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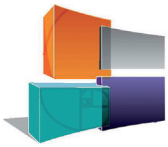

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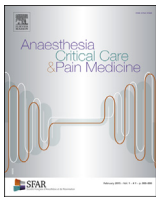

Original Article

# Choosing appropriate size of I-Gel® for initial success insertion: a prospective comparative study

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ABSTRACT

*Purpose:* The optimal size of the I-Gel® remains unclear since the manufacturer's weight-based formula (size 3 for weight < 50 kg, size 4 for weight 50–90 kg, and size 5 for weight > 90 kg) for the laryngeal mask airway I-Gel® is not evidence-based. We hypothesised that sex may also guide the choice of I-Gel® size.
*Methods:* Insertion success rates of the I-Gel® chosen according to the weight-based formula were prospectively recorded and compared with those of a patients' cohort ventilated with an I-Gel® chosen according to the sex-based formula recorded. Two periods of 18 months were randomised in three independent hospitals in France to study each choice strategy. Patients requiring I-Gel® size change were compared with those who where successfully ventilated with the initially chosen device. Complications linked to the I-Gel® and factors for changing the size of the I-Gel® were also recorded and analysed.
*Results:* Data from 900 patients were prospectively collected in the three participating centres. The overall initial ventilation was inadequate in 80 cases, including 7% ($n$ = 31) in the weight-based group and 3% ($n$ = 13) in the sex-based group ($P$ = 0.01). In the weight-based group, changing size of I-Gel® was successful in 28 (90%) cases. In the sex-based group, changing size of I-Gel® was useful in 1 case only. Endotracheal tube insertion was necessary in 15 cases despite changing I-Gel® size, including 3 cases in the weight-based group and 12 cases in the sex-based group. Ease of insertion and postoperative pharyngo-laryngeal problems were similar between groups with or without changing size of I-Gel®.
*Conclusion:* Adequate ventilation is achieved most of the time using size selection for the I-Gel® laryngeal mask airway according to the manufacturer's weight-based formula. However, our results suggest that the sex-based formula in healthy, anaesthetised, adult patients may also be appropriate for I-Gel® size choice.


## 1. Introduction

The I-Gel® (Intersurgical Ltd, Wokingham, UK) is a single-use supraglottic airway device designed for use during general anesthesia. The I-Gel® has several specific design features including a non-inflatable cuff anatomical seal by a shape which is a mirror impression of the supraglottic anatomy, a gastric channel allowing passage of a gastric drainage tube, a large flattened stem to reduce the risk of axial rotation, and an epiglottic ridge to resist upward and outward movements. Studies showed that the I-Gel® provides a good seal during anaesthesia both for spontaneously breathing and controlled ventilation. The manufacturer recommends a weight-based formula (size 3 for weight < 50 kg, size 4 for weight 50–90 kg, and size 5 for weight > 90 kg) to chose the size. However, this formula is not evidence based with a significant number of initial failure leading to change the size of the device in order to better secure the airway. Male sex, older age, poor dentition, and impaired mandibular subluxation have been associated with I-Gel® failure [1]. We hypothesized that a sex-based formula (size 4 for women and size 5 for men) for size selection will have higher first pass success rates than the weight-based formula. The aim of the study was then to compare I-Gel® insertion success rates between two formulas for choosing the I-Gel® size.

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## 2. Methods

This observational study was approved by the Local Research Ethics Committee (Comité de Protection des Personnes Ile de France 3 n°S.C. 3511). Because of the observational nature of the study, the Ethics Committees provided a waiver of patients' consent. A non-opposition statement was collected from each participant and reported in patient's notes. We prospectively evaluated all I-Gel® insertions in three independent hospitals over a period of 36 months. The study did not influence the anaesthesia provider regarding the indication for the device or the mode of its use.

We studied patients undergoing elective surgery aged from 18 to 78 years, with an American Society of Anesthesiologists physical status I-IV. Exclusion criteria were a known or predicted difficult airway, mouth opening smaller than 2.5 cm, increased risk of aspiration (hiatus hernia, gastro-oesophageal reflux, or full stomach), or body mass index greater than 35 kg/m$^2$, pregnant women, and patients unable to communicate in French.

All patients fasted for at least 6 hours and were premedicated with 1.25 or 2.5 mg diazepam 1 h before induction. Mallampati Score, mouth opening, presence of poor teeth, were measured at the pre-anaesthetic consultation. Anaesthesia was induced with 0.3 μg/kg sufentanyl and 3 mg/kg propofol and maintained with 2–3% sevoflurane in 50% O2 and air. None of the patients were paralysed. Size of I-Gel® was selected according to a weight-based formula (size 3 for weight less than 50 kg, size 4 for weight 50–90 kg, and size 5 for weight greater than 90 kg) during the first phase of the study over an 18-month period (November 1st 2014 to April 30th 2015) and compared with those of a patients' cohort ventilated with an I-Gel® chosen according to the sex-based formula (size 4 for women and size 5 for men) recorded over another period of 18 months. Patients were clustered according to the randomized period starting from November 1st 2014 to April 30th 2015 and May 1st 2015 to October 31st 2016.

All insertions were performed by eight experienced I-Gel® users (> 500 uses) using the digital insertion technique according to the manufacturer's instructions. Adequate placement of the I-Gel® was assessed by movements of the chest wall and the end-tidal CO2 waveform. If ventilation was considered inadequate, gentle manipulations such as neck flexion or head extension and pushing or pulling the device were allowed. The number of attempts required for insertion was recorded. Removal of the device from the mouth before re-insertion was considered as failed attempt. Three attempts were allowed before device use was considered a failure and replaced by a larger or a smaller size, accordingly. In the event of inadequate ventilation after a single attempt using a different size, the participant was excluded from the study and tracheal intubation performed.

Patients were ventilated for 15 min at the following settings: pressure volume to achieve at least 8 mL/kg tidal volume (TV) without exceeding a pick pressure of 40 cmH2O; respiratory rate of 12 breaths/min; inspiratory/expiratory ratio of 1:2. Failure of insertion was defined by presence of audible leaks. Leaks were detected by listening over the mouth with an ear [2]. When an audible leak was noted, leak pressure (LP) and leak volume (LV) were measured. Leak volume was calculated as the difference between inspired tidal volume (ITV) and expired tidal volume (ETV). The leak fraction was defined as LV divided by ITV. No PEEP was set up. After removal, the I-Gel® was inspected for visible blood defining mucosa injury. Patients were questioned about the presence/absence of sore throat and hoarseness postoperatively by an investigator blinded to the size selection. An unblinded observer collected data during insertion or removal of the device.

A sample size of 450 patients was required in each period to achieve a 5% precision to detect a projected difference of 50% using the sex-based formula assuming the primary success rate without changing size of the I-Gel® was 93% according the manufacturer's recommendations with 95% confidence assuming a design effect of 2. STATA (Stat Corp., College Station, TX) was used for analysis. Quantitative and qualitative variables were compared by using paired Student's *t*-tests and chi-square tests, respectively. When the frequency of events was, 5 or values did not follow normal distributions, Fisher's Exact and Mann-Whitney tests were used.

## 3. Results

Over a period of 36 months, data from 900 patients were analysed and patient characteristics are presented in Table 1. The number of attempts required for insertion was similar between groups. Failure to achieve initial satisfactory ventilation was significantly higher using the weight-based formula ($n$ = 31, 7%), compared to the sex-based formula ($n$ = 13, 3%) ($P$ = 0.01) (Table 2). The device was successfully changed in 28 cases (6%), including 19 size 5 for men and 9 size 4 for women. Intubation was required in 3 cases for failed ventilation after I-Gel® size change. Using the sex-based formula, the initial device failed in 13 (3%) cases and was successfully changed in 1 case (0%). When ventilation was inadequate, the weight group had significantly lower airway leak pressure, and higher leak volume and leak fraction, compared with the sex-based group. Intubation was required in 12 cases for failed ventilation after I-Gel® size change, including 5 and 7 cases in men and women, respectively (Table 3). The only cause of initial failure was inadequate ventilation. Characteristics of I-Gel® size insertion success according to weight and sex is detailed in Table 2. In univariable analysis, BMI and sex were significantly associated with the I-Gel® size change. Ease of insertion and postoperative pharyngo-laryngeal complications were similar between groups with or without changing size of I-Gel® (Table 4).

**Table 1**
Patient characteristics ($n$ = 900).

| | Mean (SD) or number (%) |
|---|---|
| Male | 432 (48%) |
| Age (year) | 51.6 ± 15.3 |
| Height (cm) | 170 ± 6.9 |
| Weight (kg) | 69.5 ± 11.1 |
| BMI (kg/m$^2$) | 24 ± 9.1 |
| ASA class I-IV[a] | 414 (46%)/415 (46%)/54 (6%)/9 (1%) |
| Mallampati Score (1/2/3/4)[b] | 549 (61%)/198 (22%)/99 (11%)/27 (3%) |
| Mouth opening < 3.5 cm | 108 (12%) |
| Retrognatia | 27 (3%) |
| Loose or poor teeth | 26 (3%) |
| Surgery performed | Plastics 333 (37%) |
| | Ophtalmology 334 (37%) |
| | Orthopaedics 171 (19%) |
| | Gynecology 54 (6%) |
| | Vascular 9 (1%) |
| Patients' position | Supine 828 (92%) |
| | Beach chair 63 (7%) |
| | Lateral 9 (1%) |

[a] 8 missing data.
[b] 27 missing data.

**Table 2**
Distribution of I-Gel® size according to weight or sex.

| | | Weight $n$ = 450 | | Sex $n$ = 450 | |
|---|---|---|---|---|---|
| | | Male | Female | Male | Female |
| Size 3 | Correct | 0 | 32 | NA | NA |
| | Failed | 0 | 4 | NA | NA |
| Size 4 | Correct | 86 | 218 | NA | 266 |
| | Failed | 15 | 2 | NA | 5 |
| Size 5 | Correct | 69 | 14 | 171 | NA |
| | Failed | 1 | 9 | 8 | NA |

**Table 3**
Leak volumes, pressures, and insertion data, expressed as median (IQR) or actual number.

| | I-Gel size choice | | |
|---|---|---|---|
| Characteristics *n*(%) | Weight-based (*n* = 450) | Sex-based (*n* = 450) | *P*-value |
| Insertion attempts (1/2/3) | 416/31/3 | 418/26/6 | NS |
| Ventilation inadequate | 31 (7) | 13 (3) | 0.01 |
| Airway leak pressure (cmH2O)[a] | 22 (19–29) | 34 (18–40) | 0.02 |
| Leak volume (ml)[a] | 48 (24–164) | 22 (21–179) | 0.004 |
| Leak fraction (%)[a] | 4.6 (2.0–19.0) | 2.3 (1.0–17.0) | 0.007 |
| Success after changing size | 28 (6) | 1 (0) | < 0.001 |
| Intubation | 3 (1) | 12 (3) | 0.08 |

[a] Reported when ventilation inadequate with tidal volume 8 mL/kg.

**Table 4**
Airway morbidity according to selection criteria for I-Gel® size.

| Airway morbidity *n*(%) | Weight-based (*n* = 450) | Sex-based (*n* = 450) | *P*-value |
|---|---|---|---|
| > 3 attempts for insertion | 25 (5) | 20 (4) | 0.78 |
| Mucosal injury (blood on device at removal) | 24 (5) | 19 (4) | 0.89 |
| Sore throat | 22 (5) | 15 (3) | 0.39 |
| Hoarseness | 1 (0) | 0 (0) | 1 |
| Laryngospasm | 15 (3) | 11 (2) | 0.82 |

## 4. Discussion

This comparative observational prospective multicentre study suggests that the sex-based formula results in fewer oropharyngeal leaks than the weight-based formula. The higher success rate achieved by changing size in the group "weight" strongly suggest size 4 should be used in women, regardless of patients' weight. Similarly, it seems more adequate to choose a size 5 for men, considering the difference of initial failure rate between size 4 and size 5. Moreover, failures requiring intubation in the weight group were women in 2 cases (initial size 4) and men in a single case (initial size 5). There was a possible significant decrease of failure requiring intubation in the weight-based decision, supporting the usefulness of changing size using the sex-based formula in case of initial failure. This is probably related to the use of a size fitting more adequately to the oro-pharyngeal anatomy providing a more effective seal. Indeed, three-dimensional imaging revealed that the length and volume of the larynx and hypo pharynx were significantly larger for men than for women [3]. Interestingly, height but not weight impacted on pharyngo-laryngeal anatomy in the same study. There was a possible significant decrease of failure requiring intubation in the weight-based decision.

Our findings are similar to those in other studies that comparing the sex-based formula (size 4 for women and size 5 for men) with an early version of the manufacturer's weight-based formula (size 3 for weight 30–70 kg, size 4 for weight 70–90 kg, and size 5 for weight > 90 kg) using the LMA-Classic [4,5], or the ProSeal laryngeal mask [6]. Interestingly, we found that the sex-based formula provided a better seal when a smaller size sex-based formula for women was used suggesting that the improved seal is clinically relevant. Airway morbidity and insertion success were similar in both groups despite larger sizes with the sex-based formula in men. Similar to our results, a recent study reports that insertion success rates are similar for larger and smaller sizes, whatever the supraglottic device used [7]. We choose to refer to sex-based formula rather than gender-based since sex is linked to biological differences, including chromosomes, hormonal profiles, internal and external sex organs while gender describes the characteristics that a society or culture delineates as masculine or feminine.

Our study has a number of limitations. First, experienced users conducted all insertions, and our results may not be applicable to inexperienced health care workers. Second, we cannot exclude a potential source of bias, since an unblinded observer collected the intraoperative data. Additionally, our patients were not paralyzed and depth of anaesthesia was potentially insufficient to insert easily a supraglottic device despite use of standardized hypnotic doses according to patients' weight, potentially resulting in a misclassification bias. Third, situations requiring higher peak airway pressures such as intra-abdominal surgery and obese patients may rely more on type of supraglottic device than on size choice since leak pressure were similar in both groups. Exceeding 20 cm H2O insufflation pressure exposed to the risk of gastric distension. Fourth, our study was observational and not randomized. Fourth, the anatomical position of the device in relation to vocal cords was not assessed using a bronchoscope. However, there seems to be no correlation between fiberoptic Scores and airway leak pressures [4]. Finally, factors influencing anatomical variations of oro-pharynx were not considered in our study, while external neck measurements might be the most accurate measurement to choose size of supraglottic devices [8–11].

Despite those limitations, our study suggests that size selection for the I-Gel® is more effective using the sex-based formula in healthy, anaesthetised, adult patients, compared with the recommended manufacturer's weight-based formula. The sex-orientated formula election should be compared with the weight-oriented size selection using a randomised controlled trial for generalisation.

## Ethical statement

The work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

### Funding

No funding was received to perform the study.

## Contribution

GG, CA, MA, FS, AP, IM, JME, CB designed, planned and performed the study, analyzed the data and wrote the first draft; GG and CB revised the manuscript. All authors read and approved the final manuscript. GG is guarantor of the paper.

### Disclosure of interest

The authors declare that they have no competing interest.

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