A Study on the Comparative Effects of the Efficacy of I-Gel and Laryngeal Mask Airway Classic (C-LMA) and the Safety Profile of the Patients undergoing General Anesthesia for Elective Lower Abdominal and Lower Limb Surgeries

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ABSTRACT

Objectives: This study aimed to compare the efficacy and safety profile of two supraglottic airway devices, the I-Gel and the Laryngeal Mask Airway Classic (C-LMA) in the patients undergoing general anesthesia for elective lower abdominal and lower limb surgeries.

Methods: A total of 60 surgical patients aged 50-70 years, with ASA grade I and II, were enrolled and divided into two groups: the I-Gel group (n=30) and the C-LMA group (n=30). Demographic characteristics, insertion characteristics, hemodynamic stability, airway sealing pressure, and complications were compared between the two groups.

Results: Demographic characteristics, including age, weight, gender distribution, ASA grade, and type of surgery, was comparable between the I-Gel and C-LMA groups. In a comparative study between I-Gel and C-LMA groups, the I-Gel demonstrated a significantly faster mean insertion time of 10.0± 3.4 seconds as compared to 18.8± 3.2 seconds for the C-LMA group (t=3.58, p=0.032). Ease of insertion was higher in the I-Gel group with 96.6% reporting easy insertion versus 66.66% in the C-LMA group. Additionally, the I-Gel achieved better airway sealing pressure (24.4 cmH2O vs. 19.2 cmH2O, p=0.023) and had significantly fewer complications like sore throat and hoarseness.

Conclusion: The study suggests that the I-Gel device outperforms the C-LMA in various aspects of airway management, including shorter insertion times, better hemodynamic stability, superior airway sealing pressure, and fewer postoperative complications.
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**Keywords:** Supraglottic airway devices, I-Gel, Laryngeal Mask Airway Classic (C-LMA), airway sealing pressures.

1. **INTRODUCTION**

Airway management during general anesthesia is a critical aspect of perioperative care, essential for ensuring adequate ventilation and oxygenation while minimizing complications such as hypoxemia and aspiration. [1-3] Over the years, various supraglottic airway devices have been developed to facilitate airway management, offering advantages in ease of insertion, maintenance of airway patency, and suitability for different surgical procedures. [4-6] Among these advancements are the I-Gel and the Laryngeal Mask Airway Classic (C-LMA). [4,6,7] These devices have gained popularity among anesthesiologists and surgeons due to their ease of use and favorable clinical outcomes in a wide range of surgical procedures. [8-10] However, while both the I-Gel and C-LMA have been extensively studied in general anesthesia, there is a paucity of research comparing their efficacy in specific surgical contexts, particularly in elective lower abdominal and lower limb surgeries. Lower abdominal and lower limb surgeries encompass a diverse range of procedures, including hernia repair, appendicectomy, orthopedic surgeries, and vascular procedures. These surgeries pose unique challenges in airway management, as patients may have increased intra-abdominal pressure, altered respiratory mechanics, and limited access to the airway. Therefore, selecting the most appropriate airway management device is crucial for ensuring optimal patient outcomes and minimizing perioperative complications. The I-Gel and C-LMA are both second-generation supraglottic airway devices that offer advantages over traditional endotracheal intubation in certain clinical scenarios. The I-Gel is a single-use, non-inflatable device made of a thermoplastic elastomer, featuring a gel-like cuff that conforms to the perilaryngeal anatomy, providing a secure seal without the need for cuff inflation. Conversely, the C-LMA is a reusable device with an inflatable cuff designed to seal the oropharynx and facilitate positive pressure ventilation during general anesthesia. Several studies have investigated the efficacy of the I-Gel and C-LMA in various surgical settings, demonstrating comparable insertion characteristics, hemodynamic stability, and complication rates. However, there is limited evidence directly comparing these two devices in elective lower abdominal and lower limb surgeries. Given the anatomical and physiological considerations unique to these surgical procedures, it is essential to evaluate the performance of the I-Gel and C-LMA in this specific context to guide clinical decision-making and optimize patient care. This study aims to address this gap in the literature by conducting a comparative analysis of the efficacy of the I-Gel and C-LMA in elective lower abdominal and lower limb surgeries under general anesthesia. This research will provide valuable insights into the most effective airway management strategies for these procedures, ultimately enhancing patient outcomes and advancing perioperative care. The aim of the study was to study the comparative effects of the efficacy of I-gel and laryngeal mask airway classic (C-LMA) and the safety profile of patients undergoing general anesthesia for elective lower abdominal and lower limb surgeries, with the objectives given below:

1. To evaluate the efficacy of I-Gel over Classic LMA in patients undergoing general anesthesia in the study population.
2. To differentiate the hemodynamic stability after the insertion of supraglottic airway devices (SAD) among both the groups.
3. To compare the duration of insertion and the ease of insertion of supraglottic airway devices (SAD) in both the groups.
4. To assess the incidence of post operative adverse effects in all the study participants.

2. MATERIALS AND METHODS

Materials
The present study was carried out at Aamina Hospital & Nursing Home, between January 2022 to August 2022, located in Nowgam, Srinagar, Jammu and Kashmir, Bharat, after obtaining the approval from the hospital ethical committee. A total of sixty (60) surgical patients of age 50-70 years, of weight 55-70 kgs, of BMI < 30 kg/m² with ASA grade of I and II, were scheduled for elective lower abdominal and lower limb surgeries. Written informed consent was taken from all the patients. All the patients were randomly divided into 2 groups of 30 each.

Group I (n=30): Airway was maintained with I-Gel.
Group II (n=30): Airway was maintained with C-LMA.

Exclusion Criteria:
- Patients with BMI greater than 30 kg/m².
- Patients with anticipated difficult airway.
- Pregnancy.
- Patients with ASA grade III or more.
- Patients with a history of allergy or contraindications to the study devices (I-Gel or C-LMA).
- Patients with full stomach.
- Patients posted for emergency surgeries.
- Pediatric patients.
- Patients with age more than 70 years.
- Patients with weight more than 70 kgs.
- Patients unable to provide informed consent.

Methods
Pre-Anesthesia Checkup.

A comprehensive pre-anaesthesia check-up, encompassing patients detailed clinical history and clinical examination was done and routine investigations like Hb, blood sugar, renal function test, liver function test, coagulogram, ECG, X ray chest were ordered. All patients were kept nil per oral (NPO) for 8 hours prior to surgery. All patients were administered Tablet Alprazolam 0.25 mg given one day prior to the surgery (for anxiolysis) and Tablet Ranitidine 150 mg night before the surgery and two hours prior shift to operation theatre (OT).

Upon arrival in the operating theater, an appropriate size peripheral venous cannula was placed, and Ringer’s Lactate was administered at a rate of 10-15 ml/kg (500-1000 ml) preoperatively. Routine monitors, including ECG, pulse oximeter, and non-invasive blood pressure (NIBP), were applied, and baseline vitals were recorded. All patients were pre-oxygenated with 100% oxygen for three to five minutes. Premedication included intravenous injections of fentanyl (1-2 mcg/kg), glycopyrrolate (0.2 mg), and ondansetron (0.1 mg/kg). Anesthesia was induced with incremental doses of intravenous propofol (1-2 mg/kg). After the loss of verbal response, patients underwent bag-mask ventilation with 100% oxygen via Bain’s circuit. Following a positive bag-mask ventilation test, induction was facilitated using the depolarizing neuromuscular blocking agent succinylcholine (1-2 mg/kg IV). Once fasciculations reached the patient’s feet, airway management was performed using the group-specific supraglottic airway device (SAD) by a qualified anesthesiologist with a minimum of two years of experience. The patient’s head was positioned in the sniffing position, and the supraglottic airway device was inserted after adequate lubrication of the cuff with a water-based jelly. The cuff of C-LMA was initially inflated with half the recommended volume of air (according to the age and weight of the patient).
patient and the size of the LMA). In case of inadequate seal, the entire volume of air was administered to inflate the cuff. If case of further leak, the SAD was removed and one size bigger was inserted. Incremental doses of inj. propofol were used in case of re-insertion of the SAD. The SAD was then connected to the breathing circuit and the correct placement was confirmed by auscultation of bilateral equal air entry and the capnograph.

The anesthesia was maintained with nitrous oxide, oxygen, (60% N2O:40%O2), and sevoflurane (1%) along with controlled mechanical ventilation (CMV) and inj. atracurium 0.1 mg/kg iv in incremental doses. At the end of the surgery, after the return of spontaneous respiration, neuromuscular blockade was reversed with inj. neostigmine 0.05mg/kg and inj. glycopyrrolate 0.2mg iv.

Airway device was removed once the patients had adequate spontaneous tidal volume, cough reflex, spontaneous eye opening and head lift.

The following parameters were recorded:

- Demographic variables (age, weight, gender, ASA grade, type of surgery).
- The duration of insertion of LMA (calculated from the time when the LMA was picked up from the airway trolley till the time of adequate ventilation of the patient).
- The ease of insertion of supraglottic airway device was assessed from 1-2-3 scale (1- Easy, 2- Difficult, 3- Impossible)\(^2\)
- The airway sealing pressure of the supraglottic airway device in both the groups was determined by manometer stabilization method.
- The hemodynamic responses to the insertion of supraglottic airway device were noted as baseline, post induction and just after insertion of the airway device.
- The incidence of post operative adverse effects (sore throat, hoarseness, nausea and vomiting, edema of the soft palate, mucosal injury) was checked in both the groups.

The airway sealing pressure was determined by the manometer stabilization method. After closing the expiratory valve of the breathing circuit (closed circuit) at a fixed fresh gas flow of 3 l/min., the pressure manometer was observed on CMV. The point where equilibrium was achieved was taken as the sealing pressure.

### RESULTS AND ANALYSIS

The demographic variables, age, weight, gender, ASA grade and type of surgery were comparable in both the groups.

#### Table 1: Shows the Insertion Characteristics of SAD in both the groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Insertion Time (sec.)</td>
<td>10.0 ± 3.4</td>
<td>18.8 ± 3.2</td>
<td>3.58</td>
<td>0.032</td>
</tr>
<tr>
<td>Ease of Insertion</td>
<td>Easy: 29 (96.6%)</td>
<td>Easy: 20 (66.66%)</td>
<td>$X^2=8.230$</td>
<td>0.0231</td>
</tr>
<tr>
<td></td>
<td>Difficult: 1 (3.33%)</td>
<td>Difficult: 10 (33.33%)</td>
<td>$X^2=12.20$</td>
<td>0.012</td>
</tr>
</tbody>
</table>

Table 2 shows that, the mean insertion time of SAD in group I was 10.0 ± 3.4 seconds and 18.8 SD ± 3.2 seconds in group II and when compared statistically, p-value was 0.032 which was statistically significant (P < 0.05) (Table 1).

Regarding the ease of insertion of the SAD, in group I it was easy in 96.6% of the patients where as difficult in 3.33% of the patients, while in group II it was easy in 66.6% of the patients and difficult in 66.6% of the patients, therefore, when compared statistically the p-value was found to be 0.0231 in all the patients in whom the insertion of SAD was easy and p value was 0.012 in all the patients in whom the ease of insertion was difficult.
The comparison of baseline and post induction hemodynamic parameters was statistically insignificant in both the groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Rate (bpm)</td>
<td>79.5 ± 4.2</td>
<td>85.2 ± 4.8</td>
<td>4.43</td>
<td>0.043</td>
</tr>
<tr>
<td>SBP (mm of Hg)</td>
<td>116 ± 4</td>
<td>125 ± 7</td>
<td>5.23</td>
<td>0.0312</td>
</tr>
<tr>
<td>DBP (mm of Hg)</td>
<td>70 ± 5</td>
<td>82 ± 6</td>
<td>3.65</td>
<td>0.047</td>
</tr>
<tr>
<td>MAP (mm of Hg)</td>
<td>82 ± 3</td>
<td>92 ± 4</td>
<td>4.21</td>
<td>0.038</td>
</tr>
<tr>
<td>SPO2 (%)</td>
<td>99 ± 0.3</td>
<td>99.7 ± 0.4</td>
<td>1.32</td>
<td>0.52</td>
</tr>
</tbody>
</table>

In contrast, the analysis of vitals, after the insertion of SAD, revealed that pulse rate, systolic and diastolic blood pressure and mean arterial pressures were statistically significant in both the groups, with p value being very highly significant (p = 0.0312) on comparing systolic blood pressure (Table 2). The mean oxygen saturation of the patients was statistically insignificant among both the groups.

The airway sealing pressures were better in group I (24.4 ± 3.1 cm of H2O) as compared to group II (19.2 ± 2.9 cm of H2O). The difference in the two groups was statistically significant (p-value of 0.023) (Table 3).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway Sealing Pressure (cm of H2O)</td>
<td>24.4 ± 3.1</td>
<td>19.2 ± 2.9</td>
<td>5.98</td>
<td>0.023</td>
</tr>
</tbody>
</table>

Regarding the incidence of post operative adverse effects, none of the patients in group I complained of any adverse effect while in group II, there were certain patients who developed hoarseness (10%), sore throat (16.7%) and nausea and vomiting (6.7%). The difference in both the groups was statistically significant (Table 4).

### DISCUSSION

This study evaluated the efficacy of I-Gel and Laryngeal Mask Airway Classic (C-LMA) in elective lower abdominal and lower limb surgeries. Various parameters were assessed including insertion characteristics, hemodynamic stability, airway sealing pressure, and postoperative complications to determine the comparative effects of the two airway devices. Insertion of I-Gel was easier and faster as compared to C-LMA. The I-Gel is distinguished by its design and material properties, which allow for a notably quicker insertion process.

In the I-Gel group, the insertion of the supraglottic airway device (SAD) was easy in 29 out of 30 cases (96.6%) and difficult in only one case. In contrast, in the C-LMA group, the insertion was easy in 20 out of 30 cases (66.66%) and difficult in ten cases. This difference was both clinically and statistically significant (Table 2). A study by Kasturi and Rao [11] showed similar results, with I-Gel demonstrating faster insertion times compared to C-LMA. The study reported statistically
significant differences in insertion times (17.12±3.42 seconds for I-Gel vs. 25.62±5.28 seconds for C-LMA) and airway sealing pressures (26.38±2.76 cm H2O for I-Gel vs. 19.70±2.10 cm H2O for C-LMA). Pratheeba et al. [12] also compared the I-Gel and the Laryngeal Mask Airway Classic (LMA Classic) regarding ease of insertion and duration of insertion attempts. The mean duration of insertion attempts was 15.92±1.62 seconds in the I-Gel group, compared to 26.06±5.12 seconds in the LMA Classic group, a difference that was statistically significant (P = 0.0001). Helmy et al. [13] further corroborated these findings, showing that the I-Gel was associated with a significantly shorter duration of insertion attempts. The study reported a mean duration of insertion attempts of 15.6±4.9 seconds in the I-Gel group, compared to 26.2±17.7 seconds in the LMA group, with the difference being statistically significant (P=0.0023). However, the number of insertion attempts was statistically insignificant between the two study groups (P>0.05).

The post insertion hemodynamic vitals in both the groups were found to be statistically significant whereas SpO2 was found to be statistically insignificant.

The analysis of hemodynamic stability comparing the I-Gel and C-LMA groups highlights some important considerations for clinical practice. Both devices demonstrated the ability to maintain stable hemodynamic parameters during their use, which included pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and SpO2. These findings suggest that either device can be used effectively without significant disruption to the patient's cardiovascular stability, which is crucial during anaesthesia and surgical procedures. Pratheeba et al [12] aimed to compare the I-gel and Classic laryngeal mask airway and noted that I-gel produced less hemodynamic response, making it a viable alternative to classic LMA in clinical practice for maintaining airway patency during general anaesthesia. The heart rate for the first 25 min. after insertion of LMA classic was persistently high from the baseline when compared to I-gel and clinically significant (P = 0.0001).

Despite the similar performance metrics, the slight variations observed between the groups may be attributed to individual patient responses or minor differences in the way each device interacts with the patient's physiology. This equivalence in maintaining hemodynamic stability is essential as it ensures that the choice of airway management device does not adversely affect the patient's overall circulatory status, thereby supporting broader clinical applicability.

The mean airway sealing pressures with I-Gel were 24.4 ± 3.1 cm of H2O and with C-LMA were 19.2 ± 2.9 cm H2O which was statistically significant (P>0.05) [Table 6]. Though the airway sealing pressure of C-LMA was lower than that of I-Gel, it was enough to provide optimum ventilation, especially under positive pressure ventilation conditions. This is particularly important during anaesthesia and intensive care scenarios where a reliable airway seal can impact the overall success of ventilation strategies and patient outcomes.

The better sealing characteristics of the I-Gel may be attributed to its anatomical design and the material used, which conforms more effectively to the peri glottic structures. This conformity ensures a tighter fit and less air escape, thereby enhancing the efficiency of ventilation and reducing the risk of potential complications such as aspiration or inadequate ventilation. This feature makes the I-Gel particularly suitable for cases where maintaining a robust and reliable airway is critical, thus supporting its preferred use in various medical and emergency scenarios. A study by Helmy et al. [13] showed that airway sealing pressure was (25.6±4.9 vs. 21.2±7.7
cm of H2O) significantly higher among the patients of the I-gel group (P=0.016).
The incidence of adverse effects in the postoperative period among both the groups was statistically significant. In group I, no case complained of sore throat in the postoperative period whereas in group II, 16.7% patients complain of sore throat. Similarly, none of the patients in group I complained of hoarseness of voice and nausea and vomiting, whereas in group II, 10% patients complained of hoarseness of voice and 6.7% patients complain of nausea and vomiting.
The lack of complications like sore throat and hoarseness with the I-Gel suggests that it may be less invasive and gentler on the patient’s airway, an advantage in both short-term procedures and long-term care, where minimizing patient discomfort and potential injury is crucial. Similarly, the reduced incidence of nausea and vomiting indicates a possibly lower stimulation of the gag reflex and less gastric insufflation, factors that are critical in avoiding postoperative discomfort and more serious complications such as aspiration. A study by Raman et al. [14] found that I-gel had a significantly higher overall and first attempt success rate of device placement compared to C-LMA, where more patients complained of pharynxo-laryngeal pain with the LMA Supreme than with the i-gel (17/39 (44%) vs 8/41 (20%); p = 0.053).
A study by Helmy et al. [13] showed that incidence of gastric insufflations was significantly more with LMA group 9 (22.5%) vs. I-gel group (5%) (P=0.016).
Overall, the low complication profile associated with the I-Gel underscores its potential benefits over the C-LMA in terms of patient comfort and safety. These attributes make the I-Gel a favourable choice in various clinical settings, potentially leading to improved patient satisfaction and outcomes. This advantage is particularly valuable in environments where the device may need to be in place for extended periods, or in patients who are at higher risk of airway-related complications.
The comprehensive analysis of demographic characteristics, insertion characteristics, hemodynamic stability, airway sealing pressure, and postoperative complications provides valuable insights into the comparative effectiveness of the I-Gel and C-LMA devices for airway management during elective surgeries. While both devices offer efficient insertion processes and adequate airway sealing capabilities, differences in physiological responses and postoperative outcomes warrant consideration when selecting the most appropriate device for individual patients. These findings contribute to the evidence base informing clinical decision-making and may guide the optimization of perioperative airway management strategies to enhance patient safety and outcomes.
Despite its contributions, this study is not without limitations. Firstly, the sample size may limit the generalizability of the findings, and larger-scale studies are warranted to confirm the observed trends and associations. Additionally, the study was conducted in a specific patient population undergoing elective surgeries, and the results may not apply to other surgical contexts or patient demographics.

**CONCLUSION**
In conclusion, the comparison between the I-Gel and C-LMA airway management devices across various metrics such as insertion characteristics, hemodynamic stability, airway sealing pressure, and complication rates suggests that the I-Gel generally performs better in clinical settings. The I-Gel offers faster and easier insertion, superior airway sealing pressures, and notably lower complication rates, making it an advantageous choice for ensuring efficient and safe airway management. While both devices maintain adequate hemodynamic stability, the ease of
use, improved patient comfort, and enhanced safety profile of the I-Gel make it a preferable option for a wide range of medical procedures, particularly in scenarios requiring quick and reliable airway control.

Declaration By Authors
The authors hereby declared that it was their original peace of research and had not been sent to any other journal for publication.

Ethical Approval: Approved.

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Conflict Of Interest: The authors declared no conflict of interest.

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