Section: Anaesthesiology

Original Research Article

# COMPARISON OF HEMODYNAMIC STRESS RESPONSE DURING INSERTION OF LMA SUPREME VERSUS I–GEL IN PATIENTS UNDERGOING SHORT SURGERIES UNDER GENERAL ANESTHESIA

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## Abstract

**Background:** The i-gel™ and LMA-Supreme (LMA-S) are single-use supraglottic airway devices with an inbuilt drainage channel. We compared the hemodynamic stress response during the insertion of LMA supreme versus I-gel in patients undergoing short surgeries under general anaesthesia. **Materials and Methods:** This randomised, prospective, comparative interventional study was done in ESIC Medical College & PGIMSR, Chennai, from January 2017-May 2018 on 80 patients undergoing short elective surgeries. The patients were divided into Group 1: I-Gel (n=40) and Group 2: LMA-Supreme (n=40). Preoperative evaluation included age, weight, ASA status, and baseline vital parameters. History of previous anaesthesia, surgery, significant illness, medications, and allergy was recorded. A complete physical examination and airway examination was also done. **Result:** Female predominance was reported in both groups; other parameters like mean age, height and weight were also comparable. The insertion success rate for the airway device in LMA (Group 2) was 97.50 % on the first attempt, while in the I-gel group (group 1), it was 100 % on the first attempt. The different hemodynamic parameters such as mean SBP, DBP, heart rate, MAP, SpO2 saturation and EtO2 before induction, at insertion (1, 3 and 5 min) and after removal were comparable in both groups. The incidence of blood staining was 5.00% in group 2 and 2.50% in group 1. **Conclusion:** Both LMA Supreme and I-gel did not cause significant hemodynamic instability during insertion and removal, and both show comparable performance.

## INTRODUCTION

The major responsibility of the anesthesiologist is to provide adequate ventilation to the patient. Tracheal intubation is the gold standard for maintaining a patent airway during anaesthesia. Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation leading to hypertension, tachycardia, myocardial ischemia, ventricular arrhythmias and increased intracranial tension.[1,2] Supraglottic airway devices (SAD) with gastric access tubes are increasingly used in surgery requiring general anaesthesia and positive pressure ventilation. The i-gelTM is a unique disposable supraglottic airway device introduced clinically in January 2007. It comprises a soft, gel-like, non-inflatable cuff made of thermoplastic elastomer, a widened, flattened stem with a rigid bite-block that acts as a buccal stabiliser to reduce axial rotation and malpositioning, and an oesophageal vent through which a gastric tube can be passed. Preliminary studies have demonstrated its easy, reliable insertion, providing an adequate seal with a low morbidity rate.[3] It is a reasonable alternative to tracheal intubation during pressure-controlled ventilation and can be used as a conduit for tracheal intubation and rescue airway management.[4-6]

The LMA SupremeTM, on the other hand, is another supraglottic device introduced in 2007 with many similar characteristics to the I-gel: single-use, a drain tube to separate the gastrointestinal tract from the respiratory tract, and a built-in bite block. It differs from the i-gel in that it is constructed of medical-grade silicone. It has an inflatable cuff, a reinforced tip, and an elliptical, anatomically shaped, semi-rigid airway tube.[7,8] We aimed to compare the efficacy of hemodynamic stress response during the insertion of LMA supreme


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versus I–gel in patients undergoing short surgeries under general anaesthesia.

## MATERIALS AND METHODS

This randomised, prospective, comparative interventional study was done in ESIC Medical College & PGIMSR, Chennai, from January 2017-May 2018 on 80 patients undergoing short elective surgeries. Patient informed consent and Ethical committee approval were obtained.

**Inclusion Criteria**

Patients aged 18-60 of either sex, weighing 50-90 kgs with ASA-I and II patients scheduled for elective surgeries of less than one-hour duration under general anaesthesia. Patients with a Body mass index of 20-30kg/m2 and Modified Mallampati grades 1 and 2 were included.

**Exclusion Criteria**

Patients unwilling to participate in the study and having pregnancy, Mallampati 3 and 4, chronic alcoholism, obstructive sleep apnoea and anticipated airway difficulty, reduced cervical spine mobility, hypertension patients on beta blockers and anti-hypertensive drugs, increased aspiration risk, patients with Preoperative sore throat, respiratory infection, lung diseases and neck or oropharyngeal airway surgery were excluded.

The patients were divided into Group 1: I-Gel (n=40) and Group 2: LMA-Supreme (n=40). Preoperative evaluation included age, weight, ASA status, and baseline vital parameters. History of previous anaesthesia, surgery, significant illness, medications, and allergy was recorded. A complete physical examination and airway examination was also done.

**Standard Monitors-** pulse oximetry for saturation (Spo2), non-invasive blood pressure monitoring (NIBP), and electrocardiogram (ECG) were attached, and the baseline heart rate, diastolic blood pressure, systolic blood pressure, mean arterial pressure, oxygen saturation and ETCO2 were recorded.

An intravenous line was started before the procedure with an 18G cannula and crystalloid infusion commenced. Preoxygenation was done supine with oxygen via face mask at a flow rate of 8L/min for 3 minutes. Premedication was given with injection of midazolam 0.03 mg/kg, injection of glycopyrrolate 5mcg/kg and injection of fentanyl 2mcg/kg intravenously 5 minutes before induction. All patients were induced with an injection of propofol 2.5mg/kg. No muscle relaxant was used. The patients were bag and mask ventilated with 100% O2 after confirming the lack of response to verbal commands and eyelash reflex.

The trained anesthesiologist inserted the SAD, and airway manipulations required were neck extension and flexion, jaw thrust or a chin lift. The selected size of the SAD depended on the patient's weight following the manufacturer's recommendations. For I-GEL size three was used if < 50 kg, a size four if 50–90 kg and a size five if >90 kg and for the Supreme LMA, a size three was used if <50 kg, a size 4 for 50–70 kg and a size 5 for 70-100 kg was used.

All the SADs were tested for leaks before insertion. Both the SADs were lubricated with 2% lignocaine jelly and inserted into the allotted group per the standard insertion protocol. The cuff was inflated after the device was in place. The volume of air injected was according to the manufacturer's recommendations. The leak was detected by auscultating over the neck with a stethoscope, auscultation over the epigastrium or an EtCO2> 45 mmHg. If there was airway obstruction or critical air leakage, the device was removed, and a different-sized device was reinserted. If the insertion of a SAD required more than four attempts or adequate ventilation was not achieved, it was considered a failure and the tracheal tube was inserted without giving a muscle relaxant.

Anaesthesia was maintained with sevoflurane (1 MAC), 33% O2 and 67% N2O, connected to the circle anaesthesia breathing system. After appropriate placement of SAD, pulse rate, diastolic blood pressure, systolic blood pressure, mean arterial pressure, Spo2, and ETCO2 were recorded at 1, 2, and 3 min. If there was any increase in the mean arterial pressure and heart rate of more than 20% of the induction values, an additional dose of injection propofol 40 mg was given to maintain the haemodynamics. A muscle relaxant was not given, and the patient was maintained on spontaneous ventilation. Nitrous oxide and the volatile anaesthetic were discontinued after the last skin suture, and the fresh gas inflow rate was changed to 6L/min of oxygen. After the return of the airway reflexes and after the patient became conscious, the SAD was removed after thorough suctioning of the oral cavity. Complications were investigated, such as if any visible blood stain of the device was noted on removal. Each patient was questioned in the recovery room 24 hours postoperatively for sore throat (constant pain independent of swallowing).

**Statistical Analysis**

Descriptive statistics were done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t-test. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 16 and Microsoft Excel 2007.

## RESULTS

This prospective randomised comparative interventional study was conducted in 80 patients of either gender of ASA I & II in the 18 to 60 years of either sex posted for short procedures under GA. The patients were randomly divided into two groups


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by slips in the box technique: Group 1 (I- gel) and Group 2 (LMA- Supreme). Female predominance was reported in both groups. Other parameters like mean age, height and weight were also comparable. The insertion success rate for the airway device in LMA (Group 2) was 97.50 % on the first attempt and 2.50 % on the second attempt, while in the I-gel group (group 1), it was 100% on the first attempt. The results were found to be statistically not significant with p value >0.999 [Table 1].

The different hemodynamic parameters such as mean systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate, mean arterial pressure (MAP), SpO2 saturation and EtO2 were studied before induction, at insertion (1, 3 and 5 min) and after removal and all these variables were comparable in both Group 1 (I-gel) and Group 2 (LMA-Supreme) [Table 2].

Concerning the postoperative complications table, it was evident that the incidence of blood staining was 5.00% in the LMA Supreme group and 2.50% in the I-gel group. Similarly, the incidence of sore throat was 7.50% in the LMA Supreme group and 7.50% in the I-gel group. The incidences of both side effects were statistically insignificant among both groups [Table 3, Figure 1].

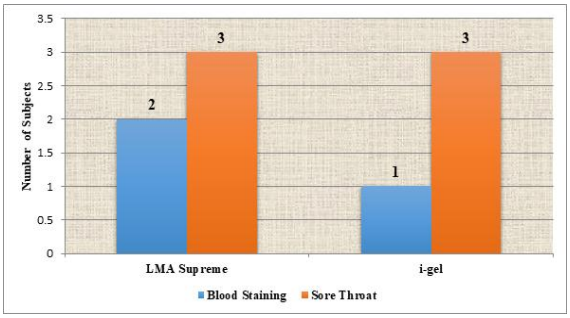


**Figure 1: Observation of postoperative compliance among patients**

**Table 1: Observation of different demographic variables of patients**

| Parameters | Observation N (%) | | P-value |
|---|---|---|---|
| | Group 1 (I-gel) (N=40) | Group 2 (LML-Supreme) (N=40) | |
| Gender | | | |
| Male | 10(25%) | 16 (40%) | 0.152 |
| Female | 30 (75%) | 24 (60%) | |
| Age Groups | | | |
| ≤ 20 years | 5 (12.5%) | 3 (7.5%) | - |
| 21-30 years | 26 (65.5%) | 27 (67.5%) | |
| 31-40 years | 7 (17.5%) | 7 (17.5%) | |
| 41-50 years | 2 (5%) | 3 (7.5%) | |
| Mean Age years ± SD | 27.18±6.96 | 27.63 (6.98%) | 0.774 |
| Weight (Kg) | | | |
| ≤ 40 | 2 (5.0%) | 0 (0%) | - |
| 41-50 | 7 (17.5%) | 7 (17.5%) | |
| 51-60 | 31(77.5%) | 33 (82.5%) | |
| Mean Weight Kg ± SD | 53.58± 5.85 | 55.60± 5.09 | 0.103 |
| Number of attempts of insertion | | | |
| 1 | 40 (100.0%) | 39 (97.50%) | >0.999 |
| 2 | 0 | 1 (2.5%) | |

**Table 2: Observation of various hemodynamic parameters of patients in both groups**

| Parameters | Observation N (%) | | P-value |
|---|---|---|---|
| | Group 1 (I-gel) (N=40) | Group 2 (LML-Supreme) (N=40) | |
| SBP distribution | | | |
| Before Induction | 130.80 (5.28%) | 119.13 (11.64%) | 0.588 |
| At Insertion | 121.35 (5.55%) | 109.80 (11.14%) | 0.619 |
| 1 Min | 141.15 (5.38%) | 128.75 (11.8%) | 0.554 |
| 3 Min | 143.20 (5.2%) | 131.35 (11.91%) | 0.521 |
| 5 Min | 147.60 (5.8%) | 140.68 (9.14%) | 0.471 |
| After Removal | 129.00 (5.45%) | 122.25 (12.20%) | 0.804 |
| DBP distribution | | | |
| Before Induction | 75.65 (6.88%) | 74.10 (7.19%) | 0.420 |
| At Insertion | 66.90 (6.93%) | 66.50 (7.30%) | 0.349 |
| 1 Min | 84.65 (6.66%) | 83.20 (7.20%) | 0.421 |
| 3 Min | 86.35 (6.61%) | 85.75 (7.85%) | 0.429 |
| 5 Min | 87.60 (5.29%) | 89.75 (5.25%) | 0.394 |
| After Removal | 78.25 (5.80%) | 76.40 (5.62%) | 0.865 |
| Heart Rate Distribution | | | |
| Before Induction | 72.85 (2.50%) | 73.28 (6.62%) | 0.795 |
| At Insertion | 65.73 (2.60%) | 65.50 (3.44%) | 0.875 |
| 1 Min | 65.85 (2.54%) | 66.60 (3.51%) | 0.788 |
| 3 Min | 65.98 (3.17%) | 67.00 (2.11%) | 0.954 |
| 5 Min | 66.00 (2.20%) | 66.73 (2.47%) | 0.783 |
| After Removal | 80.78 (5.29%) | 81.50 (6.36%) | 0.856 |
| MAP Distribution | | | |
| Before Induction | 99.90 (6.45%) | 99.55 (5.78%) | 0.821 |


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| | | | |
|---|---|---|---|
| At Insertion | 74.10 (2.76%) | 74.28 (2.75%) | 0.986 |
| 1 Min | 75.95 (2.07%) | 75.93 (2.06%) | 0.662 |
| 3 Min | 78.55 (3.37%) | 78.55 (4.30%) | 0.950 |
| 5 Min | 79.70 (2.59%) | 80.18 (3.37%) | 0.890 |
| After Removal | 91.43 (3.35%) | 91.48 (3.44%) | 0.961 |
| SPO2 Distribution | | | |
| Before Induction | 99.55 (0.64%) | 99.60 (0.59%) | 0.837 |
| At Insertion | 98.90 (0.71%) | 99.36 (0.78%) | 0.974 |
| 1 Min | 99.80 (0.52%) | 99.90 (0.30%) | 0.835 |
| 3 Min | 99.95 (0.22%) | 100.00 (0.00%) | >0.999 |
| 5 Min | 99.98 (0.16%) | 99.95 (0.22%) | 0.642 |
| After Removal | 99.38 (0.63%) | 99.45 (0.68%) | 0.818 |
| ETCO2 Distribution | | | |
| Before Induction | 39.20 (1.71%) | 36.93 (1.54%) | 0.608 |
| At Insertion | 37.60 (1.82%) | 39.80 (1.65%) | 0.884 |
| 1 Min | 36.93 (1.54%) | 37.50 (1.28%) | 0.886 |
| 3 Min | 37.23 (1.83%) | 37.68 (1.65%) | 0.963 |
| 5 Min | 37.68 (1.65%) | 37.60 (1.82%) | >0.999 |
| After Removal | 39.80 (1.65%) | 39.20 (1.71%) | >0.999 |

**Table 3: Comparison of post-op complications between the two groups**

| Postoperative Complications | LMA Supreme | % | I-gel | % | P value Fishers Exact Test |
|---|---|---|---|---|---|
| Blood Staining | 2 | 5.00 | 1 | 2.50 | 0.879 |
| Sore Throat | 3 | 7.50 | 3 | 7.50 | >0.999 |

## DISCUSSION

Supraglottic airway devices have revolutionised anaesthesia practice and are now increasingly used as an excellent alternative to masking ventilation and endotracheal intubation with minimal complications.[1,2] The I-gel is a novel SAD made up of thermoplastic elastomer with a non-inflatable cuff. It fits snugly onto the peri laryngeal structures, offering a good seal during anaesthesia for controlled and spontaneous ventilation. The LMA Supreme has a curved rigid airway tube of medical-grade polyvinyl chloride with an inflatable cuff. Both devices have an inbuilt drainage tube for gastric aspiration.[7,8] Our study was conducted on spontaneously breathing patients without using muscle relaxants. Eschertzhuber et al. have used muscle relaxants for SAD insertion in their studies.[9] Franeksen et al., in their studies, compared LMA unique and I - gel in anaesthetised non-paralysed patients.[10]

Our study found no significant difference between I-gel and LMA supreme success rate at first attempt insertion. Our finding is consistent with a study by Teoh et al. that showed 94 % with LMA supreme and 96 % with I-gel, successful insertion with the first attempt.[11] Raggazi et al. found that LMA-Supreme has fewer insertion failures than I - gel because of its inflatable cuff, which caused transient peri laryngeal pain.[12]

In our study, the HR, SBP, DBP, MAP, EtCO2, and SpO2 in LMA-S and I-gel groups were observed before insertion, at insertion and 1, 3, 5 min and after removal of SAD. We found no significant difference between the two groups. Our observations were consistent with the Singh et al. study, which concluded that both LMA-S and I-gel showed no significant statistical difference with HR.[13] Shin WJ et al. study also showed no difference in the hemodynamic data between the two SADs.[14]

Our study showed no significant postoperative complications – blood on the surface of the device on the removal or postoperative sore throat was observed between LMA-S and I -gel. Ragazzi et al. reported that sore throat was more common with LMA-S as its inflatable cuff can cause compression of peri laryngeal tissues.[12] Our findings were consistent with Helmy AM et al. study, which also concluded no significant statistical difference regarding postoperative sore throat or hoarseness between LMA-S and I-gel.[13]

Our study did not limit, standardise or record the use of pri-operative analgesics. We also did not use a fibre optic bronchoscope to confirm the position of the airway device. We have studied only low-risk patients (ASA I and II) who had normal airways and were mostly not obese.

## CONCLUSION

The I-gel was easier to insert and required fewer insertion attempts when compared with LMA-Supreme. The I-gel's non-inflatable thermoplastic elastomer cuff fitted snugly, creating a good anatomical seal. The inflatable cuff of LMA-Supreme caused transient pharyngolaryngeal slipping. LMA Supreme and I-gel did not cause significant hemodynamic instability during insertion and removal. Both show comparable performance. The I-gel showed less postoperative complications as it is a non-inflatable cuff, which probably decreased the risk of airway tissue compression and tissue ischemia. I-gel and LMA-S showed no incidence of severe airway trauma, such as laryngeal stridor, laryngospasm, bronchospasm, hypoxia or aspiration.


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