

A New Single Use Supraglottic Airway Device with a Noninflatable Cuff and an Esophageal Vent: An Observational Study of the i-Gel

- B. Richez*† **BACKGROUND:** The i-gel is a new single-use supraglottic airway device with a noninflatable cuff and an esophageal vent.
- L. Saltel* **METHOD:** In this prospective, observational study, we evaluated the i-gel in 71 women.
- F. Banchereau* **RESULTS:** Insertion success rate was 97%. Insertion was easy and performed at the first attempt in every patient. Mean seal pressure was 30 ± 7 cm H₂O and average peak pressure was 11 ± 3 cm H₂O. The gastric tube was inserted in 100% of cases.
- R. Torrielli* Only one case of coughing and one mild sore throat occurred.
- A. M. Cros* **CONCLUSION:** The i-gel is a reliable, easily inserted airway device that provides an adequate seal with a low morbidity rate.

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Supraglottic airway devices are now widely used for surgery requiring general anesthesia. They provide a perilaryngeal seal with an inflatable cuff and are an alternative to tracheal intubation.^{1,2} The i-gel (Inter-surgical Ltd., Wokingham, Berkshire, UK) is a new single-use noninflatable supraglottic airway device. It is composed of a soft, gel-like, transparent, thermo-plastic elastomer. It is designed to achieve a mirrored impression of the pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. A drain tube is placed laterally to the airway tube and allows the insertion of a gastric tube (maximum 14 F gauge) (Fig. 1). Only one study on the i-gel performed on fresh cadavers has been published.³ This study evaluated the i-gel in clinical practice.

METHODS

After IRB approval and patients' informed consent, 71 ASA physical status I–II women scheduled for gynecologic surgery were included in this prospective, observational study. Patients with known lung disease, difficult airway, hiatal hernia, and risk factors for difficult intubation or regurgitation were excluded.

Standard monitoring was applied, and administration of oxygen was performed before induction of anesthesia. Premedication and the anesthetic technique were not standardized and were left to the anesthesiologist's discretion.

A size 4 i-gel was used in patients weighing 50–90 kg and size 5 for patients above 90 kg. The device was inserted by senior anesthesiologists experienced in using the laryngeal mask airway (LMA), according to the manufacturer's recommendations. Before insertion, a water-soluble lubricant was applied to the rear of the cuff. The patient's head was placed in the sniffing position. The i-gel was grasped along the integral bite block and was introduced continuously into the mouth towards the hard palate until resistance was felt. Correct insertion was assessed by proper chest expansion, the presence of a CO₂ wave form with a plateau on the capnograph, absence of audible leak, and lack of gastric insufflation. The presence of gastric insufflation was determined by epigastric auscultation. After two failures, a LMA-ProSeal was used, and in case of failure, the patient had an endotracheal tube inserted. After a proper position with the i-gel was obtained, leak pressure was measured. The fresh gas flow was set at 6 L/min. The pressure adjustment valve was set at 40 cm H₂O. Leak pressure was recorded when airway pressure reached a plateau. Patients were ventilated either with pressure-controlled ventilation or with volume-controlled ventilation. Tidal volume was set at 8 mL/kg. Respiratory rate was set to obtain an end-tidal CO₂ between 35 and 40 mm Hg. A lubricated 14 or 12 F gauge gastric tube was then inserted down the drainage tube.

Data recorded were as follows: age, weight, and height of patient; type of surgery and anesthesia; i-gel size; number of insertion attempts; ease of insertion; presence of gastric insufflation; laryngeal leak; leak pressure; ease of gastric tube insertion; and ventilatory variables. Complications occurring during insertion,

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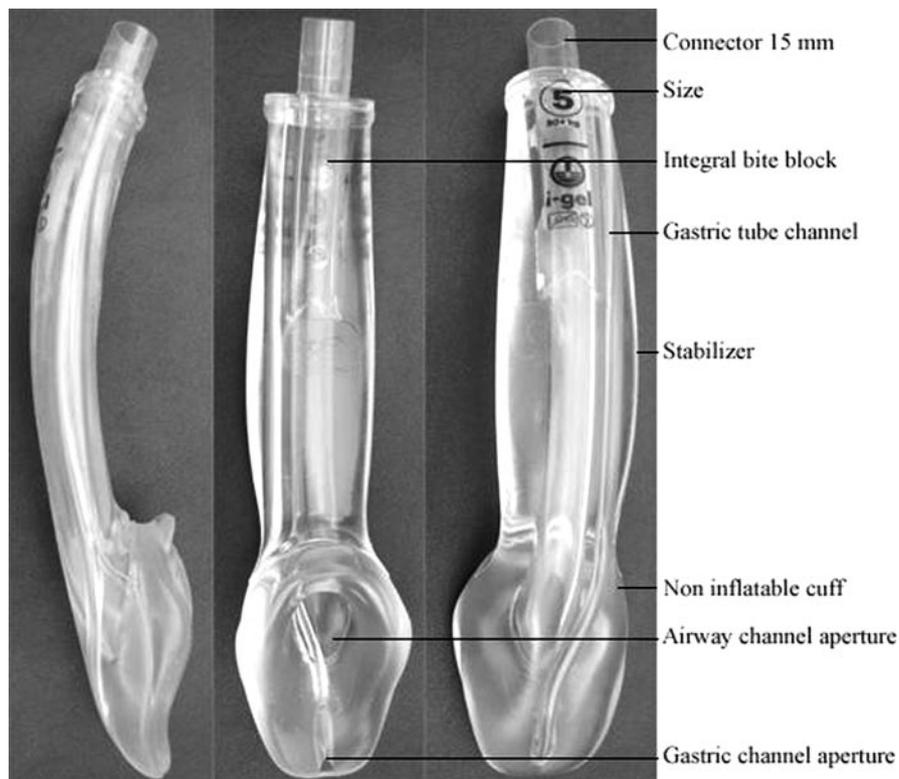


Figure 1. The i-gel.

maintenance, and removal were noted for each patient. Sore throat, coughing, dysphagia, and dysphonia were evaluated in the recovery room.

Ease of i-gel and gastric tube insertion was graded subjectively on a scale from 1 to 4 (1 = very easy, 2 = easy, 3 = difficult and 4 = very difficult).

Results were expressed as mean and standard deviation or as percentages.

RESULTS

Seventy-one women were included in this study. Patients' characteristics are given in Table 1. Duration of anesthesia ranged from 15 to 120 min. The overall insertion success rate was 97% irrespective of the anesthesiologist's previous experience with the i-gel (Table 2). The first attempt at insertion was successful in every case. Insertion was scored very easy in 66 cases (93%) or easy in 5 others (7%). Only two failures occurred. Failures were due to a large pharyngeal leak, whereas insertion was judged very easy in one case and easy in the other. Insertion of a LMA-ProSeal also failed for the same reason, and tracheal intubation was performed without difficulty. No laryngeal leak occurred, except in these two cases. No airway obstruction was noted. Ventilatory variables are summarized in Table 2. No gastric insufflation occurred. Insertion of a gastric tube was possible in every case and was very easy in 41 cases (59%), easy in 20 (29%), and difficult in 8 (12%). No regurgitation or inhalation occurred. No blood staining was noted after removal of the device. Only two minor events occurred: a short coughing episode and a transient moderate sore throat.

Table 1. Patients' Characteristics

Age (yr)	41 ± 14
Weight (kg)	65 ± 14
Height (cm)	163 ± 6
Body mass index (kg/m ²)	24.6 ± 5.5
Type of surgery (<i>n</i>)	
Hysteroscopy ± resection	24
Tumor resection	12
Curetage	17
Other	18

Results are mean and standard deviation.

Table 2. Ventilatory Parameters

Tidal volume (mL)	487 ± 92
End-tidal CO ₂ (mm Hg)	36 ± 4
Respiratory rate (bpm)	11 ± 1
Peak pressure (cm H ₂ O)	11 ± 3
Leak pressure (cm H ₂ O)	30 ± 7
Leak pressure–peak pressure (cm H ₂ O)	19 ± 7

Results are mean and standard deviation.

bpm = breaths per minute.

DISCUSSION

Our study shows that the i-gel is a reliable airway device. Insertion was easy and was obtained at the first attempt. High leak pressure and low peak pressure ensured safe ventilation and decreased the risk of gastric insufflation,^{4–6} even in 3 obese patients (body mass index >35 kg/m) who were ventilated with 22 cm H₂O peak pressure. A gastric tube ensured drainage of gastric secretions in every case.

Although we did not check the position of the device with a fiberoptic laryngoscope, high leak pressure, low peak pressure, and absence of signs of

airway obstruction suggested that the device was correctly positioned and that the epiglottis was not included or down-folded in the cuff. The noninflatable cuff is semirigid and cannot be folded over, over-inflated, or inserted in the trachea, thus diminishing the risk of airway obstruction. A study performed on fresh cadavers showed a mean percentage of glottic opening score of 82% and conformation of the device to the perilaryngeal anatomy.³

The low morbidity rate in our study is of note and could have been due to the high first attempt success rate, the tensile properties of the noninflatable cuff and a lower pressure exerted against the pharyngeal structures.³

Our study has some limitations. The sample size was small and the study was performed in women, and so the findings cannot be extrapolated to a male population. Moreover, the lack of anesthetic technique and the wide range of duration of anesthesia may influence the incidence of sore throat. However, there is no evidence with other devices that gender influences success rate or seal pressure. Three studies suggest that sore throat and discomfort are more frequent for females.⁷⁻⁹

This preliminary study shows that the i-gel seems to be a reliable, easily inserted airway device providing an adequate seal.

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