***International Journal of Biomedical and Advance Research***
ISSN: 2229-3809 (Online); 2455-0558 (Print)
Journal DOI: 10.7439/ijbar
CODEN: IJBABN

**Original Research Article**

# Comparison of clinical performance of I-Gel with LMA-Proseal in elective surgeries under general anesthesia

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## Abstract

**Aim:** To compare insertion characteristics of two different supraglottic devices [I-gel and LMA-Proseal] and to observe any associated complications.

**Materials and Methods**: This prospective, randomized study was conducted in 60 patients [Group A- LMA-Proseal (n = 30) and Group B - I-Gel (n =30)] of ASA grades I/II, of either sex in the age group 18-60 years. Both groups were compared with respect to haemodynamic response to device insertion, success rate of insertion, time taken for insertion, ease of gastric tube placement, airway trauma by post operative blood staining of the device, tongue, lip and dental trauma and 24 hours after surgery we watched for sore throat, hoarseness and dysphonia.

**Result:** Haemodynamic response to device insertion were comparable in both the groups (p >0.05). Mean insertion time for the I-gel (11.47 ± 1.914 sec) was significantly lower than that of the PLMA (13.53 ± 3.92 sec) (P = 0.0002). I-gel was easier to insert with a better anatomic fit. The success rate at first attempt of insertion were 29/30 (96.67%) for I-gel & 28/30 (93.3%) for LMA - ProSeal (P=0.0002). Ease of gastric tube insertion was significantly higher in I-gel group (P = 0.116). Blood staining of the device, trauma (tongue, lip and dental) and 24 hrs complications after surgery were more with Group A.

**Conclusion:** I-Gel is better than LMA-Proseal in terms of faster insertion and ease of insertion with a low incidence of pharyngolaryngeal morbidity

**Keywords:** I-Gel, LMA–ProSeal, supraglottic airway device

## 1. Introduction

Anesthesiologist has the prime responsibility to provide the adequate ventilation to the patient. The endotracheal tube first came in to existence in 1800 and has become the gold standard for providing ventilation during anesthesia. [1,2] With day today improvement in the pressure controlled ventilation, the I-gel a unique disposable supraglottic airway a latex free supraglottic device came into existence. It is made of medical grade thermoelastic elastomer which is soft gel like transparent. The inherent quality with I-gel is that it anatomically fits the perilaryngeal and hypopharyngeal 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. [3] 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. Considering these benefits of I-gel, we conducted a study to compare the insertion characteristics I-gel and LMA-Proseal, and to observe any associated complications.

## 2. Material and Methods

The present study was conducted in the Department of Anesthesiology and critical Care, Acharaya Shri Chander College of Medical Sciences (ASCOMS), Sidhra, Jammu, J&K, India. After the approval of College ethical committee, Sixty ASA grade I and II adult patients of either sex, aged 18-60

years, scheduled for elective meshplasty, laparoscopic cholecystectomy and excision biopsy were selected for study. Patients with known difficult airway, cervical spine disease, mouth opening < 2.5 cm, full stomach, hiatus hernia or gastroesophageal reflux disease & emergency surgeries were excluded from the study. All the patients were prepared by overnight fasting and tablet Midazolam 7.5 mg was given on the night before surgery. Injection Ranitidine 50 mg and Ondansetron 0.1mg/kg was given in the preoperative room intravenously 45 minutes before the surgery. Anesthesia was induced with Propofol 2-2.5 mg/kg and Fentanyl 0.5–1.5µg/kg. Neuromuscular blockade was achieved with Rocuronium 0.6 mg.kg. Both I-gel and LMA – ProSeal were lubricated with water soluble jelly. Once adequate depth of anaesthesia was achieved, each device was inserted by an experienced anesthesiologist. Both the devices were fixed by taping the tube over the chin and lubricated gastric tube was placed into the stomach through the gastric channel. Maintenance was achieved by oxygen, nitrous oxide, isoflurane and intermittent doses of intravenous Rocuronium. Intraoperative heart rate, noninvasive blood pressure (systolic, diastolic, mean arterial pressure), oxygen saturation were recorded before insertion, immediately after insertion 1, 2, 3, 5, 10 minutes after insertion of LMA-Proseal and I-Gel. An effective airway was judged by a square wave capnograph trace, normal thoracoabdominal movement and absence of leak. If an effective airway could not be achieved the device was removed and three attempts were permitted before failure of insertion was recorded. If three attempts were unsuccessful either an alternative device was inserted or the trachea was intubated. The number of insertion attempts was recorded. Insertion time was recorded by the independent observer defined as the time interval between picking up the device and securing an effective airway. 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 within two attempts.

**2.1 Statistical analysis**

Statistical analysis was done by SSPM statistical software. 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. Probability value <0.05 was considered statistically significant.

## 3. Results

There was no difference between the two groups with respect to demographic and surgical details (Table1). In all patients the supraglottic device, I-gel or LMA– ProSeal, was inserted within three attempts.

**Table 1: Demographic characteristics of two Groups**

| Particulars | Group B (n=30) | Group A (n=30) | P Value | Statistical significance |
|---|---|---|---|---|
| Age (yrs) | 47.63 ± 61.64 | 47.80 ± 45.23 | >0.005 | NS |
| Weight (kg) | 60.03 ± 84.06 | 59.80 ± 124.14 | >0.005 | NS |
| Sex(M/F) | 07/23 | 09/21 | >0.005 | NS |
| ASA (I/II) | 24/6 | 24/6 | >0.005 | NS |
| Duration of surgery(Min) | 50.45±12.32 | 51.31±13.10 | >0.005 | NS |
| Data expressed as mean±SD, Numbers(n),NS=non significant | | | | |

The success rate at first attempt of insertion were 29/30 (96%) for I-gel & 24/30 (80%) for LMA–ProSeal which was statistically significant (p<0.05). The mean insertion time in I-Gel was (11.47 secs), while insertion time in LMA-Proseal was (13.53 secs) and the highly significant (p<0.0002) (Table 2). The ease of insertion of gastric tube was more with I-gel (28/30) than with LMA– ProSeal (26/30) (Table 2).

**Table 2: Comparison of ease of insertion and Insertion attempts in two group**

| Parameter | Group B (n=30) | Group A (n=30) | P value | Statistical significance |
|---|---|---|---|---|
| Ease of device insertion (n):<br>-easy<br>-difficult<br>-failed | <br>29<br>1<br>0 | <br>24<br>6<br>0 | >0.002 | Significant |
| Ease of gastric tube insertion (n):<br>-easy<br>-difficult<br>-failed | <br>28<br>2<br>0 | <br>26<br>4<br>0 | >0.005 | NS |
| Mean time of insertion (sec) | 11.47 | 13.53 | >0.0002 | Significant |
| Data expressed as mean±SD, Numbers(n),NS=non significant | | | | |

Tongue , lip & dental trauma was more with LMA – ProSeal (2/30) than with I-gel (1/30) and blood staining of the device was more with LMA – ProSeal (3/30) than with I-gel (1/30) but the results were not statistically significant (Table 3). The incidence of Sore throat in I-Gel was (2/30), Dysphonia (1/30) without any hoarseness, while the incidence of in LMA-Pro-seal was (1/30), dysphonia (2/30) and hoarseness (1/30) Table-3.

**Table 3: Comparison of complications of two devices**

| Complications | Group B (n=30) | Group A (n=30) | P value | Statistical significance |
|---|---|---|---|---|
| Blood staining of devices:<br>-Yes<br>-No | <br>1<br>29 | <br>3<br>27 | >0.005 | NS |
| Tongue–lip–dental trauma:<br>-Yes<br>-No | <br>1<br>29 | <br>2<br>28 | >0.005 | NS |
| Sore throat :<br>- Yes<br>-No | <br>2<br>28 | <br>1<br>29 | >0.005 | NS |
| Hoarseness of voice :<br>-Yes<br>-No | <br>0<br>30 | <br>1<br>29 | >0.005 | NS |
| Dysphonia:<br>Yes<br>No | <br>1<br>29 | <br>02<br>28 | >0.005 | NS |
| Data expressed as Numbers(n),NS=non significant | | | | |

The mean heart rate of I-Gel was (84.32 ± 1.36) and of LMA-Pro-seal was (85.06 ± 4.92) which was statistically in significant (p>0.05) (Figure 1). The mean of *Mean Arterial* Pressure (mmHg) in I-Gel was (94.93 ± 0.54) while in LMA-Pro-seal was (93.55 ± 7.11) (p>0.05) (Figure 2).

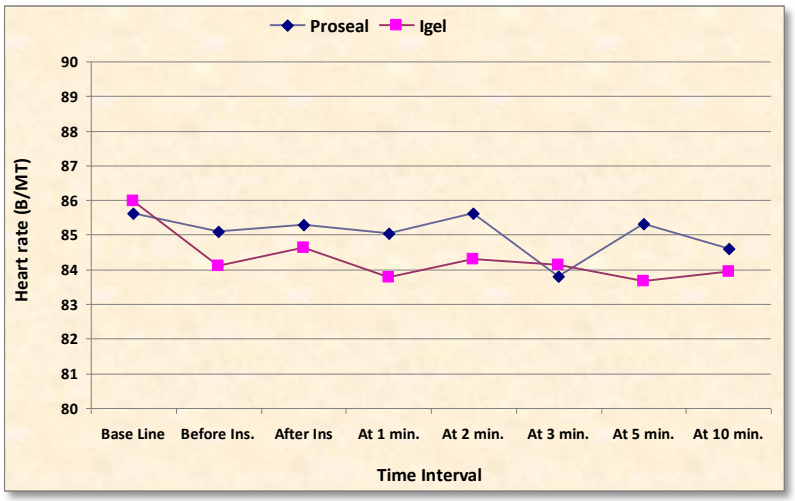


**Figure 1: Comparison on Heart Rate between 2 groups**

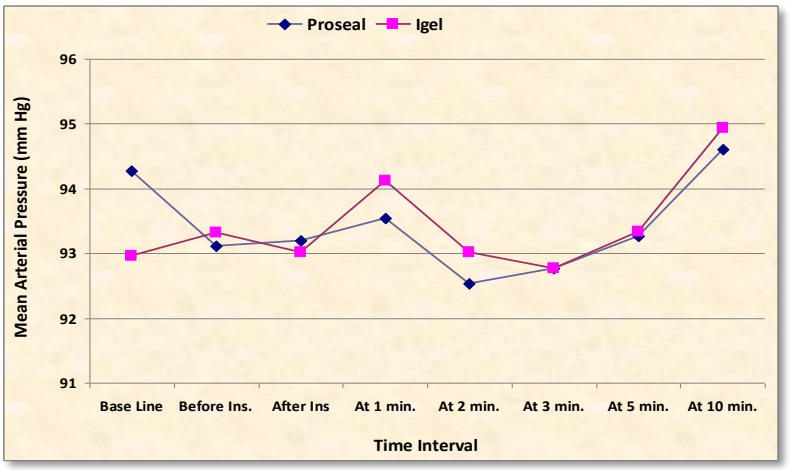


**Figure 2: Comparison of *Mean Arterial* Pressure (mmHg) in 2 Groups**

## 4. Discussion

I-Gel is a new innovation without an inflatable cuff, and is latex free disposable made of thermoplastic elastomer.[3] The results of the present clinical trial has shown ample advantages of i-gel including high success rate at first attempt, easy insertion, shorter insertion time and features designed to separate the gastrointestinal tract and respiratory tract which allows a gastric tube to be passed easily into the stomach as it has a separate gastric channel.

[5] The LMA Pro- seal may impede its proper placement and may be cause of various malpositions after insertion, besides it can absorb anesthetic gases leading to increased mucosal pressure. [6-9] Inflatable masks have the potential hazard to cause tissue distortion, venous compression and nerve injury which explains the increased incidence of postoperative complications. [3] Trauma at the time of insertion, multiple insertions, and pressure effect by cuff against the pharyngeal mucosa, cuff volume and pressure [13-15] all have been found to be the culprits for postoperative complications. In our study we observed Mean Heart Rate (beat/min) in group LMA-Proseal and group I-Gel at base line, before insertion, immediately after insertion and at 1, 2, 3,5,10 minutes. No significant difference in heart rate was found between 2 groups as reported by Helmy AM *et al* [10].

In our study, we compared the sizes of the Group LMA-Proseal and Group I-Gel; Size 3 LMA-Proseal was used in 25 (83.33%) patients and size 4 LMA-Proseal was used in 5 (16.67%) patients. Whereas size 3 I-Gel was used in 24 (80%) patients and size 4 I-Gels was used in 6 (20%) patients. The time of insertion between LMA-Proseal was significant lower in I-gel. Chauhan at el [11] in their study concluded that the mean insertion time for the I-Gel (11.12 ± 1.814 sec) was significantly lower than that of the LMA-Proseal (15.13 ± 2.91 sec). In our present study the complications at the end of procedure for blood staining; tongue, lip and mouth trauma was 3 (10.00%) patients of group LMA-Proseal had blood staining, 2 (6.67%) patients had tongue, lip and mouth trauma. One (3.33%) patient of group I-Gel had blood staining of I-Gel and 1 (3.33%) patient had tongue, lip and mouth trauma.

Singh I *et al* [12] in which they concluded that the tongue, lip & dental trauma was more with LMA-Proseal (5/30) than with I-Gel (1/30) and blood staining of the device was more with LMA-Proseal (6/30) than with I-Gel (1/30) but the results were not statistically significant. In our study, we compared the complications 24 hours after surgery in group LMA-Proseal and group I-Gel. Patients in the both the groups were asked for sore throat (constant pain, independent of swallowing), hoarseness (change in voice) and dysphonia (difficulty or pain in speaking) 24 hours after the surgery. In group LMA-Proseal 2 (6.67%) patients had sore throat, 1 (3.33%) patient had hoarseness and 2 (6.67%) patients had dysphonia whereas in group I-Gel 1 (3.33%) patient had sore throat, 1 (3.33%) patient had dysphonia and none of the patient had hoarsene Other studied also reported no statistically significant difference between both I-Gel and classical laryngeal mask airway groups with regard to sore throat was (constant pain, independent of swallowing), hoarseness (change in voice) and dysphonia (difficulty or pain in speaking) 24 hours after the surgery. [10]

So from our study, it can be concluded that I-gel is comparable to the LMA-Proseal in securing patent airway during controlled ventilation. Both LMA-Proseal and I-gel do not cause any significant alteration in the hemodynamic status and $SpO_2$ of the patients. I-Gel is better than LMA-Proseal in terms of faster insertion and ease of insertion with a low incidence of pharyngolaryngeal morbidity. It requires less manipulation and no cuff inflation is required, therefore securing an airway is rapid in most of the patients. It clearly elucidates that the I-gel appears to have more efficacious characteristics than LMA-Proseal.

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