A study to evaluate fibreoptic-guided intubation through the i-gel[™]

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Abstract

Objective: The i-gel[™] superglottic airway (Intersurgical, Berkshire, UK) has been reported to function as an airway rescue device and as a conduit for fibre-optic intubation in predicted difficult airways. The wider and shorter stem of the i-gel[™] and the absence of a grille at the distal end suggests that it may serve as an ideal channel for intubation using a fibrescope. The aim of this prospective study was to determine the feasibility of using fibreoptic-guided intubation through an i-gel[™] airway in adult patients undergoing elective surgery.

Design: A prospective clinical study.

Subjects and setting: Sixty patients of both genders, aged 18-60 years, who presented for elective surgery in a tertiary care centre, were enrolled in the study.

Outcome measures: The number of insertion attempts, ease of insertion and insertion time of the i-gel[™], fibreoptic view through the i-gel[™] tube, airway seal pressure, ease of tracheal tube placement with the help of a fibreoptic bronchoscope through the i-gel[™], time taken for tracheal tube placement and any evidence of airway injury, were determined.

Results: Successful insertion of the i-gel[™] was achieved in 96.66% of patients. The mean time of insertion of the i-gel[™] was 9.09 ± 4.17 seconds. Ease of tracheal tube placement via the i-gel[™] was found to be easy in 91.4% of cases. The mean total tracheal tube placement time through the i-gel[™] was recorded as 89.16 ± 8.29 seconds.

Conclusion: The i-gel[™] was easy to insert, with a good first attempt success rate and acceptable insertion time. The success rate for fibreoptic-guided intubation through the i-gel[™] was also acceptable. Hence it can serve as an alternative conduit for fibreoptic-guided intubation.

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Introduction

The i-gel™ (Intersurgical, Berkshire, UK) supraglottic airway was introduced into clinical practice in the UK in 2007. It is a single-use device with a noninflatable cuff. The cuff is made of a thermoplastic elastomer, ethylbutylene styrene. Its design features include the absence of an inflatable cuff, obviating the need for cuff inflation, thus reducing the risk of both airway damage and mucosal damage. The i-gel™ has been evaluated for ease of insertion by novices in manikins and in patients, and appears to compare favourably with other supraglottic airway devices.¹ Claimed potential advantages include easier insertion and use with minimal tissue compression and stability following insertion. The seal pressure of the i-gel™ is better than that of the classic

laryngeal mask airway (LMA). Seal pressure appears to improve over time because of the thermoelastic properties of the gel cuff which forms a more efficient seal around the larynx after warming to body temperature.² The i-gel™ has been reported to function as an airway rescue device and as a conduit for fibre-optic intubation in predicted difficult airways.¹ The wider and shorter stem of the i-gel™ [192 mm for an i-gel™ (size 4), compared to 205 mm for a classic LMA (size 4)], large bowl, and the absence of grilles or bars at the distal end, suggests that it may be an ideal channel for intubation using a fibrescope.³

The aim of this study was to determine the feasibility of using fibreoptic-guided intubation through an i-gel^{\mathbb{I}} in adult patients undergoing elective surgery.

Method

The study was approved by the Pt. B.D Sharma PGIMS hospital ethics committee. Informed consent was obtained from the participants. Sixty patients of both genders in the age group, 8-60 years, belonging to American Society of Anesthesiologists physical status I or II, scheduled to undergo elective surgery in the supine position under general anaesthesia, were enrolled in the study. The patients with known difficult airways, cervical spine disease, body weight < 30 kg, mouth opening < 2 cm, a history of upper gastrointestinal surgery, bleeding or clotting abnormalities, hiatus hernia, gastroesophageal reflux disease and a full stomach were excluded from the study.

Selected patients for the study were examined preoperatively and subjected to a complete general physical and systemic examination. Routine investigations were carried out. Patients fasted for six hours and were then premedicated with oral alprazolam 0.25 mg and tablet ranitidine 150 mg on the previous night, and two hours preoperatively. After the establishment of an intravenous line and attachment of a standard IntelliVue® MP50 monitor (Philips Healthcare, the Netherlands) for noninvasive blood pressure, electrocardiography and pulse oximetry in the operating room, general anaesthesia was induced using standard techniques. A suitable size i-gel™ was introduced as per the manufacturer's instructions. Correct placement of the device was confirmed by auscultation of breath sounds, together with a square wave capnography.

A maximum of three insertion attempts was permitted before placement of the device was considered to be a failure, in which case, an alternative airway device was used to secure the airway. The number of attempts, ease of insertion, insertion time, oropharyngeal seal pressure and precision of placement were recorded. Ease of insertion was graded as easy, difficult or a failure. An easy insertion was defined as placement without resistance following a single attempt. More than one attempt to seat the device was considered to be a difficult insertion. A failed insertion was deemed to have occurred when it was not possible to insert the device after three attempts. The tip of the flexible intubating fibrescope was introduced into the airway tube to score the laryngeal view, which was graded as follows: I: a full view of the vocal cords, II: a partial view of the cords or arytenoids, III: only the epiglottis was visible, and IV: no laryngeal structures were visible.4

After recording the laryngeal view grading, the fiberscope, with a well-lubricated endotracheal tube threaded over its shaft, was advanced through the i-gel™ and into the trachea. The standard polyvinyl chloride (PVC) endotracheal tube, size 6.5 or 7.0, for a size 3 or 4 i-gel[™], respectively, was railroaded over the fibrescope into the trachea. After removing the fibrescope, the tracheal tube was connected to the breathing circuit. Correct placement of the endotracheal tube was confirmed by auscultation of breath sounds and obtaining a square wave capnograph. The time of endotracheal tube placement, number of attempts for tracheal tube placement and ease of tracheal

tube placement were recorded. The ease of tracheal tube placement was graded as easy, difficult or a failure. An easy tracheal tube placement was defined as successful positioning of the endotracheal tube after a single attempt. If more than one attempt was required to do this, the placement was graded as difficult. If it was not possible to intubate the trachea through the i-gel[™] after three attempts, it was deemed to be a failure and surgery was continued with the i-gel[™] in situ.

After adequate recovery from neuromuscular blockade, both the i-gel™ and the endotracheal tube were removed simultaneously. An inspection was made for trauma to the tongue, teeth, gums and lips. The airway was also checked for blood-stained secretions. Patients were assessed for sore throats, dysphagia or hoarseness of voice in the postoperative period. The obtained data were analysed using appropriate statistical tests.

Results

Data of the 60 enrolled patients in the study were included in the analysis. The mean age, weight, height and body mass index of the patients were 36 \pm 12.72 years, 58.60 \pm 10.06 kg, 160.74 ± 8.86 cm and 22.48 ± 2.72 kg/m, respectively. An overall insertion success of 96.66% was achieved with the i-gel™ (Table I). Results of ease of insertion of the i-gel™ were as follows: it was easy in 54 cases, difficult in only four cases and a failure in two cases (Table II). The mean time of insertion of the i-gel[™] was calculated to be 9.09 ± 4.17 seconds (Table III). A good fibre-optic view was achieved in 93.10% of the cases (grades I and II). Fibreoptic grade IV was observed in only 1.7% of cases. The mean airway seal pressure obtained with the i-gel[™] was 26 ± 4.49 cmH₂O (Table III).

The overall success rate of fibreoptic-guided intubation through the i-gel™ was recorded as 93.33%. Of the 58 patients in whom successful i-gel™ placement was recorded, it was possible to place an endotracheal tube in 56 of them (Table IV). The first attempt success rate in the 58 patients was 91.4% (Table III). Ease of tracheal tube placement via the i-gel™ was found to be easy in 91.4% (53/58) of the cases, and difficult in 5.2% (3/58) (Table IV). The mean total tracheal tube placement time through the i-gel™ was recorded as 89.16 ± 8.29 seconds (Table III). This time includes both the time taken for i-gel™ placement and the time taken for fibreoptic-guided intubation through the i-gel™. At the time of insertion, mild trauma was observed in two patients, but a sore throat, dysphagia or hoarseness of voice were not reported by any of the patients.

Discussion

Various success rates have been reported for i-gel™ insertion. Gabbott et al⁵ reported 98%, Kannaujia et al⁶ 100%, and Francksen et al⁷, 100%. Gosalia et al also found a higher success rate with the i-gel™ and bougie-guided i-gel™ insertion (96% vs. 100%).8 Richez et al9 reported a success rate of 97% in 71 women scheduled for gynaecological surgeries. Wharton et al1 reported a first attempt success

Table I: Number of attempts of i-gel[™] insertion

Number of attempts	Frequency (n = 60)	%
1	54	90
2	2	3.33
3	2	3.33
A failure	2	3.33

Table II: Ease of insertion of i-gel[™]

Ease of insertion	Frequency (n = 60)	%
Easy	54	90.
Difficult	4	6.67
A failure	2	3.33

Table III:

Various recorded parameters after i-gel [™] insertion	Range	Mean ± SD
Insertion time of the i-gel [™] (in seconds)	6-34	9.09 ± 4.17
Airway seal pressure of the i-gel [™] (cmH ₂ O)	20-40	26.46 ± 4.49
Time taken for fibreoptic-guided intubation through the i-gel™ (in seconds)	58-99	80.03 ± 9.07
Total time of tracheal tube placement through the i-gel™ (in seconds)	66-107	89.16 ± 8.29

SD: standard deviation

Table IV: Ease of tracheal tube placement with the help of a fibre-optic bronchoscope through the i-gel[™]

1 1 5		
Ease of tracheal tube placement	Frequency	%
Easy	53	91.4%
Difficult	3	5.2%
A failure	2	3.4%

rate of 82.5% and no failures in 40 healthy anaesthetised patients. Gatward et al studied i-gel™ insertion in 100 patients and reported that success was achieved in 86% patients with the first attempt, in 11% with a second attempt, and in 3% with a third attempt. No failures were reported. However, effective ventilation was possible in only 98% of cases because the seal was inadequate in two patients, despite a clear airway.¹⁰ By contrast, Janakiraman et al¹¹ reported an overall success rate of 84% with the i-gel™. The first attempt success rate was 54%. They attributed their higher failure rate to gas leakage mainly, rather than misplacement. This was easily corrected, and the success rate improved significantly, when a larger-sized device was used.¹ These authors recommended that the manufacturers review the sizing guidelines.

In this study, the overall insertion and first attempt success of the i-gel™ insertion was 96.66% and 90%, respectively. The i-gel™ was successfully placed in the second and third attempts in three and two patients, respectively. Commonly employed manoeuvers were neck extension, jaw thrust and chin lift in patients in whom a second or third attempt was required. More than three attempts were required in two

patients and the insertion was considered to be a failure. Failure to insert the i-gel $^{\text{IM}}$ was due to failed pharyngeal placement in one case. A leak of < 20 cmH $_2$ O was recorded in the second case.

Ease of insertion of the i-gel™ was found to be easy in 90% of cases and difficult in 6.67% of cases. Richez et al⁹ graded the ease of i-gel™ insertion subjectively on a scale from 1-4 (1: very easy, 2: easy, 3: difficult and 4: very difficult), and found it to be very easy in 93% of cases and easy in 7% of cases. Insertion difficulty was graded on a five-point scale by Theiler et al, ranging from 1: easy to 5: impossible. However, the scale was subjective and not adequately defined for points 2, 3 and 4. Insertion was found to be easy in 20% and 33% of cases relating to the i-gel™ and LMA Supreme™, respectively, and impossible in 3% of i-gel™ cases. I2

In our study, the mean insertion time of i-gel™ placement was 9.09 ± 4.17 seconds. Wharton et al have recorded a median insertion time of 17.5 seconds (a range of 7-19.7 seconds) with the i-gel™ in 40 healthy anaesthetised nonparalysed patients.¹ The insertion times of i-gel™ placement reported by Kannaujia et al (15 seconds) and Gatward et al (11 seconds) are comparable to those recorded in our study.^{6,10} Gosalia et al³ recorded mean times for i-gel™ insertion, with and without a bougie as 13.2 ± 2.6 and 13.0 ± 2.8 seconds, respectively.³ A mean insertion time of < 5 seconds with i-gel™ use was reported by Bamgbade et al.¹³ A higher insertion time of 42 ± 23 seconds was reported by Theiler et al, probably because they evaluated the devices in a simulated difficult airway scenario, using an extrication collar.¹²

The mean airway seal pressure, after successful insertion of the i-gelTM, was $26.46 \pm 4.49 \text{ cmH}_2\text{O}$, in our study. The mean leak pressure recorded in a study that was conducted by Gabbott and Berringer⁵ was $24 \text{ cmH}_2\text{O}$. They also found that the seal pressure appeared to improve over time in a number of patients, which could be because of the thermoplastic properties of the bowl which might have led to the formation of a more efficient seal around the larynx after warming to body temperature.⁵ Airway seal pressures of $24 \text{ cmH}_2\text{O}$ and $25.27 \text{ cmH}_2\text{O}$, were reported by Gatward et al¹⁰ and Singh et al, ¹⁴ respectively. Richez et al recorded a higher mean seal pressure of $30 \pm 7 \text{ cmH}_2\text{O}$.

When a flexible fibre-optic scope was introduced into the airway tube to grade the laryngeal view, a grade of I was given to 35 patients and a grade of II to 19 patients. A grade of III was observed in three patients and fibreoptic grade IV in one. Gatward et al used similar fibreoptic view grades and reported that 87%, 4%, 4% and 1% of patients were assigned to each grade, respectively. ¹⁰

In our study, the overall success rate of fibreoptic-guided intubation through the i-gel™ was 93.33% (56/60). Graf et al¹⁵ evaluated the feasibility of fibreoptic intubation through the i-gel™ versus an intubating LMA in 250 patients with predicted difficult airways who were undergoing general anaesthesia. Fibreoptic-assisted tracheal intubation success rates through i-gel™ and intubating LMA were 95% and 93% (p-value = 0.999). No difference in the success rate was found between the two groups. More correction

manoeuvers were needed to intubate the trachea via the i-gel™ because it provided a less favourable exit angle for the stiff PVC endotracheal tube. Graf et al recommended that the easy-to-use i-gel™ might be an alternative approach for fibreoptic-assisted endotracheal intubation, particularly when the costs of the endotracheal tubes and both supraglottic airway devices were compared.¹⁵

Lloyd et al¹⁶ compared classic LMA and the i-gel[™] as adjuncts to fibrescope-guided intubation in a manikin. The tracheal placement success rate was 100% in their study.¹⁶ Francksen et al¹⁷ compared two endotracheal tubes, Portex[®] Silicone and Mallinckrodt[®] PVC, in 56 patients scheduled for blind intubation via i-gel[™], depending on the fibreoptic score. The overall success rate of blind intubation using both endotracheal tubes was found to be 48.21% (27/56).¹⁷

In our study, ease of tracheal tube placement via the i-gel™ was found to be easy in 91.4% of cases and difficult in 5.2% (3/58), while in 3.4% (2/58), an endotracheal tube could not be placed even after three attempts, and was thus labelled a failure. Lloyd et al indicated that the i-gel™ is likely to be a more appropriate conduit for fiberscope-guided tracheal intubation. Intubation is significantly faster and less likely to fail with the i-gel™ than with classic LMA.¹6

We recorded a mean tracheal tube placement time through the i-gel[™] as 80.03 ± 9.07 seconds. Graf et al observed this time to be 90 seconds. Lloyd et al, while comparing classic LMA and the i-gel[™] as adjuncts to fiberscope-guided intubation in a manikin, found this time to be 43 and 22 seconds respectively (p-value < 0.0001). Francksen et al¹⁷ reported that the insertion time via the i-gel[™] using a LMA Fastrach[™] endotracheal tube was significantly shorter than that with a Mallinckrodt[™] PVC tube (12 ± 3 seconds and 16 ± 8 seconds, p-value = 0.0032) and with a Portex[™] silicone tube (12 ± 3 seconds and 19 ± 10 seconds, p-value < 0.001).

In our study, the mean total time taken, i.e. the time taken between picking up of the i-gelTM until successful intubation through it, was found to be 89.16 ± 8.29 seconds, whereas Graf et al reported this time to be 116 ± 58 seconds. ¹⁵

In our study, there was blood on the device on removal, indicating airway injury, in two patients. Minor lip trauma upon i-gel™ insertion was reported by Theiler et al in three patients.¹² A sore throat (10%), dysphagia (15%) and hoarseness (12%) were observed for 24 hours postoperatively.¹² Gatward et al documented coughing and a brief episode of laryngeal spasm in three patients and one patient, respectively.¹⁰ Richez et al noted a short coughing episode and a transient moderate sore throat in a few patients.⁵ Keijzer et al documented that the incidence of sore throats, neck pain and dysphagia was significantly lower with the i-gel™, compared to that with the disposable laryngeal mask.¹⁵

Conclusion

The i-gel™ was easy to insert and achieved good first attempt success rates. The time taken to insert the i-gel™ was also acceptable. Adequate seal pressure required for

intermittent positive pressure ventilation can be achieved without unnecessary delays in positioning when using the i-gel[™]. The success rate for fibreoptic-guided intubation through the i-gel[™] was also very encouraging. It is proposed that the i-gel[™] can serve as an alternative conduit for fibreoptic-guided intubation.

Declaration

None of the authors have benefited from or will benefit any financial gain provided by any company or organisation for the work that was carried out in this study.

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