical spine, pharyngeal abscess/hematoma, BMI > 35 kg/m² and with increased risk of aspiration were excluded from the study. Patients were randomly allocated to two groups of 30 patients each: Group A: I-Gel was inserted where as in Group B: LMA- Supreme was inserted by grasping firmly along the integral bite block (Digital Technique). Anaesthesia induction technique was same for both the groups and study was conducted by the same team of

Anaesthesiologists who had expertise in the management of the airway.

Patients were premedicated with tab midazolam 7.5mg the night prior to surgery. On the day of surgery, IV line was secured with 18G cannula. Injection Ranitidine 50 mg and Injection Ondansetron 0.1 mg/kg was given IV approximately 30 minutes before induction. All baseline parameters i.e. heart rate, blood pressure (systolic, diastolic, and mean arterial pressure), oxygen saturation were recorded on arrival in the operating room. Continuous monitoring of heart rate, ECG, blood pressure, ETco₂ and oxygen saturation were done at regular intervals. After preoxygenation for 3 minutes, induction of anaesthesia was done with Injection Propofol 2 mg/kg and Injection Fentanyl 0.5 microgram/kg body weight. Neuromuscular blockade for insertion of airway device was achieved in both the groups with Injection Rocuronium 0.6 mg/kg and experienced anaesthesiologist inserted appropriate sized LMA (I-gel or Supreme). Appropriate LMA insertion was judged by no audible leak from drain tube, adequate chest expansion with gentle ventilation, absence of leak on auscultation of epigastrium and neck, easy passage of gastric tube into stomach via drain tube. Nasogastric tube was inserted after placement of LMA. Anaesthesia was maintained with 33% O₂, 66% N₂O, 0.5-1% Isoflurane depending on patients requirement. Ventilation was controlled mechanically and relaxation was achieved with incremental doses of Injection Rocuronium 0.1 mg/kg.

The two insertions techniques were then compared with respect to success rate of insertion, time taken for insertion and ease of gastric tube placement (number of attempts) and post-operative airway morbidity. Hemodynamic responses (HR, SBP, DBP, MBP, SPO₂) were recorded before induction and at the intervals 1, 3, 5 and 10 minutes after insertion of LMA Supreme/I-Gel. At the end of procedure, neuromuscular blockade was antagonized by Injection Neostigmine 50 microgram/kg body weight and Injection Glycopyrrolate 10 microgram/kg. Before removal of LMA, stomach was emptied again and nasogastric tube was removed. Removal of device was done when patient

was able to open the mouth on command and was oxygenated for 5-15 min. Any visible blood staining on the I-gel or LMA – supreme was noted at removal. The mouth, lip and tongue were inspected for evidence of trauma in the immediate postoperative period. Patients were asked about sore throat, hoarseness and dysphonia 24 hours after the surgery. The study variables were compared to the baseline value in each patient and inter group comparison was done using students-test and chi-square test. Probability value < 0.05 was considered statistically significant. The statistical analysis was performed with SPSS 16.0 and statistical software.

RESULTS

A total of 60 patients who underwent elective surgery under general anaesthesia were enrolled for the prospective, randomized study and were randomly divided into two groups. The demographic profiles of the patients in both groups were comparable with regard to age, weight and sex and were statistically non-significant ($P>0.05$) [Table 1]. The hemodynamics in group LMA-Supreme and group I-gel was observed at base line, before insertion, immediately after insertion and at 1, 3, 5, 10 min. No significant difference in term of mean heart rate (beat/min) and arterial pressure (mmHg) was found between 2 groups at different intervals of times when compared (P value >0.05) [Figure 1]. Insertion time of I-Gel was faster than LMA-Supreme and was found to be statistically significant ($P=0.01$) [Figure 2]. Success rate of the I-Gel and LMA-Supreme were comparable [Figure 3] and found to be statistically non-significant ($P=0.194$). Ease of gastric tube insertion was more with LMA-Supreme as compared to the I-Gel but the results were statistically non-significant ($P=0.157$). Blood staining, tongue lip and mouth trauma [Table 2] at the end of the procedure were apparently more with LMA-Supreme than I-Gel but statistically the results were non-significant ($P>0.05$). Comparison of post-operative airway morbidity occurring 24 hours after surgery amongst the two groups were comparable and statistically non-significant ($P>0.05$).

Table 1: Group comparison for age, sex and weight of patients

Group	Age(years)	sex		Weight (kgs)
		Male	Female	
LMA supreme	46.50 ± 10.10	9	21	58.60 ± 8.11
I Gel	46.60 ± 15.90	6	24	58.80 ± 10.80
p-Value	0.98	.339	.339	0.95

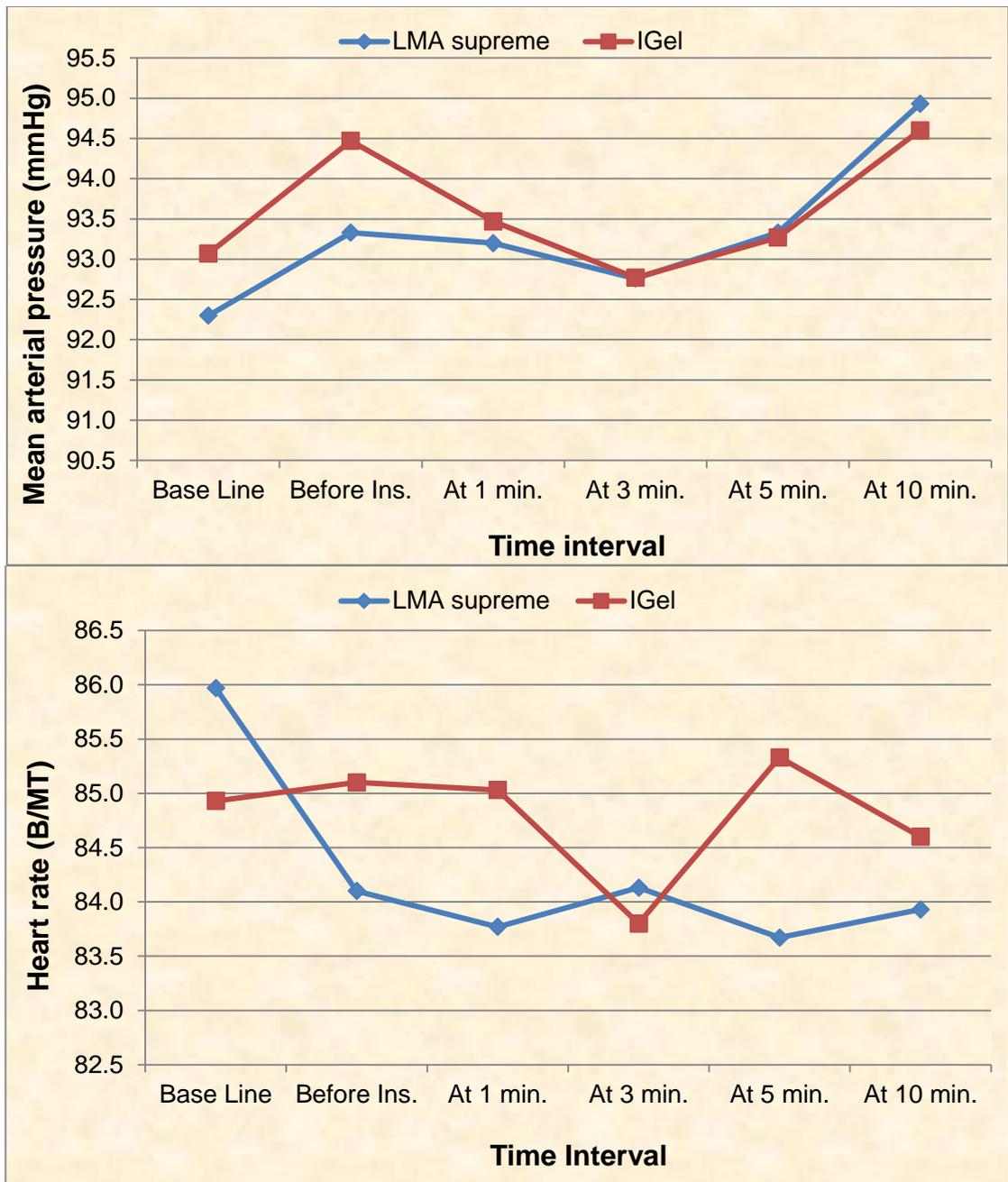


Figure 1: Comparison of mean arterial pressure and heart rate among two groups of patient

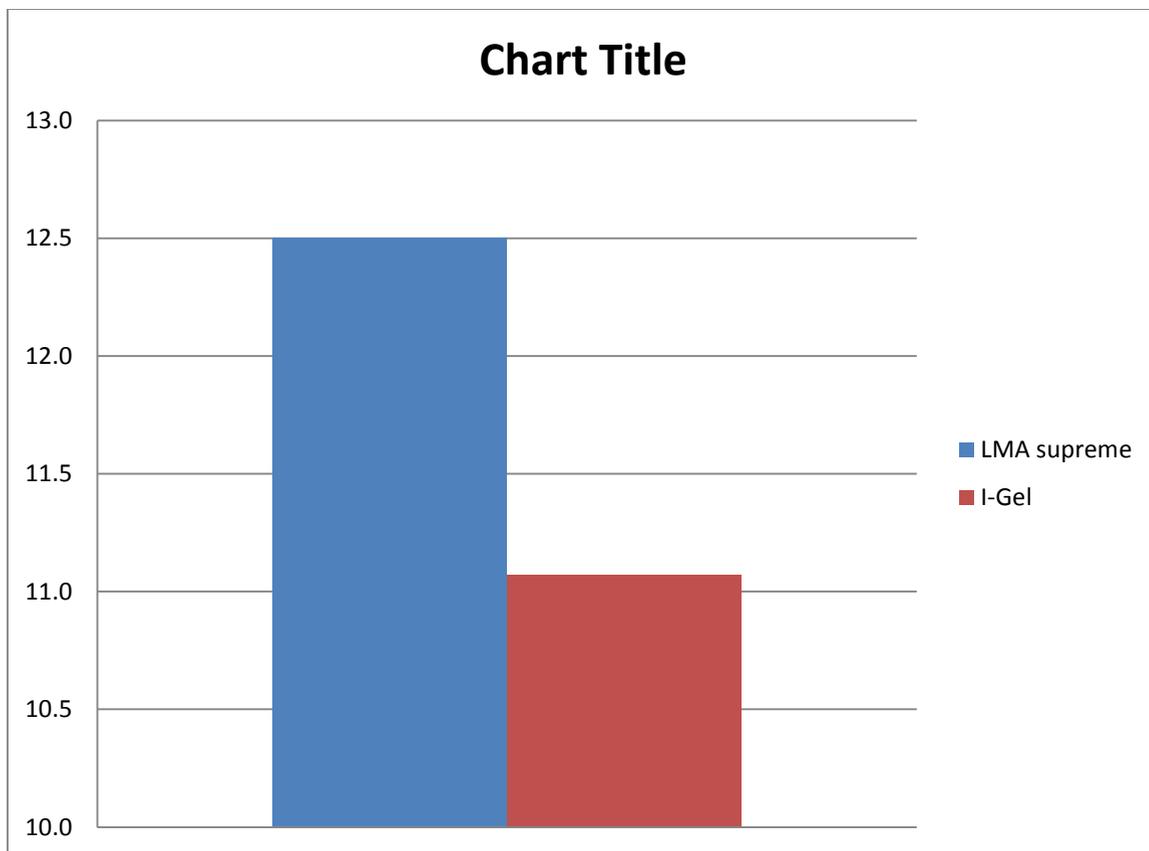


Figure 2: Group comparison of insertion time of LMA supreme and I-gel (seconds)

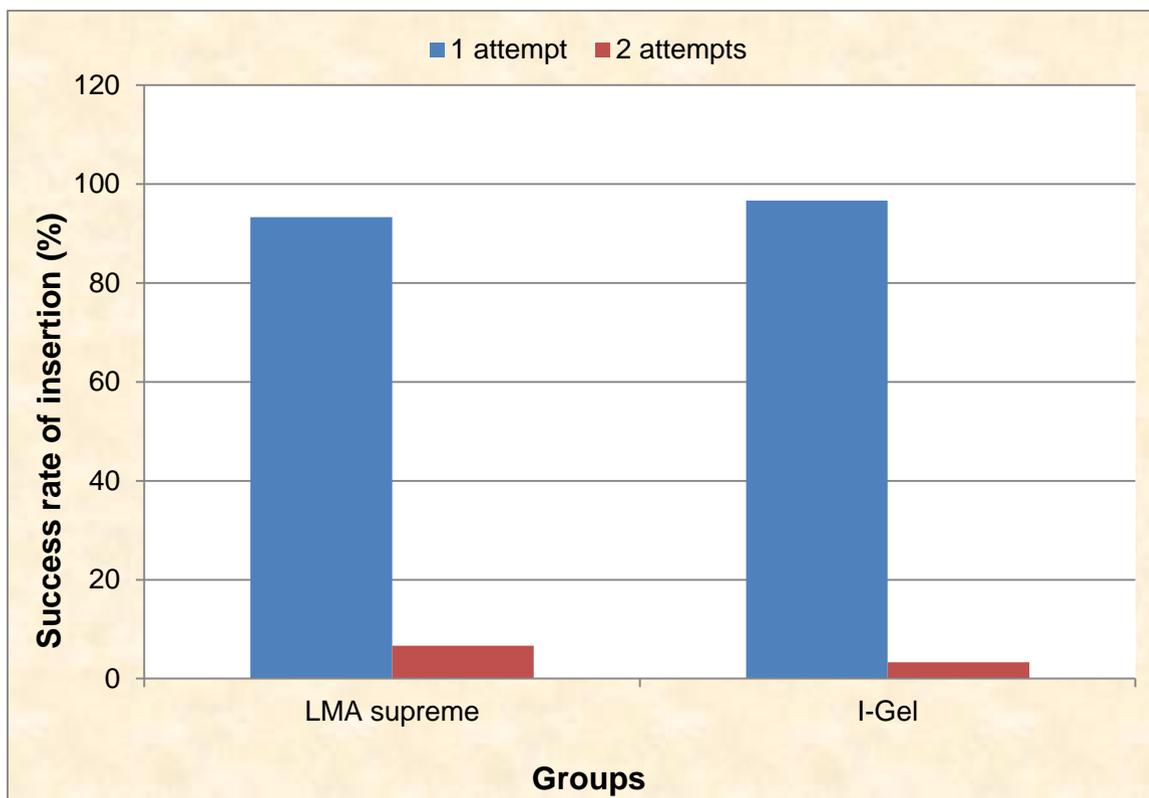


Figure 3: Group comparison of success rate of insertion of LMA supreme and I-gel

Table 2: Group comparison of complications at the end of procedure

Group	At the end of procedure		24 hours after surgery	
	Blood Staining	Tongue, lip and mouth trauma	Sore throat	Hoarseness
LMA supreme	3 (10.00%)	2 (6.67%)	2 (6.67%)	1 (3.33%)
I Gel	1 (3.33%)	1 (3.33%)	1 (3.33%)	0 (0.00%)
X ² Value	3.338	1.116	1.116	-
p-Value	0.609	0.561	0.561	-
Remarks	NS	NS	NS	-

DISCUSSION

Supraglottic airway devices have revolutionized anaesthesia practice and are now increasingly being used as an excellent alternative to mask ventilation and tracheal intubation with least complications.

The I Gel has a soft non inflatable cuff which fits snugly onto the perilarngeal framework and creates a seal which is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation [3]. LMA Supreme is another supraglottic device with an inflatable cuff and is made of medical grade silicone. Both of these devices have a drainage tube for gastric aspiration

In our study, the mean heart rate, systolic, diastolic, mean arterial blood pressure and Sp_o₂ in LMA-Supreme group and I-Gel group were observed at base line, before insertion, immediately after insertion and at 1, 3, 5, and 10 min interval thereafter and there was no significant difference between two groups at different intervals of time when compared.

In our study the mean inserting time was shorter for I-Gel (11.07+1.93 seconds) than LMA-Supreme (12.50 + 2.35 seconds) and the difference was statistically significant. Raggazi et al in their study found that LMA supreme has fewer insertion failures as compared to I Gel but because of its inflatable cuff caused transient pharyngolaryngeal pain.[4] Theiler et al in their study concluded that both LMA supreme and I Gel have a similar insertion success and clinical performance in the simulated difficult airway situation[5]. However Singh et al found that that I Gel was easier to insert and required less attempts of insertion when compared with proseal LMA [6]

Success rate of insertion was more for LMA Supreme (93.33% in first attempt and 6.67% in second attempt) than I-gel (96.67% in first attempt and 3.33% in second attempt) but the results were statistically non-significant. (P<0.05)

Our results correlate with the study of Kannaujia et al^[3] who observed that success rate for I-gel airway device at first attempt was 90% with a median insertion time of 11 sec (range 4+5).

In our study the ease of insertion of gastric tube was easy in 28/30 patients(93.33%) with LMA supreme as compared to I Gel where it was easy in 26/30

patients (86.67%) but statistically this difference came out to be non-significant (P=0.157) The findings of our study are consistent with the results of Razazzi et al^[4] in which gastric tube insertion was easy in 87% of pts in LMA supreme group compared to 73% in I-gel group. But Theiler et al^[5] observed in their study that gastric catheter introduction failed only once in each group whereas in our study we could pass the gastric tube in all the patients in both the group. Chen xiaoguang et al did a meta-analysis of the randomized controlled trials of comparison of the performance of I Gel versus LMA supreme during anaesthesia and found that both LMA supreme and I Gel were similarly successful and rapidly inserted however LMA supreme was shown to be easier for gastric tube insertion [7].

In our study, the mean heart rate, systolic, diastolic, mean arterial blood pressure and Sp_o₂ in LMA-Supreme group and I-Gel group were observed at base line, before insertion, immediately after insertion and at 1, 3, 5, and 10 min interval thereafter and there was no significant difference between two groups at different intervals of time when compared. Our observations are also consistent with Singh et al^[6] study in which they concluded that there is no statistically significant difference between both the groups regarding heart rate. Shin WJ et al^[8] conducted the similar study in which they concluded that there was no difference in the hemodynamic data immediately after insertion of device.

Mukadder et al in their study observed that I Gel has lower airway morbidity when compared to LMA supreme and proseal (9) Shin wj et al also concluded that the tongue, lip & dental trauma was more with LMA-Supreme (5/30) than with I-Gel (1/30) and blood staining of the device was more with LMA-Supreme (6/30) than with I-Gel (1/30) but the results were not statistically significant. These observations are consistent with our results and with Helmy AM et al^[10] study in which they concluded that there was no statistically significant difference found between both I-Gel and classical laryngeal mask airway groups with regard to sore throat, hoarseness and dysphonia 24 hours after the surgery. There was also no statistically significant difference found between both I-Gel and classical LMA groups

with regard to SpO₂, assessment of patients after removal of the airway device.

In this study we have concluded that I-gel is comparable to the LMA-Supreme in securing patent airway during controlled ventilation. Both LMA-Supreme and I-gel do not cause any significant alteration in the hemodynamic status of the patients. I-Gel is better than LMA-Supreme in terms of faster insertion.

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