Can J Anesth/J Can Anesth (2014) 61:794–800
DOI 10.1007/s12630-014-0198-6

REPORTS OF ORIGINAL INVESTIGATIONS

Randomized prospective trial comparing two supraglottic airway devices: i-gel™ and LMA-Supreme™ in paralyzed patients

Étude prospective randomisée comparant deux dispositifs pour voie aérienne supraglottique: i-gel™ et LMA-Supreme™ chez des patients paralysés

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Received: 22 November 2013 / Accepted: 16 June 2014 / Published online: 21 August 2014
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Abstract

Purpose *Many features can influence the choice of a supraglottic airway device (SAD), including ease of insertion, adequate ventilation pressures and lack of adverse effects. The goal of this randomized prospective trial was to compare the performance of the i-gel™ with that of the LMA-Supreme™.*

Methods *One hundred adult patients (American Society of Anesthesiologists I-III) scheduled to undergo elective surgery under general anesthesia were randomized to either an i-gel (n = 50) or an LMA-Supreme (n = 50). The primary objective was to compare ventilation pressures. Secondary objectives included time and number of attempts needed to introduce the device, adverse effects, and repositioning. The endoscopic view of the glottic aperture and the position of the drain tubes in relation to the esophagus were also evaluated.*

Results *The devices were inserted successfully in 46 (92%) patients in both groups. There was no significant difference in the [mean (SD)] leak pressure [i-gel: 23 (7) cm H_2O vs LMA-Supreme: 21 (8) cm H_2O; P = 0.14] or peak inspiratory pressure between both devices. Insertion time was shorter with the i-gel than with the LMA-Supreme [19 (7) sec vs 27 (17) sec, respectively; P = 0.003]. The vocal cords were completely visualized more often through the i-gel (70%) than through the LMA-Supreme (50%) (P = 0.007). Esophageal mucosa was easily visualized through the drain port in all but four patients, two patients in each group. There was no difference between groups regarding preoperative or postoperative complications. Postoperative patient discomfort was generally mild and comparable between both devices.*

Conclusion *Both the LMA-Supreme and the i-gel offer similar performance for positive pressure ventilation in paralyzed patients during general anesthesia. The i-gel was associated with a slightly faster insertion time and better fibrescopic visualization of the glottis. This trial was registered at Clinicaltrials.gov: NCT01001078.*

Résumé

Objectif *De nombreuses caractéristiques peuvent influencer le choix d'un dispositif pour voies aériennes supraglottiques (SAD), dont la facilité d'insertion, des pressions adéquates de ventilation et l'absence d'effets secondaires. L'objectif de cet essai prospectif randomisé était de comparer les performances de l' i-gel™ et du LMA-Supreme™.*

Author contributions *Nikola Joly* conceptualized the study and wrote the entire manuscript. *Patrick St-Pierre, Pierre Drolet,* and *François Donati* helped conceptualize the study. *Nikola Joly* and *Patrick St-Pierre* recruited patients. *Nikola Joly, Pierre Drolet,* and *Patrick St-Pierre* analyzed the results. *Louis-Pierre Poulin, Issam Tanoubi,* and *François Donati* interpreted the results. *Louis-Pierre Poulin* and *Issam Tanoubi* participated in manuscript revision. *Louis-Pierre Poulin* made the necessary steps to publication. *Pierre Drolet* performed the statistics. *François Donati* critically reviewed the manuscript.

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Méthodes *Cent patients adultes (American Society of Anesthesiologists I-III) devant subir une intervention chirurgicale programmée sous anesthésie générale ont été randomisés dans le groupe i-gel (n = 50) ou dans le groupe LMA-Supreme (n = 50). L'objectif principal était de comparer les pressions de ventilation. Les objectifs secondaires incluaient le temps mis et le nombre de tentatives nécessaires pour introduire le dispositif, ses effets secondaires et son repositionnement. La vue endoscopique de l'ouverture de la glotte et la position des tubes d'aspiration par rapport à l'œsophage ont été également évaluées.*

Résultats *Les dispositifs ont été insérés avec succès chez 46 patients (92 %) dans chacun des groupes. Il n'y a pas eu de différence significative en termes de pression de fuite (moyenne [ET]) (i-gel: 23 [7] cm H_2O contre LMA-Supreme: 21 [8] cm H_2O; P = 0,14) ou de pression inspiratoire maximum entre les deux dispositifs. Le temps d'insertion du i-gel a été plus court que celui du LMA-Supreme (respectivement, 19 [7] sec contre 27 [17] sec; P = 0,003]. Les cordes vocales ont été complètement visualisées plus souvent à travers le i-gel (70 %) qu'à travers le LMA-Supreme (50 %) (P = 0,007). La muqueuse œsophagienne a été facilement visualisée par l'orifice d'aspiration chez tous les patients, sauf quatre (deux dans chaque groupe). Il n'y a pas eu de différence entre groupes concernant les complications préopératoires ou postopératoires. La douleur postopératoire ressentie par le patient a été habituellement légère et comparable pour les deux dispositifs.*

Conclusion *Le LMA-Supreme et le i-gel offrent tous les deux des performances similaires pour la ventilation à pression positive chez des patients paralysés au cours d'une anesthésie générale. Le i-gel a été associé à un temps d'insertion légèrement plus rapide et une meilleure visualisation par fibres optiques de la glotte. Cette étude a été enregistrée sur le site www.clinicaltrials.gov: NCT01001078.*

The i-gel™ (©Intersurgical Ltd, Berkshire, UK) is a supraglottic airway device (SAD) made of thermoplastic elastomer with a gel-like texture at its tip. Unlike most other SADs, it has no cuff, but it can provide the necessary seal needed for general anesthesia. Its ease of insertion, the presence of a drain tube, and the possibility of intubation through the device make it an interesting tool. Studies have been published regarding its effectiveness.[1–6] The LMA-Supreme™ (©Teleflex Incorporated, Limerick, USA) has been on the Canadian market since 2006. Like older LMA™ products, it has an inflatable cuff and its design includes a more rigid structure, a larger size, a drain tube and the presence of gills to push the epiglottis upward. The LMA Supreme has been shown to be safe and efficacious. It may also be used as a conduit for tracheal intubation although it has not been designed primarily for this purpose.[7] Because it has no inflatable cuff, the i-gel may be inserted more easily than the LMA Supreme; however, the absence of a cuff could increase the chances of leaks with the i-gel. Accordingly, the primary objective of this randomized prospective study was to compare airway leak pressures with the i-gel *vs* the LMA Supreme. Secondary objectives were to compare time and number of attempts needed to introduce the devices, ventilatory airway peak pressure, endoscopic view of the glottis and position of the drain tubes in relation to the esophagus.

Methods

After approval from the Institutional Review Board (Comité d'éthique de la recherche de l'hôpital Maisonneuve-Rosemont, 05/14/2009) and obtaining written informed consent from each participant, one hundred adult patients (American Society of Anesthesiologists I-III) scheduled to undergo elective surgery under general anesthesia were randomized to have their airway managed with either an i-gel ($n = 50$) or an LMA-Supreme ($n = 50$). Patients were recruited by the main researcher from September 25, 2009 to April 5, 2011 in their hospital room or at the ambulatory centre before surgery and the follow-up period ended on the day after surgery. Exclusion criteria included symptomatic gastroesophageal reflux disease, absence of fasting, nasogastric tube inserted, intestinal obstruction, past major otolaryngological surgery or deformity of the upper airway, mouth opening < 3 cm and pregnancy. Additionally, patients weighing < 50 kg, with a body mass index > 35 kg·m^{-2} or scheduled for procedures expected to last more than four hours were also excluded. Orthopedic, plastic, general and urologic surgeries in the supine or lithotomy positions were included in the study.

A randomization chart was created by the research assistant.[A] The name of the device assigned to each patient was given in a sealed envelope to one of the researchers at induction. The SAD size was selected according to the manufacturer's recommendations: patients weighing 50-90 kg and those over 90 kg were assigned a size 4 and size 5 i-gel, respectively. Patients weighing 50-70 kg and those over 70 kg were assigned a size 4 and size 5 LMA-Supreme, respectively. Both devices were made

[A] http://www.randomization.com. Available from URL (accessed February 2014).

available at induction since crossover was permitted after failure of the assigned device. Tracheal intubation was performed if neither SAD could secure the patient's airway.

Before induction of anesthesia, patients were given a three-minute preoxygenation at tidal volume. Induction drugs consisted of fentanyl 1-3 $\mu g \cdot kg^{-1}$ *iv* and propofol 1-3.5 $mg \cdot kg^{-1}$ *iv*. A muscle relaxant was mandatory, but the type was left to the discretion of the anesthesiologist. Introduction of the airway device and pressure measurements were carried out while there was no twitch response to nerve stimulation. Maintenance of anesthesia consisted of intermittent fentanyl, muscle relaxant boluses and sevoflurane in a blend of oxygen and air.

The i-gel was lubricated and inserted with the patient's head in a partial sniffing position while lying on a headrest routinely used in our hospital. The i-gel was introduced while holding the bite block part in a steady movement towards the hard palate until resistance was felt in the hypopharynx. Manual ventilation with the circuit bag was used to assess the effectiveness of ventilation. The LMA-Supreme was also lubricated on the dorsal part of its tip, and the cuff was deflated before insertion. With the patient's head also resting on a headrest in a partial sniffing position, the device was advanced towards the hard and soft palate in an arc movement. The cuff was inflated initially to 25 mL and then further inflated in 5 mL increments until either no leak was heard or 45 mL was attained. Manual ventilation with the circuit bag at a maximum of 20 cm H_2O was used to adjust the initial volume in the cuff.

For both devices, if ventilation was not adequate after initial insertion, the device was removed and then reinserted once. After two failed introductions of the assigned device, a crossover to the other SAD was allowed. If the crossover also failed, tracheal intubation followed using direct laryngoscopy. All insertions were performed by the same two researchers. The total time of insertion from opening the patient's mouth to the establishment of effective ventilation (typical square wave capnography curve, symmetric thoracic expansion and absence of audible leak) was recorded.

Following satisfactory insertion of the SAD, controlled ventilation was set to a standardized tidal volume of 8 $mL \cdot kg^{-1}$, frequency of 10 $breaths \cdot min^{-1}$ and inspiratory:expiratory ratio of 1:2. Peak ventilatory pressure was recorded during three consecutive ventilation cycles. Leak pressure was measured after 30 sec of stable ventilation with sevoflurane in oxygen. It was assessed by closing the expiratory valve of the ventilation circuit and setting the oxygen gas flow to 3 $L \cdot min^{-1}$ (manometric stability method).[8] The pressure at which equilibrium was attained (up to a limit of 40 cm H_2O) was recorded. For the LMA-Supreme, the leak pressure was first recorded with the initial cuff volume and a second time with the cuff inflated to 45 mL (maximal volume recommended). The LMA-Supreme cuff was deflated to its initial adjusted volume and ventilation variables were adjusted with both SADs to obtain an end-tidal carbon dioxide of 35-40 mmHg during maintenance of anesthesia.

Following pressure readings, endoscopic evaluation was performed to visualize the larynx via the ventilation port of the device. The standardized scale proposed by Brimacombe *et al.*[9] was used to describe positioning of the ventilation device. After evaluation of the laryngeal view, the fibrescope was inserted into the drain port to visualize esophageal mucosa.

Presence of blood on SADs was noted at withdrawal. An interview with the patient was performed on the day following surgery to evaluate sore throat, postoperative cough, dysphagia, and dysphonia. The participants assessed every item on a four-point Likert scale as follows: absent, mild, moderate or severe.

The primary outcome was leak pressure. We worked under the null hypothesis that there would be no difference between the two devices since both were reported in the literature to perform adequately and safely. Two-sided tests were used. Since results of previous studies on SADs showed standard deviation values for leak pressure around 7 cm H_2O, it was estimated that 50 patients per group would be adequate to find a difference of 4 cm H_2O between groups with an alpha error of 0.05 and a beta error of 0.2.[10] Continuous data were analyzed with the Student's *t* test. Ordinal data were analyzed with either the Mann-Whitney U test (scores for postoperative complications) or with the Chi square for trends (Glottic Visualization Scale, number of insertion attempts). Categorical data were analyzed with Fisher's exact test. Analyses were carried out with Prism 5.O (GraphPad Software, La Jolla, CA, USA).

Protocol is released and can be found on clinicaltrials.gov with reference number NCT01001078.

Results

One hundred patients were randomized, 50 in each group (Fig. 1). Eight patients, four in each group, could not be managed with the assigned device; consequently, their preoperative and postoperative data were not included in the analysis. Amongst them, two in the i-gel group and one in the LMA-Supreme group needed tracheal intubation following an unsuccessful rescue attempt with the crossover device. Seven patients, five in group i-gel and two in group LMA-Supreme, could not be reached postoperatively to be interviewed.

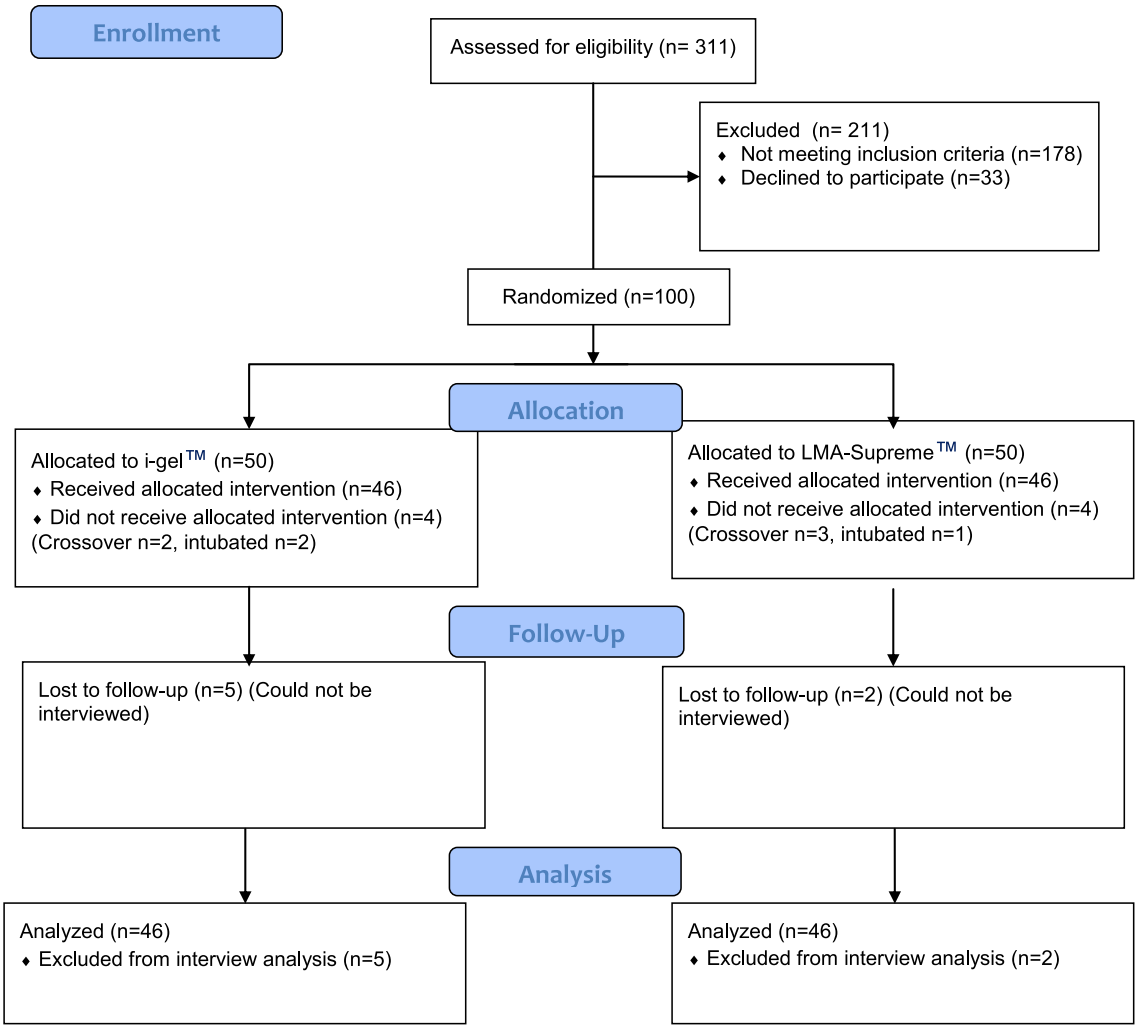

Fig. 1 Randomization flow chart

Table 1 Demographic data

	i-gel™ ($n = 50$)	LMA-Supreme™ ($n = 50$)
Age (yr)*	50 (16)	50 (18)
Height (m)*	1.68 (0.09)	1.67 (0.10)
Weight (kg)*	72 (11)	71 (13)
Body mass index ($kg \cdot m^{-2}$)*	26 (4)	26 (4)
Sex (male/female)	17 / 33	13 / 37

*Mean (SD)

Demographic data in both groups were similar (Table 1). In both groups, the primary device was inserted successfully in 46 of the 50 patients (92%). Regarding the primary outcome, there was no difference in [mean (SD)] leak pressure between both devices [23 (7) cm H_2O for the i-gel *vs* 21 (8) cm H_2O for the LMA-Supreme] after establishment of adequate ventilation [mean difference: 2; 95% confidence interval (CI): −1 to 6; $P = 0.14$] (Table 2). Increasing the cuff volume of the LMA-Supreme further to 45 mL did not influence the leak pressure [22 (9) cm H_2O] ($P = 0.51$).

Insertion was unsuccessful in four patients assigned to the i-gel. In two of these cases, ventilation was possible but inadequate (poor thoracic expansion and excessive leak). For the other two, difficulties were encountered during insertion. Two of these four i-gel failures were successfully managed with the LMA-Supreme. Insertion also failed in four patients in the LMA-Supreme group. Poor (unsatisfactory capnography curve) or ineffective ventilation was seen in three instances. In the fourth case, an insertion problem occurred. In three of these four patients, the i-gel was used successfully.

Insertion time was slightly longer with the LMA-Supreme group [27 (17) sec] than with the i-gel group [19 (7) sec] (mean difference: 8 sec; 95% CI: 2 to 13; $P = 0.003$). A mean volume of 27 (6) mL was needed in

Table 2 Insertion and ventilation data

	i-gel™ ($n = 50$)	LMA-Supreme™ ($n = 50$)	
Attempts (1 / 2 / crossover / intubation)	43 / 3 / 2 / 2	44 / 2 / 3 / 1	$P = 0.77$
	i-gel ($n = 46$)*	LMA-Supreme ($n = 46$)*	
Insertion time (sec)**	19 (7)	27 (17)	$P = 0.003$ (Difference: 8; 95% CI: 3 to 13)
Leak pressure (cm H_2O)**	23 (7)	21 (8)***	$P = 0.14$ (Difference: 2; 95% CI: −1 to 6)

*Includes only patients managed with their primary devices

**Mean (SD)

***The mean (SD) volume in the LMA-Supreme cuff during this measurement was 27 (6) mL

CI = confidence interval

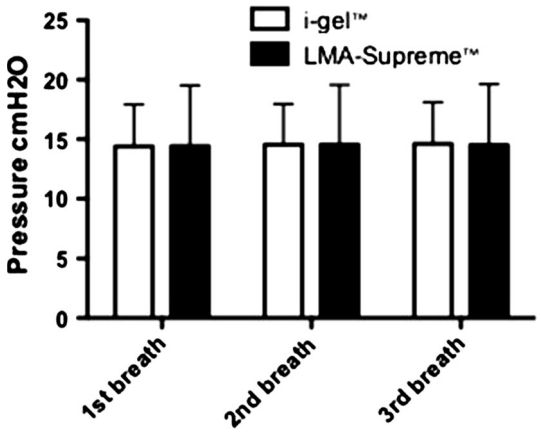

Fig. 2 Peak inspiratory pressures following insertion and ventilation with a pre-set 8 mL·kg^{-1} tidal volume. Bars show mean; error bars depict standard deviation ($P = 0.96$ between groups)

Table 3 Fibrescopic evaluation

	i-gel™ ($n = 46$)	LMA-Supreme™ ($n = 44$)*	
Glottic visualization Scale (4 / 3 / 2 / 1)**	37 / 6 / 2 / 1	22 / 13 / 8 / 1	$P = 0.01$
Esophageal mucosa seen (yes/no)	44 / 2	42 / 2	$P = 1.0$

*Two of the 46 patients who were managed with the intended device had no evaluation because of technical difficulty during fibroscopy

**Glottic Visualization Scale (4 = only the vocal cords are seen; 3 = vocal cords and posterior part of the epiglottis seen; 2 = vocal cords and anterior part of the epiglottis seen; 1 = vocal cords not seen, but adequate ventilation)

the LMA-Supreme cuff to have no audible leak following insertion. There was no difference between groups regarding peak inspiratory pressure measured during the first three breaths with the pre-set tidal volume [14 (3) cm H_2O for the i-gel *vs* 14 (5) cm H_2O for the LMA-Supreme; $P = 0.96$] (Fig. 2).

Fibrescopic evaluation was carried out in all but two patients whose airways were managed with their primary devices. Two patients in the LMA-Supreme group experienced technical problems with the fibrescope. The vocal cords were totally and exclusively visualized significantly more often through the i-gel (70%) than through the LMA-Supreme (50%) ($P = 0.01$) (Table 3).

Inserting the fibrescope through the drain tube provided easy and clear visualization of the esophageal mucosa in all but four participants, two in each group (4%) ($P = 1.0$) for whom the drain tube was not properly aligned (Table 3).

Five devices, two i-gels (4%) and three LMA-Supremes (7%) were repositioned during surgery because of ventilatory difficulties ($P = 1.0$). Blood was found on five i-gels (11%) and six LMA-Supremes (13%) at the end of anesthesia ($P = 1.0$). Postoperative patient discomfort did not differ between groups and was generally absent or mild. The median score was one (75% percentile ≤ 2) for both devices regarding the severity of postoperative sore throat ($P = 0.59$), cough ($P = 0.82$), dysphagia ($P = 0.58$), and dysphonia ($P = 0.66$) (Table 4).

Discussion

This study shows that the performance of the i-gel and the LMA-Supreme are similar regarding leak or peak ventilatory pressures, proper alignment of the drain tube, and side effects. Compared with the LMA-Supreme, the i-gel took a few seconds less to insert and it also provided a better fibrescopic view of the vocal cords.

Many characteristics can influence the choice of a SAD. Ease of insertion, adequate ventilation pressures and lack of adverse effects are amongst the most desirable features we look for in such devices. One distinctive characteristic of the i-gel is the absence of an inflatable cuff, which makes it easy to manipulate. On the other hand, the LMA-Supreme's inflatable cuff may provide a more individualized fit in the pharynx and hypopharynx. In a study with volunteers, Russo *et al*. found that the LMA Supreme protrudes deeper into the upper esophageal

Table 4 Complications

	i-gel™ ($n = 46$)	LMA-Supreme™ ($n = 46$)	
Repositioning during surgery	2	3	$P = 1.0$
Blood on device at removal	5	6	$P = 1.0$
	i-gel ($n = 41$)*	LMA-Supreme ($n = 44$)*	
Sore throat** (1 / 2 / 3 / 4)	23 / 10 / 6 / 2	26 / 13 / 4 / 1	$P = 0.59$
Cough** (1 / 2 / 3 / 4)	36 / 5 / 0 / 0	38 / 5 / 1 / 0	$P = 0.82$
Dysphagia** (1 / 2 / 3 / 4)	25 / 7 / 9 / 0	29 / 9 / 4 / 2	$P = 0.58$
Dysphonia** (1 / 2 / 3 / 4)	34 / 5 / 1 / 1	35 / 5 / 3 / 1	$P = 0.66$

*Four patients in each group did not receive the allocated intervention; seven patients could not be reached postoperatively (five in group i-gel and two in group LMA-Supreme)

**Four-point Likert scale: 1) absent; 2) mild; 3) moderate; 4) severe

sphincter than the i-gel despite fibreoptically identical positions and more compression of the laryngeal inlet by the LMA-Supreme than by the i-gel.[11] Our study suggests that both devices have similar successful insertion rates and equivalent leak and peak inspiratory pressures. These findings are in agreement with those of previous reports. When comparing the LMA-Supreme with the i-gel, Teoh *et al.* reported high success rates on first attempt and recorded no differences in leak pressure in 100 anesthetized and paralyzed female patients undergoing gynecological procedures.[10] Chew *et al.* studied spontaneously breathing anesthetized adult patients.[12] They reported higher leak pressures with the LMA-Supreme than with the i-gel [25.6 (5.1) cm H_2O *vs* 20.7 (5.9) cm H_2O, respectively], but their initial and overall successful insertion rates were not significantly different from each other. They also reported a better fibrescopic view with the i-gel. In a simulated difficult airway scenario using an extrication collar limiting mouth opening and neck movement, success rate for the LMA-Supreme was 95% *vs* 93% for the i-gel. Tidal volume and airway leak pressure were similar. Fibrescopic view through the i-gel showed less epiglottic downfolding.[1] Russo *et al.* showed similar leak pressure, insertion time, insertion success rate and fibreoptical position between the two devices.[13]

Although a slightly longer time was needed to insert the LMA-Supreme compared with the i-gel, the clinical significance of this observation remains questionable. The mean difference was only eight seconds and could probably be attributed to cuff inflation. Regarding endoscopic evaluation of the devices, glottic opening was seen significantly more often with the i-gel. Similar results were observed in a previous study conducted on spontaneously breathing participants.[12] Ragazzi *et al.* studied insertion of these two devices with novice operators. The first time insertion success rate was higher for the LMA-Supreme than for the i-gel (77% *vs* 54%, respectively; $P = 0.029$) and more placement failures occurred with the i-gel than with the LMA-Supreme (6 *vs* 0, respectively; $P = 0.025$). Mean leak pressure was greater with the LMA-Supreme than with the i-gel (29 cm H_2O *vs* 23 cm H_2O, respectively; $P = 0.007$). More patients complained of pharyngolaryngeal pain with the LMA-Supreme than with the i-gel (44% *vs* 20%, respectively; $P = 0.053$).[14] Recently, Chen *et al.* performed a meta-analysis that included ten studies comparing the i-gel with the LMA-Supreme. They found that both devices were similar and had high success rates and short insertion times. Gastric tube insertion through the LMA-Supreme was easier and associated with additional sore throat compared with the i-gel.[15]

Proper alignment of the ventilatory channel of the i-gel with the vocal cords may be necessary since the device is also marketed as an intubating device with the possibility of blind insertion of a tracheal tube. In a randomized trial comparing the i-gel with the LMA-Fastrach™ for blind tracheal intubation, Halwagi *et al.* reported initial and overall success rates of 69% and 73%, respectively, with the i-gel.[16] Others have found that blind intubation through the i-gel in mannequins had a lower success rate (57%).[17]

Although the i-gel and LMA-Supreme performed equally well with regard to ventilatory and leak pressures, clinicians often choose these SADs because the design is intended to reduce the risk of pulmonary aspiration. Both devices carry an esophageal drain designed to decrease the volume of air trapped in the stomach while providing a vent in case of regurgitation.[18] Although a proper evaluation is still required regarding the protective role of the SAD's drain tube against the risk of pulmonary aspiration, this study suggests that the drain tubes in the i-gel and the LMA-Supreme are, nonetheless, correctly positioned with regard to the esophagus in the large majority of cases. Still, in 4% of cases, the drain is not in the proper position even if the SAD provides adequate ventilation.

This study has obvious limitations. Among them, the protocol did not allow blinding of the operators inserting the SADs; therefore, a systematic bias could not be completely excluded. The study was conducted on paralyzed participants and its conclusions may not apply to patients managed without neuromuscular blockade. Moreover, sample size was calculated for leak pressure, the primary outcome; therefore, the study could be underpowered for other endpoints such as adverse effects.

In conclusion, both the LMA-Supreme and the i-gel offer similar performance for positive pressure ventilation during general anesthesia with neuromuscular blockade. The i-gel takes slightly less time to insert and it also provides better fibrescopic visualization of the glottic opening. In most cases, the drain tube of both devices was correctly positioned in relation to the esophageal inlet.

Conflict of interest The authors have no conflict of interest and no financial support of any kind to declare. Trudell Medical provided the i-gel™ and Vitaid provided the LMA-Supreme™. The fibrescope used in the trial was made available by Olympus Canada.

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