

# Randomized double-blind comparison trial among i-gel<sup>TM</sup>, LMA-ProSeal<sup>TM</sup> and tracheal intubation with manual in-line stabilization in patients with simulated cervical spine movement limitation by rigid cervical collar immobilization

Tee Chularojmontri\*

Phatthanaphol Engsusophon\* Pichaya Deeprasertvit\*

Chularojmontri T, Engsusophon P, Deeprasertvit P. Randomized double-blind comparison trial among i-gel<sup>TM</sup>, LMA-ProSeal<sup>TM</sup> and tracheal intubation with manual in-line stabilization in patients with simulated cervical spine movement limitation by rigid cervical collar immobilization. Chula Med J 2015 Sep - Oct; 59(5): 503 - 16

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<sup>TM</sup> 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.

<sup>\*</sup>Department of Anesthesiology, King Chulalongkorn Memorial Hospital, The Thai Red Cross Society

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 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  $\pm$  26.94 s; LMA-ProSeal<sup>TM</sup> 50.05  $\pm$  45.73 s; TT-MILS 68.43  $\pm$  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<sup>TM</sup> 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<sup>TM</sup> group than that of in the i-gel group (25.55  $\pm$  3.01 cmH $_{_{2}}$ O vs. 23.35  $\pm$  3.31 cmH<sub>2</sub>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<sup>TM</sup> 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 TM and TT-MILS. Regarding the less seal, i-gel might be a reasonable alternative to the LMA-Proseal 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.

Reprint request: Engsusophon P. Department of Anesthesiology, King Chulalongkorn Memorial Hospital, The Thai Red Cross Society, Bangkok 10330, Thailand. Received for publication. February 10, 2015.

# โดยเทคนิค Manual in-line stabilization ในผู้ป่วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัด September- October 2015 การเคลื่อนไหวกระดกสันหลังส่วนคอ

ธีร์ จุฬาโรจน์มนตรี, พัฒนพล เอ็งสุโสภณ, พิชญา ดีประเสริฐวิทย์. การศึกษาเปรียบเทียบ การเปิดทางเดินหายใจระหว่าง i-gei<sup>TM</sup>, LMA ProSeal<sup>TM</sup> และการใส่ท่อช**่วยหายใจโดย** เทคนิค Manual in-line stabilization ในผู้ป่วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัด การเคลื่อนไหวกระดูกสันหลังส่วนคอ. จุฬาลงกรณ์เวชสาร 2558 ก.ย. – ต.ค.; 59(5): 503 - 16

เหตุผลของการทำวิจัย

: การใส่ท่อช่วยหายใจโดยเทคนิค manual in-line stabilization เพื่อ จำกัดการเคลื่อนใหวกระดูกสันหลังส่วนคอ เป็นวิธีมาตรฐานในการเปิด ทางเดินหายใจสำหรับผู้ปวยบาดเจ็บกระดูกสันหลังส่วนคอ แต่อาจ ไม่เหมาะสมในสถานการณ์ที่บุคลากรขาดประสบการณ์ supraglottic airway device เป็นอุปกรณ์เปิดทางเดินหายใจที่มีบทบาทในสถานการณ์ ใส่ท่อชวยหายใจยาก และเป็นที่ยอมรับวาใช้งายสำหรับผู้ใช้ที่ไม่คุ้นเคย จึงอาจใชเปิดทางเดินหายใจในผู้ปวยกลุ่มนี้ได้อย่างมีประสิทธิภาพ

วัตถุประสงค์

: เพื่อศึกษาเปรียบเทียบการเปิดทางเดินหายใจระหว่างวิธีมาตรฐานกับ การใช<sup>้</sup> supraglottic airway device สองชนิดคือ i-gel และ LMA ProSeal  $^{\mathsf{TM}}$  ในผู้ปวยที่เข้ารับการผาตัดและได้รับการระงับความรู้สึก โดยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัดการเคลื่อนไหวกระดูก สันหลังส่วนคก

ฐปแบบการวิจัย สถานที่ทำการศึกษา : การวิจัยเชิงเปรียบเทียบแบบสุ่มและมีการปกปิดสองทาง ะ ห้องผ่าตัดและหอผู้ป่วยศัลยกรรม โรงพยาบาลจุฬาลงกรณ์

ตัวอย่างและวิธีการศึกษา :

ผู้ปวย 60 ราย ที่เข้ารับการระงับความรู้สึกทั่วไปเพื่อการผาตัดแบบ ไม่เร่งด่วน แบ่งเป็นสามกลุ่มโดยการสุ่ม ได้แก่ กลุ่ม i-gel กลุ่ม LMA ProSeal และกลุ่มควบคุม (TT-MILS) มีการปกปิดผู้ปวยและ ผู้ประเมินผลวิจัยหลัก คือ ระยะเวลาที่ใช้ในการเปิดทางเดินหายใจ ผลอื่น ๆ ที่ประเมินเพิ่มคือ จำนวนครั้งที่ใช้ในการเปิดทางเดินหายใจ ความดันบวกในการช<sup>่</sup>วยหายใจ (positive leak pressure) ภาพ กล่องเสียง (glottic view) ที่ประเมินจากการส่องกล้อง fiberoptic และ ภาวะแทรกซ้อนที่พบระหวางและหลังการผ่าตัด

ผลการวิจัย

ระยะเวลาที่ใช้ในการเปิดทางเดินหายใจไม่พบความแตกต่างกันอย่าง มีนัยสำคัญทางสถิติระหว่างสามกลุ่ม (i-gel 43.01  $\pm$  26.94 s; LMA-ProSeal 50.05  $\pm$  45.73 s; TT-MILS 68.43  $\pm$  46.69 s; P=0.113) การเปิดทางเดินหายใจด้วย i-gel 90% สำเร็จในครั้งแรก และอีก 10 % สำเร็จในครั้งที่สอง ขณะที่ การเปิดทางเดินหายใจด้วย LMA ProSeal Mariform และอีก 5% สำเร็จในครั้งที่สอง (P=0.536) ความดันบวกในการช่วยหายใจ (positive leak pressure) ในกลุ่ม LMA ProSeal Mariform สู่ม i-gel อย่างมีนัยสำคัญทางสถิติ (25.55  $\pm$  3.01 cmH O vs. 23.35  $\pm$  3.31 cmH O; P=0.035) ภาพกลองเสียงไม่มี ความแตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างสองกลุ่ม พบ อาการเจ็บคอและกลืนเจ็บในกลุ่ม i-gel และ LMA ProSeal Mariform ต่ำกว่า กลุ่มใส่ท่อช่วยหายใจอย่างมีนัยสำคัญทางสถิติ (P=0.000, 0.017 ตามลำดับ)

สรุป

i-gel ใช้ระยะเวลาเปิดทางเดินหายใจสั้นกว่า LMA ProSeal<sup>TM</sup> และ TT-MILS แม้จะเสียเปรียบในแง่ความดันบวกในการช่วยหายใจต่ำกว่า LMA ProSeal<sup>TM</sup> แต<sup>่</sup> i-gel อาจเป็นทางเลือกที่ดีกว<sup>่</sup>าเมื่อเทียบกับ LMA ProSeal<sup>TM</sup> และ TT-MILS ในสถานการณ์ที่ผู้ปวยขยับคอและ อ้าปากได้จำกัด

คำสำคัญ

อุปกรณ์ช่วยหายใจเหนือกล่องเสียง, สถานการณ์จำลองจำกัด การเคลื่อนไหวกระดูกสันหลังส่วนคอ, ภาวะใส่ทอช่วยหายใจลำบาก.

# Vol. 59 No. 5 การศึกษาเปรียบเทียบการเปิดทางเดินหายใจระหว<sup>่</sup>าง i-gel<sup>TM</sup>, LMA ProSeal<sup>TM</sup> และการใส่ท<sup>่</sup>อช่วยหายใจ September- October 2015 โดยเทคนิค Manual in-line stabilization ในผู้ป<sup>่</sup>วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัด การเคลื่อนไหวกระดกสันหลังส<sup>่</sup>วนคอ

Cervical spine injury occurs at the incidence of 1.5 - 3% of all trauma cases<sup>(1)</sup> and results in devastating complications. Unstable cervical spine injury needs cervical immobilization to prevent further neurological damage.<sup>(2)</sup> However, limited jaw excursion and neck motion by cervical immobilization significantly cause difficulty in tracheal intubation.<sup>(3, 4)</sup>

Tracheal intubation with manual in-line immobilization is a standard maneuver to secure airway in these patients. (5, 6) 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<sup>TM</sup> (Laryngeal mask company, Henley-on-Thames, UK) and the i-gel<sup>TM</sup> (Intersurgical Ltd, Wokingham, Berkshire, UK) have been introduced into clinical practice. The i-gel<sup>IM</sup> features an unique design of a non-inflatable cuff filled with styrene ethylene butadiene styrene which provides the seal. (7 - 9) Easier insertion, even during chest compression (10,11) and less tissue compression have been appraised for the device. (12 - 17) 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. (18)

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) I 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 administered, 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 N<sub>2</sub>O/O<sub>2</sub>/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). 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).

# Vol. 59 No. 5 การศึกษาเปรียบเทียบการเปิดทางเดินหายใจระหว<sup>่</sup>าง i-gel<sup>TM</sup>, LMA ProSeal<sup>TM</sup> และการใส่ท<sup>่</sup>อช่วยหายใจ September- October 2015 โดยเทคนิค Manual in-line stabilization ในผู้ป<sup>่</sup>วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัด การเคลื่อนไหวกระดกสันหลังส<sup>่</sup>วนคอ

Intraoperative complications were recorded as follows: displaced and unable to ventilate, hypoxia defined as  $\rm O_2$  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 per group = 
$$\frac{2(Z_{\alpha12} + Z_{\beta})^2 6^2}{(\overline{X}_1 - \overline{X}_2)^2}$$

$$6^{2} = \frac{(n_{1}-1)SD_{1}^{2} + (n_{2}-1)SD_{2}^{2}}{n_{1} + n_{2} - 2}$$

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.

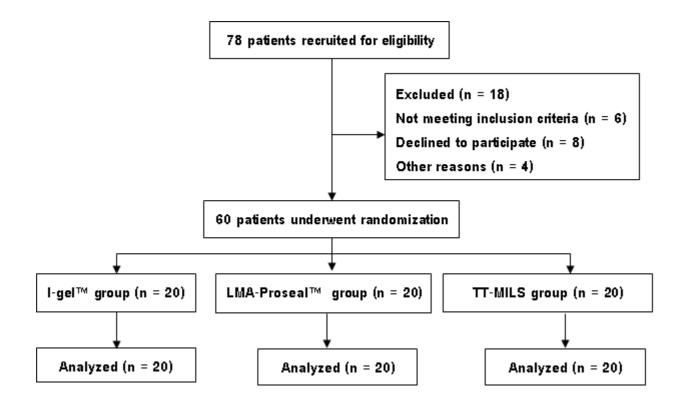
### Results

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  $5.13\pm0.75$  cm to  $3.26\pm0.69$  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 1<sup>st</sup> or 2<sup>nd</sup> 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  $43.01\pm26.94$ ,  $50.05\pm45.73$  and  $68.43\pm46.69$  seconds respectively which were not statistically



**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.

different among the groups (P=0.113). The positive leak pressure was different in the i-gel and LMA-ProSeal group ( $23.35\pm3.31~{\rm cmH_2O}~vs.~25.55\pm3.01~{\rm cmH_2O}$ , 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 ( ${\rm O_2}$  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 ( ${\rm O_2}$  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.

# Table 1. Patients' characteristics (*n*=60)

	I-gel <sup>TM</sup> (n = 20)	LMA-ProSeal <sup>TM</sup> (n = 20)	TT- MILS (n = 20)	P value
Age (yr)	48.10 (10.16)	42.45 (13.14)	42.45 (11.37)	0.216
Body weight (kg)	54.89 (8.82)	58.02 (11.02)	57.63 (10.37)	0.570
Height (cm)	158.32 (7.72)	159.05 (8.22)	156.85 (6.09)	0.634
BMI (kg/m <sup>2</sup> )	21.68 (3.46)	27.20 (4.18)	23.40 (3.82)	0.365
Sex (%female)	80	95	100	0.590
ASA I/II, n (%)	75/25	65/35	80/20	0.550
Mallampati class				
Pre - I/II/III/IV, n (%)	16/4/0/0,	16/4/0/0,	14/6/0/0,	0.286
	(80/20/0/0)	(80/20/0/0)	(70/30/0/0)	
Post - I/II/III/IV, n (%)	0/6/14/0,	0/8/12/0,	0/5/14/1,	0.560
	(0/30/70/0)	(0/40/60/0)	(0/25/70/5)	
Inter-incisor gap (cm)				
Pre - ICG	4.98 (0.87)	5.32 (0.69)	5.09 (0.67)	0.324
Post - ICG	3.14 (0.70)	3.45 (0.65)	3.19 (0.73)	0.476
Thyromental distance (cm)	8.90 (1.06)	9.20 (1.26)	8.65 (1.31)	0.364
Neck circumference (cm)	33.00 (2.36)	34.52 (4.58)	33.15 (2.10)	0.262

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

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

	I-gel <sup>TM</sup> (n = 20)	LMA-ProSeal <sup>TM</sup> (n = 20)	TT-MILS (n = 20)	P value
Insertion time (sec)	43.01 ± 26.94	50.05 ± 45.73	68.43 ± 46.69	0.113
Number of trial, n (%)				0.536
1 <sup>st</sup> attempt	18 (90)	19 (95)	19 (95)	
2 <sup>nd</sup> attempt	2 (10)	1 (5)	1 (5)	
Positive leak pressure (cmH <sub>2</sub> O)	$23.35 \pm 3.31$	$25.55 \pm 3.01$		0.035
Fiberoptic-assessed				
glottic view, n (%)				0.677
Grade 1	17 (85)	16 (80)		
Grade 2	3 (15)	4 (20)		
Grade 3	0 (0)	0 (0)		
Grade 4	0 (0)	0 (0)		
Difficulty of Gastric				
tube insertion, n (%)				0.548
Grade 1	17 (85)	16 (80)		
Grade 2	3 (15)	4 (20)		
Grade 3	0 (0)	0 (0)		

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. Aprevious study of Jackson et al<sup>(18)</sup> and Uppal et al<sup>(22)</sup> 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*<sup>(23)</sup> 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. (20) Keijzer *et al* also reported better anatomical position of i-gel comparing to that of La Premier LMA. (17) However, anatomical position of LMA-Proseal was reported more superior than that of i-gel by Schmidbauer *et al* (23), 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*<sup>24)</sup> 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<sup>(25)</sup> 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

# Vol. 59 No. 5 การศึกษาเปรียบเทียบการเปิดทางเดินหายใจระหว<sup>่</sup>าง i-gel<sup>TM</sup>, LMA ProSeal<sup>TM</sup> และการใส่ท<sup>่</sup>อช่วยหายใจ September- October 2015 โดยเทคนิค Manual in-line stabilization ในผู้ป<sup>่</sup>วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัด การเคลื่อนไหวกระดกสันหลังส<sup>่</sup>วนคอ

unrecognized fold over malposition was published by Brimacombe. (26) 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 (27) 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<sup>(28)</sup> 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<sup>TM</sup>, the in tubating and standard laryngeal mask airway; but not with fiberscope-guided nasal intubation. Kihara et al<sup>(29)</sup>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 (ASAI 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 co-operative. 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

- Hastings RH, Marks JD. Airway management for trauma patients with potential cervical spine injuries. Anesth Analg 1991 Oct;73(4): 471-82
- Hastings RH, Kelley SD. Neurologic deterioration associated with airway management in a cervical spine-injured patient. Anesthesiology 1993 Mar;78(3):580-3
- Goutcher CM, Lochhead V. Reduction in mouth opening with semi-rigid cervical collars. Br J Anaesth 2005 Sep;95(3):344-8
- 4. Arslan ZI, Yildiz T, Baykara ZN, Solak M, Toker K. Tracheal intubation in patients with rigid collar immobilisation of the cervical spine: a comparison of Airtraq® and LMA CTrach<sup>TM</sup> devices. Anaesthesia 2009 Dec;64(12): 1332-6
- Manoach S, Paladino L. Manual in-line stabilization for acute airway management of suspected cervical spine injury: historical review and current questions. Ann Emerg Med 2007 Sep;50(3):236-45
- 6. Brimacombe J, Keller C, Kunzel KH, Gaber O, Boehler M, Puhringer F. Cervical spine motion during airway management: A cine fluoroscopic study of the posteriorly destabilized third cervical vertebrae in human cadavers. Anesth Analg 2000 Nov; 91(5): 1274-8
- 7. Richez B, Saltel L, Banchereau F, Torrielli R, Cros AM. A new single use supraglottic airway device with a noninflatable cuff and an esophageal vent: an observational study of the i-gel. Anesth Analg 2008 Apr;106(4):

### 1137-9

- 8. Verghese C, Ramaswamy B. LMA-Supreme<sup>TM</sup> a new single-use LMA<sup>TM</sup> with gastric access: a report on its clinical efficacy. Br J Anaesth 2008 Sep;101(3):405-10
- Uppal V, Fletcher G, Kinsella J. Comparison of the i-gel with the cuffed tracheal tube during pressure-controlled ventilation. Br J Anaesth 2009 Feb;102(2):264-8
- 10. Nolan JP, Deakin CD, Soar J, Bottiger BW, Smith G. European Resuscitation Council guidelines for resuscitation 2005. Section 4. Adult advanced life support. Resuscitation 2005 Dec;67 Sppl1: s39-86
- 11. Gatward JJ, Thomas MJC, Nolan JP, Cook TM. Effect of chest compression on the time taken to insert airway devices in a manikin. Br J Anaesth 2008 Mar;100(3):351-6
- 12. Gatward JJ, Cook TM, Seller C, Handel J, Simpson T, Vanek V, Kelly F. Evaluation of the size 4 i-gel airway in one hundred nonparalysed patients. Anaesthesia 2008 Oct; 63(10):1124-30
- 13. Wharton NM, Gibbison B, Gabbott DA, Haslam GM, Muchatuta N, Cook TM. I-gel insertion by novices in manikins and patients.

  Anaesthesia 2008 Sep;63(9):991-5
- 14. Soar J. The i-gel supraglottic airway and resuscitation-some initial thoughts.
  Resuscitation 2007 Jul;74(1):197-9
- 15. Gabbott DA, Beringer R. The i-gel supraglottic airway: A potential role for resuscitation? Resuscitation 2007 Apr;73(1):161-2
- 16. Michalek P, Hodgkinson P, Donaldson W. Case report: Fiberoptic intubation through an i-gel

# การศึกษาเปรียบเทียบการเปิดทางเดินหายใจระหว<sup>่</sup>าง i-gel<sup>TM</sup>, LMA ProSeal<sup>TM</sup> และการใส่ท<sup>่</sup>อช่วยหายใจ 5 โดยเทคนิค Manual in-line stabilization ในผู้ป**่วยสวมปลอกคอเพื่อจำลองสถานการณ์จำกัด** การเคลื่อนไหวกระดกสันหลังส**่วนค**อ

- supraglottic airway in two patients with predicted difficult airway and intellectual disability. Anesth Analg 2008 May;106(5): 1501-4
- 17. Keijzer C, Buitelaar DR, Efthymiou KM, Sramek M, Cate JT, Ronday M, Stoppa T, Huitink JM, Schutte PF. A comparison of postoperative throat and neck complaints after the use of the i-gel® and the La Premier® disposable laryngeal mask: a double-blinded, randomized, controlled trial. Anesth Analg 2009 Oct;109(4):1092-4
- 18. Jackson KM, Cook TM. Evaluation of four airway training manikins as patient simulators for the insertion of eight types of supraglottic airway devices. Anaesthesia 2007 Apr;62(4): 388-93
- 19. Cook TM, Cranshaw J. Randomized crossover comparison of proseal laryngeal mask airway with laryngeal tube sonda during anaesthesia with controlled ventilation. Br J Anaesth 2005 Aug;95(2):261-6
- 20. Theiler LG, Kleine-Brueggeney M, Kaiser D, Urwyler N, Luyet C, Vogt A, Greif R, Unibe MM. Crossover comparison of the laryngeal mask Supreme<sup>TM</sup> and the i-gel<sup>TM</sup> in simulated difficult airway scenario in anesthetized patients. Anesthesiology 2009 Jul;111(1):55-62
- 21. Eschertzhuber S, Brimacombe J, Hohlrieder M and Keller C. The laryngeal mask airway Supreme<sup>TM</sup> a single use laryngeal mask airway with an oesophageal vent a randomized cross-over study with the laryngeal mask airway Proseal<sup>TM</sup> in paralysed,

- anesthetized patients. Anaesthesia 2009 Jan; 64(1):79-83
- 22. Uppal V, Gangaiah S, Fletcher G, Kinsella J.
  Randomized crossover comparison between
  the i-gel and the LMA-Unique in anaesthetized,
  paralysed adults. Br J Anaesth 2009 Dec;
  103(6):882-5
- 23. Schmidbauer W, Bercher S, Volk T, Bogusch, Mager G, Kerner T. Oesophageal seal of the novel supralaryngeal airway device I-Gel<sup>TM</sup> in comparison with the laryngeal mask airways Classic<sup>TM</sup> and ProSeal<sup>TM</sup> using a cadaver model. Br J Anaesth 2009 Jan; 102(1):135-9
- 24. Gibbison B, Cook TM, Seller C. Case series: protection from aspiration and failure of protection from aspiration with the i-gel<sup>TM</sup> airway. Br J Anaesth 2008 Mar;100(3):415-7
- 25. Cook TM, Gibbison B. Analysis of 1000 consecutive uses of the Pro Seal laryngeal mask airway <sup>TM</sup> by one anaesthetist at a district general hospital. Br J Anaesth 2007 Sep;99(3): 436–9
- 26. Brimacombe J, Keller C. Aspiration of gastric contents during use of a ProSeal<sup>TM</sup> laryngeal mask airway secondary to unidentified fold over malposition. Anesth Analg 2003 Oct; 97(4):1192–4
- 27. Helmy AH, Atef HM, El-Taher EM, Henidak AM.

  Comparative study between I-gel, a new supraglottic airway device, and classical laryngeal mask airway in anesthetized spontaneously ventilated patients. Saudi J Anaesth 2010 Sep;4(3):131-6
- 28. Brimacombe J, Keller C, Künzel KH, Gaber O,

Boehler M, Pühringer F. Cervical spine motion during airway management: a cine fluoroscopic study of the posteriorly destabilized third cervical vertebrae in human cadavers. Anesth Analg 2000 Nov;91(5): 1274-8

29. Kihara S, Watanabe S, Brimacombe J, Taguchi

N, Yaguchi Y, Yamasaki Y. Segmental cervical spine movement with the in tubating laryngeal mask during manual in-line stabilization in patients with cervical pathology under going cervical spine surgery. Anesth Analg 2000 Jul;91(1): 195-200