Randomized double-blind comparison trial among i-gel\textsuperscript{TM}, LMA-ProSeal\textsuperscript{TM} and tracheal intubation with manual in-line stabilization in patients with simulated cervical spine movement limitation by rigid cervical collar immobilization

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**Background**

Tracheal intubation with manual in-line stabilization (TT-MILS) is the standard management in patients with cervical spine injury. The procedure of which is not practical for inexperienced personnel. Supraglottic airway device has a role in difficult airway management and been proved to be easy for new users. It may be effective for airway management in the setting of limited cervical spine movement.

**Objective**

To compare airway management by i-gel, LMA-ProSeal\textsuperscript{TM} and TT-MILS in anesthetized, paralyzed patients with simulated difficult airway by rigid cervical collar.

**Research design**

A randomized, double-blind comparison study.

**Setting**

In the operating rooms and surgical wards, King Chulalongkorn Memorial Hospital, a tertiary hospital with 1500 beds.

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**Materials and Methods**: Sixty patients scheduled for superficial surgery which required general anesthesia were recruited and randomized into three groups as follows, i-gel, LMA-ProSeal\textsuperscript{TM} and TT-MILS. The patients and assessors were blinded. Primary outcome was the time to successful ventilation. Other measurements were insertion attempts, positive leak pressure, fiber optic-assessed glottic view, intraoperative and postoperative complications.

**Results**: Twenty patients were assigned to each groups. Times to successful ventilation were not statistically different (i-gel 43.01 ± 26.94 s; LMA-ProSeal\textsuperscript{TM} 50.05 ± 45.73 s; TT-MILS 68.43 ± 46.69 s; \( P = 0.113 \)). The success rate for i-gel was 90% in the first attempt and 10% in second attempt vs. that of LMA-ProSeal\textsuperscript{TM} which was 95% in the first attempt and 5% in the second attempt (\( P = 0.536 \)). The positive leak pressure was significantly higher in LMA-ProSeal\textsuperscript{TM} group than that of in the i-gel group (25.55 ± 3.01 cmH\textsubscript{2}O vs. 23.35 ± 3.31 cmH\textsubscript{2}O; \( P = 0.035 \)). The glottic views were not statistically different between the groups. The incidences of sore throat and odynophagia were significantly lower in the i-gel and LMA-ProSeal\textsuperscript{TM} groups, compared to that of the TT-MILS group (\( P = 0.000, 0.017 \) respectively).

**Conclusion**: I-gel had shorter insertion time compared to LMA-ProSeal\textsuperscript{TM} and TT-MILS. Regarding the less seal, i-gel might be a reasonable alternative to the LMA-ProSeal\textsuperscript{TM} and TT-MILS in patients with reduced neck movement and limited mouth opening.

**Keywords**: Supraglottic airway device, simulated cervical spine movement limitation, difficult airway management.

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หัวข้อเรื่องนี้ ผู้เขียนเพิ่มการเปรียบเทียบการเปิดทางเดินหายใจระหว่าง i-gel™, LMA ProSeal™ และการใส่ท่อช่วยหายใจโดยเทคนิค Manual in-line stabilization ในผู้ป่วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัดการเคลื่อนไหวกระดูกสันหลังส่วนคอ. การศึกษานี้ cará 2558 ก.ย. – ต.ค.; 59(5): 503 –16

เหตุผลของการทำวิจัย: การใส่ท่อช่วยหายใจโดยเทคนิค manual in-line stabilization เพื่อจำกัดการเคลื่อนไหวกระดูกสันหลังส่วนคอ เป็นวิธีมาตรฐานในการเปิดทางเดินหายใจ สำหรับผู้ป่วยบาดเจ็บกระดูกสันหลังส่วนคอ แต่อาจไม่เหมาะสมในสถานการณ์ที่ผู้ลูกยางคาดประสบการณ์ supraglottic airway device เป็นอุปกรณ์เปิดทางเดินหายใจที่มีบทบาทในสถานการณ์ใส่ท่อช่วยหายใจยาก และเป็นที่ยอมรับว่าใช้งานสำหรับผู้ใช้ที่ไม่คุ้นเคยจึงอาจใช้เปิดทางเดินหายใจในผู้ป่วยกลุ่มนี้ได้เพื่อมีประสิทธิภาพ

วัตถุประสงค์: เพื่อดำรงเปรียบเทียบการเปิดทางเดินหายใจระหว่างวิธีมาตรฐานกับการใช้ supraglottic airway device สองชนิดคือ i-gel และ LMA ProSeal™ ในผู้ป่วยที่เข้ารับการผ่าตัดและได้รับการระงับความรู้สึกโดยสมบูรณ์เพื่อจำลองการปฏิบัติการเปิดทางเดินหายใจในกระดูกสันหลังส่วนคอ

รูปแบบการวิจัย: การวิจัยเชิงเปรียบเทียบแบบสุ่ม และมีการปกปิดสองทาง

สถานที่ทำการศึกษา: ห้องผ่าตัดและหอผู้ป่วยศัลยกรรม โรงพยาบาลจุฬาลงกรณ์

ตัวอย่างและวิธีการศึกษา: ผู้ป่วย 60 ราย ที่เข้ารับการกระทำความรู้สึกทั้งไปเพื่อการผ่าตัดแบบไม่เจาะด้าน แบ่งเป็นสามกลุ่มโดยการสุ่มได้แก่ กลุ่ม i-gel กลุ่ม LMA ProSeal และกลุ่มควบคุม (TT-MILS). มีการปิดผู้ป่วยและผู้ประเมินผลภายนอก คือ ระยะแรกที่ใช้ในการเปิดทางเดินหายใจผลลัพธ์ ประเมินผลด้วยดิจิตอล fiberoptic และภาวะแทรกซ้อนระหว่างและหลังการผ่าตัด.
ผลการวิจัย: ระยะเวลาที่ใช้ในการเปิดทางเดินหายใจไม่พบความแตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างกลุ่ม (i-gel 43.01 ± 26.94 s; LMA-ProSeal 50.05 ± 45.73 s; TT-MILS 68.43 ± 46.69 s; P = 0.113). การเปิดทางเดินหายใจด้วย i-gel 90% สำเร็จในครั้งแรก และซ้ำ 10% สำเร็จในครั้งที่สอง ขณะที่การเปิดทางเดินหายใจด้วย LMA ProSeal™ 95% สำเร็จในครั้งแรก และซ้ำ 5% สำเร็จในครั้งที่สอง (P = 0.536). ความดันบวกในการช่วยหายใจ (positive leak pressure) ในกลุ่ม LMA ProSeal™ สูงกว่ากลุ่ม i-gel อย่างมีนัยสำคัญทางสถิติ (25.55 ± 3.01 cmH2O vs. 23.35 ± 3.31 cmH2O; P = 0.035). ภาพกล่องเสียงไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างสองกลุ่ม. พบอาการเจ็บคอและกลืนเจ็บในกลุ่ม i-gel และ LMA ProSeal™ ต่ำกว่ากลุ่มใส่ท่อช่วยหายใจอย่างมีนัยสำคัญทางสถิติ (P = 0.000, 0.017 ตามลำดับ).

สรุป: i-gel ใช้ระยะเวลาเปิดทางเดินหายใจสั้นกว่า LMA ProSeal™ และ TT-MILS แต่จะเสียเรียบไม่แข็งแรงดันบวกในการช่วยหายใจต่ำกว่า LMA ProSeal™ แต่ i-gel อาจเป็นทางเลือกที่ดีกว่าเมื่อเทียบกับ LMA ProSeal™ และ TT-MILS ในสถานการณ์ที่ผู้ป่วยขยับคอและช่วยกัด.

คำสำคัญ: อุปกรณ์ช่วยหายใจเหนือกล่องเสียง, สถานการณ์จำลองจำกัดการเคลื่อนไหวกระดูกสันหลังส่วนคอ, ภาวะเสียเรียบช่วยหายใจสั้นมาก.
Cervical spine injury occurs at the incidence of 1.5 - 3% of all trauma cases and results in devastating complications. Unstable cervical spine injury needs cervical immobilization to prevent further neurological damage. However, limited jaw excursion and neck motion by cervical immobilization significantly cause difficulty in tracheal intubation.

Tracheal intubation with manual in-line immobilization is a standard maneuver to secure airway in these patients. In order to minimize significant movement of the cervical spine, it may take time and need skillful personnel to perform the maneuver properly. In practice, securing the airway in emergency traumatic cervical spine injured patients with compromised airway should be simplified and made easy for in experienced personnel with the use of a simpler device. Recently, the novel supraglottic airway devices, LMA-ProSeal (Laryngeal mask company, Henley-on-Thames, UK) and the i-gel (Intersurgical Ltd, Wokingham, Berkshire, UK) have been introduced into clinical practice. The i-gel features an unique design of a non-inflatable cuff filled with styrene ethylene butadiene styrene which provides the seal. Easier insertion, even during chest compression and less tissue compression have been appraised for the device. Jackson et al have compared insertion of eight airway devices in four airway-training manikins and have found better satisfaction of the i-gel introduction than all other devices.

We have performed a comparison study in the use of i-gel and LMA-ProSeal with the conventional tracheal intubation with manual in-line stabilization, for securing the airway in anesthetized patients, which were simulated difficult airway by using the rigid cervical collar performed by the first year anesthesia residents after brief training. The primary outcome is the time to successful ventilation. We have also assessed insertion attempts, positive leak pressure, fiberoptic-assessed the glottic view, intraoperative and postoperative complications.

Methods

This study is a randomized, double-blind, comparison study conducted at King Chulalongkorn Memorial Hospital, Bangkok, Thailand from August 2010 to January 2011.

Participants

After obtaining the approval of the Ethics Committee (King Chulalongkorn Memorial Hospital, Thailand) and patients’ informed consent, 60 patients with ASA status class I-II, aged 18 - 65 years old, scheduled for elective surgery in supine position and not requiring muscle relaxant during operation were recruited. Exclusion criteria were those with body mass index greater than 30 kg/m², risk of aspiration, abnormalities of upper airway and lung pathology (COPD, asthma, restrictive lung diseases). The supine position that required head elevation more than 30 degree was also excluded.

Anesthesia and airway securing

During preoperative period, patients were visited by co-instructors of the study, informed consents were collected and airway data including Mallampati classification, inter-incisor gap (ICG; the distance between the lower border of the upper incisors to the upper border of the lower incisors), thyromental distance (the distance from the mentum...
to the thyroid cartilage notch while the patient’s neck is fully extended), neck circumference (a point just below the larynx and perpendicular to the long axis of the neck), range of neck flexion and extension were assessed and recorded. At the operating room, another co-instructor randomly assigned the patients into i-gel (I), LMA-ProSeal (P) or TT-MILS (T) group by opening a sealed opaque envelope before the induction of anesthesia. Then, rigid cervical collars were placed on the patients while sitting, and they were asked to open their mouths by themselves. Only the Mallampati class and inter-incisor gap were re-evaluated and recorded. The residents with less than one year of experience in anesthetic practice who already obtained the brief training with manikins performed the device insertion under supervision of the main instructor of the study.

Before anesthesia induction, intravenous (iv) catheter was secured and standard monitoring according to American Society of Anesthesiologists were applied to the patients. Anesthesia was induced with iv fentanyl 1 mcg/kg and iv propofol 2.5 mg/kg. Once the patient lost eyelash reflex, iv succinylcholine 1 mg/kg was administrered, proper bag-mask ventilation with 100% oxygen was delivered for one minute then the devices were inserted without removal of the rigid cervical collar. Excepted in the T group, the anterior portion of rigid cervical collar was removed before the device insertion. Immediately after insertion, the device was connected to the anesthetic machine and ventilation was assisted until patient returned to spontaneous ventilation. Anesthesia was maintained with \( \text{N}_2\text{O}/\text{O}_2/\text{Sevoflurane} \) without muscle relaxant. All patients spontaneously ventilated throughout the operation.

In case of failure of insertion of the i-gel and the LMA-Proseal up to three times, the tracheal tube was inserted instead. The patient was still considered in the original group upon the intention-to-treat basis.

The devices

I-gel was inserted in accordance with manufacturer’s guidelines. Size selection of i-gel depended on the patient weight (weight 30-50 kg: size 3; 50 – 90 kg: size 4). Similarly for the LMA-Proseal, we followed a weight-based recommended by the manufacturers (weight 30 - 50 kg: size 3; 50 – 70 kg: size 4). The size of the devices was selected according to the manufacturers’ recommendations. Tracheal tube size 7.0 or 7.5 was chosen for female and size 8.0 or 8.5 for male.

Outcomes

The primary outcome and intraoperative data were assessed and recorded by the principal investigator of the study. The time (second) required to secure airway starting from the one minute after iv succinylcholine administration to the time that lung ventilation was established to the patient was the primary outcome. The insertion attempts were also recorded, positive leak pressure was measured by audible air leakage around the anterior neck while the APL valve was closed with fresh gas flow 1 LPM.

The glottic view was assessed by fiberoptic bronchoscopy (grade I: vocal cord is entirely visible; grade II: vocal cord or arytenoids cartilages partially visible; grade III: epiglottis only visible and grade IV: no laryngeal structure visible).\(^{(19)}\) The gastric tube, lubricated with KY jelly\(^{®}\) was inserted and the difficulty of gastric catheter placement was graded (1: easy; 2: difficult or 3: impossible).\(^{(20)}\)
Intraoperative complications were recorded as follows: displaced and unable to ventilate, hypoxia defined as O₂ saturation < 95%, laryngospasm, coughing, visible bleeding, aspiration as visualized gastric content or food particle above the vocal cord, and other complications. Postoperative complications were collected by the same co-instructor of the preoperative day whom blinded to the assigned device. The patients were asked to grade the following symptoms of sorethroat, odynophagia, mandibular pain and nausea/vomiting (0: none at all, 1: little, 2: moderate and 3: severe).

Statistical Analysis

The sample size calculation was based on earlier published data regarding time to insertion i-gel by Theiler et al. [20] and LMA-ProSeal by Eschertzhuber et al. [21]. Using a two-tailed alpha value (0.05), beta value (0.1) with 20% dropping out, 20 patients per group were required in the study according to the formula shown below.

\[
n_{\text{per group}} = \frac{2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2}{(\bar{X}_1 - \bar{X}_2)^2}
\]

\[
\sigma^2 = \frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{n_1 + n_2 - 2}
\]

The study was on intention to treat basis. Continuous data were analyzed by one-way ANOVA and further analyzed by post hoc analysis in the statistical significant data. Paired was used in paired value continuous data. Categorical data was analyzed by Chi-square test. Ordinal data were analyzed by non-parametric Kruskal-Wallis test and further analyzed by Mann-Whitney U test in the statistical significant data. All data were analyzed with SPSS version 17. Data were presented as mean and SD, range and percentage. \( P <0.05 \) was considered statistically significant.

Results

From August 2010 to January 2011, 78 patients were eligible for the study. Eighteen of them were excluded. Six patients did not meet the inclusion criteria (BMI over 30 kg/m² \( n = 4 \), prone position \( n = 1 \), history of upper-airway surgery \( n = 1 \)), 10 patients declined to participate, 1 patient was excluded because the operation was cancelled due to unoptimized medical condition and 1 patient was excluded because the operation was postponed due to a technical problem (Figure 1).

Finally, 60 patients were investigated and randomized into 3 groups to be 20 patients per group. None of the patients lost to follow-up or discontinued their intervention. The patient characteristics are demonstrated in Table 1. There was no statistical significance between groups (\( P >0.05 \))

The use of rigid cervical collar significantly reduced overall inter-incisor gap from 5.13 ± 0.75 cm to 3.26 ± 0.69 cm (\( P = 0.00 \)), while significantly increased the Mallampati classification (\( P = 0.000 \)).

The results of the study are demonstrated in Table 2. All devices were inserted successfully in 1st or 2nd attempt, no difference between groups (\( P = 0.536 \)). No patient in the I group or P group needed to change to tracheal tube insertion. Insertion time for the i-gel, LMA-ProSeal and TT-MILS were 43.01 ± 26.94, 50.05 ± 45.73 and 68.43 ± 46.69 seconds respectively which were not statistically
different among the groups ($P = 0.113$). The positive leak pressure was different in the i-gel and LMA-ProSeal group ($23.35 \pm 3.31 \text{ cmH}_2\text{O} \text{ vs. } 25.55 \pm 3.01 \text{ cmH}_2\text{O}, P = 0.035$). The fiberoptic-assessed glottic view of the i-gel compared to the LMA ProSeal was similar ($P = 0.677$) and showed only grade 1 and 2. The difficulty of gastric tube insertion in the i-gel and LMA-ProSeal group was not different ($P = 0.548$).

About intraoperative complications, in the i-gel group: one patient experienced i-gel displacement during positioning for surgery so that ventilation was interrupted, the i-gel was then successfully reinserted. One patient coughed during the fiberoptic bronchoscope was inserted, propofol was administered to achieve adequate depth of anesthesia. One patient needed the second attempt of device insertion, at the end of the operation, i-gel was removed and visible blood was found at the tip of the device. In the LMA-ProSeal group, one patient experienced laryngospasm and hypoxia ($O_2$ saturation < 95%) during LMA-ProSeal insertion in the second attempt and a 100% oxygen with CPAP and succinylcholine was administered so that proper ventilation was resumed. In the TT-MILS group, one patient developed hypoxia ($O_2$ saturation < 95%) during second attempt of intubation. The preoperative airway assessment was Mallampati class II while laryngoscopic view was grade III. Thus, intubation period was unexpectedly extended (210 seconds including ventilation). No intraoperative aspiration occurred.

*Figure 1.* Flow diagram of a randomized, double-blind, comparison trial among the i-gel, LMA-Proseal and TT–MILS groups in securing the airway in simulated difficult airway patients.
Table 1. Patients’ characteristics (n=60)

<table>
<thead>
<tr>
<th></th>
<th>I-gel™ (n = 20)</th>
<th>LMA-ProSeal™ (n = 20)</th>
<th>TT-MILS (n = 20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>48.10 (10.16)</td>
<td>42.45 (13.14)</td>
<td>42.45 (11.37)</td>
<td>0.216</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>54.89 (8.82)</td>
<td>58.02 (11.02)</td>
<td>57.63 (10.37)</td>
<td>0.570</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>158.32 (7.72)</td>
<td>159.05 (8.22)</td>
<td>156.85 (6.09)</td>
<td>0.634</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>21.68 (3.46)</td>
<td>27.20 (4.18)</td>
<td>23.40 (3.82)</td>
<td>0.365</td>
</tr>
<tr>
<td>Sex (%female)</td>
<td>80</td>
<td>95</td>
<td>100</td>
<td>0.590</td>
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<tr>
<td>ASA I/II, n (%)</td>
<td>75/25</td>
<td>65/35</td>
<td>80/20</td>
<td>0.550</td>
</tr>
<tr>
<td>Mallampati class</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre - I/II/III/IV, n (%)</td>
<td>16/4/0/0, (80/20/0/0)</td>
<td>16/4/0/0, (80/20/0/0)</td>
<td>14/6/0/0, (70/30/0/0)</td>
<td>0.286</td>
</tr>
<tr>
<td>Post - I/II/III/IV, n (%)</td>
<td>0/6/14/0, (0/30/70/0)</td>
<td>0/8/12/0, (0/40/60/0)</td>
<td>0/5/14/1, (0/25/70/5)</td>
<td>0.560</td>
</tr>
<tr>
<td>Inter-incisor gap (cm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre - ICG</td>
<td>4.98 (0.87)</td>
<td>5.32 (0.69)</td>
<td>5.09 (0.67)</td>
<td>0.324</td>
</tr>
<tr>
<td>Post - ICG</td>
<td>3.14 (0.70)</td>
<td>3.45 (0.65)</td>
<td>3.19 (0.73)</td>
<td>0.476</td>
</tr>
<tr>
<td>Thyromental distance (cm)</td>
<td>8.90 (1.06)</td>
<td>9.20 (1.26)</td>
<td>8.65 (1.31)</td>
<td>0.364</td>
</tr>
<tr>
<td>Neck circumference (cm)</td>
<td>33.00 (2.36)</td>
<td>34.52 (4.58)</td>
<td>33.15 (2.10)</td>
<td>0.262</td>
</tr>
</tbody>
</table>

Results are presented as mean (SD) if not otherwise indicated.

Table 2. Outcomes of the insertion of devices (n = 60)

<table>
<thead>
<tr>
<th></th>
<th>I-gel™ (n = 20)</th>
<th>LMA-ProSeal™ (n = 20)</th>
<th>TT-MILS (n = 20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion time (sec)</td>
<td>43.01 ± 26.94</td>
<td>50.05 ± 45.73</td>
<td>68.43 ± 46.69</td>
<td>0.113</td>
</tr>
<tr>
<td>Number of trial, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.536</td>
</tr>
<tr>
<td>1st attempt</td>
<td>18 (90)</td>
<td>19 (95)</td>
<td>19 (95)</td>
<td></td>
</tr>
<tr>
<td>2nd attempt</td>
<td>2 (10)</td>
<td>1 (5)</td>
<td>1 (5)</td>
<td></td>
</tr>
<tr>
<td>Positive leak pressure (cmH₂O)</td>
<td>23.35 ± 3.31</td>
<td>25.55 ± 3.01</td>
<td></td>
<td>0.035</td>
</tr>
<tr>
<td>Fiberoptic-assessed glottic view, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.677</td>
</tr>
<tr>
<td>Grade 1</td>
<td>17 (85)</td>
<td>16 (80)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>3 (15)</td>
<td>4 (20)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 4</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
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<tr>
<td>Difficulty of Gastric tube insertion, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>0.548</td>
</tr>
<tr>
<td>Grade 1</td>
<td>17 (85)</td>
<td>16 (80)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>3 (15)</td>
<td>4 (20)</td>
<td></td>
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Regarding the postoperative complications, the incidences of sore throat in the i-gel and LMA-ProSeal groups were significantly less than the TT-MILS group ($P = 0.000$, and $0.017$ respectively). However, it was similar between the i-gel and LMA-ProSeal groups ($P = 0.096$). In addition, the incidences of odynophagia in the i-gel and LMA-ProSeal groups were also less than that of the TT-MILS group ($P = 0.011$, and $0.035$ respectively). Likewise, it was similar between the i-gel and LMA-ProSeal groups ($P = 0.496$). Besides, other postoperative complications were not statistically different between the groups, such as mandibular pain ($P = 0.601$), nausea/vomiting ($P = 0.055$), lip and dental injury ($P = 0.355$).

Discussion

In this study, we found that the time of insertion, positive leak pressure and number of attempts on insertion were not statistically different between the i-gel and LMA-ProSeal groups when performed by the first year anesthesia residents after brief trainings. The mean insertion time of i-gel (43 s) was shorter than that of LMA-ProSeal (50 s). Although this difference was not statistically significant, it might reflect the ease and simplicity of insertion or less time needed for the cuff inflation of LMA-ProSeal. A previous study of Jackson et al. and Uppal et al. demonstrated an easier and faster procedure for insertion of i-gel than other supraglottic airway devices in manikins and anesthetized, paralyzed adults, which is in accordance with our study which performed in the simulated difficult airway patients and showed the similar results.

Positive leak pressure reflects the ability of airway seal of the device. Better seal of the airway can be achieved with higher leak pressure. Schmidbauer et al. reported significantly higher leak pressure of the LMA-ProSeal than the i-gel in 8 unfixed cadavers, and concluded that LMP-ProSeal provided better seal of the esophagus than the i-gel. Our study also found higher airway leak pressure in the LMA-ProSeal than i-gel group with statistical difference. Although airway seal property of i-gel was not as good as LMA-ProSeal, relatively shorter time of insertion may be clinically preferred for an in experienced hand in emergency settings.

We also assessed the glottic view with the fiberoptic bronchoscopy. We found that the position of i-gel and LMA-ProSeal were not different. The anatomical position assessment of i-gel was also performed by Theiler et al. and revealed less epiglottic down folding compared to LMA Supreme. Keijzer et al. also reported better anatomical position of i-gel comparing to that of La Premier LMA. However, anatomical position of LMA-ProSeal was reported more superior than that of i-gel by Schmidbauer et al. performed in only 8 cadavers.

Pulmonary aspiration is a possible serious complication and considered an important issue for selecting supraglottic airway device. Gibbison et al. reported the incidence of major complications in Royal United Hospital wherein 1 pulmonary aspiration was found in 280 anesthetized patients in elective surgery securing airway with the i-gel. Cook and Gibbon analyzed 1000 consecutive uses of LMA-ProSeal by one anesthetist in the same hospital and found no pulmonary aspiration occurred. However, a case report of pulmonary aspiration of gastric contents during a use of LMA-ProSeal secondary to
unrecognized fold over malposition was published by Brimacombe. Although we did not experience gastric content aspiration in our study, the number of study population is relatively small compared to previous studies. Laryngospasm is also possible during the use of supraglottic airway device. Helmy et al reported the incidence of 4% laryngospasm in 80 patients using i-gel as well as the classic LMA. However, we found only one patient who experienced laryngospasm in the LMA-ProSeal group.

Besides, cervical motion during airway management in cervical spine injured patients is also a major concern. Laryngeal mask insertion has been reported to cause a significant displacement of destabilized cervical spine. Brimacombe et al compared six airway management techniques in 10 human cadavers with a posteriorly destabilized third cervical (C-3) vertebra and found that significant displacement of the injured segment of cervical spine occurred during airway management with face mask, laryngoscope-guided oral intubation, the esophageal tracheal Combitube™, the in-tubating and standard laryngeal mask airway; but not with fibrescope-guided nasal intubation. Kihara et al also found that the intubating LMA produced segmental movement of the cervical spine, despite manual in-line stabilization in patients with cervical spine pathology undergoing cervical spine surgery. However, evidence of cervical spine movement during airway management by i-gel and LMA-ProSeal has not been established. In our study, we also did not determine the cervical spine motion during airway management. Future study focusing on cervical spine movement during airway management with i-gel and LMA-ProSeal is suggested.

There are some limitations in our study, however. Firstly we studied only low risk patients (ASA I and II) who had normal airways and were not obese. Secondly, the patients in our study were paralyzed and unresponsive during insertion of the devices and were different from the actual emergency scenario that most patients tend to be agitated and not cooperative. Thus, further study of high risk, anticipated difficult airway, obese and non-paralyzed patients during insertion of the device is needed. Thirdly, in our study intraoperative and postoperative pain management was not recorded, inevitably it puts some impacts on postoperative sore throat, odynophagia, nausea/vomiting and mandibular pain. Evaluations of such postoperative complications are still questioned. And lastly, both devices were inserted by short experienced users so that our results may not be applicable for untrained users.

In order to distinguish the difference of effectiveness in emergency airway opening among supraglottic airway devices, other aspect of applications might be determined as primary outcome, not only the insertion time.

**Conclusion**

In summary, we found no statistical difference of time to insertion between i-gel, LMA-ProSeal and tracheal tube with manual in-line stabilization. LMA-ProSeal had superior efficacy of seal than i-gel. However, i-gel had shorter insertion time when compared to LMA-ProSeal and TT-MILS. Thus, i-gel might be an alternative to LMA-ProSeal and TT-MILS in patients with reduced neck movement and limited mouth opening for inexperienced personnel.
References


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28. Brimacombe J, Keller C, Kunzel KH, Gaber O,