

## COMPARISON OF OROPHARYNGEAL LEAK PRESSURE (OLP) OF I-GEL AND BLOCKBUSTER LMA DURING LAPAROSCOPIC CHOLECYSTECTOMY

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#### KEYWORDS

Oropharyngeal leak pressure, i-gel, BlockBuster LMA, laparoscopic cholecystectomy, supraglottic airway devices.

#### ABSTRACT:

**Background:** Supraglottic airway devices (SADs) such as the i-gel and the BlockBuster LMA are widely used in various types of surgeries to provide a secure airway and minimize the complications associated with endotracheal intubation. In laparoscopic cholecystectomy, oropharyngeal leak pressure (OLP) is a key indicator of how well an SAD can maintain a seal under positive pressure ventilation, especially with elevated intra-abdominal pressure during pneumoperitoneum. While several SADs are commercially available, there is a paucity of data comparing the i-gel and the BlockBuster LMA with regard to OLP in laparoscopic cholecystectomy.

**Methods:** A randomized comparative study was conducted in 70 adult patients (ASA I–II, aged 18–45 years) undergoing elective laparoscopic cholecystectomy under general anesthesia. Participants were allocated into two groups of 35 each: Group I (i-gel) and Group B (BlockBuster LMA). The primary outcome was OLP measured at four time points: (1) 1 minute after SAD insertion, (2) 5 minutes after pneumoperitoneum, (3) 30 minutes after pneumoperitoneum, and (4) 5 minutes after release of pneumoperitoneum. Secondary outcomes included peak inspiratory pressure (PIP), ease and time of insertion, hemodynamic changes, and device-related complications.

**Results:** The mean OLP values were significantly higher in the BlockBuster LMA group across all four time points compared to the i-gel group ( $p < 0.001$ ). However, peak inspiratory pressures and hemodynamic parameters did not differ significantly between the groups ( $p > 0.05$ ). The time to insert the device and the number of insertion attempts were comparable, and both devices demonstrated good airway quality with no clinically significant difference in complications.

**Conclusion:** The BlockBuster LMA provided higher oropharyngeal leak pressures compared to the i-gel in laparoscopic cholecystectomy. Both devices achieved adequate ventilation and demonstrated comparable safety profiles. The BlockBuster LMA may be preferable in clinical scenarios where higher OLP is desired, although i-gel remains a reliable alternative.

## INTRODUCTION

Laparoscopic cholecystectomy is a common procedure for gallbladder pathology, especially cholelithiasis, offering reduced postoperative pain, shorter hospital stays, and faster recovery compared to open cholecystectomy [1]. General anesthesia with endotracheal intubation is conventionally employed to secure the airway and facilitate controlled ventilation in these procedures. However, due to anesthesia-related concerns such as airway trauma, sympathetic stimulation during intubation, and hemodynamic fluctuations, supraglottic airway devices (SADs) have gained increasing popularity as a less invasive alternative [2].

Among the SADs, the i-gel and BlockBuster LMA have demonstrated notable efficacy for both routine and emergency airway management [3,4]. The i-gel is a second-generation SAD made of a thermoplastic elastomer that adapts to the hypopharyngeal anatomy without an inflatable cuff, potentially minimizing complications like sore throat and mucosal pressure [5]. The BlockBuster LMA, in contrast, is also a newer design with a cuff, but includes a built-in channel for easy gastric tube placement and a reinforced tip that can improve the seal, especially under moderate to high airway pressure conditions [6]. During laparoscopic surgery, the intra-abdominal insufflation of carbon dioxide (CO<sub>2</sub>) leads to elevated airway pressures, making the measurement of oropharyngeal leak pressure (OLP) critical for ensuring an effective seal of the airway device [7].

OLP reflects how well an SAD can withstand increases in airway pressure without leaking, which has implications for adequate ventilation and prevention of gastric insufflation. Previous comparative studies have reported diverse OLP values for i-gel and other LMAs; however, data comparing the i-gel and the BlockBuster LMA specifically in the context of laparoscopic cholecystectomy remain limited [8]. Identifying which device maintains a higher OLP can inform clinical decisions, especially for patients at risk for aspiration or those requiring higher ventilatory pressures.

This study was therefore designed to compare the i-gel with the BlockBuster LMA in terms of OLP, peak inspiratory pressure (PIP), ease and time of insertion, and device-related complications in patients undergoing elective laparoscopic cholecystectomy. We hypothesized that the BlockBuster LMA might provide a higher OLP due to its inflatable cuff and integrated design. The clinical applicability of these findings would help anesthesiologists make evidence-based choices regarding supraglottic devices in laparoscopic procedures [3,6,7,8].

## MATERIALS AND METHODS

### Study Design and Venue

This randomized comparative study was conducted in the Department of Anaesthesiology & Critical Care, Dr. S. N. Medical College and its associated hospitals in Jodhpur, Rajasthan. Institutional Ethical Committee approval was obtained, and written informed consent was secured from all participants. The study duration spanned from July 2022 to December 2022.

### Participants

Seventy adult patients (age 18–45 years) belonging to ASA physical status (PS) I or II, scheduled for elective laparoscopic cholecystectomy under general anesthesia, were enrolled. Patients were excluded if they met any of the following criteria:

- Emergency surgery
- Pregnancy
- Known airway anomalies (e.g., abnormal laryngeal or pharyngeal anatomy)
- Suspected difficult airway
- Risk factors for gastric reflux or significant risk of aspiration

### Sample Size Calculation

A sample size calculation was based on a previous study that reported a mean difference in OLP between two SAD groups of approximately 4 cmH<sub>2</sub>O, with a standard deviation of around 5 cmH<sub>2</sub>O [Sang Yoong Park et al.]. Using a type I error ( $\alpha$ ) of 0.05 and a study power (1 –  $\beta$ )

of 0.90, the formula suggested a minimum of 32 participants per group. Accounting for a 10% dropout or contingency, 35 participants per group were finally recruited (total N = 70).

### Randomization and Allocation

All patients meeting inclusion criteria were approached, and informed consent was obtained. Participants were assigned into one of two groups using a computer-generated random number table. Allocation concealment was maintained using sealed opaque envelopes opened just before induction of anesthesia.

- **Group I (n=35):** Airway secured with i-gel
- **Group B (n=35):** Airway secured with BlockBuster LMA

### Preoperative Preparation

Patients were instructed to follow standard fasting guidelines (clear liquids up to 2 hours, solids up to 6 hours, and a fatty meal up to 8 hours preoperatively). On arrival to the operating room, standard ASA monitors (noninvasive blood pressure, electrocardiography, and pulse oximetry) were applied, and baseline parameters such as heart rate (HR), blood pressure (BP), and oxygen saturation (SpO<sub>2</sub>) were recorded. A peripheral intravenous (IV) cannula (18G or 20G) was inserted, and lactated Ringer's solution was started.

### Anesthetic Technique

All patients received midazolam 0.05 mg/kg IV and fentanyl 2 µg/kg IV as premedication. They were preoxygenated with 100% oxygen for 3 minutes. Induction of anesthesia was achieved with propofol 2–3 mg/kg IV, titrated until loss of eyelash reflex and no response to jaw thrust. A non-depolarizing muscle relaxant (atracurium 0.5 mg/kg IV) was administered, and mask ventilation was performed for 3 minutes before inserting the respective SAD. The size of i-gel or BlockBuster LMA was selected based on patient weight according to the manufacturer's guidelines; both devices were lubricated with 2% lignocaine jelly.

- **i-gel insertion:** The device was positioned with the patient's head in a neutral alignment. The leading soft tip was guided along the hard palate until resistance was felt.
- **BlockBuster LMA insertion:** The device was similarly positioned in a neutral head alignment, then gently advanced following the curvature of the hard and soft palate. The cuff was inflated as per manufacturer recommendations.

The supraglottic airway tube was then secured with tape over the chin. Anesthesia was maintained with sevoflurane (0.6–2%) in an oxygen/air mixture, along with intermittent doses of atracurium (0.1 mg/kg) through a closed circuit with a circle absorber. Ventilation was adjusted to a tidal volume of 6–8 mL/kg at a rate of 14–16 breaths/min to maintain end-tidal CO<sub>2</sub> (ETCO<sub>2</sub>) between 35–40 mmHg. Laparoscopic cholecystectomy was conducted under standard surgical conditions with CO<sub>2</sub> pneumoperitoneum set at 12–14 mmHg.

### Data Collection and Outcomes

1. **Oropharyngeal Leak Pressure (OLP):** Measured at four specific time points:
  - T1: 1 minute after insertion
  - T2: 5 minutes after pneumoperitoneum
  - T3: 30 minutes after pneumoperitoneum
  - T4: 5 minutes after release of pneumoperitoneum

To measure OLP, the expiratory valve of the circle system was closed at 35 cmH<sub>2</sub>O with a fixed flow of 3 L/min, and the airway pressure was noted when an audible leak was detected (either by hearing a leak at the mouth or over the neck).

2. **Peak Inspiratory Pressure (PIP):** Also recorded at T1, T2, T3, and T4.

3. **Insertion Characteristics:**

- **Ease of insertion:** Graded on a scale of 1 (easy, no maneuvers) to 3 (difficult, more than one maneuver).

- **Insertion time:** Time from picking up the device to successful confirmation of ventilation (bilateral chest movement, square-wave capnograph trace, and absence of gastric insufflation).
  - **Number of Attempts:** Up to three attempts were allowed; if unsuccessful, the case was considered a failure and secured with an endotracheal tube (excluded from analysis).
4. **Airway Quality:** Assessed via neck auscultation (excellent = no leak, good = slight leak but adequate ventilation, poor = significant leak or inadequate ventilation).
  5. **Gastric Tube Placement:** Subjectively graded (1 = easy, 2 = moderate, 3 = difficult).
  6. **Fiberoptic Glottic View:** A flexible bronchoscope was introduced through the device to visualize the glottic opening. The Brimacombe score was used:  
1:                   Vocal                   cords                   not                   seen  
2:       Vocal           cords       +       anterior       epiglottis       visible  
3:       Vocal           cords       +       posterior       epiglottis       visible  
4: Only vocal cords visible
  7. **Hemodynamic Parameters:** Heart rate, systolic BP, diastolic BP, mean arterial pressure (MAP), and SpO<sub>2</sub> measured at baseline, after induction, after device insertion, and then at 1, 3, 5, 10, 15, 20, 30 minutes, and every 15 minutes thereafter.
  8. **Complications:** Device displacement, blood on device, oropharyngeal trauma, hoarseness, or sore throat were recorded at the end of the surgery.

### Statistical Analysis

Collected data were compiled in Microsoft Excel and analyzed using MedCalc Statistical Software (version 20.115). Qualitative data are presented as numbers and percentages. Quantitative data are presented as means ± standard deviation or median (range) as appropriate. Between-group comparisons were made using the unpaired t-test for continuous variables and the Chi-square or Fisher's exact test for categorical variables. A p-value < 0.05 was considered statistically significant.

### Ethical Clearance

**CTRI Number:** CTRI/2022/06/043473

### RESULTS

A total of 84 patients were initially screened, of whom 14 were excluded (10 due to not meeting inclusion criteria, 4 due to refusal to participate). The remaining 70 patients were randomized into two equal groups (n=35 each). One patient in the i-gel group required conversion to endotracheal intubation due to repeated failed attempts; thus, 69 patients completed the protocol. Data analysis was conducted on these 69 patients (34 in the i-gel group, 35 in the BlockBuster group).

### Overall Findings (Descriptive)

In both groups, there were no statistically significant differences in demographic variables such as age, gender ratio, body weight, height, or ASA classification. The mean age in Group I (i-gel) was approximately 32 years, while Group B (BlockBuster) had a mean age of about 33 years (p > 0.05). The durations of anesthesia, surgery, and pneumoperitoneum were also comparable (p > 0.05).

Below is a summary of the key findings:

1. **Ease of Insertion and Number of Attempts**
  - Most devices in both groups were inserted on the first attempt (88.2% in i-gel vs. 77.1% in BlockBuster), with no significant difference (p > 0.05).
  - The insertion time was similar: Group I ~19 seconds vs. Group B ~20 seconds (p > 0.05).
2. **Airway Integrity and Quality**
  - Airway quality was rated as "excellent" or "good" in the majority of cases (>80% in both groups).

- Fiberoptic view scores showed a similar distribution, with no statistically significant differences ( $p > 0.05$ ).
- 3. **Gastric Tube Insertion**
  - Gastric tube placement was “easy” or “moderate” in nearly all patients, with no significant group difference ( $p > 0.05$ ).
- 4. **Hemodynamic Parameters**
  - Heart rate, systolic BP, diastolic BP, mean arterial pressure, and SpO<sub>2</sub> did not differ significantly between groups at any time point ( $p > 0.05$ ).

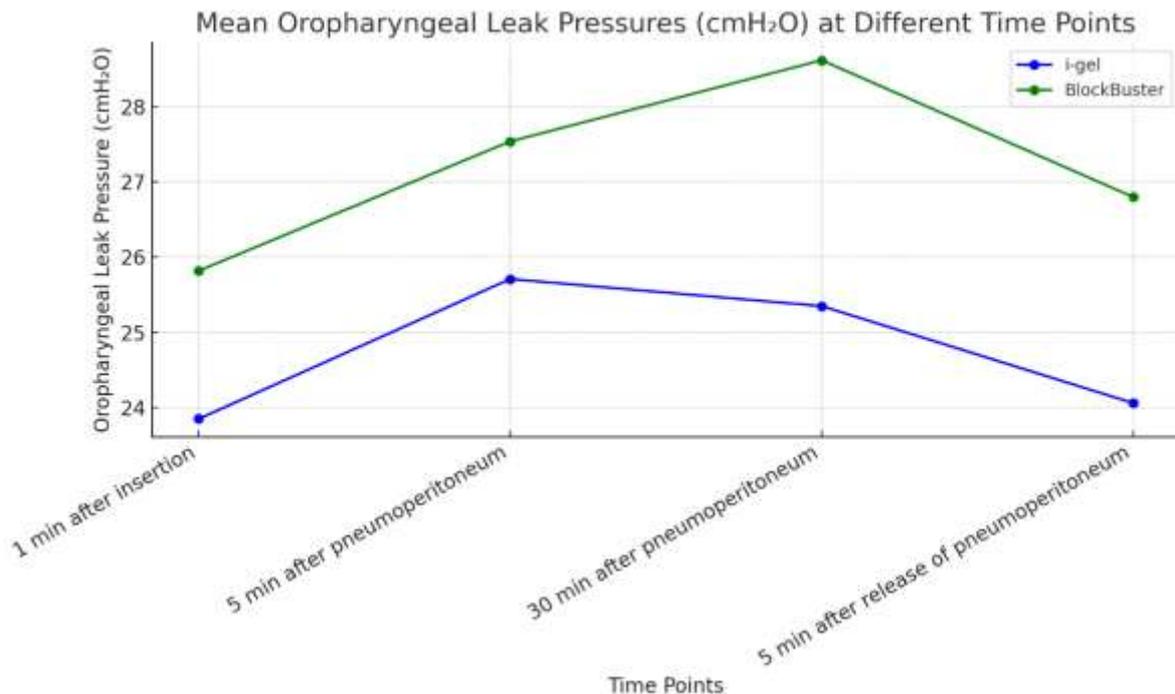
**Oropharyngeal Leak Pressure (Primary Outcome)**

Table 1 presents the OLP at four measured time points. The BlockBuster LMA consistently demonstrated a higher mean OLP compared to the i-gel. This difference was statistically significant ( $p < 0.001$ ) at all time points.

**TABLE 1. COMPARISON OF MEAN OROPHARYNGEAL LEAK PRESSURE**

Time Point	Group I (i-gel) Mean ± SD	Group B (BlockBuster) Mean ± SD	p-value
1 min after insertion (T1)	23.85 ± 1.92	25.82 ± 1.50	< 0.0001
5 min after pneumoperitoneum (T2)	25.71 ± 1.57	27.54 ± 1.42	< 0.0001
30 min after pneumoperitoneum (T3)	25.35 ± 1.74	28.62 ± 1.83	< 0.0001
5 min after release of pneumoperitoneum (T4)	24.06 ± 1.67	26.80 ± 1.84	< 0.0001

**FIGURE 1. MEAN OROPHARYNGEAL LEAK PRESSURES (CMH<sub>2</sub>O) AT DIFFERENT TIME POINTS**



**Figure 1** shows the Mean Oropharyngeal Leak Pressures (cmH<sub>2</sub>O) at different time points for the i-gel and BlockBuster groups. This line graph clearly delineates the differences between the groups across the various time points, with the BlockBuster LMA consistently demonstrating a higher mean OLP.

**Peak Inspiratory Pressure (Secondary Outcome)**

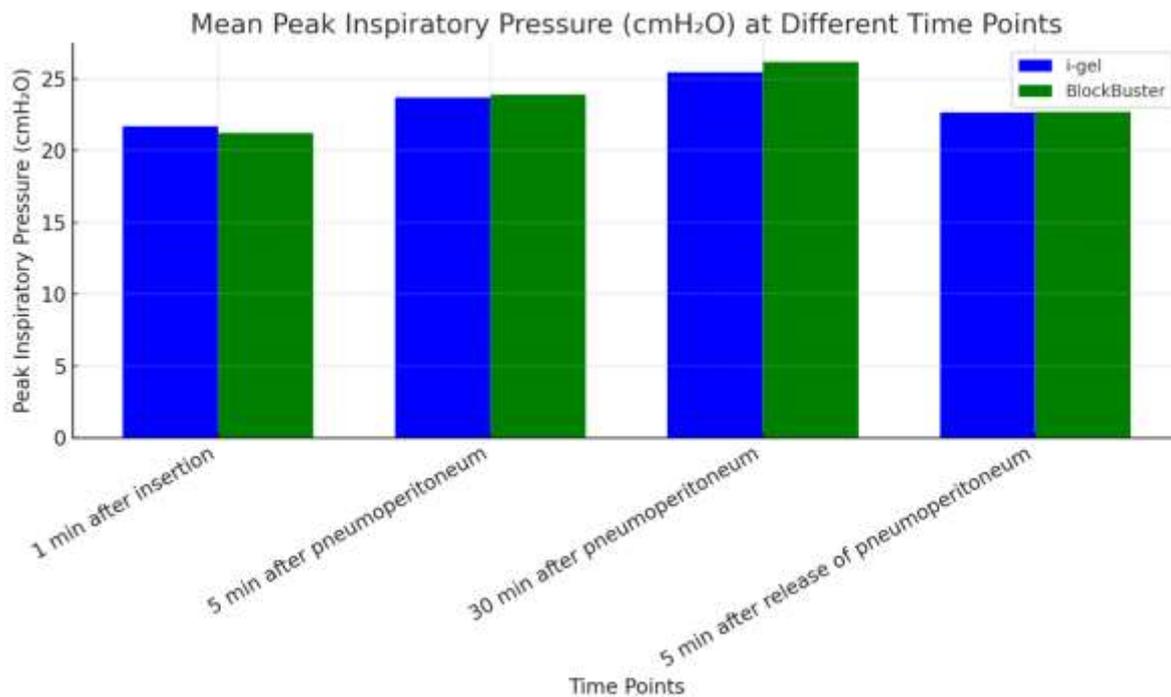
Table 2 shows that PIP did not differ significantly between the two groups at any measured time interval ( $p > 0.05$ ).

**TABLE 2. COMPARISON OF MEAN PEAK INSPIRATORY PRESSURE**

Time Point	Group I (i-gel) Mean $\pm$ SD	Group B (BlockBuster) Mean $\pm$ SD	p-value
1 min after insertion (T1)	21.68 $\pm$ 2.53	21.23 $\pm$ 2.28	0.442
5 min after pneumoperitoneum (T2)	23.68 $\pm$ 2.43	23.89 $\pm$ 2.18	0.707
30 min after pneumoperitoneum (T3)	25.44 $\pm$ 2.29	26.17 $\pm$ 2.01	0.162
5 min after release of pneumoperitoneum (T4)	22.65 $\pm$ 2.28	22.71 $\pm$ 2.02	0.897

(Unpaired *t*-test)

**FIGURE 2. MEAN PEAK INSPIRATORY PRESSURE (CMH<sub>2</sub>O) AT DIFFERENT TIME POINTS**



**Figure 2** presents the Mean Peak Inspiratory Pressure (cmH<sub>2</sub>O) at different time points as a bar chart, comparing the i-gel and BlockBuster groups. The data shows that the PIP did not differ significantly between the two groups at any measured interval.

**Device-Related Complications**

Complications such as blood staining on the device, displacement, trauma to the lip, hoarseness, and sore throat occurred infrequently and showed no statistically significant difference between the two groups ( $p > 0.05$ ). A slightly higher incidence of blood on the device was noted in the i-gel group, but this did not reach statistical significance ( $p = 0.053$ ).

## DISCUSSION

This randomized comparative study evaluated the i-gel and the BlockBuster LMA for securing the airway in patients undergoing laparoscopic cholecystectomy. The principal finding is that the BlockBuster LMA demonstrated significantly higher oropharyngeal leak pressures at all measured time points compared with the i-gel. Both devices, however, provided similar peak inspiratory pressures, safety profiles, and success rates in insertion.

Our results align with previous observations that cuffed LMAs, especially newer-generation devices, often exhibit higher OLPs than cuffless SADs such as the i-gel [1,4]. Specifically, the BlockBuster LMA's inflatable cuff might confer a better anatomical seal, which becomes particularly relevant during pneumoperitoneum where higher airway pressures are expected [9]. In laparoscopic procedures, maintaining a secure seal is paramount to avoid air leaks, ensure adequate ventilation, and reduce the risk of gastric distention [2,3].

The i-gel, on the other hand, relies on a unique gel-like thermoplastic elastomer, anatomically shaped to fit the perilaryngeal structures without inflation [5]. This design can shorten insertion times and minimize cuff-related complications, such as compression of mucosal structures [10]. In our study, although the mean insertion times were statistically similar (approximately 19–20 seconds), the i-gel insertion tended to be marginally faster, reflecting its simpler design. Nevertheless, this difference was not statistically significant, consistent with findings from other investigators [6,8].

The difference in OLP might not alone dictate the choice of device in all scenarios. The clinical significance of a few cmH<sub>2</sub>O difference in OLP depends on patient and surgical factors. For laparoscopic cholecystectomy, which often involves moderate to high airway pressures due to insufflation, a higher OLP can be advantageous. However, for lower-pressure surgeries or shorter procedures, i-gel's ease of use could be equally suitable. Notably, both devices in this study provided adequate ventilation without compromising hemodynamics or requiring frequent repositioning, indicating that either is acceptable for laparoscopic cholecystectomy from a clinical standpoint [7].

Regarding complications, both SADs were associated with low rates of adverse events. Minor blood staining on removal, displacement, and mild sore throat were the most commonly reported issues. These events were within acceptable clinical limits and did not differ significantly between groups, consistent with other studies showing that both i-gel and modern LMAs are generally safe with minimal adverse outcomes [3,9].

A limitation of our study is that it was conducted in a single center with a relatively modest sample size. We also excluded patients with high BMI or anticipated difficult airways, which limits the generalizability of our findings to these populations. Additionally, although the BlockBuster LMA had a higher OLP, we did not evaluate potential cuff hyperinflation or the volume of air needed to achieve the seal, which could influence pharyngeal mucosal integrity. Further research could expand on these findings by including obese patients, prolonged laparoscopic procedures, or other specialized contexts. Evaluating the cost-effectiveness of these devices, along with patient-reported outcomes such as postoperative pharyngeal discomfort, would also provide a more holistic assessment [4,9,10].

In summary, the BlockBuster LMA exhibits higher oropharyngeal leak pressures in laparoscopic cholecystectomy than the i-gel, without increasing complications or insertion difficulty. However, the i-gel remains a reliable alternative, particularly in settings where a slightly lower OLP is acceptable or when a cuffless device is preferred.

## CONCLUSION

In this randomized comparative study of 70 patients undergoing laparoscopic cholecystectomy, the BlockBuster LMA demonstrated significantly higher oropharyngeal leak pressures than the i-gel at all time points assessed. Both devices were otherwise comparable in terms of insertion characteristics, peak inspiratory pressures, hemodynamic stability, and safety profiles. For procedures requiring higher airway pressures, the BlockBuster LMA may be the preferred

choice, although the i-gel remains a dependable alternative for general use in laparoscopic cholecystectomy.

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