

## Evaluation of a new supraglottic airway device in ambulatory surgery: The I-gel®

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Evaluation d'un nouveau dispositif de contrôle des voies aériennes dans la chirurgie ambulatoire : le I-gel®

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### R É S U M É

**Prérequis :** Au cours d'une anesthésie générale, le contrôle des voies aériennes est assuré par l'intubation trachéale ou par une technique alternative comme les dispositifs supraglottiques. L'i-gel® est un nouveau dispositif supraglottique, à usage unique, muni d'un bourrelet non gonflable et d'un canal gastrique permettant l'évacuation du contenu gastrique.

**But :** L'objectif de notre travail était d'étudier la place de L'i-gel® dans l'arsenal de contrôle des voies aériennes mis à la disposition de l'anesthésiste.

**Méthodes :** Il s'agit d'une étude prospective non randomisée dans le cadre de la chirurgie viscérale ambulatoire incluant 100 patients. Les items évalués par notre étude sont le taux de réussite de l'utilisation de l'i-gel®, sa facilité d'insertion, la performance de ses fonctions de ventilation et de drainage gastrique, les effets indésirables et les complications en rapport avec son usage. Enfin son acceptation comme un nouveau dispositif par les praticiens a été recherchée.

**Résultats :** Le taux de réussite de pose est de 99%, alors que celui d'utilisation est de 96%. L'insertion a été qualifiée de facile et moyennement facile par les opérateurs dans 99% des cas. Cette insertion a nécessité moins de 2 manœuvres chez 92% des patients. Sa durée moyenne est de 13±5 secondes. Les principaux incidents rencontrés lors de l'insertion sont la toux chez 5 patients et le hoquet dans 7 cas. Les variations hémodynamiques lors de l'insertion ne sont pas significatives sur le plan statistique. Des fuites audibles autour de l'i-gel® ont été détectées chez 14.6% de nos malades. Le nombre de manipulations est inférieur ou égal à 2 pour 96.9% des malades au cours de l'anesthésie. La valeur moyenne des pressions crêtes est de 18 cm H<sub>2</sub>O. Après examen fibroscopique, la visualisation des cordes vocales a été complète dans 74% des cas et partielle chez 14.6%. Aucune régurgitation ni épisode hypoxique n'ont été retrouvés, malgré 2 cas d'insufflation gastrique notés. En post opératoire, 1 seul cas de maux de gorge a été signalé. 5 dispositifs étaient souillés de sang à leur retrait. Un patient a eu un traumatisme dentaire. Malgré l'expression d'une bonne satisfaction de la procédure chez 99% des utilisateurs, 28.1% d'entre-eux hésitent à réutiliser l'i-gel®, sans avancer des raisons évidentes.

**Conclusion :** Cette étude clinique semble démontrer que l'i-gel® a une insertion aisée, qu'il permet une ventilation au moins aussi efficace qu'avec le LMA classique, matériel de référence. Et qu'il présente moins d'effets secondaires que les autres dispositifs.

### S U M M A R Y

**Background:** The I-gel® is a new single-use supraglottic airway device with a non-inflatable cuff. It is composed of a thermoplastic elastomer and a soft gel-like cuff that adapts to the hypopharyngeal anatomy. Its tube is profiled to facilitate and stabilize its insertion.

**Aim :** The aim of our study is to state the efficiency and the place of I-gel® in airway management in adult anaesthetic practice.

**Methods:** One hundred patients, ASA I-II, scheduled for short-duration elective surgery under general anaesthesia were included in this prospective study. Patients with neck pathology, previous or anticipated airway problems, increased risk of regurgitation or aspiration, ASA III and above and undergoing emergency surgery were not included in the study. We collected the following data: adequacy of the size recommended to the patient, ease in inserting the I-gel®, leak fraction, gastric leak, complications during insertion and removal, ease in inserting the gastric tube, haemodynamic and ventilatory parameters, stability during patient movement and satisfaction of the anaesthetists.

**Results:** The success rate of insertion and the use of the I-gel was respectively 99% and 96%. The device was inserted at the first attempt in 92% of cases. The introduction of the I-gel® was rated easy in 99% of cases taking a median of 13 seconds. Complications of insertion were restricted to coughing in 5 patients and hiccups in 7 patients. There were no significant increase in heart rate and mean arterial blood pressure compared to pre-insertion values. An audible leak was recorded in 14.6% of cases. The need for additional manoeuvres was less than or equal to 2 in 96.9 % of patients. The mean of the recorded peak airway pressure values was 18 cmH<sub>2</sub>O. After a fiberoptic exam via the airway tube, the glottis was completely seen in 74% of cases and partially seen in 14.6%. Two cases of gastric inflation were recorded. There was no case of regurgitation or hypoxemic episode during this trial. Post-operatively sore-throat was reported by one patient in recovery. After I-gel withdrawal, trace of blood was observed in 5 devices. One case of dental trauma was noted. 95% of the anaesthetists were satisfied with the use of the I-gel in their practice.

**Conclusion:** This study showed that I-gel® can be used safely and effectively in patients undergoing short-duration elective surgery because the I-gel® has a very good insertion success rate and few complications. The fiberoptic position of the device was correct and the ventilation was highly effective. These elements must be corroborated in larger series.

### Mots-clés

Dispositifs supra-glottique, masque laryngé, anesthésie générale, anesthésie ambulatoire

### Key- words

Airways, Laryngeal mask airway, Supraglottic device, General anaesthesia, Ambulatory surgery.

The I-gel® is a new single-use, non inflatable supraglottic device in thermoplastic gel that adapts to the laryngeal anatomy. Its tube is profiled to facilitate and stabilize its insertion. [1-5] The aim of our study is to state the efficiency and the place of I-gel® in airway management in adult anaesthetic practice. We evaluated ease in inserting the I-gel® device, seal pressure, gastric leak, complications during insertion and removal, ease in inserting the gastric tube, hemodynamic response and ventilator parameters during positive pressure ventilation.

## MATERIALS AND METHODS

This prospective nonrandomized study was conducted in visceral surgery department at Habib Thameur Hospital in Tunisia.

One hundred ASA physical status I-II adult patients scheduled for short-duration elective surgery in supine position under general anesthesia were included in this study. Patients with known lung or heart disease; increased risk of regurgitation (symptomatic gastric reflux, history of hiatus hernia, full stomach, pregnancy); morbidly obese patients ( $BMI > 30 \text{ kg.m}^{-2}$ ); patients with previously documented difficult intubation and/or anatomic features predictive for difficult intubation (such as limited mouth opening less than 40 mm, reduced thyromental distance less than 65 mm, Mallampatti grade III or IV); patients with neck pathology and those with a history of relevant drug allergy were not included in the study.

Exclusion criteria were the use of a neuromuscular blocking agent; the unsuccessful placement of the device after three attempts, severe hypercapnia ( $PCO_2$  greater than 45 mm Hg); prolonged episodes of airway obstruction (peak airway pressures above 40 cmH<sub>2</sub>O) or hypoxemia ( $SPO_2$  less than 92%).

### Anaesthetic technique

Patients were premedicated with oral hydroxyzine (1 mg.kg<sup>-1</sup>). After arrival in the operating theatre, standard monitoring was installed including ECG, non-invasive blood pressure (NIBP),  $SPO_2$  and end-tidal carbon dioxide. Patients were preoxygenated. Prior to induction of anaesthesia, all patients were given fentanyl (2-3  $\mu\text{g.kg}^{-1}$ ) intravenously. A sleep dose of propofol (2-3 mg.kg<sup>-1</sup>) was titrated to induce anaesthesia.

The properly sized I-gel® was selected and inserted after loss of ciliary reflex. Correct insertion was assessed by the presence of CO<sub>2</sub> wave form with a plateau on the capnograph and absence of leak. Anaesthesia was maintained with a continuous infusion of 6-12 mg.kg<sup>-1</sup> propofol per hour and fentanyl 1  $\mu\text{g.kg}^{-1}$  boluses according to the patient's hemodynamic response to surgery.

Patients were ventilated with volume-controlled ventilation. Tidal volume was set at 7 ml.kg<sup>-1</sup> and respiratory rate was set at 12 breaths per minute without positive expiratory pressure (PEP) and with inhaled equimolar mixture of oxygen-nitrous oxide.

Endoscopy was performed in all patients by inserting the fiberscope through the main lumen of the I-gel® for evaluating glottic view. Four fiberoptic views were identified (Grade I: full

view of the cords; Grade II: partial view of the cords; Grade III: view of the epiglottis and Grade IV: No view of the cords or epiglottis).

The device was removed when the patient fully recovered cough and deglutition reflexes. Standardized postoperative analgesia including paracetamol (1g) and tramadol (100 mg) was administered.

The following data were collected every five minutes: heart rate, arterial pressure,  $SPO_2$ , end-tidal CO<sub>2</sub>, Peak pressure, leak fraction LF (LF was defined as leak volume LV divided by inspired tidal volume ITV:  $LF = LV/ITV$ ); The difference between ITV and expired tidal volume ETV was used to calculate LV, i.e.  $LV = ITV - ETV$ ), gastric leak, the necessity of optimisation manoeuvres to stabilise the device after placement. We continued monitoring in Post-Anesthesia Care Unit (PACU), at the 6th hour and the 24th hour.

The primary endpoint was the rate of successful placement of the I-gel®. The failure of insertion was defined as the difficulty to maintain an effective airway after three insertion attempts or occurrence of a major incident requiring endotracheal intubation.

A secondary endpoint was the ease of the insertion of the device. Several parameters were used such as: duration of insertion, number of attempts, need for any additional manoeuvre to manage the airway, change of size and ease of gastric tube insertion.

Additional endpoints included: ventilator parameters (Peak pressure, leak fraction, audible gastric leak), haemodynamic parameters, complications occurring during insertion, maintenance and removal of the I-gel® (coughing, laryngospasm, vomiting, regurgitation, hiccup, dental injury, incidence of visible blood on removal of the device), episodes of hypoxia ( $spo_2 < 94\%$ ), significant changes in heart rate and/or blood pressure (more than 20% of baseline values), the occurrence of minor events in the recovery room and at the 24th hour (sore throat, dysphagia, dysphonia..) and satisfaction of the anaesthetists.

### Statistics:

Statistical analysis was performed using a statistical software program (SPSS® 11.0 for windows). Qualitative variables were expressed as percentage, whereas quantitative variables were expressed as means  $\pm$  standard deviation (SD). Chi-square and student- test were used in statistical analysis. Results were considered significant at p-values less than 0.05.

## RESULTS

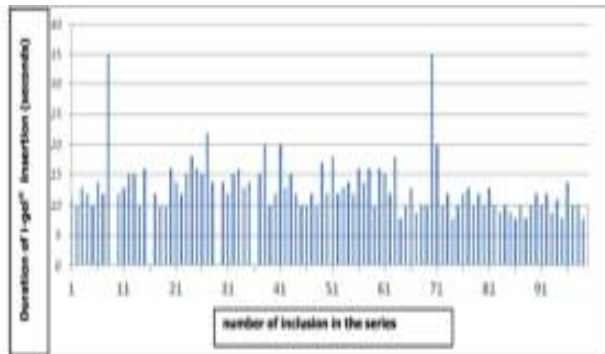
One hundred patients with mean age of  $48.5 \pm 12$  years and mean weight of  $71.3 \pm 12$  kg, scheduled for short duration elective surgery under general anesthesia, were included in this study over a period of three months. The majority of the patients were ASA class I. Types of surgery were hernia surgery in 91% of patients and proctology in 9%. The mean duration of anesthesia was  $41 \pm 6$  minutes. Mallampatti scores were I in 74%, II in 19% and III in 7% of patients.

The size 3 I-gel® was used in 3 cases (3.1%), size 4 in 71 cases

(74%) and size 5 in 22 cases (22.9%). Recommended size of the I-gel® according to the weight was considered inadequate in 12 patients.

All devices were inserted by experienced anesthesiologists. The success rate of insertion and the use of the I-gel was respectively 99% and 96%. Only four failures occurred. Failures were due to an airway obstruction in three cases and a large pharyngeal leak in one case. The device was inserted at the first attempt in 84% of cases. The introduction of the I-gel® was scored easy in 99% of cases. The insertion took  $13 \pm 5$  seconds (range 8-35 seconds). Fifteen patients (16%) needed second attempt while none needed 3rd attempt. The causes of primary failures were technical difficulties in inserting of the I-gel® in 3 patients and need for change in size of the device in 12 patients. The duration of insertion depending on the number of inclusion in the series was represented on the figure n°1.

**Figure 1 :** The duration of insertion depending on the number of inclusion in the series



The most common manipulations to achieve effective airway were the cervical extension (68%) and the traction of the tongue (29%). In 27% of patients, there were no additional manoeuvres to stabilize the device.

The clinical tolerance of the device and hemodynamic response after insertion and removal of the I-gel® are shown respectively in tables 1 and 2.

**Table 1 :** Clinical tolerance of the i-gel® and depth of anesthesia.

	At insertion (Ramsay=6)	At removal (Ramsay=2)	P
Cough	5	1	Ns
Hiccup	7	0	<0,05
Bronchospasm	2	0	Ns
Laryngospasm	0	1	Ns

**Table 2 :** Nociceptive stimuli and haemodynamic changes

		Before	After	P
Insertion	HR (beats min-1)	70 ± 16	73 ± 14	Ns
	SBP (mm Hg)	109 ± 30	106 ± 25	Ns
Removal	HR (beats min-1)	69 ± 15	70 ± 12	Ns
	SBP (mm Hg)	131 ± 24	132 ± 26	Ns

The airway management performance data (incidence of audible leak, gastric insufflation, episodes of airway obstruction) are summarized in table 3.

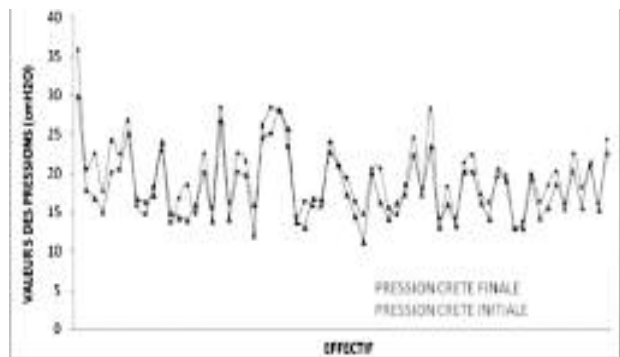
**Table 3 :** Complications and need for device replacement

	Incidence(n)	Device replacement(n)
Audible leak	14	10
Gastric insufflation	2	2
Airway obstruction	2	0

None of the patient suffered hypoxia ( $\text{spo}_2 < 94\%$ ). No regurgitation or inhalation occurred. The insertion of the gastric tube was rated easy in 87 cases, difficult in one case and impossible in five cases.

In our study, the mean end tidal  $\text{CO}_2$  was  $33.5 \pm 1$  mmHg. The mean of the recorded peak airway pressure values was  $18.2 \pm 4.6$  cmH<sub>2</sub>O. The variations of peak pressures during the procedure are shown in figure n°2.

**Figure 2:** variation of peak airway pressures during the procedure



After a fiberoptic exam via the airway tube, the glottis was completely seen in 74% of cases and partially seen in 14.6%. Post-operatively, no significant adverse event was noted in any patient. Sore-throat was reported by one patient in recovery. After I-gel withdrawal, trace of blood was observed in 5 devices. One case of dental trauma was noted. None of the patient complained of dysphonia or dysphagia. 24 h after discharge from the PACU, no patient recalled to report any complaints.

Practitioners' satisfaction was measured with a 1-4 subjective scale. They were asked about three items: the quality of ventilation, ease of hands-free anaesthesia and the maneuverability of the device. Anaesthetists rated I-gel® performance excellent/good in 95% and never poor.

Concerning the economic evaluation of I-gel® in this trial, 116 devices of different sizes were used (both devices were placed in 16 patients).

The price per unit of the device was 33.6 TND and the total cost was estimated at 3897.6 TND.

In our department, the classic laryngeal mask airway (LMA

Classic™) was the reference device. The suppliers of multiple-use laryngeal masks recommend that the devices can be used in 40 patients. If the cost per unit of LMA Classic™ is assumed to be 395 TND, the total cost of the trial is 1225 TND. Compared to the LMA Classic™, the use of i-gel® device needs an additional cost of 2672.6 TND.

## DISCUSSION

Our findings show that the success rate of insertion and the use of the I-gel was respectively 99% and 96%. A rate ranging from 97% to 100% was found in the literature. The I-gel® performance is comparable to other supraglottic airway devices with success rates between 94 and 100% [4-8].

A randomized study comparing the performance of the single use i-gel® supraglottic airway and reusable classic laryngeal mask airway (cLMA®) concluded that the quality of ventilation is identical between the two devices but the insertion of i-gel® appears easier than cLMA® [10].

Recently, in an experimental study on cardiopulmonary resuscitation, Gatward and colleagues [3] showed that the i-gel® device could reduce the time of airway management by 50% compared to other supraglottic devices (the classic LMA™ and the ProSeal™ LMA) and the endotracheal tube.

In our study, if we exclude the 12 cases that required 2 attempts to change the size of the device, the success rate of i-gel® insertion at the first attempt was 96%. This is consistent with the results of Richez and al. [9] who have found a success rate of 100% on the 1st attempt. The first time insertion success is an important data because it helps to reduce the risk of pharyngeal trauma and postoperative pain [15].

The i-gel® is a supraglottic airway device without inflatable cuff. It has some potential advantages including easier insertion and minimal risk of tissue compression. The ridge at the proximal end of mask catches the base of tongue and contributes to the positional stability of the device after insertion [5].

The low failure rate (4%) in our study is in agreement with literature findings (i-gel®: 0-3% [7-11] and other inflatable supraglottic devices: 0-6% [10-14]).

Median time to successful placement was 13±5secondes. We noticed that the i-gel® insertion time does not tend to decrease during the study period (Figure n°1). There are data to suggest that the i-gel is easily inserted by novices [3, 4, 8, 19]. Cook et al. [3] also showed that experience had no effect on insertion; neither experience with the device itself nor overall anaesthetic experience improved time to ventilation.

In our study, 14 cases of audible leak have been identified. Eight cases had a significant leak fraction (more than 0.25). Only two cases presented high peak airway pressures (more than 40 cmH2O).

Uppal et al. [18] showed that there was no statistically significant difference between the leak fractions of the i-gel® and the endotracheal tube during pressure-controlled ventilation (PCV) for pressures below 20 cmH2O. There was significant LF when using i-gel® during PCV with higher pressures (>25

cmH2O).

Proper ventilation is defined by a leak pressure around 25 cmH2O [20-22]. In a comparative study, the i-gel® achieved a median airway leak pressure of 28 cmH2O, which is higher than those of conventional LMA and ProSeal LMA (25 cmH2O), confirming a better seal of the i-gel®.

We noticed that after the first 15 minutes, the LF has decreased gradually while the peak airway pressures increase significantly ( $p<0.05$ ) at the end of the procedure. We assumed that inverse variations of LF and peak pressures are attributable to the muscle tone of pharyngeal wall around the device especially without neuromuscular block. [20]

We also postulated that this might be due to the thermoplastic properties of the gel cuff which may form a more efficient seal around the larynx after warming to body temperature.

We also assessed the anatomical position of the device in relation to vocal cords with fiberoptic bronchoscope.

The i-gel® is correctly inserted if the tip is located into the upper esophageal opening and the epiglottis blocker in the vallecula.

The laryngeal view was grade I in 74% and grade II in 14.6% of cases.

This performance is less than that reported in literature [5, 7].

The i-gel® effectively conforms to the perilaryngeal anatomy. This finding was confirmed by dissection [5], radiology [10] and endoscopy [23].

Concerning the complications in removal of the device, the incidence of oropharyngeal mucosal trauma is estimated at 7-12% [10, 27, 28] with the i-gel versus 15% with the c-LMA™ [27, 29] and 10% with the ProSeal LMA™ [30].

Sore throat is rarely reported with the i-gel. The incidence of this symptom increased with other inflatable supraglottic devices (12-28% with the c-LMA™ [31, 32] and 48% with the Combitude® [32]).

The low morbidity rate of the i-gel® may be attributed to the tensile properties of the noninflatable cuff and a lower pressure exerted against the pharyngeal structures. Concerning other inflatable devices, the trauma of pharyngeal mucosa increases with the level of pressure exerted by the cuff and the duration of ventilation. [33, 34, 35].

Intraoperative problems like arterial desaturation and hemodynamic changes were not seen in any patient. This is consistent with the literature data [21, 36].

There are several well-established advantages of using i-gel compared with endotracheal tube such us: lower incidence of sore throat [37], less hemodynamic changes [38,39], better oxygenation during emergence, lower incidence of laryngospasm and bronchospasm [17] and increased "case turnover" especially in the ambulatory surgery setting [40].

The single-use supraglottic airway device avoids viral cross infection from blood, vomit and secretions and reduces the risk of transmission of prion disease especially new variant Creutzfeld- Jacob disease. Routine cleaning and autoclaving does not remove protein deposits from reusable laryngeal mask devices [41-44].

We also evaluated the cost of the single-use devices. The cost-

benefit analysis found no material benefit (additional costs estimated at 26.726 TND per patient with i-gel® compared to the c-LMA™) but the results showed that there's less airway morbidity and increased patient comfort.

## CONCLUSION

This study showed that I-gel® can be used safely and

effectively in patients undergoing short-duration elective surgery because the I-gel® has a very good insertion success rate and few complications. The fiberoptic position of the device was correct and the ventilation was highly effective. These elements must be corroborated in larger series.

Conflict of interest:

The authors have no conflict of interest in regard to the devices tested in the study.

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