Randomised comparison of the LMA Supreme™ with the I-Gel™ in spontaneously breathing anaesthetised adult patients

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SUMMARY

We compared the performance of the LMA Supreme™ (SLMA) with the I-Gel™ (i-gel) during anaesthesia in spontaneously breathing adult patients. Ninety patients with American Society of Anesthesiologists physical status I or II were studied in a prospective randomised controlled study. Our primary outcome measure was oropharyngeal leak pressure. We also compared the overall insertion success rate, ease of insertion, adequacy of ventilation and incidence of complications. The mean (SD) oropharyngeal leak pressure for the SLMA was 25.6 (5.1) cmH₂O, which was greater than for the i-gel 20.7 (5.9) cmH₂O (P=0.0001). The first attempt and overall insertion success rates were similar between the two groups (SLMA 97.8 and 97.8%; i-gel 93.3 and 100%, P=0.132). The SLMA was rated easier to insert than the i-gel (P=0.011), but the time taken for insertion (P=0.433) was similar. The incidence of complications was low in both groups. The grade of fibroptic view was better with the i-gel than the SLMA (P=0.001). We conclude that in adults with normal airways, the SLMA is easier to insert and provides a higher oropharyngeal leak pressure, but fibroptic views are better with the i-gel.

Key Words: laryngeal mask airway, LMA Supreme, insertion, fibroptic, oropharyngeal leak pressure

Since the introduction of the LMA Classic™ laryngeal mask airway (Intravent Orthofix, Maidenhead, UK) in 1983¹ it has gained widespread popularity². The LMA Supreme™ (SLMA) and the I-Gel™ (i-gel) are two newly developed disposable supraglottic airway devices. The claimed potential advantages of both devices include easier insertion, more effective ventilation, better airway protection, minimal tissue compression and stability following insertion³⁵.

The SLMA is a single use LMA with a built-in gastric drain tube, elliptical airway tube for easy placement and prevention of kinking, an integral bite-block, a large pre-curved cuff for effective airway seal, moulded fins in the cuff to protect the airway from epiglottic folding and a reinforced tip and moulded distal cuff to prevent folding at the tip.

The i-gel is also a single-use supraglottic device with built-in gastric drain tube. It consists of an anatomical firm tube section and an anatomical non-inflatable cuff section. Along the tubing is an integral bite-block, an elliptical buccal cavity stabiliser that eliminates rotation and provides vertical strength to aid insertion, and a V-shaped connector to the cuff to prevent kinking. It has an anatomical non-inflatable silicon cuff that seals the laryngeal inlet and prevents neurovascular compression at the larynx. An epiglottic rest at the cuff prevents downfolding of the epiglottis and laryngeal inlet obstruction.

We were interested in these two devices due to their claimed advantages, and the rise in the routine use of disposable supraglottic airway adjuncts for maintenance of anaesthesia in our institution. Therefore we designed a study to compare the performance of the SLMA and i-gel during anaesthesia in spontaneously breathing adult patients. Our primary outcome was oropharyngeal leak pressure (OLP). Secondary outcomes included number of insertion attempts, ease of insertion, passage of a gastric tube, manipulations required, ventilation quality and fibroptically determined laryngeal view grade.

METHODS

With approval from the University Malaya Medical Centre Ethical Committee and informed written consent, we studied 90 patients (American Society of
Anesthesiologists physical status I or II), aged 16 to 55 years, undergoing elective surgery not requiring tracheal intubation. Exclusion criteria included patients who were at risk of regurgitation of gastric contents or if they had pathology of the neck, upper respiratory or upper alimentary tracts, previous or anticipated airway problems or body mass index >35 kg.m⁻².

All patients were fasted overnight. Intravenous access was obtained and all patients received standard monitoring before induction of anaesthesia. Patients’ heads were supported on a firm silicone headrest and were kept in a neutral position. After preoxygenation for three minutes, anaesthesia was induced with fentanyl 2.0 µg.kg⁻¹ and propofol 2 mg.kg⁻¹. Induction of anaesthesia was confirmed by loss of verbal contact with the patient, loss of eyelash reflex and relaxation of the jaw. If coughing, gagging or body movement occurred during insertion, a further dose of propofol 0.5 mg.kg⁻¹ was given to achieve an adequate depth of anaesthesia. Anaesthesia was maintained with sevoflurane 2 to 3% in oxygen. Intermittent fentanyl boluses were given for additional analgesia.

After induction, patients were randomly allocated to one of the two groups using sequentially allocated numbered, sealed opaque envelopes containing the name of one of the two devices. A single anaesthetist (with experience in using the LMA Classic™ on more than 500 patients), who had used the SLMA and i-gel devices 20 times, inserted the devices. Both devices were inserted according to the manufacturer’s instructions including weight-based recommendations for the size (SLMA: size 3 for patients 30 to 50 kg, size 4 for patients 50 to 70 kg, size 5 >70 kg; i-gel: size 3 for patients 30 to 60 kg, size 4 for patients 50 to 90 kg, size 5 for patients >90 kg). The standard pre-use tests were performed. Both devices were lubricated using a water-based lubricant on the tip and posterior surface as recommended by the manufacturers, and the SLMA was fully deflated prior to insertion. After insertion, the SLMA device was then inflated to a pressure of 60 cmH₂O using a handheld pressure gauge device (VBM, Medizintechnik, Sulz, Germany).

After insertion of the airway, the breathing system was connected to the device. An initial assessment of airway patency and the ability to ventilate the lungs was made by gently squeezing the reservoir bag, while observing the presence of end-tidal carbon dioxide waveforms and chest movement. If it was not possible to ventilate the lungs, the following airway manoeuvres were allowed: chin-lift, jaw-thrust, head extension or flexion on the neck. After any manoeuvre, adequacy of ventilation was re-assessed. If it was not possible to insert the device or ventilate through it, one more attempt at insertion was allowed. A failed attempt was defined as removal of the device from the mouth. If placement failed after two attempts, the patient was withdrawn from the study and insertion was recorded as a failure. The time to insertion, defined as the time from picking up the device to obtaining the first end-tidal carbon dioxide trace, was measured by an independent observer. The ease of insertion was graded as 1=easy, 2=moderate, 3=difficult or 4=impossible. The number of insertion attempts was recorded.

Once ventilation was successful, as confirmed by CO₂ waveform and chest movement, the OLP of each device was measured, i.e. the minimum airway pressure at which gas audibly leaks around the airway using a fresh gas flow of 3 l.minute⁻¹ with the adjustable pressure-limiting valve completely closed. The peak airway pressure is not allowed to exceed 40 cmH₂O. Following this, the device’s anatomic positioning was evaluated by fibreoptic endoscopy using the following scoring system: 1=vocal cords entirely visible; 2=vocal cords or arytenoids cartilages partially visible; 3=epiglottis only visible; 4=no laryngeal structures visible.

During maintenance of anaesthesia, if there was airway obstruction, adjusting the position of the device or the patient’s head and neck or removal and reinsertion of the device were allowed. The number of manipulations of each device during insertion and maintenance of anaesthesia were recorded.

At the end of the operation the device was removed after the patient regained consciousness and opened his or her mouth to command. The presence or absence of blood on the device, injury to the teeth or lips and the incidence of perioperative complications (i.e. coughing, gagging, hiccup, vomiting, regurgitation, aspiration, laryngospasm and bronchospasm, hypoxia [peripheral oxygen saturation, oxygen saturation measured by pulse oximetry <95%]) were noted. Patients were asked one hour postoperatively by a blinded investigator whether they had a sore throat (yes or no).

The sample size for the OLP (primary outcome) was based on a pilot study of 16 patients. The mean airway pressure at which gas leaked around the i-gel was 20 cmH₂O (SD 8 cmH₂O). Power analysis determined that a study of 31 patients in each group had 80% power to detect a difference in airway seal pressure of 5 cmH₂O. For secondary outcomes, we used the reported incidence of overall attempt successful insertions of SLMA in non-paralysed
anaesthetised patients of 95 to 100%, and a minimum clinically important difference of 20% between i-gel and SLMA, based on using a two-tailed alpha value (0.05) and a beta value (0.2). Under these conditions, a sample size of 45 patients per group was estimated to be sufficient to detect a difference in success rate of 20%. We therefore studied 90 patients.

The data for OLP were normally distributed and Student’s t-test was used for analysis. Insertion times were not normally distributed and the Mann-Whitney U-test was used. The grade of fibreoptic view and number of manipulations were compared by Mann-Whitney U-test. Complications and efficacy of ventilation between the groups were compared by Fisher’s exact test. Commercial SPSS 15.0 software for Windows (SPSS Inc., Chicago, IL, USA) was used for data processing. Data are presented as mean and standard deviations, range, interquartile range and percentage. P <0.05 was considered statistically significant.

RESULTS

Forty-five patients in each group were studied. Patients’ characteristics are presented in Table 1.

In one patient, the SLMA was inserted easily but ventilation was unsuccessful and there was no expiratory carbon dioxide waveform despite two attempts; an LMA Classic was then inserted with easy ventilation. During insertion, two patients in the SLMA had complications related to laryngospasm despite easy insertion. These patients’ data were excluded from further analysis during maintenance of anaesthesia. As a result, SLMA was used for maintenance in 42 cases and the i-gel for 45 cases.

The first-time success rates at achieving an effective airway were 44 of 45 (97.8%) for the SLMA and 42/45 (93.3%) for the i-gel. Two attempts were required in 2/45 (4.4%) for the i-gel. There was one failure to establish a patent airway with the SLMA and none with the i-gel. The ease of insertion was rated easier in SLMA compared to i-gel (P=0.011). However, the time taken for insertion was similar for the two groups (P=0.433). The OLP was higher for the SLMA than for the i-gel (P=0.0001). Once the airway was established, complications during anaesthesia were infrequent for both devices. In one patient in the SLMA group, the airway became partially obstructed soon after the surgery started (one manipulation required to maintain a patent airway). There were no complications requiring removal. One patient in the SLMA group developed mild laryngospasm and another patient had hiccups soon after surgery started, which were self-limiting after the administration of additional fentanyl. There were no arterial desaturations in either groups. Both devices were tolerated well during emergence from anaesthesia. The incidence of trauma, gastric tube passing at the first attempt and perioperative complications were similar between groups. Grade of fibreoptic view was better for i-gel than the SLMA (Table 2, P=0.001).

Table 1
Characteristics of patients (n=90) undergoing anaesthesia with the SLMA or i-gel, and size of device used. Values are mean (SD) or number (proportion).

<table>
<thead>
<tr>
<th>SLMA (n=45)</th>
<th>i-gel (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, M/F</td>
<td>15/30</td>
</tr>
<tr>
<td>Age, y</td>
<td>35 (15)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>61 (13)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>161 (8)</td>
</tr>
<tr>
<td>BMI, kg·m⁻²</td>
<td>23 (4)</td>
</tr>
<tr>
<td>Mallampati Score, 1/2/3/4</td>
<td>36/8/1/0</td>
</tr>
<tr>
<td>Size, 3/4/5</td>
<td>18/18/9</td>
</tr>
</tbody>
</table>

SLMA = LMA Supreme™, i-gel = I-Gel™, M = male, F = female, BMI = body mass index.

Table 2
Comparison of the SLMA and i-gel. Ease of insertion, measurements and complications related to insertion of the SLMA and i-gel in 90 patients (for the SLMA, n=42 for all except number of attempts and ease of insertion). Values are number (proportion), median (IQR range) or mean (SD).

<table>
<thead>
<tr>
<th>Insertion</th>
<th>SLMA (n=45)</th>
<th>i-gel (n=45)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attempts, 1/2/failed</td>
<td>44/0/1</td>
<td>42/3/0</td>
<td>0.132</td>
</tr>
<tr>
<td>Ease of insertion, easy/moderate/difficult/impossible</td>
<td>34/10/1/0</td>
<td>23/22/0/0</td>
<td>0.011</td>
</tr>
<tr>
<td>Time for insertion, s</td>
<td>20.0 (15.0-25.0 [15.0-30.0])</td>
<td>20.0 (15.0-25.0 [12.0-30.0])</td>
<td>0.433</td>
</tr>
<tr>
<td>Manipulations</td>
<td>0</td>
<td>0</td>
<td>0.242</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>2 (4.5%)</td>
<td>0 (0%)</td>
<td>0.242</td>
</tr>
<tr>
<td>Oropharyngeal leak pressure cmH₂O</td>
<td>25.6 (5.1)</td>
<td>20.7 (5.9)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Manipulations</td>
<td>1 (2.4%)</td>
<td>0</td>
<td>0.483</td>
</tr>
<tr>
<td>Laryngospasm/hiccup</td>
<td>2 (4.4%)</td>
<td>0 (0%)</td>
<td>0.230</td>
</tr>
<tr>
<td>Fibreoptic score†, 1/2/3/4</td>
<td>26/6/7/3</td>
<td>41/3/0/1</td>
<td>0.001</td>
</tr>
<tr>
<td>Mucosal injury</td>
<td>3 (7.1%)</td>
<td>4 (8.9%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Sore throat</td>
<td>4 (9.5%)</td>
<td>2 (4.4%)</td>
<td>0.4230</td>
</tr>
</tbody>
</table>

† 1 = vocal cords entirely visible, 2 = vocal cords or arytenoids cartilages partially visible, 3 = epiglottis only visible, 4 = no laryngeal structures visible. SLMA = LMA Supreme™, i-gel = I-Gel™, IQR = interquartile range.
DISCUSSION

We found that the SLMA OLP was higher than i-gel and this was both statistically significant and clinically relevant. As a result, the SLMA may be more useful than the i-gel for controlled ventilation. Our results differ from the findings of Theiler et al who found that the OLP was similar between the SLMA and i-gel. The difference in our results might relate to the different group of patients.

We did not perform any power calculations for the secondary outcome measures, so the remainder of our findings must be considered exploratory. We found that the SLMA was slightly easier to insert compared to i-gel (P=0.011) but the clinical relevance of the difference is not known. Moreover, time to achieve an effective airway was similar between the two devices. The first attempt and overall insertion success rates were similar between groups. This concords with other studies that have shown a high success rate with both devices.

There was one complete failure to establish a patent airway with the SLMA despite easy insertion. No complete failures occurred in the i-gel group. Insertion complications on the other two patients with the SLMA were related to laryngospasm. During maintenance of anaesthesia the airway was clear throughout the operation for most cases, except for one patient in the SLMA group who needed one manipulation to maintain the airway. There were two intraoperative complications in the SLMA group and none in the i-gel. One patient developed mild laryngospasm and the other patient had hiccups. No conclusions can be drawn about the incidence of these complications due to the small numbers involved.

There was minimal blood-staining with both the devices. This is similar to previous reports. Postoperative sore throat was also similar between devices.

Fibreoptic view was better with the i-gel device. This suggests that the device might be better suited to use as a conduit in difficult airway management and failed intubation, but larger studies would be required to confirm this finding. However, in this study we found no association between the fibreoptic position and the functioning of these devices. This is similar to other studies. Gastric tube insertion via the drain tube was successful at the first attempt in all patients. This is also very similar to the success rates reported in other studies.

Our study has a number of limitations. First, our study was conducted in non-paralysed patients, hence our findings may be less applicable to paralysed patients. However, there is indirect evidence from mucosal pressure studies that pharyngeal muscle tone is similar in paralysed and non-paralysed patients. Second, both devices were inserted by a single experienced user. Therefore, our results may not be applicable to inexperienced users. Further studies are needed to assess ease of insertion and first time insertion success rate by novice users, as supraglottic airways are incorporated in the difficult airway management protocol. Third, the intraoperative data were collected by an unblinded observer, introducing a potential source of bias.

We conclude that both devices are suitable for routine use during maintenance of anaesthesia in spontaneously breathing patients with normal airways, as both SLMA and i-gel appear to be effective in establishing a clinically patent airway and have high success rates of insertion and low morbidity. The SLMA provides a higher OLP. Our findings suggest also that the SLMA might be slightly easier to insert than the i-gel, and that the fibreoptic views may be better with the i-gel.

ACKNOWLEDGEMENT

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REFERENCES


