Comparison of clinical performance of I-GEL and proseal LMA in elective surgeries

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ABSTRACT

BACKGROUND: Objective: I-gel is a novel supraglottic airway device without an inflatable cuff which differentiates it from other supraglottic airway devices. This study was carried out to compare the clinical performance of I-gel with PLMA in adult patients undergoing elective surgeries under general anaesthesia.

MATERIALS AND METHODS: A prospective randomised controlled study was carried out in 60 ASA I/II patients undergoing elective surgeries. They were randomly divided into two groups comprising of 30 patients each. GROUP-I: Patients in whom I GEL was inserted. Group-P: Patients in whom PLMA (Proseal laryngeal mask airway) was inserted. Following parameters were recorded, tabulated and statistically analysed in both the groups, Effective airway time, attempts for insertion of the device and nasogastric tube, hemodynamic changes, oxygen saturation, EtCO₂ and post operative complications. RESULTS: In our study, the Effective airway time was significantly less in I-gel group (17.63 ± 2.22 sec) compared to PLMA group (30.93 ± 2.67 sec), p < 0.001. Regarding ease of insertion, attempts for insertion of airway device and nasogastric tube, hemodynamic changes, oxygen saturation, EtCO₂ and post operative complications were comparable in both the groups.

CONCLUSION: Thus I-Gel is an acceptable alternative supraglottic airway device to PLMA with significantly lesser time of insertion.

Keywords: I-Gel, LMA, airway device

INTRODUCTION

The major responsibility of anaesthesiologist is to provide adequate ventilation to the patient. Management of airway has come long way since the development of endotracheal intubation to the present day usage of sophisticated devices. The success of the classic laryngeal mask airway in resuscitation and anaesthesia has led to the introduction of several supraglottic airway devices into clinical practice. They offer several advantages over the tracheal tube with regard to ease of insertion, hemodynamic stability, favourable respiratory mechanics and decreased airway morbidity.¹⁻⁵

Proseal laryngeal mask airway (PLMA) and I-gel are two supraglottic airway devices designed for use with spontaneous as well as intermittent positive pressure ventilation, which provide higher oropharyngeal seal pressure(OSP).⁶⁻⁷ The oesophageal seal of the two devices was compared and it was reported that both the devices allowed a fast and complete drainage of oesophageal fluid through the open oesophageal lumen. The PLMA has been used as a safe alternative to endotracheal tube during PPV while the I-Gel is still being evaluated for its use in anaesthesia with PPV. I-gel airway is a novel and Innovative supraglottic airway management device designed to overcome the limitations of LMA Proseal. It is a truly anatomical device, achieving a mirrored impression of the pharyngeal, laryngeal and peri laryngeal

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structures, without causing compression or displacement trauma to the tissues and structures in the vicinity. \(^7-11\) The aim of this study was to compare the clinical performance of I-Gel and PLMA during routine surgical procedure.

**MATERIALS AND METHODS**

After the approval of local scientific and ethical committee, a prospective randomised comparative study was carried out with 60 adult patients of either sex between 20 - 60 years, who were randomly selected from the list of routine surgical procedures under general anaesthesia lasting \(<2hr\), from our institute, SSG Hospital, Govt. Medical College, Vadodara during the period of January 2010 to March 2011.

**Selection of the Patient:**

- ASA physical status I or II
- Age group between 20 – 60 years
- Undergoing Elective surface surgical procedure (breast fibroadenoma, inguinal hernia, gynaecomastia, lipoma / sinus, skin grafting)

**Exclusion Criteria:**

- Patients with anticipated difficult airway.
- Patients with risk of regurgitation or aspiration.
- Patients with cervical spine disease.
- Morbidly obese patients.
- Pregnant patients.
- Patients with URTI in past 10 days.
- Mouth opening < 2.5 cms.

**Investigation and Consent:**

Routine investigations carried out in all the patients. All patients underwent detailed pre-anaesthetic check up. All the selected patients were explained about the purpose, procedure and side effects of the study and written informed consent was taken.

**Pre-operative Preparation:**

All the patients were kept nil by mouth (NBM) for 10 hrs. All the patients were randomly allocated in two groups. **Group I:** Patients in whom I GEL was inserted. **Group P:** Patients in whom PLMA (Proseal laryngeal mask airway) was inserted.

**Anaesthesia Procedure:**

On the day of surgery, Inj.Glycopyrrolate 0.2 mg i.v: Inj.Ranitidine 50 mg i.v: and Inj. Ondensetron 4mg i.v; 10 mins before surgery. Inj. Midazolam 1mg i.v and Inj. Fentanyl 1.5µ/kg i.v administered 2 mins before surgery. All the patients were pre oxygenated for 5mins by face mask with 100%O\(_2\). Anaesthesia was induced with Inj. propofol 2mg/kg i.v. On disappearance of eyelash reflexes and after confirmation of ventilation muscle relaxant Inj. Succinylcholine 1mg/kg i.v was administered and patients were ventilated.

In group I patients the airway was secured using I-Gel of appropriate size(size 4 for adult patients weighting 60-90 kg and size3 for adult patients weighing 30-60 kg), while in group P patients airway was secured with using proseal LMA of appropriate size by digital method. (size 3 for adults weighing 30-50kgs and size 4 for adults weighing 50-70kgs)

**Proper placement of either of the devices was confirmed by:**

- B/L equal air entry
- B/L equal chest movements
- Absence of gastric insufflations over the epigastrium
- No audible leak
- Capnography tracing

If first attempt remained unsuccessful, 2\(^{nd}\) attempt with same device was repeated, maximum three attempts were tried before going for endotracheal tube insertion. Total number of attempts for I-gel/PLMA was recorded in both the groups. Nasogastric tube was inserted in all the patients. Hemodynamic parameters like heart rate, systolic and diastolic blood pressure as well as percentage oxygen saturation and end tidal CO2 were recorded before, during and after induction and after IGEL / PLMA insertion at 5, 10, 15, 20, 30, 45, 60 minutes during course of surgery, at the time of removal and in the post
operative period. Anaesthesia was maintained with O₂, N₂O and Isoflurane and neuromuscular agent inj. Vecuronium Bromide 0.1g/kg. Reversal was achieved using inj. Neostigmine 0.05mg/kg + inj. Glycopyrrolate 8-10µg/kg given intravenously. After completion of surgery, patients received O₂ 100% for at least 5mins, I GEL /PLMA were removed when patients were awake (responding to verbal commands with adequate tidal volume and good tone). Presence of any staining on the device and any lip /tongue injury was noted. Airway related complications (laryngospasm, bronchospasm, coughing) were recorded. Following observations were done:

1. **Effective airway time** (time from picking up of device to time of confirmation of bilateral equal air entry by mechanical ventilation)
2. **Ease of insertion of device** (Defined as insertion within the pharynx without resistance in a single maneuver.)
   - **Easy**: when device was inserted with ‘no or minimal resistance’.
   - **Difficult**: when device was inserted with significant resistance or impossible to pass without excessive force
3. **Number of attempts of insertion of each device.**
4. **Number of attempts of insertion of nasogastric tube.**
5. **Heart rate, blood pressure, SPO₂, EtCO₂ before and after induction and throughout surgery.**
6. **Post operative complications like**
   - Bronchospasm / laryngospasm
   - Tongue, Lip and dental trauma
   - Complaint of sore throat
   - Nausea/Vomiting

**Statistical Analysis:**

The results of the study were tabulated and statistically compared. All the qualitative data were analysed using Chi-square test and quantitative data using students unpaired t-test. Results were expressed as Mean±SD. ‘p’ value ≤ 0.05 were taken as statistically highly significant and values ≤ 0.001 were taken as statistically highly significant.

**RESULTS**

The two groups were comparable to each other w.r.t. age, weight, gender and ASA physical status.

<table>
<thead>
<tr>
<th>Table 1: Assessment</th>
<th>Group I</th>
<th>Group P</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Airway Time (seconds)</td>
<td>17.63 ±1.15</td>
<td>30.43 ±2.67</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of Attempts</th>
<th>1st attempt</th>
<th>2nd attempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st attempt</td>
<td>28 (93.33%)</td>
<td>02 (6.66%)</td>
</tr>
<tr>
<td>2nd attempt</td>
<td>27 (90%)</td>
<td>03 (10%)</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>No. of Attempts of RT Insertion</th>
<th>1st attempt</th>
<th>2nd attempt</th>
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<tbody>
<tr>
<td>1st attempt</td>
<td>28 (93.33%)</td>
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<td>2nd attempt</td>
<td>27 (90%)</td>
<td>03 (10%)</td>
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<thead>
<tr>
<th>Table 2: Post Operative Complications</th>
<th>Group I</th>
<th>Group P</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughing / Sore throat</td>
<td>NIL</td>
<td>30 (100%)</td>
<td>28 (93.33%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>00</td>
<td>02 (6.66%)</td>
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<tr>
<td>Transient</td>
<td>--</td>
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</tr>
<tr>
<td>Laryngospasm / Bronchospasm</td>
<td>NIL</td>
<td>30 (100%)</td>
<td>30 (100%)</td>
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<td></td>
<td></td>
<td>00</td>
<td>00</td>
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<tr>
<td>Partial</td>
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<tr>
<td>Total</td>
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</tr>
<tr>
<td>Tongue / Lip / Dental trauma</td>
<td>NIL</td>
<td>30 (100%)</td>
<td>30 (100%)</td>
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<td></td>
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<tr>
<td>Present</td>
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<tr>
<td>Staining of device</td>
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</tr>
<tr>
<td></td>
<td>NIL</td>
<td>30 (100%)</td>
<td>30 (100%)</td>
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The effective airway time in Group I was 17.63 ± 2.22 seconds and in Group P was 30.43 ± 2.67 seconds, ‘P’ value < 0.001. It was
statistically highly significant. The total number of attempts for insertion of IGEL (28/2) and PLMA (27/3) was comparable in both Groups. The total number of attempts for ryles tube insertion via I-gel and PLMA was also comparable in both the groups. On inter as well as intra group comparison the changes in the mean heart rate, blood pressure both systolic and diastolic, oxygen saturation and end tidal CO2 concentration showed no statistical significant difference.

DISCUSSION

Supraglottic airway devices are developed with increasing frequency following the overwhelming success of the laryngeal mask airway (LMA). To overcome the sympathetic stimulation caused by laryngoscopy and intubation today a wide variety of supraglottic airway devices are available which are used to protect the airway in both elective as well as emergency situations. I-gel airway is recently introduced supraglottic airway device without an inflatable cuff for maintaining the airway during spontaneous or intermittent positive pressure ventilation with potential advantages and stability after insertion in comparison to other devices. An observational study conducted by B.Richez, L.Saltel et al\textsuperscript{2} evaluated I-gel in 71 women. They found insertion success rate of 97% and insertion was easily performed at first attempt in every patient. The gastric tube was inserted in all patients easily. Only 1 patient had coughing and mild sore throat. Another study carried out by Parul Jindal, Aslam Rizvi and JP Sharma\textsuperscript{8} on 75 patients undergoing elective surgical procedures under general anaesthesia using three supraglottic airway devices I-gel, SLIPA and LMA; suggests that, I-gel effectively confirms to the perilaryngeal anatomy despite the lack of an inflatable cuff, it consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes, as compared to other supraglottic airway devices. Ishwar Singh, Monica Gupta, Mansi Tandon et al\textsuperscript{9} carried out a study on 60 adult patients of either sex who were divided to receive I-gel or LMA – ProSeal. They concluded that I-gel is a novel supraglottic device with an acceptable airway sealing pressure, is easier to insert, requires less attempts of insertion, has easier gastric tube placement and is less traumatic as compared to LMA-ProSeal. Thus we decided to undertake this study to compare two different supraglottic devices I-gel and PLMA for maintenance of airway in adult patients. In our study the two groups are comparable to each other with respect to age, sex, height, weight and ASA status, and type of surgery. In our study the Effective airway time was 17.63 ±2.22 seconds in Group I and in Group P it was 30.93 ± 2.67 seconds.(p<0.001) This highly significant difference in effective airway time is because IGEL does not have an inflatable cuff and has a buccal cavity stabilizer, which provides good stability and facilitates insertion without even using finger to guide the device into mouth of patient. The smooth contiguous surface, allows the device to slide potentially along the. hard palate, pharynx and into hypopharynx easily.\textsuperscript{7} Both the devices were easily inserted and number of attempts for insertion of device as well as Ryles tube were comparable in both the groups. In I-gel the epiglottic ridge at the proximal end of mask catches the base of the tongue thus prevents the device from moving and so contributes to potential stability of the device after placement. Due to this, tip of I-Gel will be located in the upper oesophageal opening, providing conduit via oesophagus and stomach. No significant hemodynamic or respiratory alterations were observed in any of the groups due to the least effect of the devices on sympathetic stimulation at the time of insertion. Coughing and sore throat occurred in two patients of group P. None of the patients in
group I reported sore throat. No other complications were observed in both the groups. Thus, I-Gel supraglottic airway device resulted in lower incidents of throat complaints than PLMA.12

CONCLUSION
From our comparative study between I-Gel and PLMA insertion; we can say that the Effective airway time is significantly less with I-gel than PLMA, both the devices can be easily inserted without any significant changes in the hemodynamic and respiratory parameters and without any significant post operative complications. Thus I-gel airway is an acceptable alternative supraglottic airway device to PLMA for short surgical procedures.

REFERENCES


