Crossover Comparison of the Laryngeal Mask Supreme™ and the i-gel™ in Simulated Difficult Airway Scenario in Anesthetized Patients

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Background: The single-use supraglottic airway devices LMA-Supreme™ (LMA-S™; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) and i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, United Kingdom) have a second tube for gastric tube insertion. Only the LMA-S™ has an inflatable cuff. They have the same clinical indications and might be useful for difficult airway management. This prospective, crossover, randomized controlled trial was performed in a simulated difficult airway scenario using an extrication collar limiting mouth opening and neck movement.

Methods: Sixty patients were included. Both devices were placed in random order in each patient. Primary outcome was overall success rate. Other measurements were time to successful ventilation, airway leak pressure, fiberoptic glottic view, and adverse events.

Results: Success rate for the LMA-S™ was 95% *versus* 93% for the i-gel™ ($P = 1.000$). LMA-S™ needed shorter insertion time (34 ± 12 *vs.* 42 ± 23 s, $P = 0.024$). Tidal volumes and airway leak pressure were similar (LMA-S™ 26 ± 8 cm H_2O; i-gel™ 27 ± 9 cm H_2O; $P = 0.441$). Fiberoptic view through the i-gel™ showed less epiglottic downfolding. Overall agreement in insertion outcome was 54 (successes) and 1 (failure) or 55 (92%) of 60 patients. The difference in success rate was 1.7% (95% CI –11.3% to 7.6%).

Conclusions: Both airway devices had similar insertion success and clinical performance in the simulated difficult airway situation. The authors found less epiglottic downfolding and better fiberoptic view but longer insertion time with the i-gel™. Our study shows that both devices are feasible for emergency airway management in patients with reduced neck movement and limited mouth opening.

THE Laryngeal Mask Supreme™ (LMA-S™; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) is a newly developed single-use supraglottic airway device featuring elements of both the ILMA Fastrach™ (Laryngeal Mask Company) and the LMA ProSeal™ (PLMA™; Laryngeal Mask Company) with its esophageal drainage tube to suction gastric content. A pilot study of 22 uses confirmed its clinical usability,[1] and one case report showed its use in a cardiopulmonary resuscitation situation.[2] Another single use report comes from the pre-

hospital environment.[3] Recently, Verghese *et al.* published a crossover trial with 36 female patients showing equal performance of the LMA-S™ and the PLMA™.[4]

The i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, United Kingdom), a recently developed single-use supraglottic airway device features also an additional tube to introduce a gastric suction catheter. Its unique design does not need an inflatable cuff because the thermoplastic elastomer (styrene ethylene butadiene styrene) provides the seal.[5] Suggested advantages are easier insertion and less tissue compression.[5] First uses in manikins,[6] case reports,[7–9] and retrospective[10,11] and prospective[12] evaluations showed its easy introduction and sufficient seal pressure for clinical use. The large airway diameter of the i-gel™ enables the introduction of an endotracheal tube.[13,14]

Both single-use devices, as other supraglottic airway management devices could have their value as backup devices in difficult airway management strategies, especially in the "cannot intubate, cannot ventilate" situation.[15,16] The i-gel™ has already been used in this setting.[13]

Two patient characteristics among others predict difficult airway management: reduced neck extension and reduced mouth opening.[17] Limited mouth opening may even be a reason why supraglottic airway devices fail. Introducing the ILMA Fastrach™ in patients with limited mouth opening of less than 25 mm was described as difficult,[18] although the outer diameter is about 20 mm.[19]

Difficulties in airway management can be simulated using a properly adjusted extrication collar[20,21] limiting mouth opening and neck movement. Until now, there were no randomized controlled trials evaluating the clinical performance of the LMA-S™ and the i-gel™ in such simulated difficult airway situations.

We planned this prospective randomized controlled clinical study comparing both single-use supraglottic devices in a crossover design in anesthetized patients while simulating impaired neck movement and limited mouth opening with an extrication collar. Our null hypothesis was that the difference in the overall success rate for insertion of the two devices was less than 15%.

Materials and Methods

Participants and Anesthesia

After obtaining both local ethics committee (Cantonal Ethics Committee Bern, Bern, Switzerland) approval and
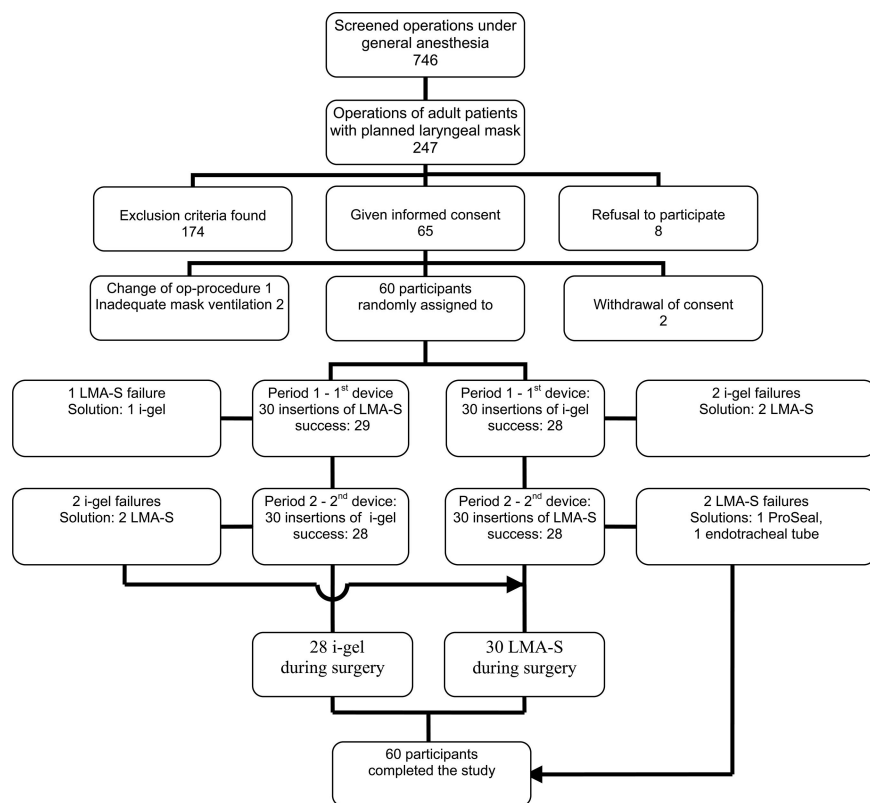
Fig. 1. Study flow chart. LMA-S[TM] = Laryngeal Mask Airway Supreme[TM].

patient informed consent, 60 patients with American Society of Anesthesiologists physical status class I-III, aged 18–80 yr, and scheduled at the University Hospital of Bern for elective surgery in supine position and not requiring tracheal intubation were included.

Exclusion criteria were planned operation time greater than 4 h,[22] high risk of aspiration (nonfasted, massive gastroesophageal reflux/treated disease), weight less than 50 kg, body mass index greater than 35 kg/m^2, cervical spine disease, mouth opening less than 20 mm, upper respiratory tract symptoms in the previous 10 days, preoperative sore throat, poor dentition with high risk of damage, and impossible facemask ventilation while extrication collar in place.

Patients were randomly assigned to two sequences: (computer-generated randomization list§) sequence 1, the LMA-S[TM] was introduced first and followed by the i-gel[TM] after all study-related measurements; sequence 2, started with the i-gel[TM] after all study-related measurements and followed by the LMA-S[TM] (fig. 1).

Four staff anesthesiologists with extensive experience in the use of supraglottic devices and more than 20 uses with both devices participated in this investigation.

After premedication with midazolam (7.5 mg orally 30 min before induction), the patients were rested in supine position, the head resting on a pillow of 7 cm in

height to achieve optimal Jefferson's position.[23] The patients opened their mouths themselves, and the distance between the lower border of the upper incisors to the upper border of the lower incisors (interincisor distance) was measured with a small ruler.[20]

Anesthesia was induced with fentanyl (1–3 μg/kg) and propofol (2.5 mg/kg). Anesthesia was maintained with propofol and fentanyl or remifentanil to keep Bispectral Index (Aspect Medical Systems, Norwood, MA) between 40 and 60 in O$_2$/Air. No muscle relaxation was used. Patients were monitored according to our clinical standard operating procedures following American Society of Anesthesiologists standard.‖

After loss of eyelash reflex and proper bag-mask ventilation (oxygenation Sao$_2$ greater than 96% and capnography reading), the extrication device (Stifneck Select Collar; Laerdal, Wappingers Falls, NY) was adjusted to fit tightly without impairing proper ventilation.

Reduced mouth opening was then recorded with the patient's mouth opened by the anesthetist with two fingers.

Insertion of the Device

The size of the devices was selected according to the manufacturer's recommendations (LMA-S[TM]: size 4 in 50- to 70-kg patients and size 5 in 70- to 100-kg patients; i-gel[TM]: size 4 in 50- to 90-kg patients and size 5 in patients over 90 kg). The cuff of the LMA-S[TM] was fully deflated. For lubrication of the devices, we used K-Y Lubricating Jelly (Johnson & Johnson Medical Limited, Gargrave,

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§ Available at: http://www.randomization.com; Accessed July 26, 2008.

‖ Available at: http://www.asahq.org/news/asanews040405.htm; Accessed July 28, 2008.

Skipton, United Kingdom). Both devices were introduced blindly as described by the manufacturer's user booklet[22,24] without the help of another person. Once in place, the cuff of the LMA-S™ was immediately inflated to 60 cm H_2O[25] by using a digital Manometer (VBM GmbH, Sulz, Germany; Rüsch GmbH, Kernen, Germany).

Immediately after insertion, each device was connected to the respiratory machine (Julian, Dräger, Lübeck, Germany; preset to the pressure controlled ventilation at 17 cm H_2O, respiratory rate 12 breaths/min, flow 30 l/min).

Three minor airway interventions adjusting head and/or neck position and changing depth of insertion were allowed to optimize ventilation of the lungs with the airway devices.[26]

Insertion difficulty was graded 1 (easy) to 5 (impossible) by the investigator. Duration of insertion was measured from the time the facemask was taken away from the face until successful ventilation of the patient. Success was defined as two consecutive tidal volumes of at least 6 ml/kg ideal body weight (height in cm – 100) applied by the anesthesia machine.[26,27] Duration of insertion of the successful attempts was compared.

After all study-related measurements (end of period 1), we removed the randomly first assigned supraglottic mask and ventilated the patient by facemask. We then introduced and evaluated the second device (start of period 2).

Break-up Criteria

Three failed attempts of insertion of a device or insufficient ventilation despite minor airway interventions was rated as failure for that device. The other device was used to provide a patent airway, again allowing three attempts and three airway maneuvers, as proposed by Brimacombe for the PLMA™.[26] In case of failure of both devices, the airway was secured according to the decision of the attending anesthesiologist.

Gastric Catheter Placement

A gastric catheter (Ch12 or Ch14, depending on device) was placed through the gastric vent tube. The correct placement of the gastric tube was confirmed by free movement during insertion and by either aspiration of gastric fluid or detection of injected air by epigastric auscultation.[28] Insertion difficulty was graded 1 (easy), 2 (difficult), or 3 (impossible) by the anesthetist.

Airway Leak Pressure

Airway leak pressure was determined by closing the circle system's expiratory valve at a fixed gas flow of 3 l/min and noting the airway pressure (maximum allowed 40 cm H_2O) at which equilibrium was reached or audible air was leaking.[29] Air entering the stomach was detected by auscultation over the epigastrium when measuring oropharyngeal leak.[28]

Anatomical Position of the Supraglottic Airway Device

After preoxygenation, the breathing system was disconnected, and a 4-mm fiberscope (Acutronic Ltd., Bubikon, Switzerland) was inserted through the airway port for evaluating glottic view. The best views from the tip of the orifice of the i-gel™ or of the LMA-S™ were graded from 1–4 as recommended by Cook et al.[30] and proposed before.[31] In addition, epiglottic downfolding was noted.

Anesthesia during Operation

The extrication collar was taken off after all study-related measurements. The second device stayed in place until the end of the operation. Any necessary airway maneuvers were recorded. The device was removed after the patient was awakened (opened eyes on command) and return of spontaneous breathing was confirmed (tidal greater than 6 ml/kg, $ETco_2$ less than 50 cm H_2O). Intraoperative data were collected by an unblinded trained assistant. Another air leak measurement took place at the end of the operation.

Adverse Events

Any adverse events were recorded, including suspicion of aspiration/regurgitation (gastric fluid in the ventilation tube or in the hypopharynx), desaturation (Sao_2 less than 92%), bronchospasm, airway obstruction, coughing, dental, tongue, or lip trauma. For the device introduced first, any visible staining of blood on the removed device was noted as well as any visible airway trauma for either device.

Evaluation of Postoperative Complaints

Twenty-four hours after operation, a structured interview was performed with the patient to obtain data about side effects.[23] We called the patients by phone in case of ambulatory surgery. The interviewer was unaware of the performance of each airway device and any problems encountered. Asked items included sore throat, hoarseness, dysphagia (graded mild/moderate/severe by the patient[32]), postoperative nausea and vomiting, rescue medication, pain and analgesics taken, and any unscheduled rehospitalization.

Statistical Analysis

For our sample size calculation, we defined a clinically relevant difference in the overall attempt success rates (primary outcome variable) between groups of 15%. That was based on attempt success rates published earlier about the PLMA™ by Brimacombe et al.[26] and Cook et al.[30] Using a two-tailed alpha value (0.05) and a beta value (0.2), 112 observations would be sufficient to detect a difference in success rate of 15%.

First, we checked if the insertion of the first device (period 1) had a carry-over effect on the insertion suc-

cess of the second device (period 2) as recommended by Jones *et al.*[33] and we compared both periods as recently reported by Verghese *et al.*[4] For our primary variable, overall attempt success rate, we calculated the difference between the two devices and provided the 95% confidence interval (CI). McNemar test compared insertion success rates and other nominal results during the insertion of the devices. Insertion times, airway leak pressures, and other interval-scaled data not normally distributed were compared by Wilcoxon signed rank test. Intraoperative events were compared by Fisher exact test. Comparison of insertion time between the four investigators was evaluated by ANOVA.

We analyzed all data with SPSS version 15 (SPSS, Inc., Chicago, IL). Data are presented as mean and standard deviations, range, and percentage. Effect sizes (with 95% CI) are reported as Cohen's d for interval data and as odds ratio for proportions. $P \leq 0.05$ was considered statistically significant.

Results

Participants and Demographics

On 92 consecutive working days, we screened 247 patients scheduled for general anesthesia with a laryngeal mask, and 73 patients qualified for the study (fig. 1). Eight patients did not give consent, two withdrew consent before induction of anesthesia, one had to be excluded because of change to prone position for surgery, and two had to be excluded before randomization because of inadequate mask ventilation when applying the extrication collar. Finally, we investigated 60 patients equally distributed to both genders ($P = 0.584$), all other patient characteristics are given in table 1.

The extrication collar reduced mouth opening significantly to 24 ± 3 mm (table 1) and immobilized the neck to virtually no possible movement anymore.

Mask ventilation was deemed easy in 50 cases; in the other 10 cases, either a Guedel Airway or two-handed ventilation was necessary. Vital signs did not differ significantly between the uses of the two devices throughout the study.

Mean anesthesia time was 122 ± 45 min, and mean operation time was 60 ± 34 min.

Insertion of the Device

Table 2 provides success rates for each device. Overall, there was a 95% success rate for the LMA-S[TM] and 93% for i-gel[TM] ($P = 1.000$). First attempt success rate was 93% for the LMA-S[TM] and 85% for i-gel[TM] ($P = 0.180$). Insertion times for the LMA-S[TM] were significantly shorter than for i-gel[TM] (34 ± 12 s *vs.* 42 ± 23 s, $P = 0.024$). The subjectively graded difficulty of insertion did not differ between the LMA-S[TM] and i-gel[TM] (table 2). Table 3 provides a crosstabulation for the primary out-

Table 1. Patient Characteristics

Patient Characteristics	n = 60
Gender men:women, n (%)	32:28 (53:47)
Age, years	47 ± 17 (18–79)
Weight, kg	74 ± 13 (52–105)
Height, cm	172 ± 8 (156–196)
BMI	25.2 ± 3.7 (18.8–34.3)
Operation by surgical specialty, n (%)	
Ophthalmology	32 (53)
Gynecology	12 (20)
Plastic surgery	7 (12)
Otolaryngology	6 (10)
Orthopedics	3 (5)
Mallampati class I/II/III/IV, n (%)	23/34/3/0 (38/57/5/0)
ASA I/II/III, n (%)	24/33/3 (40/55/5)
Beard (in males), n (%)	3 (9)
Thyreomental distance < 6 cm, n (%)	1 (2)
Subluxation of the mandibular joint, n (%)	10 (17)
Artificial dentition, n (%)	5 (8)
Mouth opening without extrication collar, mm	47 ± 7 (30–72)
Mouth opening < 3.5 cm without extrication collar, mm	4 (6.7)
Mouth opening with Stifneck, mm	24 ± 3 (20–30)
Reduction of mouth opening, mm	23 ± 7*

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

* $P < 0.001$, paired Student t test.

ASA = physical status classification according the American Society of Anesthesiologists; BMI = body mass index.

come and overall attempt success rate. Overall agreement between the two devices was 54 (success) + 1 (failure) = 55 out of 60, or 92%. The difference of the success rate was D = p (i-gel[TM]) − p (LMA-S[TM]) = −0.017 (95% CI: −0.113 to 0.076).

Inadequate ventilation was the reason for the three LMA-S[TM] failures and was solved once with an i-gel[TM], once with a PLMA[TM], and once with an endotracheal tube. The four i-gel[TM] failures due to impossible insertion two or inadequate ventilation two were solved three times by a LMA-S[TM] and once by a PLMA[TM]. The proportion of inadequate ventilation was similar between the two devices ($P = 0.546$).

Insertion time and success rate did not differ among the four investigators either for LMA-S[TM] or for i-gel[TM]. We found no influence of mouth opening after collar application on insertion success or insertion time (Pearson correlation coefficient r = −0.072, $P = 0.597$).

Gastric Catheter Placement

Insertion of a gastric catheter failed once in each mask. Gastric fluid was aspirated in 30 i-gel[TM]s and 21 LMA-S[TM] ($P = 0.064$).

Airway Leak Pressure and Tidal Volumes

Airway leak pressure and tidal volumes after insertion were similar (table 2). Seal pressure of i-gel[TM] and LMA-S[TM] remained the same comparing the beginning and the end of operation (26 ± 8 cm H_2O [$P = 0.506$] for the LMA-S[TM] and 27 ± 9 cm H_2O *vs.* 27 ± 8 cm H_2O [$P = 0.267$] for the i-gel[TM]).

Table 2. Insertion of the Supraglottic Devices

	LMA-S™	i-gel™	P Value	Effect Size (95% CI)
Devices inserted, n	60	60		
Overall insertion success rate,* n (%)	57 (95)	56 (93)	1.000	1.36‖ (0.29 to 6.34)
First attempt success rate, n (%)	56 (93)	51 (85)	0.180	2.46‖ (0.72 to 8.52)
Second and third attempt success rate, n (%)	0/1 (0/2)	2/3 (3/5)	0.625	
Difficulty of insertion†	20/22/15/3/0 (33/37/25/5/0)	12/20/18/8/2 (20/33/30/14/3)	0.171	
Successfully inserted devices further studied, n	57	56		
Insertion time, s	34 ± 12	42 ± 23	0.024	0.44# (0.06 to 0.81)
Initial tidal volume, ml	700 ± 143	726 ± 168	0.296	0.17# (−0.20 to 0.54)
Airway leak pressure, cm H_2O	26 ± 8	27 ± 9	0.441	0.12# (−0.25 to 0.49)
Fiberoptic laryngeal view,‡ n (%)	29/13/13/2 (51/23/23/4)	40/10/6/0 (71/18/11/0)	0.023**	0.41** (0.19 to 0.90)
Epiglottic downfolding, n (%)	15 (25)	4 (7)	0.021	4.64 (1.43 to 15.04)
Gastric tube insertion,§ n (%)	54/2/1 (95/4/2)	50/5/1 (89/9/2)	1.000	1.02** (0.06 to 16.69)
Manipulations required after insertion, n (%)	2 (3)	5 (8)	0.453	0.36‖ (0.07 to 1.92)

Results presented as mean ± SD or n (%).

* LMA-S™, three failures due to inadequate ventilation; i-gel™, two insertions impossible, two failures due to inadequate ventilation; † difficulty of device insertion graded from 1 (easy) to 5 (impossible); ‡ fiberoptic laryngeal view rated as 1 (only vocal cords seen), 2 (cords and/or arytenoids seen), 3 (only epiglottis seen), or 4 (other [e.g., laryngeal mask airway cuff] pharynx) seen[30,31]; § gastric tube insertion rated as easy/difficult/impossible; ‖ effect size for proportion given as odds ratio; # effect size for interval data given as Cohen's d; ** effect size given as odds ratio. Fiberoptic view dichotomized as 1 or less than 1 as described by Verghese et al.[4] Gastric tube insertion dichotomized success vs. no success.

LMA-S™ = laryngeal mask airway Supreme.

Anatomical Position of the Supraglottic Airway Device

The i-gel™ enabled better fiberoptic laryngeal view (glottis fully visible in 40 i-gel™s *vs.* 29 in LMA-S™, P = 0.023; table 2) and i-gel™ showed less epiglottic downfolding (4 of 56 i-gel™ *vs.* 15 of 57 LMA-S™, P = 0.021).

Adverse Events and Postoperative Complaints

During the intraoperative use of the 30 LMA-S™, five adverse events were observed: two with Bispectral Index greater than 60, one required airway maneuver (pushing the LMA-S™ downwards), one desaturation, and once diaphragmal movement. We observed four intraoperative events in the 28 i-gel™ used: one coughing, one Bispectral Index greater than 60, one airway maneuver necessary (pushing the i-gel™ downwards), and one new air leak; in one patient with a body mass index of 34 kg/m², the i-gel™ had the tendency to protrude upwards and required downward pressure continuously during surgery by adhesive tape to provide sufficient seal. There was no statistical difference comparing both groups (Fisher exact test, P = 1.00). No hemodynamic changes during insertion or surgery were observed in any patient.

Table 3. Success Rates and Failure

	i-gel™		
	Failure	Success	Total
LMA-S™			
Failure	1	2	3
Success	3	54	57
Total	4	56	60

LMA-S™ = laryngeal mask airway Supreme.

Minor lip trauma occurred upon insertion in three patients with i-gel™ and in two patients with LMA-S™ (P = 1.00). Of all devices introduced in the first period, four i-gel™s were blood-stained *versus* 2 LMA-S™ (P = 0.673). There were no incidents of intraoperative regurgitation, aspiration, or dental trauma. On postoperative evaluations, one of the patients with artificial dentition complained of pain at the teeth insertion site, most likely resulting from the pressure that had to be applied to open the mouth.

Minor postoperative complaints were sore throat (visual analog scale greater than 3, n = 6, 10%), dysphagia (n = 9, 15%), and hoarseness (n = 7, 12%).

Effect of First Device Insertion on the Insertion of the Second Device (Period 1 on Period 2)

We found no carryover effect for our primary outcome, the overall attempt insertion success rate. We also found no period influence among airway seal pressure, tidal volumes, or fiberoptic view. Mean insertion time was shorter for the i-gel™ by 12 s when inserted as second device (tables 4 and 5).

Discussion

We demonstrated that the overall attempt insertion rates for the LMA-S™ and i-gel™, 95% and 93% respectively, were less than the assumed threshold of 15% for statistical difference. Moreover, we determined that there was close overall agreement in the success/failure rates with the devices, 92%, with a difference in success rates of 1.7%. For the busy clinician and even more for the preclinical working emergency physicians, it is of importance to know which airway device will perform

Table 4. Possible Effect of Period 1 on Period 2 in the Crossover Design for the Patients

	First Device LMA-S™, n = 29	Second Device i-gel™, n = 28	P Value	First Device i-gel™, n = 28	Second Device LMA-S™, n = 28	P
Overall success, n	29	28	1.000	28	28	1.000
Airway leak pressure, cm H_2O	27 ± 8	29 ± 8	0.286	25 ± 9	25 ± 8	0.989
Tidal volumes, ml	698 ± 157	682 ± 152	0.670	767 ± 174	701 ± 130	0.109
Fiberoptic view (grade 1/grades > 1), n	15/14	21/7	0.070	19/9	14/14	0.210
Insertion time, s	35 ± 11	36 ± 18	0.847	48 ± 26	33 ± 12	0.004

Results presented as mean ± SD or n. Statistical tests: McNemar (success, fiberoptic view), Wilcoxon sign rank test (leak pressure, volumes, insertion time). LMA-S™ = laryngeal mask airway Supreme™.

with a high success rate because supraglottic devices are recommended in the difficult airway algorithms during life-saving procedures.[15,34] Therefore, we intended to add another piece of evidence to guide clinical decisions.

Insertion success for both devices was less than reported previously,[1,10] with a first success rate of 97% for the i-gel™ and 100% easy insertion for the LMA-S™. Our study design involving an extrication collar to allow simulation of a difficult airway without endangering the patient might be the reason for that difference. Others used extrication collars in conscious volunteers[20] and reported a mouth opening difference of 26 mm before and after application of the extrication collar. This is very close to our findings of 23 mm in anesthetized, nonrelaxed patients. Neck movement was virtually impossible after the application of the extrication collar. Use of an extrication collar is a reliable and reproducible means to simulate a difficult airway situation by reducing mouth opening and neck movement without endangering patients for the study of airway management.

Although we cannot prove equivalence with our study design, we showed that the difference in overall attempt success rate is 1.7% and does not exceed the 95% CI of 11.3%. As the 95% CI was evenly distributed around 0%, we conclude the true difference in success rate between the two devices is much smaller and of no clinical relevance.

Our obtained insertion times were much longer than the recently published results of 300 i-gel™ insertions in less than 5 s.[11] We used very clear start and end points in the measurement of the duration of insertion as recommended earlier.[27] We started the measurement with the removal of the facemask until the evident and clinically important endpoint, application of two breaths with a tidal volume of 6 ml/kg by the anesthesia machine. In contrast to Hohlrieder *et al.*[27] we preset the ventilator of the anesthesia machine to apply the breaths to overcome any bias by manually increasing ventilation frequency or pressure. We used ideal body weight (height in cm – 100) instead of absolute body weight because we felt this would better reflect clinically used tidal volumes. Time-to-connection measures only the technical flow of the procedure, and the time until effective ventilation occurs is definitely of clinical interest. Therefore, we did not measure time to connection of the ventilatory circuit.

The bulky design of the i-gel™ made insertion time not only longer, but we found a broader variance. That reinforces our observation that the insertion of the i-gel™ was less predictable compared to the LMA-S™. Interestingly, we were unable to find an influence of mouth opening on the insertion success or even insertion time, suggesting that tongue size might have an influence on the insertion of the i-gel™, but we were unable to quantify that. A paramedian approach for device insertion was often successful when median insertion failed. Indeed, the i-gel™ failed twice because of insertion difficulty and twice because of ventilation problems, whereas all three failures of the LMA-S™ were the result of ventilation difficulty, but there were no failures because of insertion problems. In the patient in which both supraglottic airway devices failed, body mass index was 32.8 kg/m², and failure was the result of inadequate ventilation.

Ventilation tidal volumes and airway seal pressure were the same for both devices after inserted. The i-gel™'s airway leak pressure was comparable to the 30 ± 7 cm H_2O found in 71 women.[10] Others measured lower leak pressures (less than 20 cm H_2O) in 40 patients[12] or

Table 5. Possible Effect of Period 1 on Period 2 in the Crossover Design for the Devices

	First Device LMA-S™, n = 28	Second Device LMA-S™, n = 28	P Value	First Device i-gel™, n = 28	Second Device i-gel™, n = 28	P
Overall success, n	29	28	1.000	28	28	1.000
Airway leak pressure, cm H_2O	27 ± 8	25 ± 8	0.487	25 ± 9	29 ± 8	0.115
Tidal volumes, ml	698 ± 157	701 ± 130	0.987	767 ± 174	682 ± 152	0.062
Fiberoptic view (grade 1/grades > 1), n	15/14	14/14	1.000	19/9	21/7	0.768
Insertion time, s	35 ± 11	33 ± 12	0.281	48 ± 26	36 ± 18	0.062

Results presented as mean ± SD or n. Statistical tests: Fisher's exact test (success, fiberoptic view), Mann-Whitney (leak pressure, volumes, insertion time). LMA-S™ = laryngeal mask airway Supreme™.

higher ones (more than 33 cm H_2O).[8] LMA-S™ airway leak pressure was lower than the 35 cm H_2O reported in 22 patients,[1] but it was interestingly similar to leak pressures found by Verghese *et al.* (28.47 cm H_2O).[4] Both supraglottic devices did not reach the high airway seal known for the PLMA™.[26] In contrast to all the reported study results, we used a fixed extrication collar that impeded the optimal placement of the supraglottic devices, which might explain those differences.

Gastric catheter introduction failed only once in each mask. This is a remarkably high success rate given the fact that we used the conventional blind introduction method proposed by the manufacturers. We cannot, therefore, judge the success rate if we had used the alternative bougie guided technique developed by Brimacombe *et al.*[23] which involves a direct esophageal catheter or bougie placement before inserting the supraglottic airway device. We also did not fiberoptically evaluate the view through the gastric channel. The i-gel™'s narrow gastric opening made it impossible to advance our 4-mm scope. In the few cases for which we checked fiberoptic view through the LMA-S™, we were unable to determine exact placement of the opening. The theoretical benefit of allowing passive gastric regurgitation through the exactly correct placement of the gastric channel is neither confirmed nor denied by our study.

Fiberoptic view of the glottis was remarkably good through the i-gel™ compared with the LMA-S™. This finding and the smaller proportion of epiglottic downfolding were the only statistically significant differences in favor of the i-gel™. That confirms earlier fiberoptic findings[5] and explains the successful fiberoptic intubation through an i-gel™ in various case reports.[8,13,14] Neither epiglottic downfolding nor fiberoptic view could be correlated to ventilation success and possible tidal volume applied.

Limitations

First, our study does not evaluate real difficult airway, but simulated difficult airway, and all our included patients were easy to ventilate by facemask and did not receive muscle relaxing medication. Therefore, conclusions to the "cannot ventilate cannot intubate" scenario must be drawn with caution. Safety and ethical concerns prevented us from recruiting patients with expected difficult airway management because the American Society of Anesthesiologists recommends the use of awake fiberoptic intubation for these patients.[15] For unexpected difficult airway patients, it is legally difficult to consent real emergencies. Our suggestions to use both airway devices in difficult airway scenarios have been confirmed in case reports for the i-gel™[13] and the LMA-S™.[3] Both the LMA-S™ and the i-gel™ enable oxygenation and suctioning of gastric content at the same time. Thus, they could be valuable backup devices in failed intubation scenarios, especially in the "cannot intubate, cannot ventilate" situation.

Second, we had to rely on very vague figures for our sample size calculations. There were no published data on the two devices when we started our study. However, the very similar crossover designs by Cook *et al.*[30] and Verghese *et al.*[4] involved only 32 and 36 patients.

Third, every crossover design bears the risk of a carryover effect of the first treatment to the second. Plotting the data to visualize a possible effect was recommended,[33] and statistical computing as recently presented[4] showed in our study no evidence of the presence of an influence of one period to the other. That is in contrast to the period effect described by Verghese *et al.* in 32 women.[4] The statistically significant difference between the i-gel™ as first device and the LMA-S™ as second has no clinical relevance because the first insertion took longer than the second. A carryover effect would suggest longer insertion time for the second insertion because of tissue edema from the airway manipulation.

Apart from statistics, we also could not observe any clinical influence on the second device after the first was inserted. However, as a result of the crossover study design, adverse events and postoperative complaints could not be related to any device. Thirteen percent of our patients showed mild sore throat, 15% showed dysphagia, and 12% showed hoarseness, which is comparable to the earlier published results for the LMA-S™ precursor, the PLMA™ (sore throat 15%, dysphagia 11%, dysphonia 6%).[23]

Summary

Both newly introduced single-use supraglottic airway devices LMA-S™ and i-gel™ are useful backup devices in the management of the difficult airway; they have a similar insertion success and clinical performance in the simulated difficult airway situation. The i-gel™ takes longer to insert, but it shows a better fiberoptic view on glottic structures. The use of an extraction collar to simulate limited mouth opening and no neck movement for the study of difficult airway management interventions is feasible and safe.

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