

RESPIRATION AND THE AIRWAY

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

L. Theiler^{1,2*}, M. Kleine-Brueggeney^{1,3†}, N. Urwyler^{1,4}, T. Graf¹, C. Luyet¹ and R. Greif¹

¹ Department of Anesthesiology and Pain Therapy, Inselspital, University Hospital Bern, and University of Bern, Switzerland

² Department of Anesthesiology, Perioperative Medicine and Pain Management, University of Miami Miller School of Medicine, Gautier Bldg—Room 415, 1011 NW 15th Street, Miami, FL 33136, USA

³ Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, WA, USA

⁴ Department of Pathology, Stanford School of Medicine, CA, USA

* Corresponding author. E-mail: ltheiler@med.miami.edu

Editor's key points

- This study compared blind intubation using two supraglottic airway devices (SADs) in patients with anticipated difficult airways.
- Intubation was successful at the first attempt in 69% of patients using the sILMA™ tube through the sILMA™.
- Success rate using a Magill PVC tube through the i-gel™ was very low (15%).
- The difference between SADs was related to the SAD rather than the type of tracheal tube used.

Background. The single-use supraglottic airway device i-gel™ has been described in several case reports as a conduit for intubation, but no prospective data about success rates of blind intubation are available. Therefore, we performed this prospective randomized controlled trial to compare the success rate of blind tracheal intubation with a Magill PVC tube through the i-gel™ with intubation using an sILMA™ PVC tube through the single-use intubating laryngeal mask airway (sILMA™).

Methods. With ethics committee approval and written informed consent, 80 patients with predictors of a difficult airway were computer randomized to either supraglottic airway device (SAD). The corresponding tracheal tube (TT) was introduced through the SAD under fiberoptic visualization but without fiberoptic guidance. Primary outcome was blind intubation success rate. Times, airway leak pressure, fiberoptic view, and adverse events were recorded. To control for the influence of the TT, we compared data from 40 patients described in an accompanying study (sILMA™ with Magill TT and i-gel™ with sILMA™ TT).

Results. Blind intubation success rate through the sILMA™ (69%) was higher than with the i-gel™ (15%, $P < 0.001$). Data from the other patient group excluded the TT type as the primary cause for the difference in success rate. Removal of SADs was without problems with no difference between the type of SAD.

Conclusions. Blind tracheal intubation using the sILMA™ tube through the sILMA™ is much more successful than blind intubation with a Magill PVC tube through the i-gel™. Because of its low success rate, we would not recommend blind intubation through the i-gel™.

Keywords: airway, complications; anaesthetic techniques, fiberoptic intubation; intubation; tracheal, laryngeal mask airway, supraglottic airway devices

Accepted for publication: 13 March 2011

The i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, UK, Figs 1B and 2) is a supraglottic airway device (SAD) that is made of a thermoplastic elastomer (SEBS, styrene ethylene butadiene styrene)¹ and does not need an inflatable cuff to provide the airway seal. The advantages are easy insertion and possibly less tissue compression. Its easy placement and sufficient seal pressure for clinical use has been well documented.^{2–6} The large airway diameter of the i-gel™

enables the introduction of a tracheal tube (TT) through the i-gel™.⁷ As fiberoptic bronchoscopes are not ubiquitously available, clinicians might use the i-gel™ for blind tracheal intubation in a cannot-intubate–cannot-ventilate scenario.

For this scenario, the Difficult Airway Society's⁸ and the American Society of Anesthesiologists'⁹ guidelines recommend an SAD, or more specifically, the intubating laryngeal mask airway™ (ILMA™, The Laryngeal Mask Company

[†] These authors contributed equally to this work and share the first authorship.

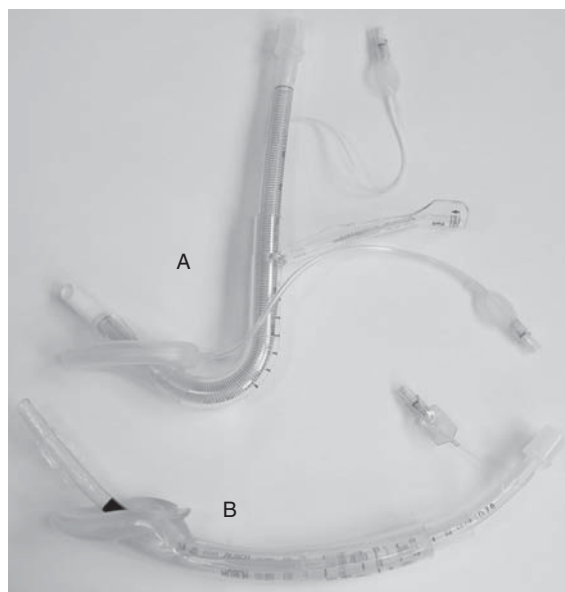


Fig 1 sILMA (TM) with sILMA TT (A) and the i-gel (TM) with Magill PVC TT in place.

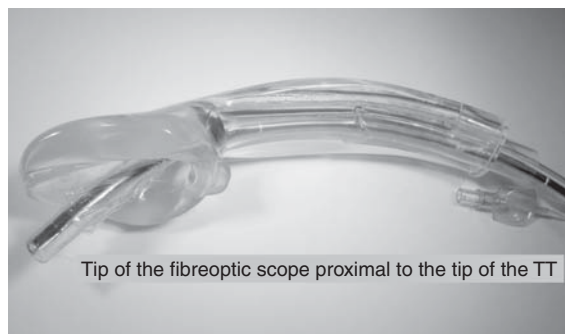


Fig 2 i-gel with Magill PVC TT and fiberoptic scope in place. The tip of the fiberoptic scope is proximal to the tip of the TT allowing visualized intubation technique without fiberoptic guidance.

Limited, Le Rocher, Victoria, Mahé, Seychelles, Fig. 1A). The ILMATM is a widely accepted and clinically investigated device to facilitate intubation.^{10 11} The first-attempt success rate for blind tracheal intubation through the ILMATM is 80–87%^{11 12} and is improved with the use of a fiberoptic to 93%.¹²

Until now, there were only case reports, a study on manikins,¹³ and one limited controlled trial evaluating the clinical performance of blind intubation through the i-gelTM.¹⁴ Therefore, we performed this prospective randomized controlled trial to evaluate the success rates of blind tracheal intubation using a Magill PVC tube through the i-gelTM with intubation using an sILMATM PVC tube through the single-use intubating laryngeal mask airway (sILMATM).

Our hypothesis was that there would be a difference of more than 30% in blind intubation success rates of the two SADs and their corresponding tubes (i-gelTM with Magill PVC tube or sILMATM with sILMATM tube).

Methods

Eighty patients were included after ethics committee approval (Cantonal Ethics Committee Bern, Bern, Switzerland, approval number 79/08, August 29, 2008, ClinicalTrials.gov identifier: NCT00888875) and with patients' written informed consent. Inclusion criteria were American Society of Anesthesiologists physical status I–IV, age 18–85 yr, undergoing elective surgery requiring tracheal intubation at the University Hospital of Bern, and presenting at least one criterion for predicted difficult airway management. We defined independent risk factors for a difficult airway as BMI >30 kg m⁻², thyromental distance <6 cm, limited mandibular protrusion or retrognathia, abnormal neck anatomy, modified Mallampati score >II,^{15 16} difficult intubation in patient history, or mouth opening of <3.5 cm.

Exclusion criteria were high risk of aspiration (non-fasted, gastroesophageal reflux disease), weight <30 kg, known difficult mask ventilation, mouth opening <20 mm, oral carcinoma or bleeding that restricted the use of SADs, patients who did not speak German, or declined to participate.

Patients were randomly assigned to two groups (computer-generated randomization: www.randomization.com) using sealed, opaque envelopes: Group 1, placement of an i-gelTM and Magill PVC tube; and Group 2, placement of an sILMATM and sILMATM tube.

Twenty-four staff anaesthetists with experience in the use of both SADs and skilled in fiberoptic-guided tracheal intubation through SADs participated in this investigation. All participants were under supervision by one of the main study authors.

Premedication was with oral midazolam 7.5 mg 30 min before induction of anaesthesia. Patients were asked to remove dentures or a dental plate before anaesthesia. A doughnut-shaped pillow was used to achieve optimal position. Patients were monitored according to our standard clinical operating procedures following the American Society of Anesthesiologists' recommendations.

Anaesthesia was induced using propofol 2% and fentanyl 2–3 µg kg⁻¹, and maintained with i.v. propofol to keep BIS 40–60. No neuromuscular blocking drugs were given before SAD insertion, which reflects the clinical practice of placing SADs at our institution. After the insertion of the SAD and completing all measurements, neuromuscular blocking drugs were administered to decrease the incidence of coughing during blind intubation and to reduce complications during SAD removal.¹⁷

After loss of eye lash reflex, monitored, sufficient bag-mask ventilation was performed (to maintain SpO₂ >96% and normal capnography reading) and the lubricated i-gelTM or sILMATM was introduced according to randomization.

Insertion of the SAD

Selection of size and introducing technique were according to the manufacturer's recommendations: for the ILMA™,¹⁸ a size 3 for 30–50 kg, a size 4 for 50–70 kg, and a size 5 for more than 70 kg; for the i-gel™,¹ a size 3 for 30–50 kg (up to 60 kg, if patient's height was <160 cm), a size 4 for 60–90 kg (down to 50 kg, if patient's height was >160 cm), and a size 5 for more than 90 kg. This adaptation for the i-gel™ for patients in the weight range 50–60 kg was made to avoid the overlap between sizes 3 and 4. The cuff of the ILMA™ was fully deflated during insertion. For lubrication of the SADs, we used K-Y Lubricating Jelly (Johnson & Johnson Medical Limited, Gargrave, Skipton, UK). Both SADs were introduced as described by the manufacturers' user booklets^{1 18} without the help of another person. Once in place, the cuff of the ILMA™ was inflated to a maximum of 60 cm H₂O,¹⁹ using a manometer (VBM GmbH, Sulz, Germany, or Rüschi GmbH, Kernen, Germany).

An initial assessment of ventilation was made by gently squeezing the reservoir bag and observing end-tidal carbon dioxide waveforms and chest movements.²⁰ In the case of adequate ventilation, leak pressure was measured as described below. Adequate ventilation was defined as two consecutive tidal volumes of at least 6 ml kg⁻¹ ideal body weight (height in cm – 100 in kg) during pressure-controlled ventilation at 17 cm H₂O applied by the anaesthetic machine.^{21 22}

When ventilation was not adequate, up to three minor airway interventions could be performed (i.e. adjusting head/neck position, changing depth of insertion).²³ If the first SAD failed after three attempts, the other SAD was used, again allowing three manoeuvres.²¹

Time necessary for insertion was measured from the time the face mask was taken away from the face until the appearance of the CO₂ trace on the capnograph.

Intubation

A fibrescope was primed with either a slightly curved lubricated size 7.0 mm Magill PVC TT (Rüschi™ Super Safety Clear, Group 1, i-gel™) or a lubricated reinforced 7.0 mm sILMA™ TT (Group 2, sILMA™) according to randomization. After effective neuromuscular block was confirmed by loss of twitch response, and after 2 min of oxygenation, the breathing system was disconnected and the tube with the fibrescope was introduced. The best fibreoptic view from the outlet of the SAD on the glottis was graded from 1 to 4 (1, vocal cords entirely visible; 2, vocal cords or arytenoid cartilages partially visible; 3, epiglottis only visible; 4, no laryngeal structures visible).²⁰

If possible, the TT was advanced through the glottic opening under continuous visualization. Because the tip of the fibrescope was proximal to the tip of the tube (Fig. 2), there was no fibreoptic guidance possible, but advancement of the tube could be stopped without applying force as soon as the tube was seen to not freely enter the tracheal opening. For patient safety reasons, we wanted to avoid

damage of the laryngeal structures. The fibrescope was not manipulated during the blind insertion attempt. This procedure could be called 'visualized blind technique' or 'tube first fibreoptic technique'. The first attempt success rate of blind tracheal intubation was our primary outcome measure. The TT was fixed to the fibrescope in a way that the tube's tip pointed upwards, and the black writing on the tube pointed to the back of the patient.^{12 14} Thus, the TT followed the same course it would have followed with a completely blind intubation. At the same time, the fibrescope was not the leading part during tube advancement, but it provided continuous visualization to instantly recognize impossible intubation conditions and to prevent glottic structure damage.

In the case of failed first attempt of blind intubation, the fibrescope was advanced beyond the tip of the tube and was introduced into the trachea, and the TT was advanced over the fibrescope as done by Joo and Rose.¹² If fibreoptic intubation failed as well, the other SAD was used, but the success was not evaluated according to intention-to-treat analysis. If the alternative SAD failed or if SpO₂ decreased to <92% at any time, the SAD was abandoned and the airway secured according to the anaesthetist's decision.

After intubation, the fibrescope was removed and the breathing circuit reconnected. Intubation time was measured from the time the breathing circuit was disconnected until the carbon dioxide curve appeared on the monitor.

During removal of the SAD, we carefully avoided accidental extubation. The ILMA™ stabilizer rod was used for both SADs, according to the ILMA™ user booklet.¹⁸ Time to remove the SAD was measured from disconnection of the breathing system until reappearance of the carbon dioxide curve on the monitor. At this time, the study was finished and anaesthesia was maintained according to the anaesthetist.

Airway leak pressure

Airway leak pressure was measured by closing the circle system's expiratory valve at a fixed gas flow of 3 litres min⁻¹ and noting the airway pressure (max. allowed 40 cm H₂O) at which equilibrium was reached or audible air was leaking.²⁴ Air entering the stomach was detected by auscultation over the epigastrium.²¹

Adverse events

During the study period, from starting anaesthesia until discharge from the postoperative recovery unit, any adverse events were recorded. Adverse events were defined as suspicion of aspiration/regurgitation (gastric fluid in the ventilation tube or in the hypopharynx), hypoxia (SpO₂ <92%), hypotension (mean arterial pressure <55 mm Hg), hypertension (mean arterial pressure +20% over pre-induction baseline), tachycardia and bradycardia (\pm 20% of pre-induction value), bronchospasm, airway obstruction, coughing, dental, tongue, or lip trauma.

Evaluation of postoperative complaints

A structured interview with the patient was performed 24 h after the operation to obtain data about adverse effects.²⁵ In the case of ambulatory surgery, we called the patients by phone. The interviewer was not aware of any problems encountered during insertion or surgery and was blinded about randomization, and the performance of the SAD/TT. Items included sore throat, hoarseness, dysphagia, postoperative nausea and vomiting, rescue medication, pain, analgesics taken, and any unscheduled re-hospitalization.

Comparison with patients from accompanying study using alternative TT (i-gel™ with sILMA™ TT; sILMA™ with Magill PVC TT)

In order to check if the difference in blind intubation success rates was caused by the fact that we used two different TTs, we compared the data from the 80 patients with those from a similar group of patients described in an accompanying study.²⁶ These 40 patients were equally randomized to either SAD but were intubated through the i-gel™ with the sILMA™ tube and through the sILMA™ with the Magill PVC tube. Again, the primary outcome was the success rate of blind tracheal intubation.

Statistical analysis

On the basis of our experience with the i-gel™, we expected a difference of at least 30% in first-attempt success rates (primary outcome measure) in favour of the sILMA™, and we calculated our sample size according to these expectations. Our null hypothesis was that the difference of first-attempt blind intubation success rates between the two SADs would be <30%. Our alternative hypothesis was that the difference of the success rates would be >30%. As first-attempt success rates for blind tracheal intubation for the ILMA™ are 80–87%,^{11 12} 76 patients would be necessary with a given α of 0.05 and a β -value of 0.2 (Primer of Biostatistics, V.4.02).

For our primary outcome variable, the success rate of the first blind intubation attempt, and other frequency data, we compared the values with χ^2 test. The devices were evaluated as intention-to-treat according to randomization. Continuous data were analysed with Student's *t*-test if normality distribution could be assumed; otherwise the Mann–Whitney test was used.

To evaluate whether the SADs or the TTs were responsible for the difference in success rate, we performed a 2×2 analysis of the intubation success (χ^2 test) after having checked for patient characteristic differences. We analysed all data with SPSS V.15 (SPSS Inc., Chicago, IL, USA/SPSS Schweiz AG, Zürich, Switzerland). Data are presented as mean (standard deviations), and percentage. A probability value of <0.05 was considered statistically significant.

Results

Participants and patient characteristics

We screened 912 patients undergoing general anaesthesia in a time period of 8.5 months (total 265 days); 677 of them required tracheal intubation (624 were adults). Inclusion criteria were not fulfilled by 534 patients, leaving 90 patients with predictors of a difficult airway eligible for the study. Five patients did not give informed consent, and five others were not randomized because of changes in surgical procedure. Therefore, we investigated 80 patients (Fig. 3).

Patients' characteristics did not differ importantly (Table 1). We investigated more males than females (64% vs. 36%), but the ratio was equal in both SAD-groups. Furthermore, there were no differences in characteristics between the 80 patients and the 40 patients described in the accompanying study.

Mask ventilation was deemed to be easy in 60 cases, in the other 20 cases, either two-handed ventilation or a Guedel Airway was necessary.

Insertion of the SADs

There was no difference in the insertion success rates between i-gel™ and sILMA™ (Table 2). In one case of a failed i-gel™ insertion, the airway was rescued by oral intubation. One sILMA™ insertion failed because of inadequate ventilation without hypoxia. This patient's trachea was intubated by fiberoptic guidance through an i-gel™. One i-gel™ had to be changed from size 4 to 5 in a male patient of 90 kg and 173 cm, although the size selection was according to the manufacturer's description.

There were no differences in first-attempt success rates of SAD insertion, insertion time, airway leak pressure, and tidal volumes (Table 2).

In the comparison group of 40 patients from the accompanying study,²⁶ ventilation after SAD insertion was successful in all i-gel™ patients, and in all but one sILMA™ patient.

Blind tracheal intubation

Blind intubation success rate was significantly higher for the sILMA™ group (69%) compared with the i-gel™ group (15%, $P<0.001$, Table 3). There was no difference in fiberoptic laryngeal view, epiglottic downfolding, and time necessary for intubation (Table 3). Of the 12 patients who could not be blindly intubated in the sILMA™ group, 10 were intubated by fiberoptic guidance and in two patients, conventional laryngoscopy was necessary to finally secure the airway.

Of the 33 failed blind intubations in the i-gel™ group, 32 patients were intubated by fiberoptic-guided intubation and one by conventional intubation. In that one case, intubation through the i-gel™ was impossible because of an unusually small glottic opening, and the patient was intubated orally with a smaller size TT by the aid of a Frova™ catheter (Frova Intubating Introducers, Cook™ Medical Ireland Ltd, Limerick, Ireland). We found no significant difference for

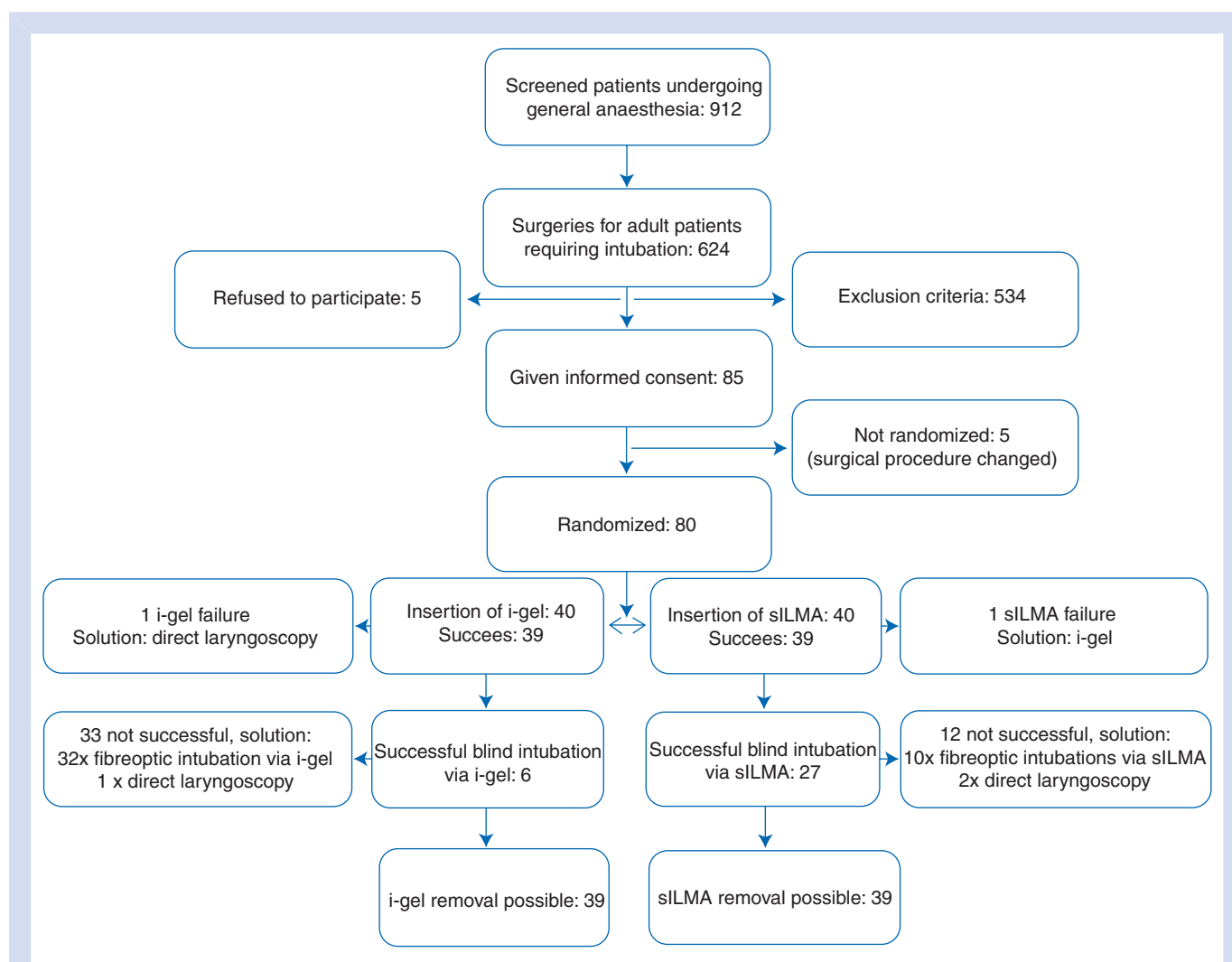


Fig 3 Study Flowchart.

the successful fiberoptic intubation rate after a failed blind intubation attempt between both SADs.

Blind intubation in the comparison group of 40 patients²⁶ revealed a success rate of 21% for the sILMA™ tube through the i-gel™ and a success rate of 60% for the Magill PVC tube through the sILMA™ ($P=0.02$). Because we found comparable patient characteristics, we performed a 2×2 analysis of the insertion success rate. That confirmed a large difference for the SADs ($P=0.001$ and 0.002), but not for the tubes ($P=0.59$ and 0.48 , Table 4).

Removal of the SAD

All 78 inserted SADs were removed without complications using the ILMA™ exchange rod. There was no difference in removal time between both SADs [44 (20) s for the i-gel™ vs. 46 (20) s for the sILMA™, $P=0.59$].

Haemodynamics, adverse events, and postoperative complaints

There were no differences in haemodynamic changes during insertion or intubation between the groups. One i-gel™ (3%)

and two sILMA™ (5%) were stained with blood after removal ($P=1.00$).

In one patient, an i-gel™ failed and he desaturated below 90% before the intubation attempt. Conventional oral intubation secured the airway without any problem. Also, one patient with an sILMA™ in place desaturated briefly below 90% during fiberoptically guided intubation. There were no other adverse events.

There were no statistically significant differences in postoperative complaints between the groups; sore throat occurred in 25% (i-gel™) vs. 8% (sILMA™), $P=0.08$.

Discussion

In this study, the success rate of blind intubation through the i-gel™ using a Magill PVC TT was significantly lower compared with the sILMA™ using the sILMA™ TT. This did not change if we used the other tube (i-gel™ with the sILMA™ tube, and sILMA™ with the Magill PVC tube).

The airway outlet of the i-gel™ is large, and provides a good view of the vocal cords. Epiglottic downfolding is rare

Table 1 Patient characteristics and perioperative results. Data shown as mean (range) or number (%). BMI, body mass index; TM, thyroid-mental distance

	i-gel	sILMA
Patients, <i>n</i> (%)	40 (50)	40 (50)
Age (yr) mean (range)	57 (24–84)	55 (21–81)
Women, <i>n</i> (%)	16 (40)	13 (33)
ASA I–IV, <i>n</i> (%)	1/27/12/0 (3/68/30/0)	7/23/9/1 (18/58/23/3)
Height (m)	1.72 (0.10)	1.73 (0.1)
Weight (kg)	84 (22)	87 (18)
BMI (kg m ⁻²)	28 (6)	29 (4)
BMI > 30 kg m ⁻² , <i>n</i> (%)	18 (45)	18 (45)
TM < 6 cm, <i>n</i> (%)	3 (08)	4 (10)
No jaw protrusion, <i>n</i> (%)	4 (10)	4 (10)
Sleep apnoea, <i>n</i> (%)	9 (23)	13 (33)
Mallampati score 1–3, <i>n</i> (%)	13/18/9 (33/45/23)	12/11/17 (30/28/43)
Mouth opening < 3.5 cm, <i>n</i> (%)	9 (23)	5 (13)
Mask ventilation possible without help, <i>n</i> (%)	32 (80)	28 (70)
Mask ventilation only possible with help, <i>n</i> (%)	8 (20)	12 (30)
Duration of surgery (min)	136 (91)	153 (104)
Duration of anaesthesia (min)	223 (122)	245 (121)

Table 2 SAD insertion. No statistically significant differences were found. Data shown as mean (sd) or number (%)

	i-gel TM (<i>n</i> = 40)	sILMA TM (<i>n</i> = 40)
Success at first attempt, <i>n</i> (%)	36 (90)	38 (95)
Overall success, <i>n</i> (%)	39 (98)	39 (98)
Minor intervention necessary, <i>n</i> (%)	11 (28)	8 (20)
Time to supraglottic airway device insertion (s)	33 (18)	36 (20)
Tidal volume (ml)	587 (164)	557 (154)
Airway leak pressure (cm H ₂ O)	26 (8)	30 (7)

which favours a successful intubation. However, in relation to the laryngeal structures, the airway outlet of the i-gelTM seems to provide an unfavourable angle. When the TT exits the i-gelTM, it often gets caught in the arytenoid cartilage or other posterior structures of the larynx. In order to enter the trachea, fibrescope and tube often need to be pushed anterior. This might be improved by reshaping the airway outlet of the i-gelTM to optimize the angle.

Compared with the success rate of the sILMATM with the sILMATM tube (69%), the i-gelTM with the Magill PVC tube had a success rate of only 15%, clearly favouring airway management using the sILMATM with the sILMATM tube. The success rate of blind intubation at the first attempt with the sILMATM was only 69%. This is similar to a study published earlier comparing ILMATM and sILMATM,²⁷ but

Table 3 Intubation through the supraglottic airway devices.

Statistically significant differences between the groups are indicated (*). Data presented as mean (sd) or number (%).

**P* < 0.001; †Laryngeal view was graded from 1 to 4 (1, vocal cords entirely visible; 2, vocal cords or arytenoid cartilages partially visible; 3, epiglottis only visible; 4, no laryngeal structures visible)²⁰

	i-gel TM (<i>n</i> = 39)	sILMA TM (<i>n</i> = 39)
Blind intubation successful, <i>n</i> (%)	6 (15)	27 (69)*
Laryngeal view†, <i>n</i> (%)	25/7/3/4 (64/18/8/10)	20/13/2/4 (51/33/5/10)
Epiglottic downfolding, <i>n</i> (%)	4 (10)	2 (5)
Time for blind intubation (s)	45 (14)	44 (22)

Table 4 Difference in success rates of blind intubation because of supraglottic airway device or tube? 2 × 2 table comparing i-gelTM and sILMATM with either the sILMATM tracheal tube or the RüschTM Magill PVC tracheal tube. Numbers are given in number (%) of blind intubation success. *P*-values of the columns are not significant (0.59, 0.48), *P*-values of the rows are < 0.001. As the comparison group, data were used from a group of patients further described in an accompanying study (see text)²⁶

	i-gel TM <i>n</i> = 58	sILMA TM <i>n</i> = 59
Tracheal tube		
Magill PVC tube (<i>n</i> = 59)	6 (15)	12 (60)
sILMA TM tube (<i>n</i> = 58)	4 (21)	27 (69)
<i>P</i> -value	0.59	0.48

lower than expected from larger studies.^{11 12} This may be a consequence of the selected patient population with predictors of difficult airway management. In addition, we performed the so-called blind intubation attempt without fiberoptic guidance, but under visual control with the scope. Therefore, whenever the TT experienced resistance from the posterior (or anterior) part of the larynx, the tube was not forced in any direction in order to prevent tissue damage. The success rate may have been higher without a visual control because one might tend to try to overcome the resistance. We only looked at first blind intubation success rate and did not allow airway manoeuvres known to facilitate blind intubation success.¹⁸ The main purpose of the present study was to compare two different airway sets rather than determining the influence of different TTs. The success rate of blind intubation through the i-gelTM might be improved by using a different TT instead of the Magill PVC tube that was used in the current study. However, the results from our comparison group of 40 patients from the accompanying study²⁶ showed that the difference in success rates was rather attributed to the different SADs than to the different TTs (Table 4). The two different TTs did not cause the large difference in blind intubation success

rate, but we were unable to quantify their influence on our primary outcome measure.

The sizes of the SADs were chosen according to the manufacturer's handbook; one i-gel™ had to be changed from size 4 to size 5 to obtain adequate seal. Two other i-gels™ had to be changed from size 4 to size 3. This reflects the ongoing discussion about SADs: size selection should also include patient characteristics such as height,²⁸ and perhaps even age and gender.²⁹

Limitations of the study

We recognize some limitations to this study. First, we compared visualized blind intubation through SADs ('tube first fibreoptic technique'). We did not compare true blind intubation, where sometimes intubation is accomplished by overcoming resistance with light force. Instead, TT advancement was closely monitored in order to avoid damage of any laryngeal structures. The tip of the fibreoptic bronchoscope always remained proximal to the tip of the TT. There was no guidance or manipulation of the fibrescope, and the tube's path was the same as in a blind intubation attempt, mimicking clinical practice.

Secondly, we included patients with predictors of difficult airway management. All predictors of difficult mask ventilation, difficult laryngoscopy, and difficult intubation qualified as inclusion criteria. Because of ethical considerations, we did not include patients with a history of difficult airway in this study, denying them the advantage of an awake fibreoptic intubation. Thirdly, we used the i-gel™ with a Magill PVC TT and compared this with the sILMA™ with its sILMA™ tube. The sILMA™ TT is specifically designed for blind intubation. By doing so, we did not only compare the SAD, but an airway set. We decided to use an everyday PVC TT for the i-gel™ and not the sILMA™ tube because in case of a cannot-ventilate-cannot-intubate situation, clinicians initially have to fall back on devices they have readily available in the operating theatre. That is, an SAD (e.g. the i-gel™) to re-establish ventilation which might be followed by intubation. Therefore, the clinician must know if a commonly used PVC tube is useful for blind airway rescue procedures. Fourthly, we compared the data from the 80 patients with data from a group of 40 patients described in another study.²⁶ These 40 patients were included in two studies, although different outcome measures were evaluated. The inclusion of these 40 patients is not a fully randomized 2 × 2 factorial analysis. We decided to include this group for comparison after analysis of the 80 patients described, in order to check if the difference in success rate was mainly attributable to the two different TTs.³⁰ The two patient populations showed no characteristic differences, they were collected with the same inclusion and exclusion criteria, and they were fully randomized. With a high probability, the SADs are largely responsible for the difference in success rates for blind intubation, and not the TTs. Finally, the study personnel were not all experts in the field of airway management; however, all 24 participating anaesthetists

were experienced in the use of both SADs and fibreoptic intubation through SADs, and they were under supervision by one of the main study authors. Our results reflect true clinical performance of the devices in a daily clinical anaesthetic setting. Failures were evenly distributed among investigators. We also found no difference between the participating anaesthetists regarding intubation time.

In conclusion, we found that blind tracheal intubation through the i-gel™ using a PVC TT was substantially inferior compared with intubation through the sILMA™ using the sILMA™ TT in patients with predictors of difficult airway management under general anaesthesia. Therefore, we do not recommend blind intubation through the i-gel™. The sILMA™ tube does not substantially improve blind intubation success with the i-gel™ as conduit. When blind intubation failed, fibreoptically guided intubation through the i-gel™ was highly successful.

Acknowledgements

Jeff Crowder, BA, Austria, and Brian Swenson, MD, USA, proof-read the English, and Andreas Vogt, MD, Switzerland, provided critical comments on the manuscript.

Conflict of interest

None declared.

Funding

This work was supported by a departmental research grant. The i-gel™ were supplied free of charge by Intersurgical™ (distributed by Manfred Kienast, MK-Med, Eyholz, Switzerland). sILMA™ devices were sold at a special research price (by Serge Viel, Laubscher, Basel, Switzerland).

References

- Intersurgical. *User Guide for the i-gel™ Single Use Supraglottic Airway*, 2006
- Bamgbade OA, Macnab WR, Khalaf WM. Evaluation of the i-gel™ airway in 300 patients. *Eur J Anaesthesiol* 2008; **25**: 865–6
- Theiler LG, Kleine-Brueggeney M, Kaiser D, et al. Crossover comparison of the laryngeal mask supreme and the i-gel™ in simulated difficult airway scenario in anesthetized patients. *Anesthesiology* 2009; **111**: 55–62
- 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
- Gatward JJ, Cook TM, Seller C, et al. Evaluation of the size 4 i-gel™ airway in one hundred non-paralysed patients. *Anaesthesia* 2008; **63**: 1124–30
- 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
- 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

- 8 Henderson JJ, Popat MT, Latto IP, Pearce AC. Difficult Airway Society guidelines for management of the unanticipated difficult intubation. *Anaesthesia* 2004; **59**: 675–94
- 9 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* 2003; **98**: 1269–77
- 10 Brain AI, Verghese C, Addy EV, Kapila A. The intubating laryngeal mask. I: Development of a new device for intubation of the trachea. *Br J Anaesth* 1997; **79**: 699–703
- 11 Baskett PJ, Parr MJ, Nolan JP. The intubating laryngeal mask. Results of a multicentre trial with experience of 500 cases. *Anaesthesia* 1998; **53**: 1174–9
- 12 Joo HS, Rose DK. The intubating laryngeal mask airway with and without fiberoptic guidance. *Anesth Analg* 1999; **88**: 662–6
- 13 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
- 14 Francksen H, Renner J, Scholz J. A comparison of two endotracheal tubes for intubation via new I-gel™ laryngeal mask. *Eur J Anaesthesiol* 2009; **26** (Suppl 45): 19AP5–1.
- 15 Mallampati SR, Gatt SP, Gugino LD, et al. A clinical sign to predict difficult tracheal intubation: a prospective study. *Can Anaesth Soc J* 1985; **32**: 429–34
- 16 Samsoon GL, Young JR. Difficult tracheal intubation: a retrospective study. *Anaesthesia* 1987; **42**: 487–90
- 17 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
- 18 Laryngeal Mask Company. *ILMA Fastrach™ Instruction Manual*, 2006
- 19 Brain AI, Verghese C, Strube PJ. The LMA 'ProSeal'—a laryngeal mask with an oesophageal vent. *Br J Anaesth* 2000; **84**: 650–4
- 20 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; **95**: 261–6
- 21 Brimacombe J, Keller C, Brimacombe L. A comparison of the laryngeal mask airway ProSeal and the laryngeal tube airway in paralyzed anesthetized adult patients undergoing pressure-controlled ventilation. *Anesth Analg* 2002; **95**: 770–6
- 22 Hohlrieder M, Brimacombe J, von Goedecke A, Keller C. Guided insertion of the ProSeal laryngeal mask airway is superior to conventional tracheal intubation by first-month anesthesia residents after brief manikin-only training. *Anesth Analg* 2006; **103**: 458–62
- 23 Ferson DZ, Rosenblatt WH, 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
- 24 Keller C, Brimacombe JR, Keller K, Morris R. Comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. *Br J Anaesth* 1999; **82**: 286–7
- 25 Brimacombe J, Keller C. Gum elastic bougie-guided insertion of the ProSeal Laryngeal Mask Airway. *Anaesth Intensive Care* 2004; **32**: 681–4
- 26 Kleine-Brueggeney M, Theiler L, Urwyler N, Vogt A, Greif R. Randomized trial comparing the i-gel™ and Magill tracheal tube with the single-use ILMA™ and ILMA™ tracheal tube for fiberoptic-guided intubation in anesthetized patients with predicted difficult airway. *Br J Anaesth* 2011 (in press)
- 27 Teoh WHL, Lim Y. Comparison of the single use and reusable intubating laryngeal mask airway. *Anaesthesia* 2007; **62**: 381–4
- 28 Brimacombe J, Keller C. Performance of the size 5 laryngeal mask airway in males and females. *Anesthesiol Intensivmed Notfallmed Schmerzther* 2000; **35**: 567–70
- 29 Stix MS, O'Connor CJ Jr, Valade DR. Extender for the size 4 ProSeal laryngeal mask airway. *Can J Anaesth* 2008; **55**: 657–8
- 30 Kanazi GE, El-Khatib M, Nasr VG, et al. 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