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**Original Research Article**

# Comparison of I-gel and laryngeal mask airway classic in terms of ease of insertion and hemodynamic response: a randomised observational study

**Anupriya Sahaya*, R. K. Singh, Nikita Baser, Shilpa Sharda**

Department of Anesthesiology, Pacific Medical College and Hospital, Udaipur, Rajasthan, India

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***Correspondence:**
Dr. Anupriya Sahaya,
E-mail: anupriya2201@gmail.com



## ABSTRACT

**Background:** The gold standard technique for preserving a patent airway throughout anaesthesia is tracheal intubation. I-gel is a relatively new addition to the SADs. I-gel has combined the concept of the non-cuffed SADs like the SLIPA and gastric tube of the proseal LMA yet retaining the shape of laryngeal mask. Hence, we have compared ease of insertion, number and duration of insertion attempts among the two devices.
**Methods:** This study was conducted on patients undergoing elective surgery under GA in Pacific Medical College and Hospital, Udaipur. Patients were divided into two groups: group A= LMA classic, a variant of supraglottic airway device and group B= I-gel, a variant of supraglottic airway device. The two devices were than 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.
**Results:** Mean insertion time was 8.66±3.21 seconds in C-LMA and 6.49±1.92 seconds in I-gel ($p<0.001$). 97.14% was the success rate of single time attempt insertion with I-gel as compared to 88.57% in C-LMA. There was a failure rate of 11.43% in single attempt insertion with CLMA as compared to 2.86% with I-gel ($p>0.05$).
**Conclusions:** We hereby concluded with our study that successful and shorter duration of insertion, with less hemodynamic response, makes I-gel™ a suitable alternative to LMA classic™ during general anesthesia.

**Keywords:** C-LMA, General anaesthesia, I-gel, SADs

## INTRODUCTION

The anesthesiologist's primary duty is to ensure that the patient has adequate ventilation. The airway is the most important component in maintaining healthy respiration. Since the invention of endotracheal intubation by Macewen in 1880 and the use of sophisticated devices today, management of the airway has advanced significantly.[1] The gold standard technique for preserving a patent airway throughout anesthesia is tracheal intubation.[2] However, this maneuver necessitates dexterity, ongoing practice, and direct laryngoscopy, which may result in laryngopharyngeal lesions.[3]

Dr. Archie Brain of UK introduced laryngeal mask airway (LMA) 30 years ago. The laryngeal mask airway (LMA), a supra glottic airway device has a well-established role in the management of patient with normal and difficult to manage airways. In situations where endotracheal intubation is not always necessary, the LMA is frequently used.[4] The risk of aspiration found in 6-9% cases as reported in beroptic studies by visualization of the esophagus via the LMA specially in patients with low pulmonary compliance e.g. obesity requiring peak inspiratory pressures greater than 20 cm $H_2O$ limit the use of LMA, though.[5-7]

***Laryngeal mask airway (LMA) classic***

The LMA is the most popular and extensively researched SAD. It consists of an oval-shaped silicon mask that fits in the hypopharynx and creates a seal around the peri glottic tissues. An airway tube that is connected to the mask exits the mouth and has a standard 15 mm connector for connecting to a bag-valve device or an anesthesia circuit. The laryngeal inlet seal permits positive pressure ventilation (PPV) at pressures up to 20 cm $H_2O$ and permits the delivery of oxygen and inhaled anesthetics during spontaneous ventilation. The cLMA comes in a range of sizes, from size 1 (for newborns) to size 6 (for large adults weighing more than 100 kg), and can be reused up to 40 times.

***I-gel***

The I-gel is made up of medical grade thermoplastic elastomer (styrene ethylene butadiene styrene-SEBS), which is soft, gel like, transparent and designed to anatomically fit the peri laryngeal and hypo pharyngeal structures without an inflatable cuff. It also has a port for gastric tube placement. I-gel is said to have easier insertion, minimal risk of tissue compression and stability after insertion. It is a latex free supraglottic device. The buccal cavity stabilizer has a widened, elliptical, symmetrical and laterally flattened cross sectional shape, providing good vertical stability upon insertion which is an advantage over LMA with inflatable cuffs where mechanical inflation can cause movement of the device because the distal wedge shape of the mask is forced out of the upper oesophagus. The firmness of the tube section and its natural oropharyngeal curvature allows the device to be inserted by grasping the proximal end of I-gel and helps to glide the leading edge against the hard palate into the pharynx. It is not necessary to insert fingers into the mouth of the patient for full insertion.

I-gel is a relatively new addition to the SADs. I-gel has combined the concept of the non-cuffed SADs like the SLIPA and gastric tube of the proseal LMA yet retaining the shape of laryngeal mask.

***Uses and indications of SADs***

The SADs have been used as rescue airways during difficult airway management and in particular “cannot intubate, cannot ventilate” scenario.

The SADs have been most suitably used in ambulatory surgery for ASA physical status I and II patients. These include short procedures not requiring controlled ventilation such as surgeries of the upper and lower limb, gynecologic procedures, etc.

These devices have been used in patients with coronary artery diseases coming for short surgical procedures under general anesthesia as their use is associated with lesser hemodynamic responses compared to tracheal intubation.

The LMA has been used at the conclusion of neurosurgery but prior to terminating anesthetic as a preventive strategy against hypertension, coughing, bucking and smoother emergence. For similar reasons of smooth placements and emergence, Supraglottic devices have also been used during ophthalmic practice to prevent risk from sudden rise in intraocular pressure associated with tracheal intubation and extubation.

SADs are becoming extremely popular in patients undergoing minor therapeutic or diagnostic procedures such as radiation therapy, diagnostic and interventional radiology, endoscopy, electroconvulsive therapy, cardioversion etc.

More and more of the routine anesthetics lasting longer e.g. 2-3 hours are being administered using SADs. Even surgeries associated with increased intrabdominal pressures (laparoscopic surgeries) are safely being done using supraglottic devices (SAD) proseal LMA, LTS, combitube etc.

***Aim and objectives***

The primary aim of the study is to compare ease of insertion, number and duration of insertion attempts among the two devices.

The secondary objectives are to evaluate the hemodynamic response and $SpO_2$ during device insertion and during maintenance of general anaesthesia.

## METHODS

This study was conducted on adult patients undergoing elective surgery under general anesthesia in Pacific Medical College and Hospital, Bhillon ka Bedla, Udaipur during the study period from July 2021 to June 2022. Patients were selected on the basis of inclusion and exclusion criteria of this study mentioned below.

After taking approval from Institutional Ethical Committee and taking informed consent, patients aged between 18 and 50 years of either sex, with American Society of Anesthesiologists (ASA) physical status I and II, with Mallampati grades I and II admitted in our hospital undergoing elective surgical procedure of less than one hour duration under general anesthesia were enrolled in the study.

Patients with limited mouth opening, patients with reduced mobility of cervical spine, pharyngeal abscess/hematoma, patients with uncontrolled hypertension, obesity (BMI>35 $kg/m^2$), diabetes mellitus, history of any cardiovascular and renal disease, patient with pharyngeal pathology and obstruction and aspiration

risk (e.g.; pregnancy, hiatal hernia) were excluded from the study.

Patients were divided into two groups: group A= LMA classic, a variant of supraglottic airway device and group B= I-gel, a variant of supraglottic airway device.

Anesthesia induction technique was same for both the groups and study was conducted by the same team of anesthesiologists who had expertise in the management of the airway.

**Sampling**

*Population*

70 adult patients aged between 18 and 50 years of either sex and American society of Anesthesiologist physical status I and II.

***Randomization details***

*Selection of participants*

70 adult patients aged between 18 and 50 years of either sex, American Society of Anesthesiologists (ASA) physical status I and II, with Mallampati grades I and II admitted in our hospital undergoing elective surgery under general anesthesia were enrolled in the study.

***Methods***

*Intervention details with standardization techniques (drugs/devices/invasive procedures/ non-invasive procedures/ others)*

*Supraglottic airway devices: 1) classic LMA 2) I-gel*

Patients were premedicated with tab alprazolam 0.25 mg the night prior to surgery. On the day of surgery, i.v. line was secured with 18 G cannula. Injection ranitidine 50 mg and injection ondansetron 0.1 mg/kg was given i.v. 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, $ETCO_2$ and oxygen saturation were done at regular intervals. After preoxygenation for 3 minutes, induction of anesthesia 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 atracurium 0.5 mg/kg and experienced anesthesiologist inserted appropriate sized device, LMA classic or I-gel.

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. Anesthesia was maintained with 33% $O_2$, 66% $N_2O$, 1-3% sevoflurane depending on patients requirement. Ventilation was controlled mechanically and relaxation was maintained with incremental doses of Injection atracurium 0.1 mg/kg.

The two devices were than 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, $SPO_2$) were recorded before induction and at the intervals 1, 3, 5 and 10 minutes after insertion of LMA classic/I-gel. At the end of procedure, residual neuromuscular blockade was reversed with 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.

The ease of insertion of device was also recorded. Ease was defined as no resistance to insertion in the pharynx in a single maneuver. In a difficult insertion there was resistance to insertion or more than one maneuver was required for the correct placement of the device. The ease of placement of gastric tube was also recorded and its correct placement was confirmed by injection of air and epigastric auscultation or aspiration of gastric contents. Failure of gastric tube placement was also recorded and it was defined as failure to advance the gastric tube into the stomach with in two attempts.

Removal of device was done when patient was able to open the mouth on command and was oxygenated for 5 min. Any visible blood staining on the I-gel or LMA classic 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.

***Statistical analysis***

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. Hemodynamic data were analysed using repeated measure ANOVA test. P value $<0.05$ was considered statistically significant. The statistical analysis was performed using statistical software SPSS 20.0.

## RESULTS

There were a greater number of females in our study in both the groups (2.5:1 and 2:1). ASA grade I patients were more than grade II (82.86% and 85.71% respectively) though there was no statistically significant difference between both the groups in demographic variables.

**Table 1: Demographic variables.**

| | | CLMA (n=35) | | I-gel (n=35) | | Total (n=70) | |
|---|---|---|---|---|---|---|---|
| | | N | % | N | % | N | % |
| **Sex** | Female | 25 | 71.43 | 23 | 65.71 | 48 | 68.57 |
| | Male | 10 | 28.57 | 12 | 34.29 | 22 | 31.43 |
| **ASA Grade** | I | 29 | 82.86 | 30 | 85.71 | 59 | 84.29 |
| | II | 6 | 17.14 | 5 | 14.29 | 11 | 15.71 |
| **Age group (years)** | <21 | 8 | 22.86 | 10 | 28.57 | 18 | 25.71 |
| | 21-30 | 7 | 20.00 | 7 | 20.00 | 14 | 20.00 |
| | 31-40 | 10 | 28.57 | 10 | 28.57 | 20 | 28.57 |
| | 41-50 | 5 | 14.29 | 4 | 11.43 | 9 | 12.86 |
| | 51-60 | 5 | 14.29 | 4 | 11.43 | 9 | 12.86 |
| | Mean±SD | 35.23±13.67 | | 33.17±13.42 | | 34.20±13.49 | |

**Table 2: Comparison of number of attempts and insertion time (seconds).**

| | CLMA (n=35) | | I-gel (n=35) | | P value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| **Insertion time (seconds)** | 8.66 | 3.21 | 6.49 | 1.92 | <0.001 (HS) |
| **Mean no. of attempts** | 1.11 | 0.32 | 1.03 | 0.17 | 0.19 (NS) |

**Table 3: Number of attempts with success and complications in both groups.**

| | | CLMA (n=35) | | I-gel (n=35) | | P value |
|---|---|---|---|---|---|---|
| | | N | % | N | % | |
| **Single attempt** | | 31 | 88.57 | 34 | 97.14 | 0.16 (NS) |
| **>1 attempt** | | 4 | 11.43 | 1 | 2.86 | |
| **Immediate after surgery** | Arrhythmia | 0 | 0 | 0 | 0 | NS |
| | Laryngospasm | 0 | 0 | 0 | 0 | |
| | Tongue, lip and mouth trauma | 2 | 5.71 | 1 | 2.86 | |
| | Blood staining | 3 | 8.57 | 1 | 2.86 | |
| **After 24 hours of surgery** | Sore throat | 2 | 5.71 | 1 | 2.86 | NA |
| | Hoarseness of voice | 2 | 5.71 | 1 | 2.86 | |

Mean age was comparable in both the groups i.e. 35.23±13.67 and 33.17±13.42. The overall age was 34.20±13.49 years (Table 1).

Mean insertion time was 8.66±3.21 secs in C-LMA and 6.49±1.92 secs in I-gel. This was statistically highly significant (p<0.001), i.e. ease of insertion of I-gel was much more than that of c-LMA (Table 2).

Mean number of attempts of successful insertion was 1.11±0.32 times in C-LMA group and 1.03±0.17 times in I-gel group, which was statistically non-significant (p>0.05).

97.14% was the success rate of single time attempt insertion with I-gel as compared to 88.57% in C-LMA. There was a failure rate of 11.43% in single attempt insertion with CLMA as compared to 2.86% with I-gel (p>0.05) (Table 3).

Blood staining, tongue lip and mouth trauma at the end of the procedure were apparently more with C-LMA than I-Gel but statistically the results were non-significant (p>0.05).

Similarly sore throat and hoarseness of voice after 24 hours of surgery was more in C-LMA than I-gel, but was statistically non-significant (p>0.05).

## DISCUSSION

There were a greater number of females in our study in both the groups (2.5:1 and 2:1). Prateeba et al had similar findings that of ours with female predominance. Out of 50 patients in each group there were 43 females and 7 males in LMA group and in I-gel group both.[8]

ASA grade I patients were more than grade II (82.86% and 85.71% respectively) though there was no statistically significant difference between both the groups in demographic variables.

The observations of sex and ASA parameters by Gupta et al and Jacob et al were in concordance of present study.[4,9]

In study by Dhimar et al, patients with ASA grade I and grade II were 72.4% and 27.6% respectively in group I and 79.3% and 20.7% in group C.[10] Similar were the findings of Prateeba et al who had 48 ASA grade I patients and only 2 ASA grade II patients in I-gel group as compared to all patients of ASA grade I in LMA group.[8]

In present study mean age was comparable in both the groups i.e. 35.23±13.67 and 33.17±13.42. The overall age was 34.20±13.49 years. Our findings were similar to findings those of Dhimar et al, who reported 35.0±10.1 years in group I and 36.1±11.2 years in group C.[10]

In study by Prateeba et al compared two supraglottic airway devices LMA Classic™ and I-gel™, in relation to ease of insertion, duration of insertion, hemodynamic responses, and $SpO_2$ changes. I-gel was easier and faster in insertion in single attempt as compared to LMA.[8]

In present study mean insertion time was 8.66 ± 3.21 secs in C-LMA and 6.49±1.92 secs in I-gel. This was statistically highly significant ($p<0.001$), i.e. ease of insertion of I-gel was much more than that of c-LMA. Dhimar et al had a mean insertion time of 26.2±2.3 secs in group I as compared to 44.7±9.1 secs in group C with a significant difference of $p<0.05$.[10] Prateeba et al noted the duration of insertion time was significantly longer with CLMA compared to I-gel with median insertion time of 16s with I-gel. Helmy et al, Hashemian et al and Chauhan et al observed significantly lower insertion times with i-gel.[8,11-13]

Since no cuff inflation is required in the I-gel, time required to achieve an effective airway was shorter, and does not require an introducer, the device can be simply pushed into place. The mean insertion time observed by Durrani et al. was statistically insignificant. Theiler et al have attributed the longer insertion time of I-gel due to the bulky design of the airway device.[14,15]

Jacob et al the mean time to insertion was 29.32±6.88 seconds in the I-gel group, whereas it was 36.72±7.33 seconds in the cLMA group. It was highly significant, with a p value of <0.001.[9] In study by Gupta et al the mean inserting time was shorter for I-gel (11.07±1.93 seconds) than LMA (12.50±2.35 seconds) and the difference was statistically significant.[4]

We found mean number of attempts of successful insertion was 1.11±0.32 times in C-LMA group and 1.03±0.17 times in I-gel group, which was statistically non-significant ($p>0.05$). 97.14% was the success rate of single time attempt insertion with I-gel as compared to 88.57% in C-LMA. There was a failure rate of 11.43% in single attempt insertion with CLMA as compared to 2.86% with I-gel ($p>0.05$).

Jacob et al insertion was difficult in six patients in the I-gel group and in eight patients in the LMA group and required second attempt and jaw stabilization by an assistant. Successful insertion was achieved in first attempt in 87.5 and 77.5% of patients of the I-gel and LMA groups, respectively, but was not statistically significant ($p=0.986$).[9] Prateeba et al observed that both the devices were easy to insert <two attempts, but the success rate in the first attempt was 100% with I-gel and 84% with LMA C, which is statistically significant ($p=0.003$).[8]

Kalra et al the ease of insertion was more with the I-gel (41/50 patients required single attempt with no resistance at insertion than with the LMA (39/50 patients required single attempt with no resistance at insertion, which was statistically comparable. As the I-gel provided a better view of the glottis than the LMA (92% in group II and 66% in group I), which was statistically significant ($p<0.05$).[16]

In present study blood staining, tongue lip and mouth trauma at the end of the procedure were apparently more with C-LMA than I-gel but statistically the results were non-significant ($P>0.05$).

Jacob et al observed I-gel had a lower incidence of complications such as cough, sore throat, blood staining, etc.[9]

Similarly, we found sore throat and hoarseness of voice after 24 hours of surgery was more in C-LMA than I-gel, but was statistically non-significant ($p>0.05$).

I-gel also provides a good fiberoptic score, and similar results were also reported in various studies. Improved glottic view confirms that I-gel forms a good seal at laryngeal structures and ensures better ventilation and passage of a tracheal tube. In recent times, I-gel has been recommended as a conduit for tracheal tube insertion in cases of difficult intubation. I-gel has been proved to be a better alternative in various other studies also. The incidence of complications is also low, which may be due to less pressure effects.

Our study was conducted for assessing the airway placement. All the patients were ASA grade I or II with no anticipated difficult intubation. This does not represent the general population. The devices were inserted by postgraduate students, after prior training, thus the results of ease of insertion and duration of insertion were similar to experienced personal.

## CONCLUSION

We hereby concluded with our study that successful and shorter duration of insertion, with less hemodynamic response, makes I-gel™ a suitable alternative to LMA Classic™ during general anesthesia.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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