A Prospective, Randomized, Comparative Study of Ease of Insertion of Laryngeal Mask Airway Classic and I-Gel Supra Glottic Airway Devices in Anaesthetized, Adult Patients

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Abstract

Background And Objectives: Maintenance of airway is an integral part of general anaesthesia. Various airway devices are used for this purpose. Hemodynamic changes are major hazards of general anaesthesia and are probably generated by direct laryngoscopy & endotracheal intubation. Supraglottic airway devices have been widely used as an alternative to tracheal intubation during general anaesthesia. Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. Thei-gel is a novel supraglottic airway device made of thermoplastic elastomer which is soft, gel-like and transparent. Unlike the conventional LMA, it does not have an inflatable cuff. In view of this, the present study was undertaken to compare the performance of two supraglottic airway devices classic laryngeal mask airway and i-gel in anaesthetized, paralyzed adult patients posted for elective surgeries under general anaesthesia.

Methodology: One hundred patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA class I and II were included in the study and were randomly divided into two groups with 50 patients in each group. In Group 1 (n=50), i-gel supraglottic airway device was used and in Group 2 (n=50) classic laryngeal mask airway was used. Both the devices were compared in relation to the ease of insertion, number of insertion attempts, and time of insertion, airway leak pressure, haemodynamic changes, intra and post-operative complications.

Results: There was no statistically significant difference between the devices with respect to ease of insertion and number of attempts of insertion. The mean airway leak pressure with i-gel was significantly higher as compared with c-LMA (26.38±2.76 and 19.7±2.10 cm H2O, respectively, p=0.000). The mean time of insertion for i-gel was 17.12±3.42 seconds which was significantly shorter compared to c-LMA with a mean insertion time of 25.62±5.28 seconds (p=0.000). There were no statistically significant differences in haemodynamic changes and the postoperative complications between the devices.

Interpretation And Conclusion: Both i-gel and c-LMA are easy to insert and provide an effective airway during positive pressure ventilation, with i-gel providing a better airway seal at a pressure as compared to c-LMA.

Keywords: Laryngeal mask airway; i-gel; supraglottic airway device

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I. Introduction

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Dr Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway in 1983, designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet, be simple and traumatic to insert. Careful observations and clinical experience have led to several refinements of Brain’s original prototype leading to development of newer supraglottic airway devices with better features for airway maintenance. The wide variety of airway devices available today may broadly be classified as intraglottic and extraglottic airway devices, which are employed to protect the airway in both elective as well as emergency situations. There are a large number of supraglottic airway devices, some of which appear similar to the LMA family and others that work under a different concept. Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension,
tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. 4, 5 Transitory hypertension and tachycardia are probably of no consequence in healthy individuals but either or both may be hazardous to those with hypertension, myocardial insufficiency or cerebrovascular diseases. 4 This laryngoscopic reaction in such individuals may predispose to development of pulmonary edema, myocardial insufficiency and cerebrovascular accident. 6, 7 Supraglottic airway devices are now widely used for surgery requiring general anaesthesia, so as to avoid the complications associated with tracheal intubation. 7 LMA-classic is the gold standard for supraglottic airway devices and is in use since 1981. 8 The popularity of the device for routine use stems from its perceived benefits to the patient and anaesthetist over traditional forms of airway management. 9 Laryngeal mask airway is a supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation. 7 The i-gel is a new supraglottic airway device with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. A drain tube is placed lateral to the airway tube, which allows insertion of the gastric tube. 7 The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation. 10 The newer supraglottic airway device, i-gel was introduced by Dr. Muhammad Aslam Nasir in 2007. It has the potential advantages including easier insertion, minimal risk of tissue compression, stability after insertion and an inbuilt bite block. 8 It seals the laryngopharyngeal space without any air being insufflated and additionally has an oesophageal lumen. It can be assumed that airway devices that offer an especially good seal and that are equipped with an additional oesophageal lumen are superior for use in patients with an increased risk of aspiration. 11 This study was undertaken at S V R G H & S V Medical College, Tirupati during the period January 2017 to May 2018 to compare these two supraglottic airway devices in relation to the ease of insertion, number of insertion attempts, time of insertion, airway leak pressure, haemodynamic changes, intra and post-operative complications in anaesthetized, adult patients posted for elective surgeries under general anaesthesia.

II. Objectives

To study and compare two supraglottic airway devices i-gel and classic laryngeal mask airway, in anaesthetized adult patients posted for elective surgeries under general anaesthesia with respect to:

Primary objectives
1. Ease of insertion
2. Number of insertion attempts
3. Time for insertion
4. Airway leak pressure
5. Haemodynamic changes and O2 saturation

Secondary objectives
Adverse effects like,
- Tongue, lip or dental trauma
- Postoperative sore throat, dysphagia or hoarseness

III. Methodology

A study entitled “A PROSPECTIVE, RANDOMIZED, COMPARATIVE STUDY OF EASE OF INSERTION OF LARYNGEAL MASK AIRWAY – CLASSIC AND I-GEL SUPRAGLOTTIC AIRWAY DEVICES IN ANAESTHETIZED, ADULT PATIENTS” was undertaken at S V R G H & S V Medical College, Tirupati during the period January 2017 to May 2018.

The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients. One hundred patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA class I and II were included in the study.

INCLUSION CRITERIA FOR THE STUDY
1) Adult normotensive patients aged between 18 and 50 years of both sex
2) Mallampatti grade I and II
3) Elective surgeries under general anaesthesia with controlled ventilation
4) Duration of surgery less than 60 minutes
EXCLUSION CRITERIA FOR THE STUDY
1) Age <18 years and > 50 years
2) ASA class III and above
3) Mallampatti grade III and above
4) Emergency surgeries
5) Head and neck surgeries
6) Patients with decreased mouth opening
7) Patients with increased risk of aspiration
8) Patients with abnormal or distorted anatomy of the pharynx
9) Patients with obstruction of the airway beyond the larynx
10) Patients with decreased compliance of the lungs
11) Obese patients with BMI >28 kg/m2

The study population was randomly divided into two groups’ with 50 patients in each group using sealed envelopes containing the name of the group and the patient was asked to pick up the envelope. The envelope was opened by senior anaesthesiologist who was not involved with the study.

Group 1 – i-gel group (n=50)
Group 2 – classic LMA group (n=50)

Pre-anaesthetic evaluation was done on the evening before surgery. A routine pre-anaesthetic examination was conducted assessing:

- General condition of the patient
- Airway assessment by Mallampatti grading and rule of 1-2-3
- Nutritional status and body weight of the patient
- A detailed examination of the cardiovascular system
- A detailed examination of the Respiratory system

The following investigations were done in all patients

- Haemoglobin estimation
- Urine examination for albumin, sugar and microscopy
- Standard 12-lead electrocardiogram
- X-ray chest/Screening of chest
- Blood sugar
- Blood urea, Serum creatinine

All patients included in the study were premedicated with tablet Alprazolam 0.5 mg and tablet Ranitidine 150 mg orally at bed time the previous night before surgery. They were kept nil orally for solids 10 pm onwards on the previous night and for clear fluids up to 2 hours before induction. On arrival of the patient in the operating room, an 18-gauge intravenous cannula was inserted and an infusion of normal saline was started. The patient’s head was placed on a soft pillow of 10 cms before induction of anaesthesia with the neck flexed and head extended. The patient was connected to multiparameter monitor, which records heart rate, non-invasive measurements of SBP, DBP, MAP, etCO2 and continuous ECG monitoring and oxygen saturation. The baseline systolic, diastolic blood pressure, mean arterial pressure and heart rate were recorded. The i-gel supraglottic airway was used in Group 1 patients. The size of the device was decided by anaesthetist based on patient’s body weight and manufacturer’s recommendation. Size 3 for patients weighing between 30-50 kgs, size 4 between 50-90 kgs and size 5 for patients weighing > than 90 kgs. Classic LMA device was used in group 2 patients. The size 3 classic-LMA for patients weighing 30-50 kgs, size 4 for 50-70 kgs and size 5 for patients of >70 kgs. The standard pre use tests for both devices were performed. Both devices were lubricated using Lignocaine jelly on the tip and posterior surface as recommended by the manufacturer and the c-LMA fully deflated prior to insertion. After recording the baseline reading, the patient was premedicated with injection Midazolam 0.02 mg/kg body weight. Then the patient was preoxygenated with 100% oxygen for 3 minutes via a face mask with Bain’s circuit. Intravenous lignocaine (2%) 2 ml was given to prevent pain on injection of Propofol. Anaesthesia was induced with Propofol 2 mg/kg body weight. Induction of anaesthesia was confirmed by loss of verbal communication with the patient and loss of eyelash reflex. Once an adequate depth of anaesthesia was achieved, patient was paralyzed by giving intravenous Succinylcholine (2 mg/kg body weight). The patient was mask ventilated with 100% oxygen for 1 minute. The allotted device was inserted according to the manufacturer's instructions. The patient’s head was placed in “sniffing the morning air” position. Insertion of all the devices was done by the same anaesthesiologist who had an experience of introducing successfully more than 400 c-LMA and 20 i-gel. The lubricated i-gel was grasped along the integral bite block and introduced into the mouth in the direction towards the hard palate and glided downwards and backwards along the hard palate until definite resistance was felt. The device was connected to breathing circuit and patient ventilated manually. The recommended volume of air was introduced into the cuff (20 ml, 30 ml, 40 ml of air for size 3, 4, 5 size LMA respectively). An effective airway was confirmed by bilateral symmetrical chest movement, square waveform.
capnograph, normal end tidal CO2 and stable SpO2 (>95%). The device was secured with adhesive tape. Bite block was kept in case of c-LMA and secured along with it with adhesive tape. Anaesthesia was maintained using 66% nitrous oxide and 33% of oxygen with 1 dial setting of Sevoflurone. After the patient recovered from Succinylcholine further neuromuscular blockade was maintained with Vecuronium 0.05 mg/kg body weight. At the end of the procedure, patient was reversed with Neostigmine 0.05 mg/kg body weight and atropine 0.02 mg/kg body weight. The patient remained in the supine position and the device removed after the patient was fully awake and met all the reliable signs of recovery from neuromuscular blockade. The patients were inspected for any injury of the lips, teeth or tongue and the device for blood stain. 18-24 hours after surgery, patient was interviewed for any postoperative complications like sore throat, dysphagia and hoarseness.

PARAMETERS STUDIED DURING THE PROCEDURE

1. Ease of insertion: Graded subjectively on a scale from 1 to 3.

<table>
<thead>
<tr>
<th>Table 1: Grading of ease of insertion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Very easy</td>
</tr>
<tr>
<td>2 Easy</td>
</tr>
<tr>
<td>3 Difficult</td>
</tr>
</tbody>
</table>

Insertion of device was recorded as; very easy (when assistant help was not required), easy (when jaw thrust was needed by assistant) and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).22

Time of insertion
Time from picking up the device, to the time of confirmation of effective ventilation by bilateral symmetrical chest movement, square waveform on capnograph, normal range end tidal CO2 and stable arterial SpO2 (>95%).2,8,9,15,18

3. Number of insertion attempts
Number of attempts required for the insertion of each device was noted.

4. Airway leak pressure
It is detected by using closed circuit with mechanical ventilation in Drager-Fabius machine. Keeping the flow rate of 3 litres/min and maximum pressure limit of 40 cm H2O, the airway pressure was gradually increased. The pressure at which an audible noise was detected using a stethoscope placed just lateral to the thyroid cartilage was taken as the airway leak pressure.17,19,20

5. Haemodynamic Parameters
The following haemodynamic parameters were recorded in all patients.
• Heart rate [HR] in beats per minute
• Systolic blood pressure [SBP] in mm of Hg
• Diastolic blood pressure [DBP] in mm of Hg
• Mean arterial pressure [MAP] in mm of Hg
• Saturation SpO2

The above haemodynamic parameters were monitored in the following time interval –
1. Basal before premedication
2. At the time of insertion
3. 1 minute after insertion
4. 2 minutes after insertion
5. 5 minutes after insertion
6. At the time of removal
7. 1 minute after removal

6. Injuries
The patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery.23
7. Post Operative Complications

18-24 hours after surgery, patient was interviewed for any post operative complications like sore throat, dysphagia and hoarseness. Post operative sore throat was graded as nil, mild, moderate and severe.\textsuperscript{17,23}

**Statistical Methods Employed and Sample Size Calculation**

Sample size calculation was based on the previous studies on LMA and i-gel\textsuperscript{15,23}. Accordingly, we calculated the sample size to detect at least the difference between both the devices which was described previously for the primary end point (airway leak pressure) with an error of 0.05 and a power of 0.9. For a difference of 6 cm H\textsubscript{2}O and a standard deviation of 8 cm H\textsubscript{2}O, 40 patients per group were needed. Considering some dropouts of patients from the study, a sample size of 50 in each group was taken.

**IV. Results**

**Table 2: Showing the age distribution**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Group-1 (i-gel)</th>
<th>Group-2(c-LMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO OF PATIENTS</td>
<td>PERCENTAGE</td>
</tr>
<tr>
<td>&lt;20</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>21-30</td>
<td>13</td>
<td>26</td>
</tr>
<tr>
<td>31-40</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>41-50</td>
<td>23</td>
<td>46</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

Mean age in years ±SD: 36.9±10.21, 36.52±10.60

<table>
<thead>
<tr>
<th>t-value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.091</td>
<td>0.84 (NS)</td>
</tr>
</tbody>
</table>

Table 2 shows age distribution of the patients in both the groups. The minimum ages in both groups were 18 years. The maximum age in both groups was 50 years. The mean age in group 1 and 2 were 36.9±10.21 and 36.52±10.60 years respectively. There was no significant difference in the age of the patients between Group 1 and Group 2 (p=0.84).

**Table 3: Showing the sex distribution between Group 1 and Group 2**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Group-1 (i-gel)</th>
<th>Group-2(c-LMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO OF PATIENTS</td>
<td>PERCENTAGE</td>
</tr>
<tr>
<td>MALE</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>FEMALE</td>
<td>42</td>
<td>84</td>
</tr>
<tr>
<td>TOTAL</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

From the above table it is seen that statistically there is no significant difference in the gender in both the groups.

**Table 4: Showing the comparison of ease of insertion in between group 1 and group 2**

<table>
<thead>
<tr>
<th>Ease of insertion</th>
<th>Group-1 (i-gel)</th>
<th>Group-2(c-LMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO OF PATIENTS</td>
<td>PERCENTAGE</td>
</tr>
<tr>
<td>Very easy</td>
<td>49</td>
<td>98</td>
</tr>
<tr>
<td>Easy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Difficult</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

p-value – 0.079 (NS)

The insertion of i-gel in group 1 patients was graded very easy in 49 patients and was difficult in 1 patient. The insertion of c-LMA in group 2 patients was graded very easy in 42 patients, easy in 3 patients and difficult in 5 patients. The ease of insertion was not statistically significant between the two groups. (p=0.079)

**Table 5: Showing number of attempts of insertion of devices**

<table>
<thead>
<tr>
<th>Insertion attempt</th>
<th>Group-1 (i-gel)</th>
<th>Group-2(c-LMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO OF PATIENTS</td>
<td>PERCENTAGE</td>
</tr>
<tr>
<td>First attempt</td>
<td>49</td>
<td>98</td>
</tr>
<tr>
<td>Second attempt</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

49 of 50 (98%) insertions in group 1 were in the first attempt and only 1 patient required 2nd attempt. 45 of 50 (90%) in the group 2 required only one attempt and 5 patients required 2nd attempt. In 2nd attempt for insertion, airway manipulation with jaw thrust was required in both the groups.
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Table 6: Showing the mean duration for insertion

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean duration of insertion (seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group-1</td>
<td>17.12±3.42</td>
</tr>
<tr>
<td>Group-2</td>
<td>25.62±5.28</td>
</tr>
<tr>
<td>p-value</td>
<td>0.000 (HS)</td>
</tr>
</tbody>
</table>

HS-Highly significant
The mean duration of insertion of i-gel in group 1 patients and c-LMA ingroup 2 patients were 17.12±3.42 and 25.62±5.28 seconds respectively and was statistically highly significant. (p<0.001).

Table 7: Showing the mean airway leak pressures

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean airway leak pressure (cm H2O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group-1</td>
<td>26.38±2.76</td>
</tr>
<tr>
<td>Group-2</td>
<td>19.70±2.10</td>
</tr>
<tr>
<td>p-value</td>
<td>–0.000(HS)</td>
</tr>
</tbody>
</table>

p-value – 0.000(HS)
HS-Highly significant
The mean airway leak pressure with i-gel in group 1 patients was 26.38±2.76 (cm H2O) and with c-LMA in group 2 patients was 19.70±2.10(cm H2O) and was highly significant statistically. (p<0.01).

Table 8: Showing the intergroup comparison of mean heart rate (bpm) changes in response to insertion of i-gel in group 1 and c-LMA ingroup 2 patients

<table>
<thead>
<tr>
<th>Time</th>
<th>Group 1 (i-gel)</th>
<th>Group 2 (c-LMA)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal</td>
<td>81.24±14.14</td>
<td>84.12±13.80</td>
<td>0.3054 (NS)</td>
</tr>
<tr>
<td>During insertion</td>
<td>97.12±15.53</td>
<td>95.36±12.22</td>
<td>0.5304 (NS)</td>
</tr>
<tr>
<td>1 min-AI</td>
<td>88.72±12.69</td>
<td>90.60±12.16</td>
<td>0.4515 (NS)</td>
</tr>
<tr>
<td>3 min-AI</td>
<td>84.48±10.407</td>
<td>87.66±11.57</td>
<td>0.1518 (NS)</td>
</tr>
<tr>
<td>5 min-AI</td>
<td>80.80±10.49</td>
<td>85.54±11.13</td>
<td>0.050 (NS)</td>
</tr>
<tr>
<td>During removal</td>
<td>97.08±14.09</td>
<td>96.42±14.22</td>
<td>0.3162 (NS)</td>
</tr>
<tr>
<td>1 min-AR</td>
<td>91.52±13.49</td>
<td>94.42±11.67</td>
<td>0.2533 (NS)</td>
</tr>
</tbody>
</table>

p<0.01) – Highly significant (HS); (p<0.05) – Significant (S);
(p>0.05) – Not significant (NS); AI-After insertion; AR-After removal
The basal heart rate was comparable in both groups (p=0.305). Statisticalevaluation between the groups showed no significant difference in HR changes between group 1 and group 2 during the insertion of i-gel or c-LMA respectivelyand also after 1 min, 3 min and 5 min after insertion. There were also no significant changes in heart rate during removal and 1 min after removal of the devices inboth the groups.

Table 9: Showing the intergroup comparison of mean arterial blood pressure MAP (mm of Hg) changes in response to insertion of i-gel in group 1 and c-LMA in group 2 patients

<table>
<thead>
<tr>
<th>Time</th>
<th>Group 1 (i-gel)</th>
<th>Group 2 (c-LMA)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal</td>
<td>92.36±10.12</td>
<td>92.08±9.62</td>
<td>0.8876 (NS)</td>
</tr>
<tr>
<td>During insertion</td>
<td>97.42±11.26</td>
<td>101.54±10.38</td>
<td>0.0602 (NS)</td>
</tr>
<tr>
<td>1 min-AI</td>
<td>94.46±10.51</td>
<td>92.12±9.63</td>
<td>0.2489 (NS)</td>
</tr>
<tr>
<td>3 min-AI</td>
<td>88.88±8.25</td>
<td>89.74±7.64</td>
<td>0.5900 (NS)</td>
</tr>
<tr>
<td>5 min-AI</td>
<td>87.96±9.22</td>
<td>87.02±8.00</td>
<td>0.5874 (NS)</td>
</tr>
<tr>
<td>During removal</td>
<td>98.96±12.89</td>
<td>98.92±9.98</td>
<td>0.0862 (NS)</td>
</tr>
<tr>
<td>1 min-AR</td>
<td>94.22±16.33</td>
<td>90.64±9.94</td>
<td>0.4030 (NS)</td>
</tr>
</tbody>
</table>

(p<0.01) – Highly significant (HS); (p<0.05) – Significant (S);
(p>0.05) – Not significant (NS); AI-After insertion; AR-After removal
The mean basal MAP were comparable in both groups (p=0.88). Statisticalevaluation between the groups showed no significant difference in MAP changes between group 1 and group 2 during the insertion of i-gel or c-LMA and also after 1 min, 3 min and 5 mins of insertion. There were also no significant changes in MAP during removal and 1 min after removal of the devices in between the groups.
### Table 10: Showing the intergroup comparison of oxygen saturation (%) SpO2 changes in response to insertion of i-gel in group 1 and c-LMA in group 2 patients

<table>
<thead>
<tr>
<th>Time</th>
<th>Group 1 (i-gel)</th>
<th>Group 2 (c-LMA)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal</td>
<td>99.98±0.14</td>
<td>100±0.00</td>
<td></td>
</tr>
<tr>
<td>During insertion</td>
<td>99.96±0.19</td>
<td>99.98±0.1414</td>
<td>0.5624 (NS)</td>
</tr>
<tr>
<td>1 min-Al</td>
<td>99.98±0.14</td>
<td>100±0.00</td>
<td></td>
</tr>
<tr>
<td>3 min-Al</td>
<td>99.98±0.14</td>
<td>100±0.00</td>
<td></td>
</tr>
<tr>
<td>5 min-Al</td>
<td>99.98±0.14</td>
<td>99.84±0.1456</td>
<td>0.055 (NS)</td>
</tr>
<tr>
<td>During removal</td>
<td>99.96±0.28</td>
<td>99.9±0.30</td>
<td>0.3086 (NS)</td>
</tr>
<tr>
<td>1 min-AR</td>
<td>100±0.00</td>
<td>99.96±0.2828</td>
<td>0.43 (NS)</td>
</tr>
</tbody>
</table>

(p<0.01) – Highly significant (HS); (p<0.05) – Significant (S); (p>0.05) – Not significant (NS); AI-After insertion; AR-After removal

The mean SpO2 were comparable in both groups. Statistical evaluation between the groups showed no significant difference in arterial SpO2 between group 1 and group 2 during the insertion of i-gel or c-LMA respectively and also after 1 min, 3 min and 5 mins of insertion. There was also no significant changes in SpO2 during removal and 1 min after removal of the devices in between the groups.

### Table 11: Showing the occurrence of post operative tongue/lip/tooth injury

<table>
<thead>
<tr>
<th>POSTOPERATIVE COMPLICATIONS</th>
<th>Group 1 (i-gel)</th>
<th>Group 2 (c-LMA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients</td>
<td>Percentage</td>
</tr>
<tr>
<td>Tongue/lip/tooth injury</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Sore throat</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

NS-not significant

Lip injury was noted in 3 patients in group 1 (i-gel) out of 50 and in 4 patients out of 50 in group 2 (c-LMA). However the incidence was not statistically significant (p=0.695) when compared between both the groups. Two cases in the i-gel group had blood stain on the device on removal while there was no blood staining in any case of c-LMA group. Only 1 patient in group 1 had developed sore throat post operatively compared to 4 patients in group 2. The incidence was not statistically different (p=0.169) when compared between the groups. The sore throat in all the 5 cases was mild requiring no treatment. None of the patients in both the groups developed post operative hoarseness or dysphagia.

### V. Discussion

The present prospective, randomized study was undertaken to compare two supraglottic airway devices i-gel and classic-LMA in anaesthetized patients with respect to ease of insertion, number of attempts of insertion, airway leak pressure, haemodynamic changes and post operative complications.

The study population consisted of 100 patients divided into two groups randomly using simple closed envelope method with 50 patients in each group. Group 1 consisted of 50 patients in whom i-gel supraglottic airway device was used and group 2 consisted of 50 patients in whom classic-LMA was used.

### Demographic criteria

Both the groups were comparable and there was no statistically significant difference with regards to mean age, weight, sex, duration and type of surgery.

### Ease of insertion

One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study conducted by Siddiqui et al.\(^\text{19}\), where insertion of device was recorded as; very easy (when assistant help was not required), easy (when jaw thrust was needed by assistant) and difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion). In our study, the ease of insertion of i-gel was very easy (score 1) in 49 (98%) patients and difficult (score 3) only in 1 (2%) patient. In group 2 insertion of c-LMA was very easy (score 1) in 42 (84%) patients, easy (score 2) in 3 (6%) patients and difficult (score 3) in 5 (10%) patients. There was no statistically significant difference between the two groups with respect to ease of insertion (p>0.05). The insertion of i-gel was found comparatively easier.
and required less skill as compared to LMA but the results were not statistically significant. The i-gel having a non-inflatable cuff and firm in consistency is much easier for insertion as compared to LMA.

Insertion of i-gel in our study was similar to Richez B et al.7, study, who graded insertion of no 4 i-gel as very easy in 93% (66 of 71) patients and easy in remaining 7% (5 of 71) patients. Insertion of c-LMA in our study was comparable with Janakiram et al.13, study where 90% (45 of 50) c-LMA insertions were easy insertions. In this study, insertion of i-gel was successful in first attempt in 98% patients as compared to 90% first time insertion with c-LMA. Airway manipulation like jaw thrust was required during second attempt insertion in one patient of i-gel insertion and 5 patients with c-LMA insertions. Very similar results were found in studies conducted by Helmy AM et al.2, Uppal V et al.13, Franksen H et al.13, Amini S et al.16, Siddiqui AS et al.18. In Janakiram et al.13, study, the success rate with first time i-gel insertion was only 54%, and with c-LMA of 86% which was statistically highly significant. This was because, during the use of i-gel in 14 patients a larger size i-gel had to be used due to presence of audible leak and hence required 2nd attempt. However, in our study we did not have such problem and hence the success rate of first time insertion was comparable between both the devices.

The time for insertion was considered according to the study conducted by Helmy AM et al.2, from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography, normal range end tidal CO2 and stable arterial SpO2 (>95%)15,16. In our study, the time for insertion of i-gel (17.12 sec) was shorter compared to c-LMA (25.6 sec) which was highly significant statistically (p=0.000). The i-gel SAD is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to c-LMA which has a cuff to be inflated after its insertion. Consistent with our results, Helmy AM et al.2, Uppal V et al.13, Parul J et al.12 also significant difference in the insertion times. In Franksen H et al.13, Amini S et al.13, Ali A et al.17 studies, though the mean time for i-gel insertion was clinically shorter as compared to c-LMA, it was not statistically significant. Airway leak pressure detection was performed in a similar manner done by Uppal V et al.13,14 in their study. The difference in the leak pressures between i-gel SAD and c-LMA were statistically significant in our study (p=0.000) similar to the previous studies of Janakiram et al.13, Franksen H et al.13, Amini S et al.16, and Helmy AM et al.2. Airway leak pressure of i-gel in our study was comparable with Uppal V et al.13, and Helmy AM et al.2, studies and of c-LMA with Amini S et al.13, study. The efficacy of the oropharyngeal seal of the SAD depends on the fit between the structures surrounding the glottis and the distal mask of the SAD. With c-LMA, in order to obtain a good seal, the distal cuff has to be inflated. The i-gel made of thermoplastic elastomer is designed anatomically to fit the oropharyngeal and the hypopharyngeal structures without the use of an inflatable cuff. Its airway seal is likely to be higher than that of the LMA-Classic.24 This maybe the reason for improved seal with the i-gel and hence higher airway leak pressures as compared with the c-LMA.

Haemodynamic changes

During the insertion of LMA, pressor response (i.e. increase in heart rate and arterial pressure), may be induced by the passage of the LMA through the oraland pharyngeal spaces, pressure produced in the larynx and the pharynx by the inflated cuff and the dome of the LMA.12 During removal of LMA the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of the cuff.12,14 The same thing can also occur with insertion and removal of i-gel

The following haemodynamic parameters were recorded in all patients.

- Heart rate [HR] in beats per minute
- Systolic blood pressure [SBP] in mm of Hg
- Diastolic blood pressure [DBP] in mm of Hg
- Mean arterial pressure [MAP] in mm of Hg
- Saturation SpO2

The above haemodynamic parameters were monitored in the following time interval — Basal before premedication, at the time of insertion, 1 minute after insertion, 2 minutes after insertion, 5 minutes after insertion, at the time of removal and 1 minute after removal.15 In our study, there was no statistically significant difference between i-gel and c-LMA with regard to heart rate, systolic, diastolic and mean blood pressure and arterial saturation (SpO2). The results of our study were similar to the studies done by Helmy AM et al.2, Franksen H et al.13, who in their studies found no significant difference between i-gel and c-LMA with regard to heart rate, arterial BP, SpO2 and end tidal CO2. Jindal P et al.12, in their study observed that i-gel produced less haemodynamic changes compared to other SADs. The authors concluded that i-gel effectively confirms to the perilyngeal 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 like c-LMA which because of an inflatable cuff can produce more haemodynamic changes.

Injuries
The inflatable supraglottic airway devices, during insertion, the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue and can cause pharyngeal injury. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury. In our study, the patients were inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery similar to study done by Siddiqui AS et al. Lip injury was noted in 3 patients ingroup 1 (i-gel) out of 50 and in 4 patients out of 50 in group 2 (c-LMA). However, the incidence was not statistically significant (p=0.169). Two cases in the i-gel group had blood stain on the device on removal while there was no blood staining in any case of c-LMA group. Similar results have been observed in studies done by Helmy AM et al. In the study conducted by Siddiqui AS et al., blood on device was noted in 18% of the LMA group while none in the i-gel group which was statistically significant. The authors attributed the cause may be due to inflatamaskings having the potential to cause tissue distortion, venous compression and nerve injury.

**Post operative complications**

In a time period of 18-24 hours after surgery, patients were interviewed for any post operative complications like sore throat, dysphagia and hoarseness. Post operative sore throat graded as nil, mild, moderate and severe. Only 1 patient in group 1 had developed sore throat post operatively compared to 4 patients in group 2. The incidence was not statistically different (p=0.169) when compared between the groups. The sore throat in all the 5 cases was mild requiring no treatment. None of the patients in both the groups developed post operative hoarseness or dysphagia. Our results were consistent with the studies done by Siddiqui AS et al., Helmy AM et al., Fanksen H et al., where the difference between LMA and i-gel regarding post operative complications was not statistically significant except for nausea and vomiting which was significantly higher in LMA due to high incidence of gastric inflation. There was a higher incidence of sore throat and dysphagia at 1, 24, and 48 h in the LMA group compared with the i-gel group. Neck pain was also more common at 24 and 48 hours in the LMA group. Because of the absence of an inflatable cuff, the authors hypothesized that use of i-gel produced fewer postoperative throat and neck complaints compared with standard LMA.

**VI. Conclusion**

Classic-LMA and i-gel can be used safely and effectively during general anaesthesia with positive pressure ventilation in selected patients. Both devices are easy to insert. The i-gel provides a better airway sealing pressure compared to toc-LMA. The i-gel has low pharyngolaryngeal morbidity rate as compared to c-LMA.

**References**


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