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i-gel™ supraglottic airway in clinical practice: a prospective observational multicentre study

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Editor's key points

- In this paper, data on 2049 uses of i-gel have been presented.
- The overall success rate was 96% and average leak pressure 26 mm Hg.
- The risk factors for failure were male gender, impaired mandibular subluxation, poor dentition, and old age.
- Importantly, the study provides a large retrospective data on i-gel usage in the everyday clinical setting.

Background. The i-gel™ supraglottic airway device has been studied in randomized controlled studies, but it has not been evaluated in a large prospective patient cohort. Therefore, we performed this prospective multicentre observational study to evaluate success rates, airway leak pressure, risk factors for i-gel failure, and adverse events.

Methods. With Ethics Committee approval and waiver of patients' consent, data about anaesthesia providers, patient characteristics, and the performance of the i-gel were recorded in five independent hospitals in Switzerland over a period of 24 months. We analysed success rates, leak pressures, adverse events, and risk factors for failure.

Results. Data from 2049 i-gel uses were analysed. Patients' mean age was 47 (range 6–91) yr. The primary i-gel success rate without changing size was 93%; the overall success rate was 96%. Insertion was deemed very easy or easy in 92%. The mean airway leak pressure was 26 (8) cm H_2O. The mean anaesthesia time was 67 (42) min. Risk factors associated with i-gel failure were males ($P<0.001$), impaired mandibular subluxation ($P=0.01$), poor dentition ($P=0.02$), and older age ($P<0.01$). Adverse events recorded were laryngeal spasms ($n=25$, 1.2%), blood stained airway devices ($n=79$, 3.9%), transient nerve damage ($n=2$, 0.1%), one case of transient vasovagal asystole, and one glottic haematoma.

Conclusions. The i-gel is a reliable supraglottic airway device failing in <5% and providing high airway leak pressures. Males, impaired mandibular subluxation, poor dentition, and older age are risk factors associated with primary device failure. Serious adverse events are rare.

Keywords: airway management; i-gel; laryngeal masks

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The i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, UK) is a supraglottic airway device that features a non-inflatable cuff and the possibility to introduce a gastric catheter. Its successful use has been described in randomized controlled studies,[1 2] including studies showing the possibility to intubate through the i-gel.[3 4] However, large prospective data about the application in daily clinical practice, side-effects, and possible predictors of i-gel failure are lacking. In order to describe rare adverse events and to find risk factors for failure, observational trials may be preferable to randomized clinical trials.[5] Only relatively small observational evaluations have been published: the largest one is a short communication about an audit of 300 cases.[6] We performed a prospective multicentre observational study in a variety of patients and surgical indications in order to obtain data about the i-gel's clinical performance, risk factors for failure, and adverse events in an everyday clinical setting.

Methods

This observational study was approved by the relevant Swiss Institutional Review Boards for each region (*Cantonal Ethics Committee Bern*, Bern, and *Commission Cantonale Valaisanne d'Éthique Médicale*, Sion). Because of the observational nature of the study, the Ethics Committees provided a waiver of patients' consent. We prospectively evaluated all i-gel insertions in five independent hospitals from the French- and the German-speaking part of Switzerland over a period of 24 months. The study did not influence the anaesthesia provider regarding the indication for the device or the mode of its use. The type of anaesthesia induction, maintenance, emergence, and ventilation mode were left to the discretion of the anaesthesia consultant. After anaesthesia, the anaesthesia provider filled out a two-page evaluation form that was attached to the i-gel device. The first

page of this questionnaire was regarding the information about the patient, the surgical procedure, and the performance of the supraglottic airway device, as further described below. The second page was filled out in the case of failure of the device. All patients in whom an i-gel was used as the initial airway device were included in the study.

Data obtained included patient characteristics (age, sex, height, and weight), airway assessment, surgical specialty, positioning of the patient, and data about the anaesthesia provider (experience with device). Initial i-gel size chosen was based on the manufacturer's recommendation based on body weight. The i-gel was evaluated in regard to the following points: ease of insertion graded from 1 (very easy) to 5 (very difficult), the use of minor airway manoeuvres (changing insertion depth or head/neck position) to correct improper seal, the ease of insertion of a catheter through the oesophageal port and whether gastric contents could be suctioned, the mode of ventilation (spontaneous, controlled, or pressure support), and the duration of anaesthesia. Airway leak pressure was measured as previously recommended,[7] with a maximum allowed pressure of 40 cm H_2O. Success was defined as insertion of the device and the ability to deliver adequate tidal volumes. In the case of i-gel failure, the anaesthesia provider described the cause of the failure in detail. The categories of failure were failed passage of the device into the hypopharynx (either because of the tongue/teeth or because of failed passage through the pharyngeal curvature), malpositioning with an airway leak pressure of <5 cm H_2O, and inadequate tidal volume/inadequate ventilation. The further airway management was recorded (change to smaller or larger i-gel size, other supraglottic airway device, or tracheal intubation), but this decision was left to the consultant anaesthesiologist and not predefined by a protocol. Finally, we prospectively evaluated perioperative complications and the causes of i-gel failures. Patients in whom any perioperative or postoperative airway-related complication occurred or who complained of discomfort were followed up until recovery. Completed forms were collected daily and checked for completion by designated study personnel. Two members of the study group checked the final digital database for accuracy.

For all statistical analysis, we used SPSS v.19.0.0 (SPSS Inc., Chicago, IL, USA). For comparisons between anaesthesia providers, the Student' *t*-test, Mann–Whitney's *U*-test, or Kruskal–Wallis' test for continuous data were used as appropriate; the χ^2 test and Fisher's exact test were used for frequencies. Correlations were analysed by Spearman's rank correlation. To identify parameters influencing i-gel performance, a manual logistic multivariable regression with a stepwise backward elimination analysis was applied and odds ratios were calculated. The following patient factors and covariates were used for the regression model: sex, age, height, weight, BMI, ASA status, Mallampati class, mouth opening <3.5 cm, impaired subluxation of the mandible, dentures (upper, lower, both), presence of loose teeth or rotten teeth, and presence of a beard. Results are presented as mean (SD) or number and percentage. A *P*-value of <0.05 was considered statistically significant.

Results

Over a period of 24 months, we prospectively collected and analysed data from 2049 i-gel uses. Another five data sheets could not be analysed because of insufficient data. Patient characteristics, type of surgery, and patients' positions during surgery are listed in Table 1.

A size 3 i-gel was used in 197 cases (10%), size 4 in 1531 cases (75%), and size 5 in 249 cases (12%). Seventy-two (4%) data sets did not indicate i-gel size.

Data regarding i-gel performance and alternative airway management in the case of failure of the primarily chosen i-gel are summarized in Table 2. A total of 1914 (93.4%) i-gel devices were successful without changing the size of the device (primary success rate); 135 devices failed initially. In 52 of these failures (2.5%), changing the size of the i-gel was sufficient to achieve a patent airway. Successful ventilation was therefore established by an i-gel device of some size in 1966 (95.9%) cases (overall success rate). The mean airway leak pressure was 26 (8) cm H_2O. The allowed maximum of 40 cm H_2O was reached in 213 cases (10%).

In 65 of 1966 cases (3.3%), the i-gel was removed before the end of surgery. In 48 cases (2.4%), this was planned and the i-gel served as a guide for fibreoptic intubation. In 17 (1%) cases, this was not planned and the i-gel was removed for either surgical or patient-related reasons such as uncontrollable hiccup.

In total, 47 cases (2.3%) of sore throat were reported. Throughout the period of observation, a total of 25 cases of laryngo-/bronchospasms were reported (1.2%). One case of vagal reflex bradycardia followed by asystole during i-gel insertion was reported. Cardiopulmonary resuscitation was initiated and atropine administered, with return of spontaneous circulation after $\sim$1 min. Despite chest compressions, ventilation was successfully maintained with the i-gel in place throughout the episode. The patient was young and healthy and showed no signs of neurological or cardiac sequelae after emergence from anaesthesia. One case of bilateral paraesthesia at the tip of the tongue persisted after operation for 2 months and one case of transient glossopharyngeal nerve impairment was reported. Lastly, one case of glottic haematoma was encountered after an uneventful insertion of an i-gel. The patient showed marked sore throat and pain upon swallowing. ENT consultation revealed a glottic haematoma that was treated symptomatically and resolved after 2 days without long-term sequelae.

Table 3 lists data about the anaesthesia providers who inserted the i-gel. All providers were under surveillance of a consultant anaesthesiologist. Airway leak pressure was not influenced by experience with the i-gel ($P=0.18$). There was no correlation between experience with the i-gel and percentage of airway manoeuvres necessary ($P=0.12$), or difficulty of insertion ($P=0.51$). There was a negative correlation between experience with the i-gel and success rate

Table 1 Patient characteristics (n=2049). *For termination of pregnancy in the first trimester

	Mean (SD) or number (%)
Sex	883 (43%) males
Age (yr)	47 (21) (range 6–91)
Weight (kg)	71 (16) (range 20–148)
Height (cm)	168 (10) (range 115–200)
BMI (kg m^{-2})	25 (5) (range 13–45)
ASA class I–IV/missing	874 (43%)/808 (39%)/302 (15%) /12 (1%)/53 (3%)
Mallampati class I–IV/missing	1194 (58%)/680 (33%)/103 (5%)/3 (<1%)/69 (3%)
Mouth opening <3.5 cm	238 (12%)
Thyromental subluxation impaired	
To level of upper front teeth	209 (10%)
Fixed retrognathia	65 (3%)
Full dentures: upper/lower/both	109 (5%)/17 (1%)/131 (6%)
Teeth: loose/rotten (poor)	31 (2%)/77 (4%)
Beard present (of males, n=883)	81 (9%)
Surgical specialty (missing n=12)	Obstetrics*/gynaecology: 648 (32%) Urology: 579 (28%) Orthopaedics: 398 (19%) Ophthalmology: 223 (11%) ENT and neurosurgery 77 (5%) External chest and Vascular surgery: 55 (3%) Paediatrics: 47 (2%)
Patients' position other than supine	Beach chair: 40 (2%) Prone: 11 (1%) Lateral: 13 (1%)
Anaesthesia time (min)	67 (42) (range 8–390)
Anaesthesia maintenance	
Total i.v. anaesthesia	1395 (68%)
N_2O used	76 (4%)
Patient in spontaneous ventilation	198 (10%)

(P=0.002), meaning more experienced providers were less likely to succeed.

The stepwise regression revealed the independent factors predicting i-gel failure reported in Table 4.

Discussion

This observational prospective multicentre study confirmed the high success rates and airway leak pressures obtained with use of the i-gel that have previously been described in a smaller number of patients. The 93% first-attempt and 96% overall success rate are similar to other second-generation supraglottic airway devices like the LMA ProSeal.[8]

The leak pressures obtained were comparable with our earlier findings.[2 4 9] The i-gel provided leak pressures in the upper range of comparable supraglottic airway devices, but not as high as the ProSeal Laryngeal Mask.[10]

The insertion of an i-gel is found difficult during its passage past the teeth and the tongue,[2 11] or passage through the hypopharyngeal curvature. Therefore, a slightly off-midline approach[2] or depressing the tongue with the thumb[11] has been advocated. In addition, this study showed the difference between successful insertion and successful ventilation: in over 90%, the anaesthesia provider graded insertion as 'very easy' or 'easy', and insertion was possible in 98% of all cases without changing i-gel size. Despite successful insertion, in 103 cases (5%), sufficient ventilation could not be established.

One of the intentions of our study was to find risk factors associated with primary i-gel failure, leading to either change of size or change of device. We found that males, older age, poor dentition, and impaired mandibular subluxation made primary i-gel success less likely. Some of these risk factors have been described for difficult facemask ventilation as well.[12 13] Males and poor dentition have also been identified as risk factors for Laryngeal Mask Airway™ failure in a recent study.[14] This overlap of risk factors for difficult mask ventilation and risk factors for difficult ventilation with a supraglottic airway raises concerns because supraglottic airway devices are often used as back-up devices when the primary airway management attempt fails. Furthermore, these findings also suggest that the correct size of a supraglottic airway device does not only depend on weight, but perhaps also on height, age, and sex. Interestingly, neither

Table 2 Clinical performance $n=2049$. *Primary success defined as success without changing size; overall success defined as success of i-gel device including changing size. †Minor airway manoeuvres defined as changing insertion depth or head/neck position. ‡Ease of insertion of successfully inserted i-gels subjectively graded from 1 (very easy) to 5 (difficult). Missing data: 26 (1%). Ease of insertion does not reflect adequate ventilation and is therefore listed separately

	Mean (SD) or number (%)
Primary i-gel success rate*	1914 (93)
Overall i-gel success rate*	1966 (96)
Primary i-gel failures	135 (7)
Insertion impossible	31 (2)
Ventilation inadequate	103 (5)
Cause of failure unknown	1 (<1)
Alternative airway management of primary i-gel failures	
Change of i-gel size	52 (3)
Change of type of supraglottic device	34 (2)
Tracheal intubation	42 (2)
Face-mask ventilation	5 (<1)
Missing data	2 (<1)
Airway manoeuvres necessary†	265 (13)
Ease of insertion‡	
1	1466 (73)
2	390 (19)
3	96 (5)
4	33 (2)
5	7 (0.3)
Mean airway leak pressure (cm H_2O)	26 (8)
Gastric catheter insertion ($n=1171$)	
difficulty with insertion	14 (1)
gastric contents suctioned	685 (59)
Laryngospasm or bronchospasm	25 (1)
Blood on the i-gel at removal	
Stain/bloody	68 (3)/11 (1)

Table 3 Provider analyses. *Missing data, $n=27$ (1%). †Missing data, $n=64$ (3%)

	Numbers (%)
i-gel inserted by*	
Student Nurse Anaesthetist	376 (18)
Certified Nurse Anaesthetist	950 (46)
Resident	451 (22)
Consultant	245 (12)
Experience with i-gel†	
0–1 times used before	171 (9)
2–5 times used before	372 (18)
6–9 times used before	252 (13)
10–20 times used before	59 (3)
>20 times used before	1131 (57)
i-gel insertion rated 'very easy' or 'easy'	
Student Nurse Anaesthetist	342 (93)
Certified Nurse Anaesthetist	876 (94)
Resident	378 (90)
Consultant	185 (86)
i-gel overall successful	
Student Nurse Anaesthetist	372 (99)
Certified Nurse Anaesthetist	921 (97)
Resident	423 (94)
Consultant	231 (94)
Airway manoeuvres necessary	
Student Nurse Anaesthetist	58 (16)
Certified Nurse Anaesthetist	144 (16)
Resident	79 (19)
Consultant	51 (25)

Table 4 Risk factors for i-gel failure. *Effect size given as odds ratio for frequencies and as Cohen's *d* for interval data. CI, Confidence interval

	P-value	Effect size (95% CI)*
Males/male sex	<0.001	2.25 (1.57–3.22)
Impaired mandibular subluxation	0.012	1.76 (1.12–2.79)
Rotten (poor) teeth	0.019	2.62 (1.34–5.10)
Older age	0.001	0.38 (0.21–0.56)

weight nor BMI were identified as risk factors for i-gel failure. Therefore, the i-gel could be used as a guide for fibreoptic intubation in overweight patients.

As expected, the supine position was most often used, but we also report the successful use of the i-gel in the beach chair, lateral and prone positions. The use of supraglottic airway devices in positions other than supine is under discussion in the anaesthesia community, as experienced providers continue to expand the use of supraglottic airway devices.[15–17]

One feature of the i-gel is the possibility of gastric access via insertion of a gastric catheter. Corroborant to our earlier findings,[18] the gastric catheter suctioned gastric fluids in more than half of the patients despite the fact that all cases were elective, and all patients had fasted for >6 h. Pulmonary aspiration of gastric contents was not reported in any of the 2049 patients. However, the importance of gastric access for the prevention of aspiration remains unknown.[19]

In this study, a negative correlation between the experience of the provider and success rate was found. One likely explanation is that less experienced providers predominantly managed patients with 'easy' airways. Another explanation is that experienced providers were taking over at a certain point if the i-gel insertion was difficult, and the last provider dealing with the airway was recorded as the responsible provider. This would also explain why consultants performed more airway manoeuvres compared with Certified Registered Nurse Anesthetists (CRNAs) and Student Registered Nurse

Anesthetists (SRNAs) and why they were less likely to state that an insertion was easy. The high success rates in novices might also be a result of the apparent easy handling of the airway device. This would suggest either the absence of a learning curve or perhaps a very steep learning curve necessary to gain proficiency with this supraglottic airway device.

Among the adverse events that were noted, transient laryngospasms and bronchospasms were most common. In our view, this relates more to episodes of light anaesthesia than to the use of the supraglottic airway devices.[8] Only 47 (2.3%) sore throats were reported. We believe that sore throat was underreported because the severity of sore throat was not evaluated and therefore might not have been reported at all if mild. Of the 2049 cases analysed, two incidents of nerve damage were encountered: in one case, the tip of the tongue got caught between the i-gel and the lower teeth. This caused a bilateral numbness that recovered fully within 2 months. Although we did not specifically evaluate this problem, the relatively bulky construction of the i-gel quite frequently causes the tongue to protrude outwards and to be clenched between the teeth and the i-gel. We recommend to specifically check for this when securing the i-gel in order to avoid entrapment. Perhaps, the protrusion of the tongue occurs in other supraglottic airway devices as well, but there are no reports specifically addressing this issue. The second neurological impairment reported was damage to the glossopharyngeal nerve, which was confirmed by a neurologist. The patient recovered fully within 1 month. In this overweight patient, an i-gel size 5 was initially placed, but as explained above, we believe that the choice of the i-gel should not be made primarily according to weight, but rather according to height, sex, and age. In order to minimize pressure presumably caused by the i-gel, we would recommend using the smallest sized i-gel that provides enough airway seal pressure, especially in overweight patients and for prolonged procedures. However, according to a recent study,[20] mucosal pressures during i-gel use are generally low and not different than during the use of other supraglottic devices.

In conclusion, the i-gel proved to be a reliable supraglottic airway device with a high mean airway leak pressure of 26 (8) cm H_2O and a high overall insertion and ventilation success rate of 96%, in a broad variety of patients, patient positions, and modes of ventilation. Male sex, older age, poor dentition, and impaired mandibular subluxation were identified as risk factors for i-gel failure. Corrective minor airway manoeuvres were necessary in about one-fifth of all cases. Adverse events were rare; they included laryngeal spasms, transient nerve damage, haematoma, and vagal responses.

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Declaration of interest

None declared.

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