INTRODUCTION

Supraglottic airway devices are now widely used for surgery requiring general anaesthesia.\textsuperscript{1,2} They provide a perilaryngeal seal with a cuff and an alternative to tracheal intubation.\textsuperscript{3,4} But there are some contraindications, like non-fasting patients, morbidly obese patients and obstructive or abnormal lesion of oropharynx.\textsuperscript{1}

Supraglottic airway devices allow rapid access to airway, not requiring laryngoscope or relaxant for insertion and provide safe airway for spontaneous or controlled ventilation and tolerated at lighter anaesthetic planes.\textsuperscript{3} But they do not fully protect against aspiration in non-fasting patient or allow high positive pressure ventilation.\textsuperscript{6,7} They may be used as a rescue airway and fiberoptic conduit when intubation is difficult or unsuccessful. They can also be used for bronchoscopy in the awake or asleep patients.\textsuperscript{8-10}

The I-gel is a novel and innovative supraglottic airway management device made of a medical grade thermoplastic elastomer, which is soft, gel-like and transparent. The I-gel is designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structure. The I-gel is designed as a latex free, single patient use device introduced clinically in 2007.\textsuperscript{1,8} The device has buccal cavity stabilizer which has propensity to adopt its shape to oropharyngeal curvature of the patients. The device has integral bite block which is marked with a horizontally placed black line, which acts as a guide to depth of insertion (Figure 1).\textsuperscript{4} Preliminary studies have demonstrated its easy reliable insertion, providing an adequate seal with a low morbidity rate.\textsuperscript{3,5}

The I-gel also has a channel for gastric tube drain which runs through the device from its proximal opening at the side of flat connector wing to the distal tip of the non-inflatable mask. The size of I-gel is selected according to patient's body weight. But individual anatomical variations should always be considered in conjunction with a clinical assessment of the patient's anatomy. I-gel of size 4 can be used for average adult (50-90 kg).\textsuperscript{1,11} It is a reasonable alternative to tracheal intubation during pressure controlled ventilation.\textsuperscript{12} Insertion of I-gel does not require laryngoscopy, it is quick, safe, effective, associated with good haemodynamic stability. All these features help in rapid patient turn over, especially in large tertiary care hospitals.

ORIGINAL ARTICLE

New Single Use Supraglottic Airway Device with Non-Inflatable Cuff and Gastric Tube Channel

Ali Sarfraz Siddiqui, Jamil Ahmed, Safia Zafar Siddiqui, Saeeda Haider and Syed Amir Raza*

ABSTRACT

Objective: To assess ventilatory characteristics and airway complications associated with the use of I-gel in patients undergoing gynaecological surgeries.

Study Design: Experimental study.

Place and Duration of Study: Department of Anaesthesiology, Surgical Intensive Care Unit and Pain Management, Civil Hospital, Dow University of Health Sciences, Karachi, from July 2008 to June 2009.

Methodology: One hundred adult female patients aged 15 - 75 years, ASA-I and II scheduled for elective gynaecologic surgical procedures under general anaesthesia with controlled ventilation were included in this study. After insertion of device, ease of insertion, time of insertion, peak airway pressure, leak pressure were noted. After proper placement of device, gastric tube was also passed in every patient. Pharyngolaryngeal morbidities (sore throat, dysphagia, dysphonia, neck pain and coughing at 1 hour and 24 hours postoperatively) were also noted.

Results: I-gel was inserted in the first attempt in 92% patients while second attempt was required in 8% of patients. Average time of insertion was 9.68 ± 2.69 seconds. Average leak pressure of 22.48 ± 2.07 cm H2O. After removal of I-gel no blood staining was found on any device. Coughing was noted in 6% patients after removal of device and mild sore throat was noted in only one patient after 24 hours of surgery.

Conclusion: I-gel is a simple and easy to use supraglottic airway device. Its insertion do not require laryngoscopy and airway can be maintained in very short time in adult female patients.

Key words: Supraglottic airway device. I-gel. General anaesthesia. Gynaecological surgeries.
This study was conducted to assess whether I-gel is safe and suitable supraglottic airway device for general anaesthesia using pressure controlled ventilation in patients undergoing elective gynaecological surgeries.

**METHODOLOGY**

This study was conducted at the Department of Anaesthesiology, Surgical Intensive Care and Pain Management, Civil Hospital, Dow University of Health Sciences, Karachi. The study was carried out from July 2008 to June 2009. All patients were recruited through consecutive non-probability sampling. After approval from the Hospital's Ethical Committee and Departmental permission, informed and written consent were taken from one hundred adult female patients aged 15 to 75 years, weighing 50 - 90 kg, ASA I and II, Mallampati I and II with no contraindication to supraglottic airway device presenting for gynaecologic surgical procedure were included in this study. Patients with BMI > 35 kg.m⁻², predicted difficult airway, high risk of regurgitation or aspiration, respiratory tract pathology, pre-operative sore throat or planned operation time > 4 hours were excluded.

All patients selected for study were assessed pre-operatively for inclusion and exclusion criteria. Standard monitoring were applied and intravenous line taken. After pre-oxygenation, patients were induced with nalbuphine 0.1 mg.kg⁻¹, propofol 2 mg.kg⁻¹ and atracurium 0.5 mg.kg⁻¹. Patients lungs were ventilated with 50% O₂ and 50% N₂O and 1-2% isoflurane for 3 minutes prior to insertion of device. Before insertion, a water soluble lubricant was applied on the cuff of device.

I-gel of size-4 was used in all patients. The device was inserted by senior anaesthesiologists experienced in using the laryngeal mask airway (LMA), according to the manufacturer's recommendations. The patient's head was placed in the sniffing position. The I-gel was grasped along the integral bite block and was introduced continuously into the mouth towards the hard palate until resistance was felt. Three insertion attempts were allowed. Insertion failure was defined as more than three unsuccessful attempts. In case of failure of device, the airway was secured by endotracheal intubation.

Once the I-gel was in place, it was fixed over the patient's cheek. Correct placement of device was assessed by gently squeezing the reservoir bag and observing proper chest expansion and appearance of end-tidal carbon dioxide wave form with a plateau on the capnograph, absence of audible leak and lack of gastric insufflation by epigastric auscultation.

After proper placement of the I-gel, leak pressure was measured using 'leak test'. Airway leak tests was performed by manometer stability method keeping fresh gas flow to 3 litre min⁻¹ and the adjustable pressure limiting (APL) valve of the circle system was completely closed. Airway pressures were not allowed to exceed 40 cm H₂O. Manometer stability involving observation of the aneroid manometer dial as the pressure from the breathing system increased and noting the airway pressure at which the dial reached stability i.e. the airway pressure at which the leak was in equilibrium with fresh gas flow.

A lubricated 12 F gauge gastric tube was then inserted down the drainage tube. Ease of I-gel and gastric tube insertion was graded subjectively on a scale from 1 to 4 (1 = very easy, 2 = easy, 3 = moderately difficult and 4 = very difficult).

Anaesthesia was maintained by 40% O₂ and 60% N₂O mixture and 1-2% Isoflurane. All patients were ventilated with pressure-controlled ventilation at 15 - 20 cm H₂O, an inspiratory-to-expiratory ratio of 1:2 with no positive end expiratory pressure. Respiratory rate was set to obtain an end-tidal CO₂ between 35 and 40 mmHg. Patient's blood pressure, heart rate, ECG, oxygen saturation and end-tidal CO₂ were also recorded throughout surgery and after removal of device.

At the end of procedure, I-gel was removed after adequate reversal of neuromuscular blockade with...
neostigmine 0.04 mg.kg⁻¹ and atropine 0.02 mg.kg⁻¹, spontaneous breathing and eye opening of the patient, presence of airway reflexes and opening of mouth on command. The I-gel was then inspected for the presence of visible blood. One hour and 24 hours postoperatively, all patients were assessed for postoperative sore throat, cough, dysphonia, dysphagia and neck pain.

Data was recorded regarding age, weight, height, ASA physical status, duration of surgery, number of insertion attempts, time of insertion, ease of insertion, peak airway pressure, leak pressure and airway complications during insertion, maintenance and removal of device were noted for each patient. Pharyngolaryngeal morbidities like sore throat, dysphagia, dysphonia, neck pain, blood on device and coughing at 1 hour and 24 hours postoperatively were also noted.

Data was entered and analyzed in Statistical Package for Social Science (SPSS 10). Mean, standard deviation and 95% confidence interval were computed for quantitative variables like age, weight, height, duration of surgery, time of insertion, tidal volume, respiratory rate, peak pressure and leak pressure. Frequency and percentages were computed for qualitative outcomes like ease of insertion and insertion of gastric tube.

**RESULTS**

A total of 100 adult female patients presenting for various elective gynaecological surgical procedures under general anaesthesia were included in study. The average age, weight, height of women, time of insertion, ASA status and duration of surgery are shown in Table I.

I-gel was inserted in the first attempt in 92% patients while second attempt was required in 8% of patients. Ease of insertion of I-gel is presented in Figure 2. Insertion of I-gel was found very easy in 67% patients, easy in 30% patients while difficulty was observed in only 3% cases where insertion required second attempts and assistant's help.

Insertion of gastric tube was possible in every case which was very easy in 12% cases and easy in 88% patients. No gastric insufflation or regurgitation occurred in any patient.

Averages of peak and leak airway pressures were 16.21 ± 1.78 and 22.48 ± 2.07 cm H₂O respectively which were adequate for controlled ventilation. Ventilatory parameters are presented in Table II.

After removal of I-gel no blood staining on device was noted in any patient. Coughing was observed in 6% patients after removal of device and mild sore throat was noted in only one case after 24 hours of surgery. No dysphagia, dysphonia, neck pain or oral trauma were observed in any patient.

### Table I: Patient's characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean ± SD</th>
<th>95% CI</th>
<th>Max - Min</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>37.92 ± 12.07</td>
<td>35.52 to 40.32</td>
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<tr>
<td>Weight (kg)</td>
<td>59.98 ± 8.79</td>
<td>58.42 to 61.54</td>
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<tr>
<td>Height (cm)</td>
<td>158.84 ± 14.87</td>
<td>155.89 to 161.79</td>
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<tr>
<td>Duration of surgery (min.)</td>
<td>68.01 ± 25.76</td>
<td>62.87 to 73.15</td>
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<tr>
<td>Time of insertion (sec.)</td>
<td>9.68 ± 2.69</td>
<td>9.14 to 10.21</td>
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<tr>
<td>ASA status (n)</td>
<td>Ⅰ/Ⅱ 80 / 20</td>
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</table>

† Mean ± SD; ‡ Number of patients

### Table II: Ventilatory parameters.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean ± SD</th>
<th>95% CI</th>
<th>Max - Min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tidal volume (ml)</td>
<td>510 ± 23.57</td>
<td>505.32 to 514.68</td>
<td>600 - 450</td>
</tr>
<tr>
<td>Respiratory rate (breaths/ min)</td>
<td>13.43 ± 0.88</td>
<td>13.26 to 13.60</td>
<td>14 - 12</td>
</tr>
<tr>
<td>Peak pressure (cm of H₂O)</td>
<td>16.21 ± 1.78</td>
<td>15.86 to 15.56</td>
<td>20 -12</td>
</tr>
<tr>
<td>Leak pressure (cm of H₂O)</td>
<td>22.48 ± 2.07</td>
<td>22.07 to 22.89</td>
<td>26 -18</td>
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</tbody>
</table>

DISCUSSION

Supraglottic airway devices have produced a major change in the anaesthesia practice and management of airway during elective anaesthesia. The LMA has become the gold standard as a simple and safe alternative to both the ordinary face mask and intubation in elective and uncomplicated daycare anaesthesia.12 Study by Uppal and Fletcher supports the use of the I-gel for pressure controlled ventilation, provided pressures can be limited to 25 cm H₂O. There was no evidence of gastric insufflations, regurgitation, or aspiration while using the I-gel for PCV.13 The I-gel is a new single use supraglottic airway device. It has been shown clinically to be a feasible alternative to the LMA.15,16

The I-gel is a truly anatomical supraglottic device. Its soft non-inflatable cuff fits snugly onto the perilaryngeal framework, mirroring the shape of the epiglottis, aryepiglottic folds, periform fossae, peri-thyroid, pericricoid, posterior cartilages and spaces. Each receives an impression fit, thus supporting the seal by enveloping the laryngeal inlet. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation (IPPV). It is anatomically widened and concaved to eliminate the potential for rotation after insertion, thereby reducing the risk of mal-positioning.14,17

In this study I-gel was easy to insert, does not require laryngoscope for insertion, cause less pharyngolaryngeal morbidity and better cardiovascular stability on insertion. Studies have also demonstrated that I-gel is a reliable, easily inserted airway device that provides adequate seal with low pharyngolaryngeal morbidity rate.4,6 Study by Singh et al. showed that insertion of I-gel was much easier than with LMA pro seal.7

When correctly inserted, the tip of the I-gel will be located into the upper oesophageal opening, providing a conduit via the gastric channel to the oesophagus and stomach. This then allows for suctioning, passing of a
gastric tube and can facilitate venting. I-gel provides a reliable clear airway with interventions rarely required. Airway seal is nearly 25 cm H$_2$O (30±7), between that of the LMA-classic and LMA-proSeal. Ventilation is highly effective with excellent anatomical positioning and any laryngopharyngeal trauma is rare.21,22

In a randomized, double blinded study, Keijzer et al. compared I-gel and La Premiere LMA for postoperative throat and neck complaints. This study showed that insertion time of I-gel was 8.5 ± 6.3 second and leak pressure was 26.8 ± 9.5 cm H$_2$O. They concluded that the I-gel supraglottic device resulted in a lower incidence of throat and neck complaints than the La Premiere LMA.23

Both classic LMA and I-gel can be used safely and effectively during general anaesthesia with positive pressure ventilation in selected patients. Both are easy to insert and have good haemodynamic stability after insertion. I-gel has edge over classic LMA because it provide comparatively better seal and low pharyngolaryngeal morbidity rate.24

Teh and colleagues demonstrated that the airway seal pressure offered by the I-gel is comparable to that of the LMA supreme using volume controlled, positive pressure ventilation. Both supraglottic airway devices are comparable in terms of ease of insertion, success rates on the first attempt, time to insertion and oropharyngeal leak pressure, proving to be equally effective ventilatory devices for gynaecological laparoscopic procedures in this study.25

In this study, insertion of gastric tube was possible in every case which was very easy in 12% cases and easy in 88% patients. No gastric insufflation or regurgitation occurred in any patient.

CONCLUSION

I-gel is a simple and easy to use supraglottic airway device. I-gel is easy to insert without the need of laryngoscopy and many airway manipulations with maintenance of airway in a very short time. The device is very useful for adult female patients requiring surgical procedures of upto 90 minutes duration with pressure controlled ventilation.

REFERENCES

