# A Comparative Study of Supreme LMA Vs I-gel: Two Supraglottic Airway Devices in Short Surgical Procedures

#### Balasaheb Tukaram Govardhane<sup>1</sup>, Shantanu Kulkarni<sup>2\*</sup>, Mukesh Parmar<sup>3</sup>

<sup>1,2</sup>Assistant Professor, Department of Anaesthesia, Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai - 400022, Maharashtra, India; drbgovardhane@gmail.com, drshan70@rediffmail.com <sup>3</sup>Resident, Department of Anaesthesia, Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai - 400022, Maharashtra, India; dr.mukesh\_parmar@indiatimes.com

### Abstract

**Background and Aims**: The objective of this prospective, randomized trial was to compare I-Gel with Supreme LMA in anaesthetized spontaneously breathing patients for short surgical procedures. **Material and Methods**: Sixty patients of ASAI -ASAII of either gender between 18-60 years undergoing short surgical procedures were randomly assigned to I-gel (Group I) or LMA-Supreme (Group S). After induction with propofol the supraglottic airway device was inserted. We compared the ease and time required for insertion, airway sealing pressure and adverse events related to airway. **Results**: There were no significant differences in demographic and haemodynamic data. I-gel insertion was easier than LMA Supreme but statistically not significant (p > 0.05) (Chi square test). Numbers of attempts for successful insertions were comparable and in majority device was inserted in first attempt. Although the airway sealing pressure was significantly higher with Group S (25.73+2.21 cm of H<sub>2</sub>O), the airway sealing pressure of Group I (20.0+2.94 cm of H<sub>2</sub>O) was very well within normal limit (Student's t test). There was no evidence of airway trauma, regurgitation and aspiration. **Conclusion**: I-Gel with acceptable airway sealing pressure, easier to insert, less traumatic with lower incidence of sore throat. Hence I-Gel can be a good alternative to LMA-Supreme.

Keywords: Adverse Events, I-gel, Supreme LMA, Seal Pressure, Time for Insertion

### 1. Introduction

During the past decade, several Supraglottic Airway Devices (SAD) have been introduced for airway management as an alternative to tracheal intubation in general anaesthesia and in cardiopulmonary resuscitataion. These devices have become popular because of their ability to maintain airway without perturbing the trachea and can be used in patients without muscle relaxation.

Both the i-gel<sup>™</sup> (i-gel) and LMA Supreme<sup>™</sup> (Supreme) are new, single-use, second-generation, Supraglottic Airway Devices (SAD). The i-gel (Intersurgical Ltd., Wokingham,

Berkshire, UK) is a latex-free SAD with a non-inflatable cuff and a gastric drain tube. The Supreme (The Laryngeal Mask Company Ltd., St Helier, Jersey, UK) has a curved and rigid airway tube, a drain tube positioned within the center of the airway tube and a relatively large inflatable cuff made of polyvinyl chloride<sup>1–5</sup>.

There are many studies comparing the Supreme with other SADs that have shown effective clinical performances in adults and children<sup>4-6</sup>.

These two SADs which provide higher airway leak pressure than the classic LMA (cLMA) and can be used for spontaneous as well as Positive Pressure Ventilation (PPV).

\*Author for correspondence

Though studies have been done comparing i-gel with SLMA, we proposed to compare the two devices, especially with regards ease, time taken for insertion, number of attempts, airway sealing pressure and occurrence of airway complications.

# 2. Materials and Methods

This prospective, randomized, comparative study was conducted after obtaining approval from the institutional ethical committee. American Society of Anesthesiologists physical status I and II of either gender aged 18-60 years, with body mass index 18-30 kgm<sup>-2</sup> undergoing elective short surgical procedures (duration between 30 and 120 min) requiring general anesthesia without muscle relaxation were included.

Patients with anticipated difficult airway, restricted mouth opening, pregnant females, cervical spine disease, obese with body mass index >  $30 \text{ kg/m}^2$  and patients with history of regurgitation were excluded from the study.

Sixty patients were randomly allocated into two groups each based on the computer generated codes. Group I in whom I-Gel was inserted and Group S in whom LMA-Supreme was inserted. Anesthesiologist in post-anesthesia care unit monitoring the post-operative parameters and incidence of sore throat and the patient were all blinded to the group assignment.

All the patients were evaluated pre-operatively and all the baseline vitals were recorded.

The randomly selected patients for the study were pre-medicated with the Inj. Glycopyrrolate 0.2 mg, Inj. Midazolam 0.02 mg/kg and Inj. Fentanyl 2 mcg/kg intravenously. All patients pre - oxygenated with 100% oxygen for 3 minutes.

Each patient then received induction dose of Inj. Propofol (2-2.5 mg/kg iv) till the loss of eyelash reflex. The patient's head was placed in sniffing the morning air position, device was inserted by a qualified anesthesiologist with minimum 2 year's experience. The supraglottic airway device was inserted after lubricating posterior surface of the cuff with a water based jelly.

LMA-Supreme cuff was inflated with half the recommended volume of air and in case of inadequate seal entire recommended volume of air was used to inflate the cuff. In case of further leak, the device was removed and one size bigger was inserted. Additional doses of propofol were used in case of reinsertion if required. The device was then connected to the breathing circuit and capnometer assembly and secured after confirming bilaterally equal air entry. Nasogastric tube was inserted. An effective airway was confirmed from the bilaterally symmetrical chest movements, square wave form on the capnograph and a normal saturation.

Ease of insertion was defined as no resistance to insertion of device in the pharynx in single attempt.

The time taken for the insertion of device was noted. It was the time from the end of the propofol bolus to the connection of the airway to the breathing circuit.

The airway seal pressure was measured after closing the adjustable pressure limiting valve with a fresh gas flow of 3 lit/min, noting the airway pressure at equilibrium or when there was an audible air leak from the throat. The maximum pressure allowed was 40cm  $H_2O$ . The epigastrium was also auscultated when measuring the oropharyngeal leak pressure to detect any air entrainment in the stomach.

If an effective airway was not achieved then manipulations were done in the form of increasing the depth of insertion, giving jaw thrust or chin lift or changing the size of the device.

The device insertion was abandoned after 3 unsuccessful attempts. Then patient was given muscle relaxant and was intubated with endotracheal tube.

Anaesthesia was maintained on oxygen, nitrous oxide and propofol infusion with spontaneous respiration.

At end of the procedure, all the patients were ventilated with 100% oxygen during emergence from anesthesia. The device was removed when the patient was able to open the mouth on command. The patient was inspected for any injury to lips, teeth or tongue and the device was inspected for the presence of any blood stains. The mask of the supraglottic device was inspected for the presence of any gastric contents to confirm regurgitation.

All the patients were observed for a period of 24 h for any complaints of sore throat. Sore throat in the postoperative period was treated using warm saline nebulization and in patients with sore throat 24 h later warm saline gargles were advised. Laryngospasm was given standard treatment. We gave 100% oxygen followed by injection scoline 0.5 mg/kg. Hiccups were tackled by increasing the depth of anesthesia by increasing the maintenance dose of Injection propofol.

# 3. Statistical Analysis

Sample size was calculated based on the results of previous study to detect a projected difference in airway sealing pressure of 30% between groups with 80% power and 5% alpha error and a reported difference in airway sealing pressure of 15% between two groups, a sample size 22 patients were required, which was rounded off to 30 patients in each group.

Table 1. Patient characteristics: Data are expressedas mean  $\pm$  standard deviation for age and body massindex; and absolute number for gender, MPC and ASAstatus

Parameters	Group I	Group S
* Age (yrs)	$32.07 \pm 11.42$	$33.20\pm9.14$
* Weight (kg)	51.73±7.77	53.23± 3.02
@Sex	13:17	20:10
@MPC	21:09	26:04
@ASA	26:04	26:04

\* Student t test P > 0.05, Not Significant

@Chi square test P > 0.05, Not Significant

The two groups were compared with each other in terms of age, weight and sex.

The statistical test used was Unpaired Students t test for age and weight.

For qualitative data like the sex of the patient the statistical test employed was Pearson's Chi-square test.

Hemodynamic parameters such as mean heart rate, blood pressure both systolic and diastolic, respiratory rate, SpO<sub>2</sub> and end tidal  $CO_2$  were compared using Analysis of Variance (ANOVA).

The mean time required for insertion and the mean seal pressure was compared using

Unpaired Student's t test.

The ease of insertion, attempts required for insertion, airway manipulations and the incidence of adverse events were compared using Pearson's Chi-Square test.

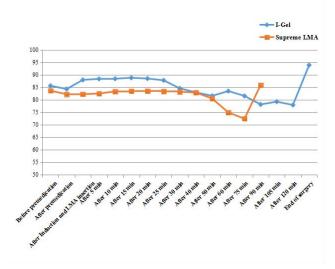
In all the parameters, p < 0.05 was considered to be significant.

**Table 2.** Comparison of Time for successful insertion, ease of insertion,insertion attempts, ease of RT insertion and airway sealing pressure

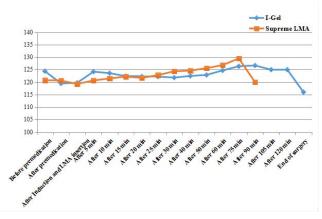
Variables	Group I	Group S	P value
Mean time for Successful insertion	29.53 ± 8.23	31.77 ± 2.38	> 0.05
Ease of LMA insertion			> 0.05
Yes	28	27	
No	2	3	
Insertion Attempts			> 0.05
1	28	27	
2	2	3	
Ease of Ryle's Tube insertion			> 0.05
Easy	30	30	
Difficult	0	0	
Mean Airway Sealing Pressure	20.07 + 2.94	25.73 + 2.21	0.0000

#### Table 3. Profile of adverse events

Events	Group I	Group S	P value
Coughing	02	01	> 0.05
Laryngospasm	-	01	
Leak	03	01	
Regurgitation	-	-	
Injury to teeth, gum and lips	-	-	
Sore throat	-	03	
Aspiration	-	-	
Blood on device	-	-	
Gastric insufflation	-	-	
No. of patients	05	06	



**Figure 1.** Comparison of changes in mean heart rate between two groups.



**Figure 2.** Comparison of changes in mean systolic pressure between two groups.

### 4. Results

The demographic profile is comparable in two groups (Table 1).

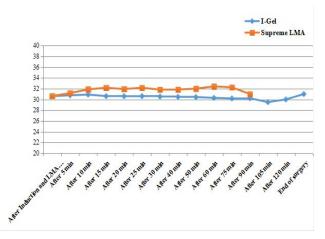
In both groups the mean heart rate (Figure 1), other hemodynamic parameters (Figure 2) and end-tidal  $CO_2$  (Figure 3) were comparable.

In both I-gel and Supreme-LMA groups, mean time for successful insertion, ease of insertion, insertion attempts and ease of ryle's tube insertion were comparable (Table 2).

Higher airway sealing pressure was noted with Supreme LMA (25.73+2.21) as compared to I-gel (20.07+2.94) and difference was statistically significant (P<0.0001) (Table 2).

This analysis reveals that 16.7% of the total cases among I-Gel group had an adverse event where the proportion of cases was less as compared to 19.9% in Supreme LMA group but the difference was not statistically significant (Table 3).

Out of these most common was sore throat and leak followed by coughing, laryngospasm.



**Figure 3.** Comparison of changes in mean ETCO<sub>2</sub> between two groups.

### 5. Discussion

In both the groups, the mean heart rate was comparable and no statistically significant difference was observed. Also the systolic blood pressure and diastolic blood pressure difference was comparable in both groups and was not statistically as well as clinically significant. There was no episode of de-saturation and hypotension throughout the surgery.

Our results of hemodynamic parameters were in concordance with those reported by Amr Helmy et al. and W. H. L. Teoh et al<sup>6–8</sup>.

The mean time required for insertion of I-GEL was 29.53+08.23 sec and for Supreme LMA was 31.77+02.38 sec which was statistically insignificant (p = 0.165). Tuoh et al, also found similar results. Both devices had similar first attempt insertion rates (LMAS 94% vs. I-GEL 91%) with similar ease and comparable times to achieve an effective airway, LMA Supreme 14.3 (4.7) versus I-GEL 15.4 (8.2),  $P = 0.4^{6.9}$ .

In our study, insertion was easy in 28/30 cases (93.3%) as compared to 27/30 cases (90%) in the Supreme LMA. The difference was statistically as well as clinically insignificant. Similar results were demonstrated by W. H. L. Teoh et. al.<sup>6</sup>

In our study ease of Ryle's Tube insertion for both the devices were comparable and the difference was statistically

as well as clinically insignificant. But Teoh et al. found that it was more difficult and took significantly longer to insert the gastric tube in the I-Gel group (78%) than Supreme LMA group (100%)<sup>6</sup>. Ragazzi et al. and Suhitharann et al. also found similar results, I-Gel (77%)/Supreme LMA (100%) and I-Gel (73%)/Supreme LMA (87%)<sup>5.9</sup>.

The mean airway sealing pressure with I-Gel was 20.07+02.94 cm of H<sub>2</sub>O and with Supreme LMA 25.73 + 02.21 cm of H<sub>2</sub>O which was statistically significant (p =  $0.0000^*$ ) but it was not clinically significant. The higher values of EtCO<sub>2</sub> among the LMA-Supreme group can explain the high airway sealing pressure and a better seal provided by it. Though the seal pressure of I-gel was lower than that of LMA-Supreme, it was enough to provide optimum ventilation.

Chew et al. also reported higher seal pressure with Supreme LMA (25.6 cm  $H_2O$ ) than I-Gel (20.7 cm of  $H_2O$ )<sup>10</sup>. Ragazzi R et al. also noted that the airway sealing pressure provide by Supreme LMA (28 cm of  $H_2O$ ) was higher than that with the I-GEL (24 cm of  $H_2O$ )<sup>5</sup>. However Teoh WH et al. found no difference in seal pressure, between the Supreme LMA and the I-Gel (mean (SD) 26.4 (5.1) vs 25.0 (5.7) cm  $H_2O$ , respectively; p = 0.18)<sup>6</sup>. Gabbot et al. also concluded that I-Gel provides a good airway sealing pressure which improved over time and may be due to the thermoplastic properties of gel cuff which forms a effective seal around the larynx after warming to body temperature<sup>11</sup>.

Richez et al. and Kannaujia et al. both had performed preliminary studies on I-Gel and determined the airway seal pressure to be  $(30\pm7 \text{ cm of H}_2\text{O})$  and oropharyngeal seal pressure was 20 cm of H<sub>2</sub>O (range 16-40 cm of H<sub>2</sub>O) respectively.<sup>12,13</sup>

We compared the incidence of adverse events intraoperatively, during emergence and in the postoperative period. Coughing was noted in 2/30 (6.7%) cases of I-Gel whereas there was only 1/30 (3.3%) case of coughing with Supreme LMA. The difference was statistically insignificant (p > 0.05) and the complaints were relieved after warm saline nebulisation. Cook et al. reported that 2 out of 100 patients developed coughing without a fall in arterial oxygen saturation<sup>14</sup>.

Laryngospasm was observed in 1/30 (3.3%) of the Supreme LMA case during emergence, though it was statistically insignificant (p > 0.05) it was clinically significant. The incidence of laryngospasm can be attributed to the lighter plane of anaesthesia during the end of the procedure. None of the patients in I-Gel group had laryngospasm<sup>14</sup>.

Intra-operatively leak was present in 3/30 (10.0%) cases of the I-Gel and 1/30 (3.3%) cases with the Supreme LMA. The difference was statistically as well as clinically insignificant. Hosten et al. reported reported the incidence of 2/30 patients with intra-operative oropharyngeal leak<sup>15</sup>. Suhitharan et al. found that there was a significantly greater leak fraction with the I-Gel of 0.06 (0.03) versus 0.04 (0.02) with the LMAS, P =  $0.013^{9}$ .

There was no evidence of injury to lip, teeth, tongue or gums and blood on device with either device. Yao et al., reported 2.6% patients had on supreme on removal<sup>16</sup>. Russo et al., reported the incidence of blood stains on Supreme LMA, I-Gel and Laryngeal Tube Suction-D<sup>17</sup>. Suhitharan et al., reported 2.9% patients had mucosal injury<sup>2</sup>.

There was no incidence of gastric insufflation with either device probably due to a good seal around the laryngeal inlet and presence of nasogastric tube through the gastric channel. Hosten et al., reported the incidence of 3/30 patients with intra-operative gastric insufflation<sup>15</sup>.

In the Supreme LMA group 3/30 (10.0%) case complained of sore throat immediately in the postoperative period whereas in the I-Gel group 1/30 (3.3%) patients complained of sore throat. Though the difference was not statistically significant it was clinically significant. According to the 3-point scale all the patients had class 1 sore throat that is just throat discomfort, which was relieved to some extent by warm saline nebulisation. 24 hours later the same patient had throat discomfort in Supreme LMA group where as in the I-Gel group there was NO throat discomfort. Teoh et al. and Ragazzi et al. also found that the use of Supreme LMA produces more sore throat as compared to the I-Gel<sup>5-7,13,18,19</sup>. The lower incidence of sore throat in our study can be attributed to the soft seal non inflatable mask of I-GEL. I-GEL being a supraglottic airway device without an inflatable mask has some potential advantage of easier insertion and minimal tissue compression whereas supraglottic airway device with inflatable cuff like the Supreme LMA in our study can absorb anaesthetic gases leading to increased mucosal pressure<sup>20,21</sup>. Hosten T et al. conducted a randomized cross-over study of Proseal LMA and Supreme LMA in 60 adult patients. He observed that both Proseal LMA and Supreme LMA show significant increase in intra-cuff pressure  $(p < 0.05)^{15}$ .

# 6. Conclusion

Hence to conclude, I-Gel is a simple and safe supraglottic airway device made of a soft gel like material. It has potential advantage of providing an effective airway sealing pressure which was within normal limit and sufficient to prevent aspiration. It has a gastric channel providing a means to drain the gastric secretions.

Being made of a soft gel like material and the presence of non inflatable mask makes it less irritant to the airway and hence there was no incidence of laryngospasm and comparatively lower incidence of sore throat.

Hence I-Gel can be a good alternative to Supreme LMA and other supraglottic airway devices.

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