Tracheal Intubation Through the I-gel™ Supraglottic Airway Versus the LMA Fastrach™: A Randomized Controlled Trial

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BACKGROUND: The i-gel™ is a supraglottic airway device not requiring inflation of a cuff for lung ventilation. Its design allows for unobstructed passage of a tracheal tube and previous studies have demonstrated a favorable alignment with the glottic inlet. In this prospective randomized study, we compared the success rate of blind tracheal intubation using the i-gel and the laryngeal mask airway (LMA) Fastrach™.

METHODS: One hundred sixty patients requiring general anesthesia and airway management were randomized to tracheal intubation using the i-gel or the LMA Fastrach. After induction of general anesthesia, the allocated device was inserted and adequate lung ventilation was confirmed. Blind tracheal intubation was then attempted. First attempt and overall tracheal intubation success rates were evaluated and tracheal intubation times were measured.

RESULTS: Eighty patients were recruited in each study group. Successful tracheal intubation was obtained on the first attempt in 69% of patients with the i-gel and 74% of patients with the LMA Fastrach (95% confidence interval [CI] of difference, −9% to 19%, $P = 0.60$). The overall intubation success rate was lower using the i-gel than it was using the LMA Fastrach (73% vs 91%, 95% CI of difference, 7% to 31%, $P < 0.0001$).

CONCLUSIONS: On first attempts, successful blind tracheal intubation was obtained at comparable rates using the i-gel and the LMA Fastrach. However, when the first attempt was unsuccessful, subsequent attempts through the i-gel did not significantly increase tracheal intubation success rate. The LMA Fastrach yielded a higher overall intubation success rate. (Anesth Analg 2012;114:152–6)

The i-gel™ (Intersurgical Ltd., Berkshire, UK) is a recently introduced single-use supraglottic airway device that allows effective ventilation without requiring inflation of a cuff. Randomized controlled trials have demonstrated higher airway leak pressures[1–3] and a favorable side effect profile[3] when compared with other laryngeal mask airways (LMA). Fiberoptic visualization through the i-gel has demonstrated an improved view of the glottic aperture in comparison with the LMA Unique™ (Intavent Direct, Berkshire, UK),[1] the LMA Classic™ (The Laryngeal Mask Company, Ltd., Intavent Direct, Berkshire, UK),[2] and the La Premiere™ (Armstrong Medical, Coleraine, Ireland) laryngeal airway.[3] Better glottis visualization and less epiglottic downfolding was also observed when compared with the LMA Supreme™ (LMA North America, Inc., San Diego, CA).[4] The large diameter of the airway tube and absence of bars in the mask bowl allow passage of a tracheal tube. Several case reports[5–9] of successful fiberoptic-guided intubation through the i-gel have been published. In addition, Michalek et al.[10] recently published a manikin study evaluating the success rate of blind intubation through the i-gel.

The aim of our study was to compare the success rate of blind tracheal intubation through the i-gel versus the LMA Fastrach (The Laryngeal Mask Company Limited, San Diego, California, USA). We hypothesized that the favorable glottic alignment of the i-gel™ would result in a superior first attempt success rate during blind tracheal intubation.

METHODS

After receiving Centre Hospitalier de l'Université de Montréal (CHUM)'s ethics and scientific review board approval and written informed patient consent, 160 patients were randomly assigned using a computer-generated list divided in blocks of ten, to one of two study groups: the LMA Fastrach™ (FT) group and the i-gel (IG) group. All patients were recruited between March and May 2010. Included patients were older than 18 years of age and required general anesthesia and tracheal intubation for an elective surgical procedure. Exclusion criteria were ASA class >III, contraindication to the use of rocuronium, mouth opening <2 cm, increased risk of aspiration, and known or anticipated difficult tracheal intubation or facemask ventilation.

After collection of demographic and anthropometric data, patients were brought to the operating room and clinically indicated monitoring was installed. After adequate oxygen administration and general anesthesia induction, each patient received rocuronium 0.6 $mg \cdot kg^{-1}$.

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Patients were then mask-ventilated with a mixture of oxygen and sevoflurane, for an end-tidal concentration of 2%. The supraglottic device was inserted once ulnar nerve train-of-4 stimulation produced no visually detectable response. Before insertion, the patient's head was placed in a neutral position. All airway manipulations (device insertion and tracheal intubation) were performed by a senior anesthesiology resident (A.H.) who had comparable previous experience with both devices (>20 uses).

The size of the Fastrach and i-gel was selected on the basis of the patient's weight, in accordance with the corresponding manufacturer's recommendations. Conventional Hi-lo Mallinckrodt single-use polyvinyl chloride (PVC) tracheal tubes (Mallinckrodt Company, Juarez, Chihuahua, Mexico) were used for blind tracheal intubation in both groups: size 7.0 mm ID tracheal tubes for patients weighing ≥50 kg and 6.0 mm ID tubes for patients <50 kg. Intubation through both supraglottic devices was facilitated using a water-based lubricant.

In the FT group, a single-use Fastrach intubating LMA was inserted. Once in place, the cuff was inflated and ventilation attempted, using optimization maneuvers when necessary.[11,12] Device position and lung ventilation were deemed appropriate when adequate chest excursion and capnography curves were observed without an audible leak while ventilating with an inspiratory pressure of 20 cm H_2O. If lung ventilation remained unsuccessful, the LMA Fastrach was completely removed and reinserted. If correct placement failed, the use of a different size LMA could be attempted if judged clinically appropriate.

The tracheal tube was then inserted with a reverse orientation, its concave bend facing posteriorly, because this method yielded a higher success rate during blind tracheal intubation in previous studies.[13–15] If no resistance was felt while advancing the tracheal tube, it was fully inserted into the device. Tracheal intubation was successful if ventilation through the tracheal tube produced an adequate chest expansion and a capnographic curve. The supraglottic device was then removed using a second, smaller-sized, tracheal tube as a stabilizing rod. If resistance was encountered during insertion of the tracheal tube, the intubation attempt was judged unsuccessful. A standardized algorithm was then followed on the basis of the distance at which the resistance was felt, as recommended by the manufacturer.

In the IG group, an i-gel single-use supraglottic airway was inserted, and successful placement was defined using the same ventilation criteria as in the FT group. If successful ventilation was not established, accepted maneuvers were used, as recommended by the manufacturer. After confirmation of adequate ventilation, intubation through the device was attempted. The tracheal tube was rotated 90 degrees counterclockwise before insertion. This allowed the tube's bevel to point posteriorly, thus minimizing the risk of impingement on glottic structures during insertion. If resistance was felt during insertion, the tracheal tube was removed, the i-gel readjusted, and a subsequent intubation was attempted. If no resistance was felt during insertion of the tracheal tube, it was advanced fully into the i-gel and adequacy of lung ventilation was tested. At confirmation of correct placement of the tracheal tube, the i-gel was removed using a smaller-sized tracheal tube as a stabilizing rod.

In both study groups, 3 attempts at device insertion and intubation were allowed. Intubation was only attempted if appropriate ventilation was obtained or after 3 device insertion attempts. If tracheal intubation through the device was unsuccessful, it was performed by direct laryngoscopy. Lung ventilation through the supraglottic device was permitted between intubation attempts.

The primary outcome of the study was success rate of tracheal intubation through the supraglottic airway device on the first attempt. Secondary outcomes included overall success rate of tracheal intubation and time required to perform tracheal intubation through the device (tracheal intubation time). Intubation time was calculated from the insertion of the tracheal tube in the device until confirmation of adequate lung ventilation through the tracheal tube.

Statistical Analysis

The success rate of tracheal intubation on the first attempt with the LMA Fastrach, as reported in previous randomized controlled trials, varies between 48% and 87%.[13,15–27] Considering a mean first attempt success rate of 65%, a sample size of 70 patients per group would have a power of 80% at an α of 0.05 (2-tailed) to detect a 20% difference in intubation success rate between both supraglottic airway devices, a difference that we considered clinically significant. A sample size of 80 patients per group was chosen to allow for potential patient drop-outs. Data were analyzed using GraphPad InStat version 3.10 (GraphPad Software, San Diego, CA). Continuous data were analyzed using Student t test (2-tailed, unpaired, unequal variance), and categorical data were analyzed using a Fisher exact test or χ^2 test when there were more than 2 categories (Tables 1 and 2). Continuous data are presented as mean and standard deviation (SD), whereas categorical data are presented as number of patients and percentage. Ninety-five percent confidence intervals (CI) of difference in intubation success rates and mean intubation times are also presented.

RESULTS

A total of 201 patients were evaluated for study inclusion; 41 patients were excluded according to exclusion criteria mentioned above. One hundred sixty patients were randomly allocated to 1 of 2 study groups. Demographic data were similar in the 2 groups (Table 1).

Tracheal intubation was successful on the first attempt in 59 patients (74%) with the LMA Fastrach and in 55 patients (69%) with the i-gel (95% CI of difference, −9% to 19%, $P = 0.60$). However, the LMA Fastrach yielded a significantly higher overall successful intubation rate than did the i-gel (91% vs 73%, 95% CI of difference, 7% to 31%, $P < 0.0001$). Times to achieve successful intubation differed between the 2 groups; however, the mean difference was clinically insignificant (Table 2). There was no unintended tracheal extubation when removing the supraglottic airway device.

Table 1. Patient Characteristics

	I-gel™ (n = 80)	LMA Fastrach™ (n = 80)
Sex, male/female, n (%)	26/54 (32.5/67.5)	27/53 (33.8/66.3)
Age, years	53.8 (14.3)	53.3 (14.2)
Edentulous status, yes/no (%)	21/56 (27.3/72.7)	19/59 (24.4/75.6)
Weight, kg	72.8 (14.9)	73.6 (18.1)
Height, m	1.64 (0.10)	1.64 (0.09)
Body mass index, kg/m^2	27.1 (5.6)	27.3 (6.3)
ASA physical status I/II/III, n (%)	15/51/14 (18.8/63.8/17.5)	23/41/16 (28.8/51.3/20.0)
Mallampati score 1/2/3/4, n (%)	35/42/3/0 (43.8/52.5/3.8/0)	31/45/4/0 (38.8/56.3/5.0/0)
Mouth opening, cm	5.0 (0.8)	5.0 (0.7)
Thyromental distance, cm	7.6 (1.0)	7.6 (1.0)
Neck circumference, cm	36.6 (3.4)	36.7 (3.4)

Data expressed in mean (SD) or number (%). LMA = laryngeal mask airway.

Table 2. Success Rates and Times for Device Insertion and Tracheal Intubation

	I-gel™ (n = 80)	LMA Fastrach™ (n = 80)	Difference	P
Supraglottic device insertion				
First attempt success rate, %	84	80	4 (−8 to 16)	0.68
Overall success rate, %	96	100	4	0.25
Insertion time, seconds	26 ± 24	36 ± 28	9 (1 to 18)	0.03
Insertion time when 1st attempt successful, seconds	19 ± 8	29 ± 16	10 (6 to 15)	<0.0001
Tracheal intubation				
First attempt success rate, %	69	74	5 (−9 to 19)	0.60
Overall success rate, %	73	91	19 (7 to 31)	0.0035
Intubation time, seconds	22 ± 13	30 ± 31	9 (1 to 17)	0.04
Intubation time when 1st attempt successful, seconds	19 ± 4	18 ± 3	−1 (−2 to 1)	0.37

Success rates expressed in percentage, times expressed in mean ± SD. Difference expressed in mean or percentage and shown with 95% confidence interval of difference in parentheses. P values are from Fisher exact test for success rates and Student t test for times.

DISCUSSION

Our study demonstrates that on the first attempt, tracheal intubation is obtained successfully with comparable success rates using both the i-gel and LMA Fastrach. Although our study was not designed to assess equivalence between the 2 devices, this can be assumed considering that the 95% confidence interval of the difference between both success rates (−9% to 19%) lies between the previously defined zones of clinical indifference. However, the overall success rate is significantly lower with the i-gel. This could be explained by the various maneuvers that have been recommended to optimize the LMA Fastrach's position, to minimize epiglottic downfolding and improve intubation success rate. None of these maneuvers could be extrapolated to the i-gel because of the differences in the device design and, notably, the absence of a handle. Consequently, when tracheal intubation through the i-gel was unsuccessful on the first attempt, the success rate did not improve significantly with subsequent attempts. The results obtained for both first attempt and overall intubation success rates using the LMA Fastrach were comparable to those in published studies.[23–25,27]

The use of the i-gel as a conduit for tracheal intubation has been documented in several case reports. These cases described anticipated or unanticipated difficult airway situations, and they all involved the use of a fiberoptic bronchoscope.[5–9] Michalek et al.[10] evaluated blind intubation through the i-gel in 3 different airway manikins, obtaining a success rate of 51%. Theiler et al.[28] studied "visualized blind intubation" through the i-gel and the LMA Fastrach in patients presenting at least 1 criterion for difficult intubation. Their results demonstrated a substantially inferior success rate with the i-gel when compared with the LMA Fastrach (15% vs 69%, respectively). Although marked by significant methodological differences, this low intubation success rate was also confirmed in an unpublished preliminary study at our center, with a successful first attempt intubation rate through the i-gel of 23%. However, we observed that rotating the tracheal tube 90 degrees counterclockwise before its insertion in the i-gel increased the success rate by >50%. In fact, we found that this maneuver prevented impingement of the tip of the tracheal tube on the right arytenoid cartilage during insertion. It was therefore decided to incorporate this maneuver as an integral part of this study.

Our data suggest that tracheal intubation was achieved faster with the i-gel; however, the difference is not clinically significant. Also, the intubation times are skewed by the fact that more patients' tracheas were intubated successfully on the 2nd or 3rd attempt using the LMA Fastrach, hence artificially prolonging the intubation times within that group. When considering solely the patients successfully intubated on the first attempt, the 2 groups had similar intubation times.

In comparison with other nonintubating laryngeal masks, the i-gel has a shorter and wider stem, allowing unobstructed passage of larger diameter tracheal tubes. These characteristics allow direct tracheal intubation without the use of a bougie or an exchange catheter.[10] In our study, patients' tracheas were intubated using standard PVC tubes, which are readily available in various settings. It is possible that the use of other types of tracheal tubes

(such as the more malleable, wire-reinforced tubes) could yield a higher success rate. Furthermore, we used smaller tracheal tubes than the devices could accommodate to minimize the risk of cuff damage, and this could have influenced the intubation success rate.

There are several limitations to our study. All airway manipulations were performed by a single, unblinded investigator with a fair but not extensive prior experience with either device. This aspect might have resulted in a slight increase in supraglottic device insertion times. However, the intubation success rate obtained using the LMA Fastrach was comparable to those recently published, as previously mentioned. Analysis of our data demonstrates that although intubation times improved throughout the study period in both groups, intubation success rates did not vary significantly over time. This confirms previous data suggesting that the learning curve flattens after 20 insertions when using an intubating LMA.[29] The etiology of unsuccessful intubation was not assessed systematically by fiberoptic visualization, and oropharyngeal trauma was not formally evaluated in our study; thus, no conclusions can be made regarding the safety differences, if any, between the 2 devices. Finally, patients with known or clinically anticipated difficult airways were excluded from the study, and our data cannot be extrapolated to that population.

In conclusion, blind tracheal intubation can be achieved using the i-gel as a conduit with a comparable first attempt success rate to the LMA Fastrach. However, overall intubation success rate was significantly higher with the LMA Fastrach. We suggest that if blind tracheal intubation is to be attempted through the i-gel using a conventional tracheal tube, it should be attempted only once, inserting the tracheal tube with its bevel directed posteriorly. Repeated attempts should be avoided, because they did not improve the success rate significantly. Further studies are required to confirm the use of the i-gel as a conduit for tracheal intubation in various populations and to describe optimization maneuvers when the first attempt is unsuccessful.

DISCLOSURES

Name: Antoine Elie Halwagi, MD, B Pharm.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Antoine Elie Halwagi has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
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REFERENCES

1. Francksen H, Renner J, Hanss R, Scholz J, Doerges V, Bein B. A comparison of the i-gel™ with the LMA-Unique™ in non-paralysed anaesthetised adult patients. Anaesthesia 2009;64:1118–24
2. Janakiraman C, Chethan DB, Wilkes AR, Stacey MR, Goodwin N. A randomized crossover trial comparing the i-gel supraglottic airway and classic laryngeal mask airway. Anaesthesia 2009;64:674–8
3. Keijzer C, Buitelaar DR, Efthymiou KM, Srámek M, ten Cate J, 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 Premiere® disposable laryngeal mask: a double-blinded, randomized, controlled trial. Anesth Analg 2009;109:1092–4
4. Theiler LG, Kleine-Brueggeney M, Kaiser D, Urwyler N, Luyet C, Vogt A, Greif R. Crossover comparison of the laryngeal mask supreme™ and the i-gel™ in simulated difficult airway scenario in anesthetized patients. Anesthesiology 2009;111:55–62
5. Sharma S, Scott S, Rogers R, Popat M. The i-gel™ airway for ventilation and rescue intubation. Anaesthesia 2007;62:419–20
6. Michalek P, Hodgkinson P, Donaldson W. Fiberoptic intubation through an i-gel supraglottic airway in two patients with predicted difficult airway and intellectual disability. Anesth Analg 2008;106:1501–4
7. Bamgbade OA, Macnab WR, Khalaf WM. Evaluation of the i-gel airway in 300 patients. Eur J Anaesthesiol 2008;10:865–6
8. Campbell J, Michalek P, Deighan M. I-gel supraglottic airway for rescue airway management and as a conduit for tracheal intubation in a patient with acute respiratory failure. Resuscitation 2009;8:963
9. Emmerich M, Dummler R. Einsatz der i-gel®-Larynxmaske bei schwierigem Atemweg. Anaesthesist 2008;57:779–81 [abstract]
10. Michalek P, Donaldson W, Graham C, Hinds JD. A comparison of the I-gel supraglottic airway as a conduit for tracheal intubation with the intubating laryngeal mask airway: a manikin study. Resuscitation 2010;81:74–7
11. Ferson DZ, William HR, Johansen MJ, Osborn I, Ovassapian A. Use of the intubating LMA-Fastrach™ in 254 patients with difficult-to-manage airways. Anesthesiology 2001;95:1175–81
12. Brain AIJ, Verghese C, Addy EV, Kapila A, Brimacombe J. The intubating laryngeal mask: II. A preliminary clinical report of a new means of intubating the trachea. Br J Anaesth 1997;6:704–9
13. Joo HS, Rose DK. The intubating laryngeal mask airway with and without fiberoptic guidance. Anesth Analg 1999;3:662–6
14. Ye L, Liu J, Wong DT, Zhu T. Effects of tracheal tube orientation on the success of intubation through an intubating laryngeal mask airway: study in Mallampati class 3 or 4 patients. Br J Anaesthesia 2009;102:269–72

15. Lu PP, Yang CH, Ho AC, Shyr MH. The intubating LMA: a comparison of insertion techniques with conventional tracheal tubes. Can J Anaesth 2000;47:849–53
16. Murashima K, Fukutome T, Brimacombe J. A comparison of two silicone-reinforced tracheal tubes with different bevels for use with the intubating laryngeal mask. Anaesthesia 1999;54: 1198–200
17. Fan KH, Hung OR, Agro F. A comparative study of tracheal intubation using an intubating laryngeal mask (Fastrach) alone or together with a lightwand (Trachlight). J Clin Anesth 2000;12:581–5
18. Kihara S, Watanabe S, Taguchi N, Suga A, Brimacombe JR. A comparison of blind and lightwand-guided tracheal intubation through the intubating laryngeal mask. Anaesthesia 2000;55: 427–31
19. Kihara S, Watanabe S, Taguchi N, Suga A, Brimacombe JR. Tracheal intubation with the Macintosh laryngoscope versus intubating laryngeal mask airway in adults with normal airways. Anaesth Intens Care 2000;28:281–6
20. Van Vlymen JM, Coloma M, Tongier WK, White PF. Use of the intubating laryngeal mask airway: are muscle relaxants necessary? Anesthesiology 2000;93:340–5
21. Kundra P, Sujata N, Ravishankar M. Conventional tracheal tubes for intubation through the intubating laryngeal mask airway. Anesth Analg 2005;100:284–8
22. Sastry SG, Lemmens HJ. The intubating laryngeal mask airway: rocuronium improves endotracheal intubating conditions and success rate. J Clin Anesth 2005;3:163–6
23. Fun WL, Lim Y, Teoh WH. Comparison of the GlideScope video laryngoscope vs. the intubating laryngeal mask for females with normal airways. Eur J Anaesthesiol 2007;24: 486–91
24. Nileshwar A, Thudamaladinne A. Comparison of intubating laryngeal mask airway and Bullard laryngoscope for orotracheal intubation in adult patients with simulated limitation of cervical movements. Br J Anaesth 2007;99:292–6
25. Teoh WH, Lim Y. Comparison of the single use and reusable intubating laryngeal mask airway. Anaesthesia 2007;62:381–4
26. Kanazi GE, El-Khatib M, Nasr VG, Kaddoum R, Al-Alami A, Baraka AS, Ayoub CM. A comparison of a silicone wire-reinforced tube with the Parker and polyvinyl chloride tubes for tracheal intubation through an intubating laryngeal mask airway in patients with normal airways undergoing general anesthesia. Anesth Analg 2008;107:994–7
27. Liu EH, Goy RW, Lim Y, Chen FG. Success of tracheal intubation with intubating laryngeal mask airways: a randomized trial of the LMA Fastrach and LMA CTrach. Anesthesiology 2008;108:621–6
28. Theiler L, Kleine-Brueggeney M, Urwyler N, Graf T, Luyet C, Greif R. Randomized clinical trial of the i-gel™ and Magill tracheal tube or single-use ILMA™ and ILMA™ tracheal tube for blind intubation in anaesthetized patients with a predicted difficult airway. Br J Anaesth 2011;107:243–50
29. Kapila A, Addy EV, Verghese C, Brain AIJ. The intubating laryngeal mask airway: an initial assessment of performance. Br J Anaesth 1997;79:710–3