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# A Prospective Randomized Comparative Study of Supreme Lma Versus I-Gel In Short Surgical Procedures

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***Abstract:***
***AIM****: The aim of this prospective randomized comparative study is to compare I-Gelwith Supreme LMA in anesthetized spontaneously breathing patients for elective shortsurgical procedures up to 1 hour.*
***Methods:*** *The prospective randomized, open study was carried out after approval from the ethics committee . Patients were randomly selected and explained about the study, and written informed consent was taken. A total of 60 patients were selected and randomly divided into a group of 30 each. Group I: I-Gel,Group S: Supreme LMA. Then ease, time and a number of attempts to insert the supraglottic airway device, hemodynamic changes, and any adverse effects were noted, tabulated, and analyzed*
***Results****: There were no significant differences between the two groups regarding demographic data,haemodynamic parameters, insertion time,number of attempts , and the use of airway manipulation. All devices were inserted on the first attempt, excluding one case in each group. but there were no significant differences between the groups.*
***Conclusion****,: I-Gel is a handy tool in adult and pediatric anesthesia.I-Gel can replace Supreme LMA as an alternative in cases requiring intermittent positive pressure ventilation.*
***Keywords:*** *I-gel, Laparoscopic cholecystectomy, Supreme laryngeal mask airway*

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## I. Introduction:

Airway management is a fundamental aspect of anesthesia practice and emergency critical care. The first skill that the anesthetist must acquire is how to keep the airway patent. There is a loss of upper airway reflexes following general anesthesia, resulting in accidental aspiration of gastric contents into the tracheobronchial tree with the risk of extensive lung injury.

Endotracheal intubation is a rapid, simple, safe, and non-surgical technique that achieves all airway management goals, namely maintaining airway patency, protecting lungs from aspiration, and permitting leak-free ventilation and hence remains gold standard for airway management. This procedure has its problems; it often requires neuromuscular blockade, stimulates unwanted reflex activity, and may damage the vocal cords and tracheal mucosa.[1]

With these problems in mind, **Dr.A I J Brain** developed a new approach in 1981. Instead of being applied to the face, the anesthetic face mask was reduced in size to be positioned over the laryngeal opening itself.[2] This prototype, used in 1981, was inserted blindly under deep halothane anesthesia. A satisfactory airway was immediately obtained, and inflating the lungs with gentle, positive pressure ventilation was possible..

The laryngeal mask airway provides a patent airway for spontaneous breathing as well as during controlled ventilation. In contrast to the conventional facemask, the laryngeal mask fits around the upper end of the larynx and it protrudes in the pharynx.

A new variant of the supraglottic airway device, I-GEL, was invented in January 2007 in London by **Dr.Nasir**.[3] I-Gel is a supraglottic airway device with an anatomically designed,non-inflatable mask, soft gel-like, and transparent medical grade thermoplastic elastomer called SEBS(Styrene Ethylene Butadiene Styrene).[4] The soft non-inflatable cuff fits snugly onto the perilaryngeal framework. Its tips lie in the esophagus's proximal opening, thus isolating the oropharyngeal space from the laryngeal opening. The device has a buccal cavity stabilizer with a propensity to adapt its shape to the patient's oropharyngeal curvature, airway tubing, and a separate gastric channel. The tube section is firmer than the gastric channel. The gastric channel allows suction andpassage of the gastric tube, determining the airway's correct positioning.

The Supreme LMA was introduced in late 2007 by **Dr. A I J Brain**. The Supreme LMA is a supraglottic airway device with the following features: Single-use to alleviate concerns of cross-contamination, an anatomical curve that facilitates easy insertion, a drain tube to allow gastric aspiration, high volume / low-pressure cuff which generates higher seal pressure, a built-in bite block and fixation tab to help secure the airway, an oval airway cross-section for improved stability of the airway once placed, a reinforced tip and semi-rigid airway.[5] In this present prospective randomized, open study, comparision of the safety and efficacy of I-Gel and Supreme LMA was done.

## II. Aims And Objectives

**AIM:**

The aim of this prospective randomized comparative study is to compare I-Gel

with Supreme LMA in anesthetized spontaneously breathing patients for elective shortsurgical procedures up to 1 hour.

**OBJECTIVES:**

- To study the ease of insertion of the device.
- Time taken for insertion of the device.
- Number of attempts required for insertion of the device.
- Hemodynamics changes.
- Adverse effects.

## III. Materials And Methods:

The prospective randomized, open study was carried out for 18 months after approval from the ethics committee in Government General Hospital, Siddhartha medical college, Vijayawada. Patients were randomly selected and explained about the study, and written informed consent was taken. A total of 60 patients were selected and randomly divided into a group of 30 each.

- Group I: I-Gel
- Group S: Supreme LMA

All the patients were evaluated preoperatively, and all the baseline vitals wererecorded.

**INCLUSION CRITERIA**

1. Patients of either gender.
2. ASA grade I&II.
3. Age between 18 years to 60 years.
4. Planned for elective short surgical procedures for up to 1 hour.

**EXCLUSION CRITERIA**

- Patient refusal.
- Patients with known difficult airway.
- Pregnant females.
- Obesity BMI>30 kg / m2.
- Patients with ASA grade 3, 4, and 5.
- Cervical spine disease.
- Mouth opening <2.5 cm.
- Full stomach, hiatus hernia, GERD.
- Head injury.

## IV. Methodology

- 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 were pre-oxygenated with 100% oxygen for 3 minutes.Each patient was given an induction dose of Inj. Propofol (2.5 mg/kg iv).

- The supraglottic airway device either I-GEL or Supreme LMA was inserted after the lubricating posterior surface of the cuff with a water-based jelly. It was then connected to the breathing circuit and secured after confirming bilaterally equal air entry. A nasogastric tube was inserted.
- Anesthesia was maintained with 67% N2O in O2 along with 1-3vol% Sevoflurane.

 Then ease, time and a number of attempts to insert the supraglottic airway device, hemodynamic changes, and any adverse effects were noted, tabulated, and analyzed.
 At the end of the procedure, all the patients were ventilated with 100 % oxygen during emergence. 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, ortongue, and the device was checked for the presence of any bloodstains. The mask of the airway was inspected for the existence of any gastric contents to confirm regurgitation. All the patients were observed for 24 hours for any complaint of sore throat.

**STATISTICAL ANALYSIS:**

The two groups were compared in terms of age, weight, and sex. The statistical test used was the Unpaired Student's 't' test for age and weight. For qualitative data like the sex, 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, and SpO2 were compared using analysis of variance (ANOVA). The mean time required for an insertion was compared using the UnpairedStudent's 't' test. In all parameters, $p< 0.05$ was considered to be significant.

## V. Observations And Results

This prospective randomized open study was carried out in 60 adult patients belonging to ASA physical status I and II undergoing short surgical procedure under general anaesthesia. The patients were randomly divided into two groups of 30 each. Ingroup I , I-Gel was used and in group S ,Supreme LMA was used to secure the airway.

**DEMOGRAPHICAL DATA**

 Age of the patients were ranging from **18-58** years with average age being **32.07** years in I-GEL and **33.20** years among Supreme lma group which were comparable and difference was not statistically significant.
 Mean weight was **51.73** kg in I-GEL group which was comparable with **53.23** kg among supreme LMA group and the difference was not significant.
 **43.3%** of the cases were male in I-GEL group which was less compared to **66.7%** among Supreme LMA group but difference was not significant.

 **70.0%** cases among I-GEL group had MPC I which was less than **86.7%** cases among Supreme LMA group but difference was insignificant.
 **86.7%** of cases each among both the groups had ASA I which was same and thedifference was not significant.

**COMPARISION OF CHANGES IN MEAN HEART RATE BETWEEN THE TWO GROUPS**

 As per above analysis mean heart rate before premedication was **85.70** in I-GEL which was comparable to **83.73** in Supreme LMA group and the difference was not significant.
 After premedication, mean heart rate was **84.40** in I-GEL which was more as compared to **82.30** in Supreme LMA but difference was not significant.The same trend was observed till the end.
 This profile states that mean systolic blood pressure before premedication was

**124.40** in I-GEL which was more as compared to **120.73** in Supreme LMA but difference was not significant.The same trend was observed at the end of 5 and 10 mins.
 After premedication , mean systolic blood pressure was **119.47** in I-GEL which was comparable with **120.60** in Supreme LMA group. The same trend wasobserved after induction and at 15 mins.
 Above study reveals that mean diastolic blood pressure before premedicationwas **80.60** in I-GEL which was comparable with **79.07** in Supreme LMA group butthe difference was not significant.
 After premedication, mean diastolic blood pressure was **79.33** in I-GEL which was comparable with **79.27** in Supreme LMA group and the difference was not significant.
The same trend was continued til the end of 60 mins.

 This data suggests that mean spo2 before premedication was **99.00** among

I-GEL and among Supreme LMA group which was same and thus the differencewas not statistically significant. The same trend was continued till the end.
 According to above study,mean respiratory rate before premedication was **14.80** among I-GEL group which was more as compared to **13.90** among Supreme LMA group
 After premedication,mean respiratory rate was **14.73** among each group but the difference was not

significant.

 After induction and LMA insertion , mean respiratory rate was **18.03** among I-GEL group which was significantly more as compared to **17.00** among SupremeLMA group.

**Table 1 -COMPARISION OF MEAN TIME TAKEN FOR INSERTION BETWEENTHE TWO GROUPS**

| **GROUPS** | **Mean Time taken for insertion (sec) (x̄±SD)** |
|---|---|
| I-GEL(N=30) | 29.53±8.23 |
| SUPREME LMA (N=30) | 31.77±2.38 |
| P Value | 0.17 |

By student t test NS = Not Significant

This study reveals that mean time taken for insertion was **31.77 seconds** in Supreme LMA group which was comparable with **29.53 seconds** among I-GEL group and the difference was not significant.

**Table 2- PROFILE OF EASE OF INSERTION**

| **EASE OF INSERTION** | **I-GEL (N=30) N0.** | **%** | **SUPREME LMA NO.** | **%** |
|---|---|---|---|---|
| YES | 28 | 93.3 | 27 | 90.0 |
| NO | 02 | 06.7 | 03 | 10.0 |

By Chi- Square test p > 0.05 Not Significant

Above profile states that **93.3%** of the cases among I-GEL group had ease of insertion which was more as compared to **90.0%** among Supreme LMA group but the difference was not significant.

**Table-3 COMPARISION OF NUMBER OF ATTEMPTS IN BOTH THE TWOGROUPS**

| **Attempts** | **I-GEL(N=30) NO.** | **%** | **SUPREME LMA NO.** | **%** |
|---|---|---|---|---|
| 1 | 28 | 93.3 | 27 | 90.0 |
| 2 | 02 | 06.7 | 03 | 10.0 |

By Chi- Square test p > 0.05 Not Significant

According to above data **93.3%** cases among I-GEL group had one attempt which wasmore then **90.0%** in Supreme LMA group but the difference was not significant.

## VI. Discussion

Anesthesia is a pharmacologically induced, reversible state of amnesia, analgesia, muscle relaxation, and reflex suppression. Hence it is necessary to keep the airway patent, which is the first skill that an anesthetist must acquire.. Investigations have progressed from using a gold or silver cannula to the advent of the endotracheal tube by the development of supraglottic airway devices. Endotracheal intubation, first used in 1878, has its complications like the requirement of neuromuscular blockade, unwanted hemodynamic response, and damage to vocalcords.[1]

In 1981, **Dr. A.I.J. Brain**, a British Anaesthesiologist, was the prime brain behind recognizing the principle of LMA.

**Dr. Brain** encountered several problems, including looking for suitable device materials (latex, PVC, silicon), difficulties with insertion, creating an effective airwayseal, the problem of epiglottic down folding, and protection against aspiration. He tried several techniques and modifications.

In 1988, Classic LMA was first officially released in England. The FDA approved its use in the USA only in 1991.

The LMA is extremely useful when used conservatively and has proved valuable as a rescue device. The LMA is a key device at several places in the ASA algorithm for difficult airways.[6,7] There are many reports of successful use of an LMA as a rescue airway when tracheal intubation has failed, including the "cannot ventilate, cannot intubate" situation, and lives have been saved.[7]It was **AIJ Brain** who used LMA in three cases of difficult intubation.[8]

LMA is easier to insert than an endotracheal tube. Neuromuscular blockade is not necessary for insertion. It is inserted blindly under an adequate depth of anesthesia to prevent excitatory phenomena such as coughing and laryngospasm. The hemodynamic response to insertion and the changes in intraocular pressure are less than those after endotracheal intubation.[9]

Supraglottic Airway Devices [SADs] are increasingly being used as an excellent alternative to mask ventilation and tracheal intubation with fewer complications.

The liberal use of the classic LMA started in 1990. Due to this inability to prevent aspiration at high airway pressure due to inadequate seal, a modification of LMA, Proseal LMA, was introduced in 2000. It was said to provide a better airway sealing pressure and be used for surgeries lasting for more than 2 hrs. Proseal LMA was also not without any disadvantages. Its higher cost, the complexity of insertion, and higher incidence of trauma and postoperative sore throat urged for developing a novel, supraglottic airway device I-Gel.

I-Gel was introduced in 2007 by **Dr.Mohd.Aslam Nasir** was unveiled at the Association of Anaesthesiologists, Great Britain and Ireland annual scientific meeting in Central London.[4] It is cheaper, readily available, made of soft gel medical-grade thermoplastic elastomer, and designed to anatomically fit the perilaryngeal and hypopharyngeal structures without an inflatable cuff. It is a latex-free supraglottic airway device. It provides a good airway sealing pressure, which is just enough to prevent aspiration.

To ensure patient safety, it is essential that their advantages and limitations be studied. In present study, two newer generations of SADs- LMA SUPREME AND I-GEL are compared.

The Supreme LMA is a new supraglottic airway device introduced in late 2007 that presents combined features of the LMA-ProSeal (high seal cuff to facilitate ventilation, gastric access for airway protection, and bite block to prevent airway obstruction), the LMA-Fastrach (fixed curve tube and guiding handle – facilitate insertionand fixation)and the LMA Unique(single-use –prevention of disease transmission).[10]

Since Supreme LMA has an almost similar design as I-Gel, it was decided to compare both these devices. The present study was designed to assess the ease of insertion, attempts required for insertion, the incidence of adverse effects with both devices.

Present study is a prospective, randomized comparative open study to avoid any experimental or personal bias. Study consists of 60 patients of ASA class I and II in the age group 18-60 years of either sex, undergoing short surgical procedures, with a duration of surgery lasting up to 60 min In Group I, I-Gel was inserted to secure the airway. I-Gel and Supreme LMA, both sizes 3 and 4, depending upon the patient's weight. After premedication with Inj.Glycopyrrolate, Inj.Midazolam, Inj.Fentanyl patients in both groups were induced with Inj. Propofol 2-2.5 mg/kg iv till the loss of eyelash reflex. The patient's head was positioned in sniffing the morning air position, and the respective supraglottic airway was inserted, which was selected randomly. The device was fixed and connected to the breathing circuit.

A nasogastric tube was inserted through the gastric channel in both devices. Anesthesia is maintained with 67% N2O in O2 along with 1-3vol% Sevoflurane with patient breathing spontaneously. Throughout the procedure, heart rate, blood pressure, saturation, and respiratory rate were recorded.

Time for insertion was noted from the end of the propofol bolus until achieving an effective airway. An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, and normal SpO2.

At the end of the procedure, all patients were ventilated with 100% Oxygen during emergence from anesthesia. When the patient was able to open the mouth on command, the device was removed. Then the patients were inspected for any injury to the lips, teeth, tongue, or gums, and the device was examined for the presence of any bloodstains. The mask was examined for the presence of food particles to rule out regurgitation. Intraoperatively, any incidence of laryngospasm, leak, bloodstains on the device, and gastric insufflation were noted. Postoperatively patients were enquired for sore throat immediately and after 24 hrs.

The patients in both groups were comparable in their demographic characteristics and surgical details. Hemodynamic parameters were compared from the preoperative period through the intraoperative period till the removal of the device. 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 desaturation and hypotension throughout the surgery. Hemodynamic parameters results in the present study were concordant with those reported by **Amr Helmy et al.** and **W.H.L. Teoh et al.**[11,12]

The time required for the insertion of individual devices was studied. The mean times from the airway device's insertion to the first capnograph trace were similar for both Supreme LMA and I-Gel. The mean time required for I-Gel insertion was 29.53 ± 08.23 sec, and for Supreme LMA was 31.77 ± 02.38 sec, which was statistically insignificant (p =0.17 ). **Suhitharan et al**. also found similar results.Both devices had similar first attempt insertion rates (L MAS 94% vs.I-Gel 94%) with similar ease and comparable times to achieve an definite airway, LMAS 14.7(2.7) versus I-GEL 16.5(9.6)s, P =0.306.

In 28/30 cases (93.3%), I- Gel was successfully inserted in the first attempt. Only two-second attempt was required, whereas in Supreme LMA first attempt was successful in 27/30 cases(90 %) 3 cases required a second attempt. The difference wasstatistically insignificant

In present study, the ease of Ryle's tube insertion for both the devices was similar, and the difference was clinically as well as statistically insignificant. But **Teoh et al.** found that it was more difficult and took significantly longer to insert the gastric tubein the I-Gel group (78%) than supreme LMA group (100%).[12]

**Keller C et al.** and **Lopez Gil et al.** compared four kinds of measurement of airway sealing pressure, that is the detection of audible noise over the mouth, detection of exhaled carbon dioxide inside the mouth with capnograph, manometric stabilitytechnique, and detection of audible noise using a stethoscope on the thyroid cartilage. They concluded that all four tests were excellent.[13]

**Ragazzi. R et al.** also noted that the airway sealing pressure provided by Supreme LMA (28 cms of H2O ) was higher than that of I-Gel (24 cms of H2O ). However, **Teoh et al**. found no difference in seal pressure between the Supreme LMA and I-Gel (mean (SD )26.4 (5.10 )vs. 25.0 (5.7) cm of H2O, respectively; p=0.18.[14]

**Gabbot et al.** also concluded that I-Gel provides good airway sealing pressure, which improved over time and may be due to the I-GEL cuff's thermoplastic properties, which form an effective seal around the after warming to body temperature.[15]

The incidence of adverse events were compared intraoperatively, during emergence, and in the postoperative period. There were no adverse events noted. There was no evidence of regurgitation or aspiration with either of the devices.

In present study, we included all the elective cases, all the patients were adequately fasting preoperatively, and all the patients had a nasogastric tube in situ, so none of the patients had episodes of regurgitation No such similar study has been performed for the Supreme LMA and whether the drain tube remains efficacious remains unproven. The design features of Supreme LMA would suggest that it might confer similar protection, but more evidence is required before the Supreme LMA can be considered to be as safe as the Proseal LMA

There was no sign of injury to lip, teeth, gums, or tongue and blood on the devicewith either device. In present study there was no evidence of gastric insufflation with either device, probably due to a good seal around the laryngeal inlet and the presence of a nasogastric tube through the gastric channel.

In both the I-Gel group and Supreme LMA group, there was NO throat discomfort. **Teoh et al**. and **Ragazzi et al**. found that the use of Supreme LMA produces more sore throat compared to I-Gel.

Various studies have reported identical findings wherein the incidence of sore throat is minimal with I-Gel compared to other supraglottic airway devices.

I-Gel's soft seal non-inflatable mask attributed to lower incidence of sore throat. I-Gel is a supraglottic airway device without an inflatable mask. It has some potential advantages of easier insertion and minimal tissue compression In contrast, a supraglottic airway device with an inflatable cuff like the Supreme LMA in present study can absorb anesthetic gases leading to increased mucosal pressure.

It can be said that I-Gel is a simple, excellent, and easy to use supraglottic airway device. It is easy to insert without many manipulations within a short time; hence, it can be used as an airway adjunct in resuscitation. It has an advantage of effective seal pressure, than Supreme LMA but is enough to prevent aspiration and maintain effective ventilation and oxygenation. As it lacks the inflatable cuff, there is a minimalrisk of tissue compression, resulting in lesser adverse events like sore throat and nerve injury.

With all these advantages, I-Gel is a handy tool in adult and pediatric anesthesia. I-Gel can replace Supreme LMA as an alternative in cases requiring intermittent positivepressure ventilation.

## VII. Conclusion:

I-Gel is a simple and safe supraglottic airway device made of a soft gel-like material. It has the potential advantage of providing an effective airway sealing pressure which was within normal limits and sufficient to prevent aspiration. It has a gastric channel, providing a means to drain gastric secretions. As it is made of a soft gel-like material, and non-inflatable mask makes it less irritant to the airway. Hence I-Gel can be an better alternative to Supreme LMA and other Supraglottic airway devices.

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