

Positive Pressure Ventilation with i-gel versus LMA-Unique: A Randomised Comparative Study

R. F Danha¹, S. Sreevathsa¹, N. Crombie², C. Hillermann¹ and C. Mendonca¹

¹Consultant Anaesthetist, Department of Anaesthesia, University Hospital Coventry and Warwickshire NHS Trust Clifford Bridge Road Coventry, CV2 2DX, United Kingdom

²Consultant Anaesthetist, Selly Oak Hospital Raddlebarn Road Selly Oak Birmingham B29 6JD, United Kingdom

Abstract

Purpose: GPurpose: The present study compared the two disposable supraglottic airway devices, the LMA-Unique™ (LMA-U) and i-gel™ during positive pressure ventilation in paralysed adult patients. The aim of this randomised study is to test the hypothesis that the i-gel performs comparably to the LMA-U during elective positive pressure ventilation

Methods: Thirty adult patients undergoing elective surgery and requiring positive pressure ventilation were randomly allocated to have the LMA-U (N=15) or i-gel for airway maintenance and positive pressure ventilation. The insertion success and time taken to insert the device, the number of insertion attempts, any manipulations required, inspired tidal volume, expired tidal volume, leak volume and leak pressure were compared.

Results: The mean insertion time (SD) for LMA-U and i-gel were 19 (4) and 13 (3) seconds respectively ($p < 0.0001$). There was a significant difference in the number of manipulations needed to facilitate insertion with the i-gel requiring fewer manipulations than LMA-U. There was no significant difference between the mean leak volumes [mean (SD) 23 (16) vs 34 (30) ml for the LMA-U and i-gel respectively, $p = 0.36$], expired tidal volumes [mean (SD) 514 (69) vs 509 (82) for the LMA-U and i-gel respectively, $p = 0.99$] and peak airway pressures [mean (SD) 15 (3) vs 14 (3) cm H₂O for the LMA-U and i-gel respectively, $p = 0.34$] for the two devices.

Conclusion: When compared to the LMA-U, the i-gel was equally effective for positive pressure ventilation. The i-gel was quicker to insert and required fewer manipulations for first time insertion.

Keywords: ASupraglottic airway; Laryngeal mask airway; LMA-Unique; i-gel; Positive pressure ventilation.

Introduction

Many disposable supraglottic airway devices that are based on the design of the classic laryngeal mask airway have been introduced into clinical practice [1]. One of them is the LMA-Unique™ (Figure 1, Intavent Orthofix, Maidenhead, Berkshire, UK), which has been in clinical use since 1997 and has been shown to perform similarly to the classic LMA [2,3]. A common feature of these devices is the cuff that depends on being inflated with the optimal volume of air for effective ventilation to be achieved [4].

The i-gel™ (Figure 2, Intersurgical Ltd, Wokingham, Berkshire, UK) was introduced in 2007 and its main distinguishing feature is the supraglottic component that is made of a thermoplastic elastomer gel (styrene ethylene butadiene styrene) and thus does not require inflation with air [5]. There is also an independent gastric drain tube that provides a means of inserting a tube into the stomach to aspirate air and residual gastric fluid while the integral bite block prevents occlusion of the airway during emergence. In common with the LMA-U, the i-gel is designed for single use and appears to have comparable leak pressures to other supraglottic devices that are currently available [6].

Ideally any supraglottic airway device should enable positive pressure ventilation both during anaesthesia and resuscitation. The i-gel has already been shown to provide reliable ventilation during resuscitation [7,8]. During positive pressure ventilation with the LMA-U, peak pressure should be limited to 20-22 cmH₂O and with the i-gel, the manufacturer recommends not to use a peak pressure above 40 cmH₂O [9]. In the following randomized comparison, we tested the

hypothesis that the i-gel performs comparably to the LMA-U during elective positive pressure ventilation.

Methods

Following approval from local research ethics committee and written informed consent, thirty, ASA 1 to 3 patients scheduled for elective orthopaedic, general and middle ear surgery under general anaesthesia, requiring positive pressure ventilation were invited to participate in the study. Patients with anticipated difficult airway, children below 18 years of age, those with moderate to severe asthma, restrictive lung disease, lung surgery, gastro-intestinal pathology and those considered to be at risk of pulmonary aspiration were excluded. Patients with a body mass index greater than 35 kg/m² were also excluded as they were not suitable for positive pressure ventilation through a supraglottic device.

The anaesthetic machine (Datex Ohmeda S5 Avance, GE Healthcare, Madison, USA) with an integral pressure gauge and spirometer was

***Corresponding author:** Cyprian Mendonca, Consultant Anaesthetist, University Hospitals Coventry and Warwickshire NHS Trust, Clifford Bridge Road, Coventry, CV2 2DX, Tel: + 44(0)2476964000; Fax: + 44(0)2476965888; E-mail: cyprian.mendonca@uhcw.nhs.uk

Received October 13, 2011; **Accepted** November 14, 2011; **Published** November 18, 2011

Citation: Danha RF, Sreevathsa S, Crombie N, Hillermann C, Mendonca C (2011) Positive Pressure Ventilation with i-gel versus LMA-Unique: A Randomised Comparative Study. J Anesthe Clinic Res 2:173. doi:10.4172/2155-6148.1000173

Copyright: © 2011 Danha RF, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

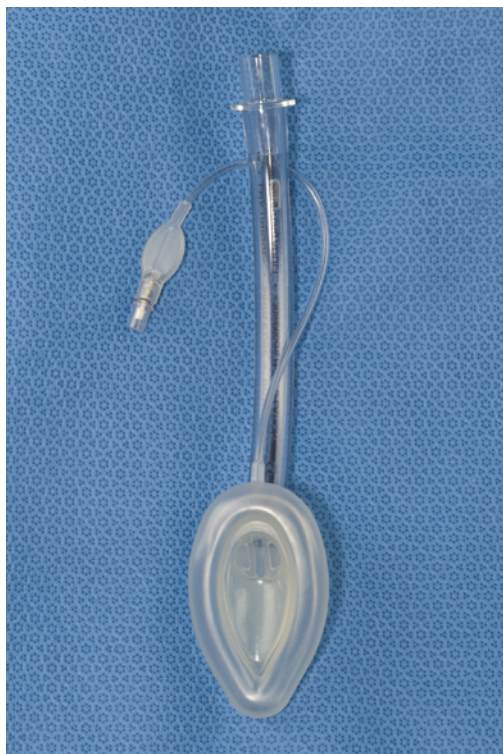


Figure 1: LMA –Unique supraglottic airway device.



Figure 2: i-gel supraglottic airway device.

checked and calibrated before use on each patient and the measured leak volume was noted. When the patient arrived in the anaesthetic room, blood pressure, heart rate and ECG monitoring were instituted.

Patients were randomly allocated to the LMA-U or i-gel group using sealed opaque numbered envelopes. A size 4 or 5 device was selected by the anaesthetists based on the patient's weight and according to the manufacturers' recommendations. Routine pre-use checks were then performed on the chosen airway and it was lightly lubricated with Aqua gel™ (Adams Healthcare, Leeds, UK). After securing venous access and performing 3 minutes of pre-oxygenation, anaesthesia was induced with propofol 2-3 mg.kg⁻¹ and fentanyl 1.5 µg.kg⁻¹. When hand-ventilation with a facemask was confirmed, atracurium 0.3 mg.kg⁻¹ was administered to facilitate muscle relaxation. During the first three minutes, anaesthesia was maintained with sevoflurane 3-4 % in oxygen at 6 l.min⁻¹ and the airway was maintained with an appropriate sized face mask. The chosen airway was then inserted according to the manufacturer's instructions [9,10]. In the LMA-U group the cuff was inflated with 30 ml of air for size 4 and 40 ml air for size 5, according to manufacturer's recommendation.

The patients' vital parameters were continuously monitored throughout the anaesthetic. All the devices were inserted by two investigators (CM and CH) in order to standardize the observations as the population size was small. Both investigators had previous clinical experience of using i-gel (>50) and LMA-U (>1000). All patients were ventilated using a tidal volume of 7 ml.kg⁻¹ body weight, inspired: expired ratio of 1:2 and a respiratory rate of 10 breaths per minute when the observations were made.

Each patient had one pillow and the head was maintained in the neutral position prior to device insertion. The insertion time was recorded from the moment the anaesthetist picked up the device until the first breath was delivered. A maximum of two attempts were allowed and the device was removed from the mouth because of an obstructed airway or inadequate ventilation caused by a leakage of gas. The following manipulations were allowed to facilitate insertion: assisted mouth opening, jaw thrust, head extension or neck flexion. The number and type of manipulations required were documented. An insertion that lasted more than two minutes was also considered to be a failure for the purpose of the study. However, if insertion lasted more than two minutes but the device was correctly positioned then the patient was excluded from the study but the device was kept in place for the surgery. This ensured that those patients in whom insertion took longer than our cut off time did not end up having an unnecessary endotracheal intubation as repeated airway manipulations are associated with morbidity [11,12].

The primary outcome for the study was the leak volume (difference between the inspired and expired tidal volumes) of the two devices. After the insertion of device, at fresh gas flow of 6 l.min⁻¹, adjustable pressure limiting valve was occluded to gradually increase the pressure and the pressure at which gas leak was first detected was noted as leak pressure by listening for audible leak around the device. Three minutes after insertion of the device, the fresh gas flow was reduced to 1 l.min⁻¹ and both inspired and expired tidal volumes were noted every 30 seconds for further two minutes. The leak volume was calculated as the difference between inspired and expired tidal volume (leak volume = Inspired tidal volume - expired tidal volume). All volumes were recorded using the integral spirometer in the anaesthetic machine (Datex Ohmeda S5 Avance, GE Healthcare, Madison, USA). We also recorded the insertion times, the number of manipulations required to facilitate insertion and the peak pressure. The ease of insertion was graded as 1 = easy, 2 = slight difficulty, 3 = moderate difficulty and 4 = impossible to insert. During post-operative visit, the patients were

assessed for postoperative sore throat by asking them if they had throat discomfort.

Sample size was based on a previous study comparing classic LMA with Proseal LMA [13] and was selected to demonstrate a leak volume of 75 ml (15% of the inspired tidal volume). For a significance level of 5% with 90% power, we needed 28 patients to demonstrate a significant difference between two groups. The normality of data was assessed using a Sapiro-Wilkes test. In no cases was significant deviation from normality detected. The effect of patient height, weight, body mass index, age and sex on each variable was assessed. The data relating to number of insertion attempts, ease of insertion, number of manipulations and incidence of postoperative sore throat were analysed using Fisher's exact test. The other data such as leak pressure, peak airway pressure, leak volume and tidal volumes were analysed using normal linear modeling approach. All data were analysed using R statistical software version 2.1.1.

Results

There were no significant differences between the groups with regards to demographic and surgical procedures undertaken (Table 1). The first attempt insertion success rate for LMA-U was 15 of 15 (100%) and 15 of 15 (100%) for i-gel. The mean insertion time (SD) for LMA-U and i-gel were 19 (4) and 13 (3) seconds respectively (p<0.0001). Manipulations in the form of jaw thrust or neck extension were required to facilitate 11 out of 15 LMA-U insertions compared to 3 of 15 i-gel insertions (Table 2). The tidal volumes, leak volumes, peak airway pressures and airway leak pressures were compared for the LMA-U and i-gel (Table 3). The incidence of postoperative complications in terms of sore throat was seen in 5 of 15 in LMA-U group (mild in 3, moderate in 1 and severe in 1), compared to 3 of 15 in the i-gel group (mild in 2 and moderate in 1). This difference was not statistically significant (p=0.68, Fisher's exact test).

Discussion

The results of our study showed no significant difference between LMA-U and i-gel for tidal volumes, leak volumes, peak airway

	LMA-Unique	i-gel
Age, years	45 (21)	45 (21)
Height, cm	172 (9)	173 (9)
Weight, kg	75 (10)	76 (9)
Body Mass Index, kg.m ²	25 (3)	25 (3)
Sex M/F (n)	9/6	9/6
ASA grade 1/2	10/5	11/4
Mallampati score, 1/2	11/4	12/3
Procedures(n)		
Orthopaedic	9	10
General surgery	3	1
Middle ear surgery	3	4

Table 1: Demographic data; mean (SD) and Surgical procedures.

	LMA-Unique	i-gel	p
Mean insertion time (SD) in seconds	19 (4)	13 (3)	<0.0001
Manipulations			
Assisted mouth opening	15	15	
Additional manipulations (jaw thrust by assistant +/-head extension)	11	3	0.009

Table 2: Mean insertion time and manipulations required during insertion of LMA-Unique and i-gel.

	LMA-Unique	i-gel	p
Tidal volume-inspired, ml	537 (76)	543 (88)	0.96
Tidal volume expired, ml	514 (69)	509 (82)	0.99
Leak volume, ml	23 (16)	34 (30)	0.36
Leak volume in %	4%	6%	
Peak airway pressure, cm H ₂ O	15 (3)	14 (3)	0.34
Airway leak pressure, cm H ₂ O	21 (4)	20 (3)	0.39

no significant difference

Table 3: The tidal volume, leak volume, peak airway pressure and airway leak pressure; mean (SD) for LMA-Unique and i-gel.

pressures and airway leak pressures. The i-gel was significantly quicker and required significantly fewer manipulations to facilitate insertion than the LMA-U. Previous studies have shown that both the LMA-U and i-gel are reliable, easily inserted airway devices that provide a good seal with low morbidity [14,15]. We found a significant difference between the devices regarding the insertion times and our findings are consistent with observations from another study where the i-gel was inserted in significantly shorter times than LMA-U [16]. The difference in insertion times may also be due to the fact that the i-gel does not have a cuff that needs to be inflated before the first breath, which was our end-point for the insertion time.

We found that not only was the i-gel quicker to insert but it required fewer manipulations to facilitate insertion than the LMA-U. This is in spite of the i-gel being the newer of the two devices and the anaesthetists having less experience with its use. Of note is that the only manoeuvre required for twelve of the fifteen i-gel insertions was assisted mouth opening without the need for neck repositioning and jaw thrust while most of the LMA-U insertions required at least jaw thrust by an assistant in order to insert them.

If insertion with minimal manipulation is shown by other studies to be a consistent feature of the device, the i-gel may become the preferred supraglottic device for management of patients with limited neck movement and those for whom neck manipulation is considered detrimental. The firmness of the shaft of the i-gel due to the bite block may render it easier and faster to insert without the need for jaw thrust and neck manipulation. A device that requires minimal manipulations by the anaesthetist and the assistant to facilitate insertion is likely to be inserted in a shorter time than one which requires jaw thrust and neck adjustment. Although the difference in insertion time was statistically significant, this is unlikely to make a difference in airway management in the elective setting.

The i-gel has been described as an anatomical supraglottic device with a non-inflatable cuff that fits snugly onto the perilyngeal structures [17]. The leak volume during pressure-controlled ventilation with a cuffed endotracheal tube was found to be similar to that measured when the i-gel was used during pressure-controlled ventilation in a cross-over trial [18]. Leak volumes were also observed to be similar when the i-gel was compared with the LMA-U during pressure-controlled ventilation [16]. Helmy AM et al compared i-gel with classic LMA in spontaneously breathing patients and demonstrated a significantly higher leak pressure with i-gel [19]. We decided to compare the devices using volume controlled ventilation as this is our usual practice. However we did not compare the devices with higher tidal volumes that may be required in clinical practice in

patients with low lung compliance. Although we compared the devices using volume-controlled ventilation our results for leak volumes were very similar to those from Uppal et al.'s study [16]. It therefore appears not to matter what mode of controlled ventilation is employed as the leak volumes observed were similar. We had expected i-gel to fit snugly onto peri-laryngeal tissues and to produce a better seal than a device with a cuff that depends on filling with the optimal volume of air to produce a good seal. The volume of air determines the final position and the function of the LMA with under-inflation causing gas leak and inadequate ventilation while over-inflation is associated with excessive pressure on the mucosa and airway obstruction [4]. However a recent study has demonstrated a lower leak pressure with i-gel when compared with LMA Proseal [20].

The supraglottic component of the i-gel is made of an elastomer gel and this is postulated to form a more efficient seal around the larynx after warming up to body temperature. We compared the two devices only at the beginning of the procedure, so we don't know if the seal obtained with the i-gel would have improved with time. However we recorded the overall quality of the airway during the maintenance phase of anaesthesia.

Our study has certain limitations. Firstly, we included healthy patients with normal lung compliance. In situations where lung compliance is low such as morbid obesity, restrictive lung disease and intra-abdominal surgery, a higher peak airway pressure may be required. Our data may not apply in these circumstances. Secondly, we neither checked the position of the device fibre optically nor measured the cuff pressures in LMA as this is not our standard clinical practice. And finally we did not to compare the tidal volumes later during the procedures as this would have necessitated further administration of muscle relaxants towards the end of the procedure.

Although our sample size was small and we studied patients with normal airway, we found the i-gel significantly easier and quicker to insert with fewer manipulations needed to facilitate insertion than the LMA, which has been in use for a much longer period. However the leak volumes and peak pressures during the first part of volume-controlled ventilation were the same. Functionally the i-gel performs similarly to the LMA-U, and the appealing features are fast and easy insertion.

Acknowledgement

We would like to thank Nigel Stallard, Professor of Medical Statistics, Warwick Medical School, University of Warwick, for his help with the statistical analysis.

References

1. Brain AIJ (1983) The LMA – a new concept in airway management. *British Journal of Anaesthesia* 55: 801-805.
2. Verghese C, Berlet J, Kapila A, Pollard R (1998) Clinical assessment of the single use laryngeal mask airway –the LMA-unique. *Br J Anaesth* 80: 677- 679.
3. Keller C, Brimacombe J (1999) Mucosal Pressure, Mechanism of Seal, Airway Sealing Pressure and Anatomic Position for the Disposable versus Reusable Laryngeal Mask Airways. *Anesth Analg* 88: 1418- 1420.
4. Keller C, Pühringer F, Brimacombe JR (1998) Influence of cuff volume on oropharyngeal leak pressure and fibre optic position with the laryngeal mask airway. *Br J Anaesth* 81: 186-187.
5. Levitan RM, Kinkle WC (2005) Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. *Anaesthesia* 60: 1022-1026.
6. Nagappala R, McGoldrick K (2004) Comparison of the LMA-Classic(TM) with the New Disposable Soft Seal Laryngeal Mask in Spontaneously Breathing Adult Patients. *Survey of Anaesthesiology* 48: 179.
7. Gabbott DA, Beringer R (2007) The i-gel supraglottic airway; potential role for resuscitation. *Resuscitation* 73: 161-162.
8. Soar J (2007) The i-gel supraglottic airway and resuscitation-some initial thoughts. *Resuscitation* 74: 197.
9. I-gel User Guide (2009), 7th Edition Wokingham, UK: Intersurgical Ltd.
10. Brimacombe J, Brain AIJ, Berry A (1996) The laryngeal mask airway instruction manual. Henley-on-Thames, UK: Intavent Research Limited.
11. Mort TC (2004) Emergency Tracheal Intubation: Complications Associated with Repeated Laryngoscopic Attempts. *Anesth Analg* 99: 607-613.
12. Henderson JJ, Popat MT, Latto IP, Pearce AC (2004) Difficult Airway Society guidelines for management of the unanticipated difficult intubation. *Anaesthesia* 59: 675-694.
13. Brimacombe J, Keller C, Boehler M (2001) Positive Pressure Ventilation with the ProSeal Versus Classic Laryngeal Mask Airway: A Randomized, Crossover Study of Healthy Female Patients. *Anesth Analg* 93: 1351–1353.
14. Richez B, Saltel L, Banchereau F, Torrielli R, Cros AM (2008) A New Single Use Supraglottic Airway Device with a non-inflatable cuff and an Esophageal Vent: An Observational Study of the i-Gel. *Anesth Analg* 106: 1137-1139.
15. Cook TM, Truempelmann P, Beringer R (2005) A randomized comparison of portex soft seal laryngeal mask airway with the LMA-Unique during anaesthesia. *Anaesthesia* 60: 1218- 1225.
16. Uppal V, Gangaiah S, Fletcher G, Kinsella J (2009) Randomized crossover comparison between the i-gel and the LMA-Unique in anaesthetized, paralysed adults. *British Journal of Anaesthesia* 103: 882-885.
17. Gupta L, Bhadoria P (2008) The I-Gel™ airway for Difficult Intubation. *The Internet Journal of Anesthesiology* 18: 1.
18. Uppal V, Fletcher G, Kinsella J (2009) Comparison of the i-gel with the cuffed tracheal tube during pressure-controlled ventilation. *British Journal of Anaesthesia* 102: 264-268.
19. Helmy AM, Atef HM, El-Taher E M, Henidak AM (2010) Comparative study between I-gel, a new supraglottic airway device, and classic laryngeal mask airway in anaesthetized spontaneously ventilated patients. *Saudi Journal of Anaesthesia* 4: 131-136.
20. Gasteiger L, Brimacombe J, Perkhofor D, Kaufmann M, Keller C (2010) Comparison of guided insertion of the LMA Proseal vs the i-gel. *Anaesthesia* 65: 913-916.