J Anesth (2015) 29:654–659
DOI 10.1007/s00540-015-2016-x

ORIGINAL ARTICLE

Laryngoscopy facilitates successful i-gel insertion by novice doctors: a prospective randomized controlled trial

Yu Miyazaki[1] · Nobuyasu Komasawa[1] · Sayuri Matsunami[1] · Yusuke Kusaka[1] · Toshiaki Minami[1]

Received: 2 February 2015 / Accepted: 8 April 2015 / Published online: 25 April 2015

Abstract
Background This study investigated the hypothesis that the efficacy of insertion of the supraglottic device i-gel® (i-gel) can be improved by laryngoscopy and can provide better sealing pressure in anesthetized patients by novice doctors.
Methods Eighty-four adult patients were assigned to the laryngoscopy group (L group, 42 patients) or control group (i.e., conventional blind insertion; C group, 42 patients). Anesthesia was induced with propofol and remifentanil, and rocuronium 0.6–0.9 mg/kg was administered. The number of attempts until successful insertion, sealing pressure, vital sign changes upon insertion, and subjective difficulty of insertion by novice doctors were compared between the groups.
Results The total number of insertion attempts was one (L group 36 cases, C group 23 cases), two (L group 6 cases, C group 18 cases), and three (L group 0 case, C group 1 case), with significant differences between groups ($P = 0.007$). The sealing pressure was significantly higher in the L group than in the C group (L group 22.3 ± 2.6 cmH_2O, C group 19.5 ± 2.7 cmH_2O, $P < 0.001$). Vital sign changes (heart rate and blood pressure) did not differ between the two groups. The subjective difficulty of insertion was significantly lower in the L group than in the C group (L group 26.8 ± 11.8 mm, C group 47.0 ± 15.1 mm, $P < 0.001$). The incidence of postoperative pharyngeal pain was significantly lower in the L group than in the C group ($P < 0.001$), while the incidence of hoarseness did not differ between the two groups ($P = 1.00$).
Conclusion Our results suggest that laryngoscopy facilitates i-gel insertion by novice doctors, as reflected in the rate of successful insertions, higher sealing pressure, and lower subjective difficulty of insertion in anesthetized patients.

Keywords i-gel® · Laryngoscopy · Novice doctors · Insertion efficacy · Randomized controlled trial

Introduction

The advantage of supraglottic devices (SGDs) relative to airway management is their ease of use by novice operators [1]. In emergency situations, airway management is often performed by less experienced physicians [2]. Some reports suggest that SGDs require less professional skill and are suited for novice and occasional operators [3, 4]. However, insertion of SGDs by novice doctors can lead to hemorrhage and postoperative pharyngeal pain [5].

The i-gel® (i-gel; Intersurgical, Wokingham, United Kingdom) is a single-use SGD that has a non-inflatable, soft, gel-like cuff composed of a styrene ethylene butadiene styrene, which fits to the laryngeal structure [6]. Previous studies have shown that the i-gel has good airway sealing pressure and can be used not only for mechanical ventilation under general anesthesia, but also emergency airway management during resuscitation [7–9].

We considered the difficulties experienced by novice doctors to be at least partially attributable to the conventional blind insertion of the i-gel, and hypothesized that assistance with a laryngoscope may improve its

Trial registry number: UMIN000015013.

✉ Nobuyasu Komasawa
ane078@poh.osaka-med.ac.jp

[1] Department of Anesthesiology, Osaka Medical College, Daigaku-machi 2-7, Takatsuki, Osaka 569-8686, Japan

insertion efficacy. The primary hypothesis was tested by the successful insertion of the i-gel with sufficient sealing pressure. The secondary hypothesis was tested by the subjective difficulty of insertion and vital sign change. Accordingly, this study aimed to investigate these hypotheses by comparing the insertion efficacy of the i-gel by novice doctors with or without laryngoscopy in anesthetized patients.

Methods

The research ethics committee of Osaka Medical College approved this study. We also enrolled this study in the UMIN Clinical Trials Registry; the trial registration number was UMIN000015013. From September to December 2014, 90 patients aged 20–80 years who were scheduled to undergo general anesthesia in the supine position were assessed for eligibility to participate. Four patients were excluded and two patients refused to participate. After obtaining written informed consent, 84 patients were assigned randomly using an envelope method to the laryngoscopy group (L group, 42 patients) or control group (C group, 42 patients) (Fig. 1). Exclusion criteria included contraindications for the use of SGDs [such as obesity (body mass index >30), gastro-esophageal reflux, and previous upper abdominal surgery] or a recent (within 7 days) history of upper respiratory tract infection [10].

Eighteen novice doctors who took an anesthesia module during their initial training (all non-anesthesiologists with clinical experience <1 year) were recruited. They were all initial trainee doctors in Japanese medical systems and had no clinical experience of the Macintosh laryngoscope or i-gel usage before anesthesia module. Before data collection, novice doctors had performed laryngoscopy with the Macintosh laryngoscope at least 10 times and i-gel insertion at least 5 times. Each doctor inserted the i-gel in 3–6 patients during the trial period. The training period was a maximum of 2 months.

Routine monitoring of blood pressure, heart rate, electrocardiography, percutaneous oxygen saturation, bispectral index (BIS), and end-tidal carbon dioxide tension was performed. Without any premedication, anesthesia was induced with propofol 1–2 mg/kg and remifentanyl 0.3–0.5 μg/kg/min. After loss of consciousness, mask ventilation was performed with 3–5 % sevoflurane; rocuronium 0.6–0.9 mg/kg was administered. The supervising anesthesiologists confirmed the zero count of train-of-four with TOF watch® (Nihon Kohden, Tokyo, Japan) before the insertion trial. We used doubled-over normal cutout cushions which we usually use for anesthesia induction with approximately 8 cm height.

Using the patient's body weight, a size 3, 4, or 5 i-gel was chosen based on the manufacturer's guidelines. The supervising anesthesiologist made size selections for patients weighing 50–60 kg (size 3 or 4) [11]. In the L group trial, laryngoscopy was performed with Macintosh blade size 3 or 4, which was also selected by the supervising anesthesiologist. Novice doctors in the L group trial were instructed to perform gentle laryngoscopy at upward angle of 45° as they performed tracheal intubation. In the C group trial, they crossed their fingers on upper and lower incisors to open the mouth manually as wide as possible. Sealing pressure was measured after insertion of the i-gel by the supervising anesthesiologist. Successful insertion was confirmed by the supervising anesthesiologist based on bilateral chest wall movement, auscultation, and normal capnograph curves; a sealing pressure of >15 cmH_2O was considered a successful insertion. When ventilation failed, an insertion attempt was made immediately, and the number of insertion attempts recorded. In the case of insertion

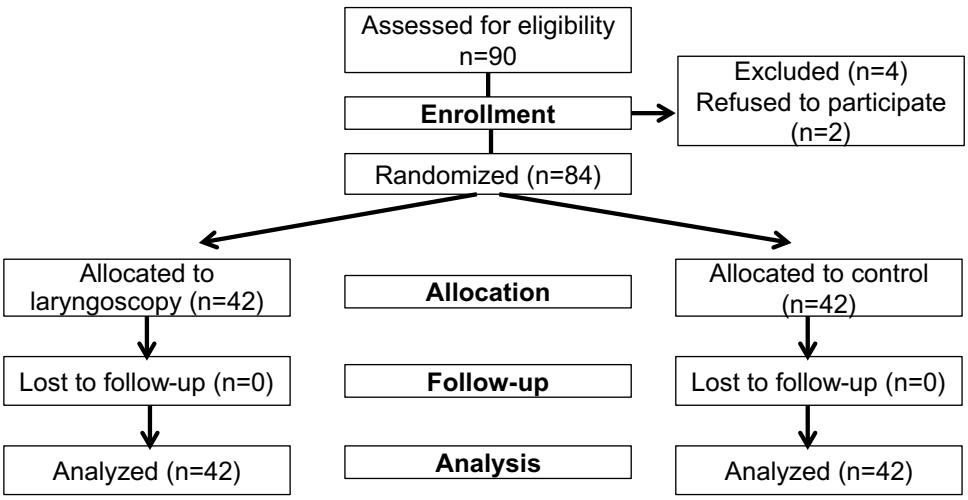

Fig. 1 Flowchart of patient recruitment

Table 1 Patient characteristics

	C group ($N = 42$)	L group ($N = 42$)
Age (years)	65.9 ± 13.3	64.5 ± 13.9
Gender, male/female	19/23	17/25
Body weight (kg)	61.6 ± 11.0	56.5 ± 10.9
Height (cm)	159.7 ± 8.6	159.1 ± 8.1
BMI (kg/m^2)	24.7 ± 3.4	22.2 ± 3.2
Duration of surgery (min)	73.8 ± 34.9	86.0. ± 48.4
Duration of anesthesia (min)	124.2 ± 47.1	132.3 ± 58.2
ASA 1/2/3/4	8/30/4	9/23/10/0
Mallampati score 1/2/3/4	12/27/3/0	15/24/3/0
i-gel size 3/4/5	19/23/0	26/15/1

Mean ± SD or number of patients

C group: i-gel inserted without laryngoscopy

L group: i-gel inserted with laryngoscopy

ASA American Society of Anesthesiologists

failure, novice doctors were not allowed to change or add insertion techniques such as jaw thrust maneuver. Changing the size of the i-gel was also not allowed during the three trials. If the third attempt failed, this was recorded as a failure, and the supervising anesthesiologist took over the insertion. The supervising anesthesiologist did not give any advice during the trials but took over the airway management in the case of patient crisis such as ventilation failure.

Systolic and diastolic blood pressure and heart rate were monitored both before and after insertion. Blood pressure and heart rate measurements were performed before insertion at the time of the first trial. Measurements after insertion were maximum values after 60 s of successful i-gel insertion.

After successful insertion, mechanical ventilation was immediately initiated, and anesthesia was maintained with inhalation of sevoflurane and administration of remifentanil with 33–40 % oxygen in air. After the operation, the i-gel was extubated, and postoperative hoarseness and pharyngeal pain after arousal were assessed by the supervising anesthesiologist. At the end of insertion, novice doctors rated the difficulty of i-gel insertion on a visual analog scale (VAS) from 0 mm (extremely easy) to 100 mm (extremely difficult).

Statistical analysis was performed using JMP® 11 (SAS Institute Inc., Cary, NC, USA). The χ^2 test was used to analyze the number of insertion attempts and incidence of hoarseness and pharyngeal pain. The Mann–Whitney U test was used to compare sealing pressure, heart rate, blood pressure, and VAS. Data are presented as mean ± SD unless otherwise indicated. $P < 0.01$ was considered statistically significant.

We first considered that a total of 180 patients were needed in this study. However, after preliminary study for the sample size calculation, the incidence of successful i-gel insertion (sealing pressure >15 cmH_2O upon first insertion) by novice doctors without laryngoscopy was approximately 60 %. As such, we hypothesized that laryngoscopy would increase the successful insertion rate of the i-gel to 90 %. To detect this difference with 80 % power at a 5 % significance level, 38 patients would be necessary in each group. Therefore, we planned to recruit 42 patients for each group to allow for missing data.

Results

Patient characteristics, including age, sex, height, weight, duration of surgery, duration of anesthesia, Mallampati score, and i-gel size, are summarized in Table 1. No case was abandoned or lost to follow-up during this trial.

Number of attempts until successful insertion and sealing pressure

The number of insertion attempts was one for 36 cases and two for 6 cases in the L group, and one for 23 cases, two for 18 cases, and three for 1 case in the C group, which showed a significant difference ($P = 0.007$) (Table 2). The number of successful insertions in the first trial differed significantly between the L and C groups ($P < 0.001$). After successful insertion, the sealing pressure was higher in the

Table 2 Comparison of factors related to airway management between laryngoscopy and control groups

	C group ($N = 42$)	L group ($N = 42$)	P value
Number of attempts until successful ventilation, 1/2/3/fail	23/18/1/0	36/6/0/0	0.007*
Hoarseness	1	1	1.00
Pharyngeal pain	18	1	<0.001*

Values for hoarseness and pharyngeal pain represent the number of patients

C group: i-gel inserted without laryngoscopy

L group: i-gel inserted with laryngoscopy

* $P < 0.01$

L group than in the C group (L group 22.3 ± 2.6 cmH_2O, C group 19.5 ± 2.7 cmH_2O, $P < 0.001$) (Fig. 2).

Subjective difficulty of i-gel insertion

As shown in Fig. 2, the subjective difficulty of i-gel insertion according to the VAS was significantly lower in the C group than in the L group (L group 26.8 ± 11.8 mm, C group 47.0 ± 15.1 mm, $P < 0.001$) (Fig. 3).

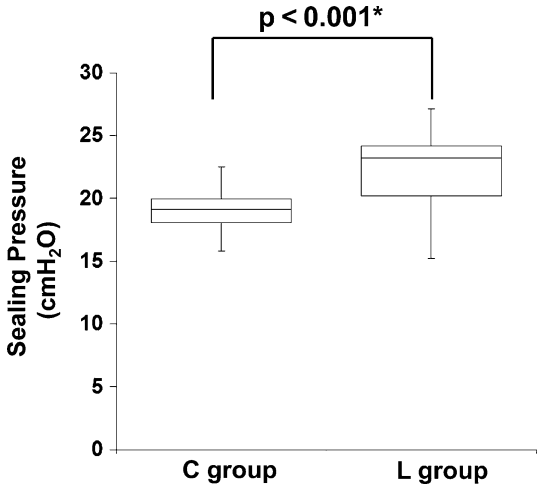

Fig. 2 Box-and-whisker plot (median, interquartile range, and range) of sealing pressure after successful insertion in the C and L groups. C group: i-gel inserted without laryngoscopy, L group: i-gel inserted with laryngoscopy. *$P < 0.01$

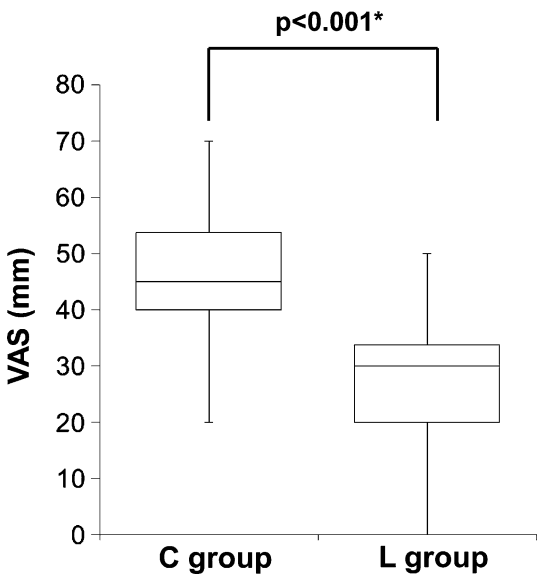

Fig. 3 Box-and-whisker plot (median, interquartile range, and range) of subjective difficulty of insertion using a visual analogue scale (*VAS*) after successful insertion in C and L groups. C group: i-gel inserted without laryngoscopy, L group: i-gel inserted with laryngoscopy. *$P < 0.01$

Incidence of hoarseness and pharyngeal pain after general anesthesia

The incidence of postoperative pharyngeal pain was significantly lower in the L group than in the C group ($P < 0.001$), while the incidence of hoarseness did not significantly differ between the two groups ($P = 1.00$) (Table 2).

Blood pressure and heart rate changes before and after insertion

Changes in blood pressure and heart rate between the C and L groups before and after insertion are shown in Table 3. SBP, DBP, and heart rate did not significantly differ between the two groups both pre- and postinsertion. The ratio of increase between pre- and postinsertion did not differ either.

Discussion

Various SGDs exist, and most have an inflatable cuff, such as conventional laryngeal masks including the LMA-Classic®, LMA-ProSeal®, and LMA-Supreme® [12, 13]. Recently, non-cuff-type SGDs such as the i-gel have been developed. Several clinical studies have shown that the i-gel effectively conforms to the perilaryngeal anatomy and consistently achieves proper positioning for supraglottic ventilation [14, 15].

SGDs are also suited for difficult airway management, especially in "cannot intubate, cannot ventilate" situations [16, 17]. The concept of "difficult airway management" includes physical difficulties associated with the patient, such as a small jaw and restricted opening of the mouth. It also includes situations such as during resuscitation or positions other than supine that make airway management more difficult [18]. Some reports suggest that SGDs require less professional skill and are suited to novice and occasional operators [3, 5]. While the advantage of SGDs is their ease of use by novice operators [6], rapid and definite insertion of SGDs for sufficient quality ventilation can be difficult for novice doctors. Many reports have described effective i-gel insertion methods [19, 20], but no consensus method currently exists.

Pharyngeal sealing pressure is a measure of how well an SGD seals the laryngeal structure and is important for the evaluation of the success of SGD insertion. In the present study, laryngoscopy significantly facilitated the success of i-gel insertion with lower subjective difficulty. Sealing pressure was also higher in the L group than in the C group. A higher sealing pressure is an indicator of how well a device might perform during controlled ventilation. Theoretically, sealing pressure is affected by mispositioning of

Table 3 Comparison of changes in blood pressure and heart rate pre- and postinsertion between laryngoscopy and control groups

	C group ($N = 42$)	L group ($N = 42$)	P value
Systolic blood pressure, pre-insertion (mmHg)	99.8 ± 16.9	93.5 ± 21.3	0.03
Systolic blood pressure, postinsertion (mmHg)	98.5 ± 16.8	90.5 ± 19.8	0.02
Systolic blood pressure increase ratio (post-/pre-insertion)	1.00 ± 0.18	0.99 ± 0.17	0.58
Diastolic blood pressure, pre-insertion (mmHg)	56.5 ± 13.4	53.9 ± 14.6	0.36
Diastolic blood pressure, postinsertion (mmHg)	56.5 ± 14.2	51.5 ± 12.6	0.09
Diastolic blood pressure increase ratio (post-/pre-insertion)	1.04 ± 0.37	0.99 ± 0.25	0.87
Heart rate, pre-insertion (min^{-1})	67.0 ± 12.5	67.0 ± 10.7	0.84
Heart rate, postinsertion (min^{-1})	66.1 ± 12.1	64.7 ± 12.5	0.60
Heart rate increase ratio (post-/pre-insertion)	0.99 ± 0.08	0.97 ± 0.13	0.71

Values are expressed as mean ± SD

C group: i-gel inserted without laryngoscopy

L group: i-gel inserted with laryngoscopy

* $P < 0.01$

SGDs, leading to insufficient ventilation and airway trouble during surgery. Results from our study suggest that laryngoscopy can assist novice doctors to successfully insert and position the i-gel. The incidence of pharyngeal pain was significantly lower in the L group than in the C group. This suggests that novice doctors often perform rough blind insertion, which can lead to pharyngeal damage or pain, while laryngoscopy-guided insertion diminishes the compression force [21, 22]. One possible reason for the utility of laryngoscopy in i-gel insertion by novice doctors is that they can place the i-gel in the appropriate position in the pharyngeal space. Another possible reason is that the novice can push the tongue aside more effectively by laryngoscopy than by the conventional manual method.

Another advantage of laryngoscopy-guided insertion is that it does not adversely affect vital signs. Blood pressure and heart rate did not increase significantly by laryngoscopy and did not differ between the C and L groups. One possible reason is that the use of laryngoscopy for i-gel insertion does not require a complete view of the glottis and its surrounding structures, which is reflected in the low VAS score in the C group [23].

Our study has several limitations. First, the i-gel insertion was performed by novice initial trainee doctors with little experience of airway management. Trials by short-term trained doctors or experienced anesthesiologists may further clarify the effects of laryngoscopy on i-gel insertion [24, 25]. Second, demographic data showed a significant increase in body weight and BMI in the C group compared to the L group, leading to inherent bias. Third, we calculated the estimated sample size by our primary endpoint, the insertion success rate determined by >15 cmH_2O sealing pressure. To further clarify the difference in other data such as vital sign change or VAS, the sample size may need to be re-evaluated.

For future directions based on the present study, as it was conducted at a single institute, a large-scale multicenter study or meta-analysis will be needed to clarify the utility of laryngoscopy in i-gel insertion [26]. Additionally, evaluation of laryngoscopy for other SGDs such as air-Q® or LMA-ProSeal® may further clarify the utility of this insertion method. Furthermore, evaluation of the educational effect such as shortening the training period by this method may be significant.

In conclusion, laryngoscopy improved i-gel insertion performed by novice doctors, as reflected in the successful insertion rate, higher sealing pressure, lower pharyngeal pain, and subjective difficulty of insertion in anesthetized patients.

Acknowledgement Financial support for the study was provided by our institution.

Conflict of interest The authors have no affiliation with any manufacturer of any device described in the manuscript and declare no financial interest in relation to the material described herein.

References

1. Neumar RW, Otto CW, Link MS, Kronick SL, Shuster M, Callaway CW, Kudenchuk PJ, Ornato JP, McNally B, Silvers SM, Passman RS, White RD, Hess EP, Tang W, Davis D, Sinz E, Morrison LJ. Part 8: adult advanced cardiovascular life support: 2010 American heart association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2010;122:S729–67.
2. Reinhart DJ, Simmons G. Comparison of placement of the laryngeal mask airway with endotracheal tube by paramedics and respiratory therapists. Ann Emerg Med. 1994;24:260–3.
3. Kohama H, Komasawa N, Ueki R, Samma A, Nakagawa M, Nishi S, Kaminoh Y. Comparison of Supreme® and Soft Seal® laryngeal masks for airway management during cardiopulmonary

resuscitation in novice doctors: a manikin study. J Anesth. 2011;25:98–103.
4. Asai T, Hidaka I, Kawachi S. Efficacy of the laryngeal tube by inexperienced personnel. Resuscitation. 2002;55:171–5.
5. de Montblanc J, Ruscio L, Mazoit JX, Benhamou D. A systematic review and meta-analysis of the i-gel® vs laryngeal mask airway in adults. Anaesthesia. 2014;69:1151–62.
6. Häske D, Schempf B, Gaier G, Niederberger C. Performance of the i-gel™ during pre-hospital cardiopulmonary resuscitation. Resuscitation. 2013;84:1229–32.
7. Theiler L, Gutzmann M, Kleine-Brueggeney M, Urwyler N, Kaempfen B, Greif R. i-gel™ supraglottic airway in clinical practice: a prospective observational multicentre study. Br J Anaesth. 2012;109:990–5.
8. Russo SG, Cremer S, Eich C, Jipp M, Cohnen J, Strack M, Quintel M, Mohr A. Magnetic resonance imaging study of the in vivo position of the extraglottic airway devices i-gel™ and LMA-Supreme™ in anaesthetized human volunteers. Br J Anaesth. 2012;109:996–1004.
9. Gabbott DA, Beringer R. The iGEL supraglottic airway: a potential role for resuscitation? Resuscitation. 2007;73:161–2.
10. Fujiwara A, Komasawa N, Nishihara I, Miyazaki S, Tatsumi S, Nishimura W, Minami T. Muscle relaxant effects on insertion efficacy of the laryngeal mask ProSeal® in anesthetized patients: a prospective randomized controlled trial. J Anesth. 2015. doi:10.1007/s00540-015-1982-3.
11. Komasawa N, Nishihara I, Tatsumi S, Minami T. Pre-warming i-gel® to 42 C facilitates successful insertion and ventilation efficacy with muscle relaxation: a randomized study. J Clin Anesth. 2014;26:663–7.
12. Komasawa N, Ueki R, Fujii A, Samma A, Nakagawa M, Nishi S, Kaminoh Y. Comparison of Laryngeal Mask Supreme® and Softseal® for airway management in several positions. J Anesth. 2011;25:535–9.
13. Asai T, Murao K, Shingu K. Efficacy of the ProSeal laryngeal mask airway during manual in-line stabilisation of the neck. Anaesthesia. 2002;57:918–20.
14. Janakiraman C, Chethan DB, Wilkes AR, Stacey MR, Goodwin N. A randomised crossover trial comparing the i-gel supraglottic airway and classic laryngeal mask airway. Anaesthesia. 2009;64:674–8.
15. Sanuki T, Uda R, Sugioka S, Daigo E, Son H, Akatsuka M, Kotani J. The influence of head and neck position on ventilation with the i-gel airway in paralysed, anaesthetised patients. Eur J Anaesthesiol. 2011;28:597–9.
16. Apfelbaum JL, Hagberg CA, Caplan RA, Blitt CD, Connis RT, Nickinovich DG, Hagberg CA, Caplan RA, Benumof JL, Berry FA, Blitt CD, Bode RH, Cheney FW, Connis RT, Guidry OF, Nickinovich DG, Ovassapian A. American Society of Anesthesiologists task force on management of the difficult airway. Practice guidelines for management of the difficult airway: an updated report by the American Society of Anesthesiologists task force on management of the difficult airway. Anesthesiology. 2013;118:251–70.
17. Japanese Society of Anesthesiologists. JSA airway management guideline 2014: to improve the safety of induction of anesthesia. J Anesth. 2014;28:482–93.
18. Komasawa N, Ueki R, Kaminoh Y, Nishi S. Evaluation of chest compression effect on airway management with air-Q®, aura-i®, i-gel®, and Fastrack® intubating supraglottic devices by novice physicians: a randomized cross over simulation study. J Anesth. 2014;28:676–80.
19. Kim HC, Yoo DH, Kim HJ, Jeon YT, Hwang JW, Park HP. A prospective randomised comparison of two insertion methods for i-gel placement in anaesthetised paralysed patients: standard vs. rotational technique. Anaesthesia. 2014;69:729–34.
20. Hashimoto Y, Asai T, Arai T, Okuda Y. Effect of cricoid pressure on placement of the I-gel™ : a randomised study. Anaesthesia. 2014;69:878–82.
21. Yih PS. Laryngoscopy for pediatric laryngeal mask airway insertion. Can J Anaesth. 1999;46:617.
22. Elwood T, Cox RG. Laryngeal mask insertion with a laryngoscope in paediatric patients. Can J Anaesth. 1996;43:435–7.
23. Ismail SA, Bisher NA, Kandil HW, Mowafi HA, Atawia HA. Intraocular pressure and haemodynamic responses to insertion of the i-gel, laryngeal mask airway or endotracheal tube. Eur J Anaesthesiol. 2011;28:443–8.
24. Wharton NM, Gibbison B, Gabbott DA, Haslam GM, Muchatuta N, Cook TM. I-gel insertion by novices in manikins and patients. I-gel insertion by novices and patients. Anaesthesia. 2008;63:991–5.
25. Abukawa Y, Hiroki K, Ozaki M. Initial experience of the i-gel supraglottic airway by residents in pediatric patients. J Anesth. 2012;26:357–61.
26. Asai T, Liu EH, Matsumoto S, Hirabayashi Y, Seo N, Suzuki A, Toi T, Yasumoto K, Okuda Y. Use of the Pentax-AWS in 293 patients with difficult airways. Anesthesiology. 2009;110:898–904.