

Assessment of awake i-gel™ insertion for fiberoptic-guided intubation in patients with predicted difficult airway: A prospective, observational study

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Abstract

Background and Aims: Orotracheal intubation (OTI) with fiberoptic bronchoscope (FOB) in spontaneous ventilation is one of the main techniques for patients with predicted difficult airway. Latest generation supraglottic airway devices have been designed to allow OTI through them. We assessed the safety and effectiveness of FOB-guided OTI through i-gel™ device which was inserted in spontaneously breathing patients with predicted difficult airway.

Material and Methods: Eighty-five patients with difficult airway predictors were included. The i-gel was inserted under oropharyngeal local anaesthesia and sedation. After checking the adequate ventilation through the i-gel with capnography curve, general anaesthesia was induced in order to introduce the endotracheal tube guided by FOB. We recorded the i-gel insertion time (t_{gel}), intubation time (t_{int}), O₂ saturation in pulse oximetry (SpO₂) at different times: basal (t_0), after 3 min of preoxygenation with a face mask at 100% FiO₂ (t_1), after i-gel mask insertion (t_2) and after intubation (t_3). Adverse events during the procedure were also recorded.

Results: All patients were successfully intubated. SpO₂ values were: 96.9 ± 1.2 (t_0), 99.0 ± 0.9 (t_1), 96.2 ± 2.4 (t_2), 96.0 ± 2.5 (t_3). t_{gel} and t_{int} were 38.0 ± 7.8 s and 36.5 ± 5.6 s, respectively. No serious adverse events were recorded and no patient suffered airway trauma.

Conclusion: I-gel insertion in spontaneous ventilation secures the airway before achieving fiberoptic intubation without the occurrence of adverse events. More studies might be necessary in order to confirm the results presented, but we consider that the technique described is a safe and effective alternative to classic OTI with FOB in spontaneously breathing patients with predicted difficult airway.

Keywords: Airway management, fiberoptic intubation, intratracheal intubation, laryngeal mask

Introduction

It is widely known that the adequate management of the difficult airway is one of the most important challenges for anaesthesiologists during their daily clinical practice. In patients with predicted difficult airway, fiberoptic-guided

intubation while the patient is spontaneously breathing is the gold standard technique for securing the airway,^[1,2] as it minimizes the possible complications caused by repeated direct laryngoscopy attempts or a decrease in the oxygenation of the patient after long periods of apnoea.^[3,4] Latest generation videolaryngoscopes (VLs) and supraglottic airway devices (SADs) developed over the last few years that allow orotracheal intubation (OTI) through them, are

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How to cite this article: Ludeña JA, Bellas JJ, Rementeria RA, Muñoz Alameda LE. Assessment of awake i-gel™ insertion for fiberoptic-guided intubation in patients with predicted difficult airway: A prospective, observational study. *J Anaesthesiol Clin Pharmacol* 2018;34:490-5.

Access this article online

Quick Response Code:



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DOI:
10.4103/joacp.JOACP_329_15

a significant advance in difficult airway management.^[5-8] These SADs also ease the manoeuvrability with the flexible fiberoptic bronchoscope (FOB), achieving very high rates of successful OTI.^[8]

I-gel™ supraglottic airway device (Intersurgical Ltd, Wokingham, Berkshire, UK), introduced into clinical practice in 2007, has proved to be effective and safe for ventilating patients under general anaesthesia, with or without muscle relaxants^[9,10] and has been even successfully used for bronchoscopic procedures.^[11] FOB-guided OTI through the i-gel is also described in the user's manual,^[12] and different studies have been recently published proving the viability and effectiveness of that technique.^[13,14] On the other hand, i-gel has been used on different occasions in spontaneously breathing patients, being well tolerated by the patient, either awake or under light sedation.^[15,16] However, at present, as far as we know, there are no published clinical studies analyzing the use of the i-gel as a conduit for OTI in awake patients with predicted difficult airway.

We therefore designed a prospective observational study to assess the safety and effectiveness of FOB-guided OTI through the i-gel device™ which had been previously inserted in spontaneously breathing patients with predicted difficult airway.

Material and Methods

Over a period of 12 months, 85 patients >18 years old undergoing different types of elective surgery requiring endotracheal intubation were selected. Demographic data and types of surgery are shown in Table 1. The main inclusion criterion was to show three or more predictive factors of difficult airway. Patients with difficult intubation and/or ventilation history in previous procedures were also included in the study, regardless of showing other predictive factors of difficult airway [Table 2]. Exclusion criteria for the study were: patient's refusal to be intubated with the proposed technique, the presence of pharyngolaryngeal or mediastinal masses and an interdental distance <2 cm. The technique was always performed by the same anaesthesiologist with >10 years of experience in the use of FOB and difficult airway management. Local Ethics Committee approval was obtained and patients were informed of the technique and gave their verbal and written consent in the preanaesthesia unit the same day or some days before the surgery. Procedures were video recorded and data collected and analyzed from the recordings.

Patients were premedicated in the anaesthetic preparation room with midazolam 2 mg IV, and three pharyngeal

Table 1: Demographic data and types of surgery

Male/female (n)	46/39
ASA n(%)	
I	13 (15.2)
II	41 (48.2)
III	29 (34.1)
IV	2 (2.3)
Age (years; mean (range))	56 (33-76)
BMI (n)	
<25	29
26-35	47
>35	9
Types of surgery n(%)	
Brain surgery	8 (9.5)
Gynaecological surgery	8 (9.5)
Thoracic surgery	20 (23.5)
Bariatric surgery	7 (8.2)
Thyroidectomy	9 (10.5)
Lumbar disc herniation	10 (11.7)
Cervical disc herniation	8 (9.5)
Colon surgery	15 (17.6)

BMI=Body mass index, ASA=American Society of Anesthesiologists classification

Table 2: Difficult airway predictors

	n (%)
Mallampati	
III	35 (41.7)
IV	27 (31.7)
Thyromental distance <6 cm	43 (50.5)
Interincisor distance <3 cm	39 (45.8)
Upper lip bite test III	29 (34.1)
Neck circumference >45 cm	25 (29.4)
History of snoring	18 (21.1)
Limited neck extension	49 (57.6)
Cervical radiotherapy	25 (29.4)
Difficult airway history	14 (16.4)

Patients included showed three or more difficult airway predictors. Difficult airway history was sufficient to include the patient in the study

instillations of 10% lidocaine spray. Patients were told to rinse their mouths with it and to keep the liquid in for as long as possible before swallowing or spitting it out. Atropine 0.01 mg/kg IV and ranitidine 50 mg IV were also administered. After 20 min, the patient was moved to the operating room, and then monitored by pulse oximetry, non-invasive arterial pressure, 5 lead ECG and bispectral index (BIS). A further three instillations of 10% lidocaine were repeated and the patient was preoxygenated for 3 min with a face mask and 100% O₂. Afterwards, Patients were sedated with fentanyl 0.5 mcg/kg IV and propofol 0.4–0.8 mg/kg IV, until achieving a 2–4 level of sedation in the Ramsay scale. Then, we gently inserted the i-gel mask asking the patient to open the mouth and to confirm a level of comfort.

If the patient did not tolerate the insertion of the device, an extra dose of fentanyl was administered up to a maximum of 0.8 mcg/kg in total. If after a second attempt of placing the mask it was still not tolerated, or if we did not get capnography curve, we considered that the technique had failed and then the airway was approached with another technique. After i-gel insertion we connected the breathing system until we observed a capnography curve in spontaneous ventilation. The FOB was then introduced through the i-gel channel until obtaining an adequate view of the glottic anatomy. Through the working channel of the FOB, a continuous flow of 3 l of 100% O₂ was constantly administered. Once a proper glottic view was obtained, we placed in the FOB an appropriate non-reinforced endotracheal tube (ETT) (Rüsch, Teleflex Medical, Co Westmeath, Ireland) for i-gel size according to the user's guide^[11] (6.5 mm ETT for i-gel no. 3; 7 mm ETT for i-gel no. 4, and 7.5 mm ETT for i-gel no. 5). General anesthesia was induced with fentanyl 2 mcg/kg IV, propofol 2 mg/kg IV and rocuronium bromide 0.6 mg/kg IV. Once the patient was apnoeic, the FOB was introduced in the airway and then ETT was passed until viewing its bevel just over the tracheal carina. Then the FOB was removed and the ETT was connected to the breathing system to obtain a capnography curve. For i-gel removal, we used Magill forceps to hold the ETT in its proper position inside the trachea, disconnecting the universal 15 mm ETT connector.

The number of i-gel insertion attempts and i-gel insertion time (t_{gel}) were recorded, measured from the time it began to be introduced in the patient's mouth until a proper capnography curve in spontaneous ventilation was obtained. Likewise, we recorded the number of patients where OTI was achieved and the intubation time (t_{int}), measured from the loss of spontaneous ventilation until obtaining a capnography curve through the ETT. Moreover, we recorded pulse oximetry saturation (SpO₂) in different times of the procedure: once they entered the operating room (t_0), after 3 min of preoxygenation with face mask and 100% O₂ (t_1), after i-gel insertion (t_2) and after intubation (t_3). Furthermore, correlation between the decrease in SpO₂ in t_2 and in t_3 and the t_{gel} and t_{int} , respectively, was also assessed. Total time required for the airway management was not analyzed because sometimes the procedure was interrupted or slowed down due to educational reasons.

The technique was considered successful if, apart from achieving OTI (primary objective), it was accomplished with an SpO₂ >90% in t_2 and t_3 , if no more than two i-gel insertion attempts were required and if there were no serious adverse events such as laryngospasm or bronchospasm (secondary objectives). Haemodynamic changes of >25% with respect to basal values were also

recorded. Adverse events during the procedure such as laryngospasm, bronchospasm, cough, bleeding or airway trauma (palate, vocal cords, arytenoid cartilages, epiglottis) were recorded. Moreover, in the recovery room, patients were asked if they remembered the procedure, and their level of discomfort with a Visual Analogue Scale (VAS), where 0 was no discomfort and 10 was the worst possible experience.

For statistical analysis, the Student's *t*-test and Pearson correlation coefficient were used with the R 3.1.2 programming language (The R Foundation for Statistical Computing).

Results

Main results obtained are shown in Table 3. OTI (primary objective) was achieved in 100% of patients. In regards to the secondary objectives, three patients suffered an SpO₂ decrease <90% in t_2 , and four in t_3 , with success rates of 96.5% in t_2 [confidence interval (CI) 95% = 90.0–99.3] and of 95.3% in t_3 (CI 95% = 88.4–98.7). In case of desaturation in t_2 , patients were spontaneously breathing and they recovered saturation levels without clinical consequences, and desaturations in t_3 were solved by ventilating through the ETT once it was introduced in the trachea. Sixteen patients required a second i-gel insertion attempt after mild coughing spells in 6 of them, and because of discomfort in the other 10. In these cases, the extra dose of fentanyl was administered, and the i-gel could finally be inserted after a second attempt. No patient needed more than two attempts of i-gel mask insertion.

Twelve patients showed elevation in heart rate and 9 in mean arterial pressure of >25% above its basal values, but in no cases there were clinically relevant consequences. Two patients had mild sore throat. There were no serious adverse events such as laryngospasm or bronchospasm.

Considering the results obtained for primary and secondary objectives, the overall success rate for the technique described was 94.1% (CI 95% = 86.8–98.1).

Correlation between t_{gel} and SpO₂ decrease in t_2 was 0.41 (CI 95% = 0.22, 0.57), and between t_{int} and SpO₂ decrease in t_3 was 0.07 (CI 95% = -0.15, 0.28), meaning that SpO₂ could decrease slightly in those cases where i-gel insertion time and/or intubation time were considerably longer. Eleven patients remembered the procedure and their mean level of VAS was 2 [inter-quartile range (IQR) 1–3].

Table 3: Clinical outcomes and adverse events

I-gel insertion time (s)			38±7.8	
Traqueal intubation time (s)			36±16	
I-gel insertion attempts n(%)				
1			69 (81.1)	
2			16 (18.9)	
3			0 (0)	
SpO ₂ (%)	t ₀	t ₁	t ₂	t ₃
>90 n(%)	96.9±1.2	99.0±0.9	96.2±2.4	96.0±2.5
85-90 n(%)	85 (100)	85 (100)	82 (96.4)	81 (95.3)
<85 n(%)	0 (0)	0 (0)	3 (3.5)	3 (3.5)
	0 (0)	0 (0)	0 (0)	1 (1.2)
Cough n(%)			6 (7.1)	
Hemodynamic parameters changes n(%)				
Heart rate >25%			12 (14.1)	
Mean arterial pressure >25%			9 (10.5)	
Bispectral index	t ₀	t ₁	t ₂	t ₃
	95±3	94±4	75±8	37±5
Bronchospasm			0	
Laryngospasm			0	
Bleeding			0	
Airway injury (lips, teeth, palate, tongue, vocal cords)			0	
Sore throat			2	
Recall n(%)			11 (12.9)	
Visual analogue score			2 (1-3)	

Values refer to mean±SD, n (%) and (IQR). t₀=Arrival at operating room; t₁=After face mask preoxygenation with 100% O₂; t₂=After i-gel insertion; t₃=After intubation; SD=Standard deviation; IQR=Inter-quartile range

Discussion

Supraglottic airway devices have meant a significant advance in airway management since their introduction >30 years ago.^[17] They are one of the indicated devices for difficult airway rescue in cases of impossible intubation and/or inadequate manual ventilation. In fact, SADs can achieve an effective ventilation in difficult intubation situations, especially in cases of unexpected difficult airway.^[18,19] According to the last update of the guidelines for management of the difficult airway by the American Society of Anesthesiology (ASA), one of the options for approaching the difficult airway in the awake patient is placing a SAD (LMA™ or ILMA™) and obtaining exhaled CO₂ in a capnography curve.^[20] It is possible to introduce gastric tubes through these devices to avoid gastroesophageal reflux, perform blind OTI and, what is even more effective, perform OTI with the aid of a FOB.^[21,22] Difficult airway management algorithms recommend the need for obtaining a patent airway through which the patient could be ventilated before inducing apnoea.^[1,18] With an adequate i-gel mask insertion in spontaneous ventilation, a possible 'cannot ventilate' scenario is solved and we can approach subsequent OTI from a non-emergency pathway. In our study, in all three occasions where saturation decreased <90% in t₂ (after i-gel insertion), it was recovered by the patient breathing spontaneously

through the i-gel. On the other hand, in all four cases where SpO₂ decreased <90% in t₃ (after intubation), the recovery was achieved by ventilating the patient through the ETT. One of these patients reached a minimum SpO₂ of 82%. The episode lasted for 11 s and it was not clinically relevant. This patient showed a history of chronic obstructive pulmonary disease, a basal SpO₂ of 92% and intubation time was 56 s. For this kind of patient, another type of approach may be considered for difficult airway management with less or no sedation to avoid desaturation periods.

Neuromuscle relaxation is another issue to consider. It is well known that OTI in paralyzed patients is a technique with a higher success rate and lower complication index than OTI without neuromuscular relaxants.^[23] The decision to induce general anaesthesia with neuromuscular relaxants before OTI was only made in case a capnography curve was obtained through the i-gel mask with the patient in spontaneous ventilation. At that moment, we assumed that if the patients were able to ventilate by themselves through the i-gel, we could also do it in case the intubation time with FOB lengthened and saturation decreased. This situation could happen in case excessive secretions or blood were present, or because the technique was performed by a non-expert trained in the use of the FOB. One of the main advantages of FOB-guided OTI through the i-gel is that the tip of the FOB is just over

the vocal cords, so the subsequent passage into the trachea is easier than performing the technique only with the FOB or with an oral airway. In fact, in two of the patients of our study, ventilation through the i-gel was necessary after the induction of general anaesthesia because of technical problems with the FOB and saturation did not decrease <90%. It should also be considered that, using muscle relaxants for performing OTI, more doses of local anaesthetic would not be necessary, thus avoiding serious systemic complications.^[24,25]

For sedation prior to the insertion of the i-gel we decided to use an opioid (fentanyl) and propofol. Dexmedetomidine has proved to be highly safe and effective for performing OTI in awake spontaneously breathing patients,^[26] but unfortunately it is not an available drug in our environment. The dose of fentanyl used (0.4–0.8 mcg/kg) causes mild respiratory depression but no suppression of spontaneous ventilation.^[27] Another option we thought about for sedation, when we designed the study, was using controlled infusion of remifentanyl, but considering the good results obtained in first attempts, we decided to perform the whole study with boluses of fentanyl at the indicated doses.

An adequate level of sedation and the appropriate administration of local oropharyngeal anaesthesia are crucial for performing any OTI technique for an ‘awake’ patient, whether it is with SAD, with FOB or with a VL. The proper combination of both methods facilitates the work of the anaesthesiologist, provides comfort to the patient and avoids the occurrence of adverse events due to reflexes such as coughing, laryngospasm or airway injuries.

Another recommendation from the international guidelines for management of the difficult airway consists of having a secondary plan or alternative strategy in case the first technique is unsuccessful or unpredicted complications occur. In case of encountering difficulties in inserting the i-gel mask with the technique described in this article, we would have the possibility to approach the airway any other way because the patient is spontaneously breathing. Although they were not necessary during our study, we have a VL in the operating room as a rescue device and sugammadex is also available for being able to reverse neuromuscular relaxation caused by rocuronium bromide.^[28]

The insertion of the i-gel is not an exempt from the occurrence of complications, but given the low number of patients that can be included in studies related to the difficult airway, it is more improbable that we find any of them, this being one of the limitations of the study. Moreover, the insertion of the i-gel can cause bleeding or obstruction of the airway in the presence of pharyngeal or laryngeal masses. Therefore, the authors

recommend that this technique should not be undertaken in those circumstances.

Another limitation that we can point out is that the technique was always performed by the same anaesthetist with >10 years of experience in difficult airway management and FOB. A wider study with the participation of anaesthesia residents or less expert staff would be necessary to verify if the technique is viable despite the increase in i-gel insertion or intubation times.

With regards to the possible advantages of performing the technique of OTI with the aid of the i-gel over the VLs, it is worth remembering that the latter are not ventilation devices and they can also cause airway injuries.^[29] It is proved that VL improve I or II grades the Cormack–Lehane scale compared with direct laryngoscopy, but if we find any difficulties in performing OTI during its use, it would only be possible to ventilate the patient manually with a face mask or proceed with the insertion of a SAD to recover the eventual desaturation of the patient. Moreover, some of the factors that may complicate the manoeuvre with the VL, like a limitation in cervical mobility (e.g., in patients that have received cervical radiotherapy or in those with a cervical disease that impedes its movement), Grade III in the upper lip bite test or thyromental distance (TMD) <6 cm could favour the use of the technique described in this article with i-gel instead of a VL.^[30] This could be the object of future comparative studies between both the techniques.

Conclusion

Given the good results obtained in this study, we consider that the technique of OTI through the i-gel™ device previously inserted in spontaneously breathing patients could be an alternative option for securing the airway in certain patients with predicted difficult airway.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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