Crossover comparison of the i-gel with the cuffed tracheal tube during anaesthesia for pressure-controlled ventilation

V Uppal[1]*, G Fletcher[2], J Kinsella[1]

[1]Section of Anaesthesia, Pain and Critical Care, Faculty of Medicine, University of Glasgow, UK. [2]Department of Anaesthesia, Royal Alexandra Hospital, Paisley, UK

**Corresponding author. E-mail: drvishal76@rediffmail.com*

Summary

Background. The i-gel (Intersurgical Ltd) is a novel device that differs from other supraglottic airway devices currently in use in that it has a softer and a non-inflatable cuff. Our study was designed to assess whether the i-gel is suitable to provide pressure-controlled ventilation (PCV) during anaesthesia by measuring the gas leaks and comparing these values with that of the tracheal tube.

Methods. Twenty five patients with ASA physical status 1-2 were recruited to the study. Patients received a standard anaesthetic technique followed by an initial placement of the i-gel. The lungs were then ventilated at three different pressures (15, 20, 25 cm H_2O) using PCV. The difference between the inspired and expired tidal volumes was used to calculate the leak volume. The leak fraction was defined as the leak volume divided by the inspired tidal volume. Following these observations the i-gel was removed and replaced with the conventional tracheal tube and the recordings repeated.

Results. There was no statistically significant difference between the leak fractions of the i-gel and the tracheal tube at 15 and 20 cm H_2O PCV. At 25 cm H_2O PCV the median difference in leak fraction was 0.02 ($p=0.014$) and the median difference in leak volume was 26.5 ml ($p=0.006$). There was no evidence of gastric insufflations with any of the pressures used during PCV.

Conclusion. The data from our study suggests that the i-gel can be used as a reasonable alternative to tracheal tube for a vast majority of patients to provide PCV.

Keywords: Equipment - airway, Ventilation - mechanical, LMA, Tracheal tube

Laryngeal mask airways (LMAs) are routinely used during anaesthesia for spontaneously breathing patients. LMAs are also used to ventilate patients' lungs during anaesthesia but may be associated with a less effective seal compared to the conventional tracheal tubes.[1] The i-gel (Intersurgical Ltd, Crane House, Molly Millars Lane, Wokingham, Berkshire) is a novel supraglottic airway device made of thermoplastic elastomer which is soft, gel-like and transparent. Unlike the conventional LMA it does not have an inflatable cuff. Cadaver studies have shown that i-gels effectively conformed to the perilaryngeal anatomy and consistently achieved proper positioning for supraglottic ventilation.[2] Studies performed on manikins and patients have shown that the insertion of the i-gel was significantly easier when compared to insertion of other supraglottic airway devices available on the market.[3 4] Furthermore, there is evidence to suggest that it is easier to train non-anaesthetists how to correctly insert i-gels, compared to the conventional supraglottic airway devices, thus making it a potentially useful device for situations such as resuscitation.[5 6] The i-gel may also have a role in management of the difficult airway as there are case reports of fibreoptic intubations being successfully preformed with the aid of the i-gel.[7 8] Recent studies support its use during anaesthesia for spontaneously breathing patients.[9-11] There are currently no published studies showing that the i-gel provides a good seal during pressure-controlled ventilation (PCV). Our study was designed to assess whether the i-gel is a suitable airway device to ventilate patients' lungs while using PCV during anaesthesia.

Methods

After obtaining approval from the Local Research Ethics committee and written informed consent, we aimed to recruit 20 adult patients. Patients scheduled for elective surgery that ordinarily involves tracheal intubation were recruited to the study. Most of our participants were undergoing abdominal hysterectomy or laparoscopic cholecystectomy. Patients with ASA physical status 1 or 2 between the age of 16 to 70 years, who had the ability to give informed consent, were included in the study. Patient exclusion criteria included (1) presence of any significant acute or chronic lung disease, or pathology of the neck or upper respiratory tract; (2) potential difficult intubation; (3) an increased risk of aspiration (hiatus hernia, gastroeosophageal reflux, full stomach); (4) pregnant women; (5) body mass index greater than 35 $kg.m^{-2}$ and (6) patients unable to communicate in English.

We used Datex-Ohmeda Aestiva/5 anaesthetic machines (GE Healthcare) with its built-in spirometer and pressure gauge for the study. Before induction of anaesthesia, the anaesthetic machine and circuits were checked as per manufacturers' guidelines. Intravenous access was secured and standard monitors, including a peripheral nerve stimulator, were attached. After pre-oxygenation, anaesthesia was induced with fentanyl 1 $microgram.kg^{-1}$ and a target control infusion (TCI) of propofol to achieve a target plasma concentration of propofol to 4-7 $microgram.ml^{-1}$. Once loss of verbal contact was achieved, the anaesthetist checked that the patient could be hand ventilated with a facemask. A bolus dose of rocuronium (0.5 $mg.kg^{-1}$) was then given. Neuromuscular blockade was confirmed using a train-of-four stimulation count (TOF=0). The anaesthetist then inserted the i-gel in accordance with manufacturer's guidelines. Size selection of the i-gel depended on patient weight, Size 3 was used for

patients less than 50 kg, size 4 was used for those between 50 and 90 kg, and size 5 was used for those over 90 kg in weight. Adequate placement of the device was assessed by gently squeezing the reservoir bag and observing the end-tidal carbon dioxide waveform and chest movements. If ventilation was inadequate, the following manipulations were allowed: gentle pushing or pulling of the device, chin lift, jaw thrust, head extension or neck flexion. The number of attempts required for insertion was recorded. A “failed attempt” was defined as removal of the device from the mouth before re-insertion. If the device was not successfully inserted by the second attempt, this was recorded as a failure of the i-gel. TCI propofol with oxygen-enriched air was used for maintenance of anaesthesia during data collection. Once a clear airway was established, the lungs were ventilated at three different pressures (15, 20, 25 cm H_2O) using PCV at a rate of 10 breaths per minutes and an inspiratory-to-expiratory ratio of 1:2 with no positive end expiratory pressure. Inspired and expired tidal volumes were recorded. Measurements were taken over 10 breaths for each pressure setting. Gastric insufflation was assessed by auscultation over the patient’s epigastric area. Airway leak tests were then preformed. The fresh gas flow was adjusted to 3 litre.min^{-1} and the adjustable pressure limiting (APL) valve of the circle system was completely closed. Airway pressures were not allowed to exceed 40 cm H_2O

- Test 1 (auscultation) measuring the minimal airway pressure at which an audible gas leak occurred using a stethoscope placed just lateral to thyroid cartilage.
- Test 2 (manometer stability) involving observation of the aneroid manometer dial as the pressure from the breathing system increased and noting the airway

pressure at which the dial reached stability (i.e. the airway pressure at which the leak was in equilibrium with fresh gas flow).

Following completion of the above tests the i-gel was removed and any visible blood on the device was noted. The trachea of the participant was then intubated with an appropriate size tracheal tube (Sims Portex); Size 8.5 was used for the male participants and size 7.5 was used for the female participants. The tracheal tube was used for the remaining duration of anaesthesia.

The difference between inspired tidal volume (ITV) and expired tidal volume (ETV) was used to calculate leak volume (LV) i.e. LV = ITV – ETV. The primary end point of our study was difference in the leak fraction between two airway devices under investigation. The leak fraction was defined as leak volume divided by inspired tidal volume. (i.e. Leak fraction = LV/ITV).

In order to estimate the sample size, we considered a difference in the leak fraction of more than 0.20 for the i-gel when compared with the tracheal tube to be clinically significant. There is no generally accepted standard for a significant difference in the leak fraction in the literature. A previous study has used a difference of 0.25 in the leak fraction for power calculation.[12] We chose a value of 0.20 following a survey in our institute in which the majority of anaesthetists considered less than 0.20 of the leak fraction to be clinically insignificant. We used a standard deviation value (0.15) for the leak fraction from a previous study performed with conventional LMAs.[1] A two sample study design, using a t-test for comparison of group means, would

therefore require a total of 20 patients for 80% power at a significance level of 5% (MINITAB 15.1).

Secondary outcomes were difference in the leak volume between the i-gel and the tracheal tube, airway leak pressures, gastric insufflations, success of first attempt insertion, number of manipulations after insertion and the incidence of visible blood on removal of the i-gel.

Statistical analysis was performed using MINITAB 15.1 Statistical Software (Minitab Inc. State College, USA). The paired data (leak fractions, leak volumes and airway leak pressures) were analysed using Wilcoxon signed rank test.

Results

25 patients were recruited to the study. Five patients were excluded for analysis of primary end point because of calibration errors of spirometer. The mean (SD) age, weight and body mass index of the participants is shown in table 1.

There was no statistically significant difference between the leak fractions of the i-gel and the tracheal tube at 15 and 20 cm H_2O PCV (p=0.61 and p=0.60 respectively). At 25 cm H_2O PCV the median difference in leak fraction was 0.02 (95% CI 0.002-0.057; p=0.014). Two of the 20 cases analysed had a difference in leak fraction of more than 0.20. This difference was observed at all the pressures used during pressure-controlled ventilation (Fig. 1). The volume of gas leak for these two cases was more than 200 ml for all pressure settings. The airway leak pressures for these two cases were 11 and 15 cm H_2O.

On analysis of the volume of gas leak we saw a similar trend (Fig 2). The volume of gas leak at PCV 15 and 20 cm H_2O was not statistically different between the two groups (p=0.11 and p=0.67 respectively). At 25 cm H_2O PCV the median difference in leak volume was 26.5 ml (95% CI 4.5- 62; p=0.006).

The median (IQR) airway leak pressure for the i-gel was 28 (20-35.5) cm H_2O using the auscultation method and 28 (20.5-36) cm H_2O using the manometer stabilization method. There was no statistical difference in the values obtained by using either test (p=0.068). Airway leak pressures for all the participants when intubated consistently reached 40 cm H_2O.

None of the participants in our study tested positive for gastric insufflations by auscultation over epigastric area. All the i-gels were inserted at the first attempt. Only four of the 25 needed minor manipulations after insertion. None of the cases needed more than one manipulation. An acceptable airway could be achieved for all the study patients using the i-gel. On removal, visible blood was noticed on three i-gels. Two other cases had a minor trauma to the lip.

Discussion

There are several well-established advantages of using a supraglottic airway device (SAD) compared to a tracheal tube. The major ones include lower incidence of sore throat[13], less hemodynamic upset during induction and maintenance of anaesthesia[14] [15], better oxygenation during emergence[16] and an increased case turnover[17]. Therefore, recently there has been a trend towards substituting a SAD for a tracheal tube for controlled ventilation in patients with a minimal risk of aspiration. The i-gel is a relatively new SAD made of gel-like material and does not have an inflatable cuff. It is designed to reduce airway morbidity even further. Absence of an inflatable cuff means, that theoretically it may be more prone to gas leaks during PCV. Data from our study shows that compared to a tracheal tube there is no significant difference in the gas leak when using an i-gel in a vast majority of cases. The small difference at higher pressure although statistically significant is unlikely to be clinically important.

For sample size calculations we assumed that the values of leak fraction would be normally distributed. This assumption was found to be incorrect as there were two out-liers. In the analysis we included these two out-liers and therefore analysed the data using a non-parametric test. Minor variation in the upper airway anatomy might be the cause of the clinically significant gas leaks observed in these two out-lier cases. This may be because the i-gel relies on normal airway anatomy to provide a good airtight seal.

The tracheal tube is conventionally used to ventilate the lungs of the patients during anaesthesia, therefore any alternative device should be compared to this gold standard. We assumed that differences between inspired and expired tidal volumes are exclusively attributable to the gas leaks. In fact, a part of the difference may be due to the compliance of the breathing system. But this possible confounding factor would apply to both the tracheal tube and the i-gel groups.

In this study, we used pressure-controlled mode instead of volume-controlled mode to ventilate the patients' lungs, as the amount of leak volume is affected by the pressure generated between the airway device and the supraglottic tissues. Furthermore there is evidence to suggest that PCV is more efficient and safer than volume-controlled ventilation for controlled ventilation with a SAD.[18]

We measured airway leak pressure using two methods (Auscultation and Manometer stability). A previous study on a conventional SAD showed that, the values obtained are similar using either method.[19] We found that this also applies to the i-gel. Our results suggest that the i-gel achieved a median airway leak pressures of 28 cm H_2O this is higher than those of the conventional LMA (20 cm H_2O) and similar to those of Proseal LMA.[20] The value of the airway leak pressure for the i-gel in our study is comparable to the value quoted in an unpublished study [Paralkar U, Al-Shaikh B, Jones M, Dent H. Trustwide Evaluation of the i-gel - Novel Supraglottic Airway].

There was no evidence of gastric insufflations, regurgitation or aspiration while using the i-gel for PCV during our study. We had no cases of failed insertions. The incidence of visible blood on the i-gel after removal, in our study, was 12% (3/25).

This is similar to those reported with other SAD. The incidence of visible blood with use of other SAD has been quoted from 12% to 18%, depending upon the type of SAD, the technique of insertion and ease of insertion.[21] [22] We did not assess the anatomical position of the device in relation to vocal cords with fibreoptic bronchoscope as it has been shown that anatomical findings do not correlate with the clinical consequences.[23] [24]

Possible limitations of our study are that it was neither blinded nor randomised, although by the use of a crossover design we were able to limit the influence of inter-patient variability on the comparison. In addition we did not study pressures higher than 25 cm H_2O that can be associated with laparoscopic procedures.

Our study supports the use of the i-gel for PCV in a vast majority of patients, provided pressures can be limited to 25 cm H_2O, although there can be large gas leaks for a small proportion of patients. Attempts should be made to recognise these soon after insertion using spirometry and if the gas leaks are excessive, it should be replaced with an alternative device.

Acknowledgements

We would like to thank Department of Anaesthesia, Royal Alexandra Hospital, Paisley, for supporting our research project.

References

1. Devitt JH, Wenstone R, Noel AG, O'Donnell MP. The laryngeal mask airway and positive-pressure ventilation. *Anesthesiology* 1994; **80**: 550-5.
2. Levitan RM, Kinkle WC. Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff. *Anaesthesia* 2005; **60**: 1022-6.
3. Jackson KM, Cook TM. Evaluation of four airway training manikins as patient simulators for the insertion of eight types of supraglottic airway devices. *Anaesthesia* 2007; **62**: 388-93.
4. Wharton NM, Gibbison B, Gabbott DA, Haslam GM, Muchatuta N, Cook TM. I-gel insertion by novices in manikins and patients. *Anaesthesia* 2008; **63**: 991-995.
5. Soar J. The I-gel supraglottic airway and resuscitation-some initial thoughts. *Resuscitation* 2007; **74**: 197.
6. Gatward JJ, Thomas MJ, Nolan JP, Cook TM. Effect of chest compressions on the time taken to insert airway devices in a manikin. *Br J Anaesth* 2008; **100**: 351-6.
7. Sharma S, Scott S, Rogers R, Popat M. The i-gel airway for ventilation and rescue intubation. *Anaesthesia* 2007; **62**: 419-20.
8. Michalek P, Hodgkinson P, Donaldson W. Fiberoptic intubation through an I-gel supraglottic airway in two patients with predicted difficult airway and intellectual disability. *Anesth Analg* 2008; **106**: 1501-4.
9. Gatward JJ, Cook TM, Seller C et al. Evaluation of the size 4 i-gel trade mark airway in one hundred non-paralysed patients. *Anaesthesia* 2008; **63**: 1124-30.

10. Richez B, Saltel L, Banchereau F, Torrielli R, Cros AM. A new single use supraglottic airway device with a noninflatable cuff and an esophageal vent: an observational study of the i-gel. *Anesth Analg* 2008; **106**: 1137-9.
11. Bamgbade OA, Macnab WR, Khalaf WM. Evaluation of the i-gel airway in 300 patients. *Eur J Anaesthesiol* 2008; **25**: 865-6.
12. Natalini G, Franceschetti ME, Pantelidi MT, Rosano A, Lanza G, Bernardini A. Comparison of the standard laryngeal mask airway and the ProSeal laryngeal mask airway in obese patients. *Br J Anaesth* 2003; **90**: 323-6.
13. Higgins PP, Chung F, Mezei G. Postoperative sore throat after ambulatory surgery. *Br J Anaesth* 2002; **88**: 582-4.
14. Dyer RA, Llewellyn RL, James MF. Total i.v. anaesthesia with propofol and the laryngeal mask for orthopaedic surgery. *Br J Anaesth* 1995; **74**: 123-8.
15. Cork RC, Depa RM, Standen JR. Prospective comparison of use of the laryngeal mask and endotracheal tube for ambulatory surgery. *Anesth Analg* 1994; **79**: 719-27.
16. Webster AC, Morley-Forster PK, Dain S et al. Anaesthesia for adenotonsillectomy: a comparison between tracheal intubation and the armoured laryngeal mask airway. *Can J Anaesth* 1993; **40**: 1171-7.
17. Brimacombe J, Berry A. A simple method of ventilation via the laryngeal mask during transportation and recovery from anaesthesia. *Acta Anaesthesiol Scand* 1996; **40**: 1258
18. Bordes M, Semjen F, Degryse C, Bourgain JL, Cros AM. Pressure-controlled ventilation is superior to volume-controlled ventilation with a laryngeal mask airway in children. *Acta Anaesthesiol Scand* 2007; 51: 82-5.

19. Keller C, Brimacombe JR, Keller K, Morris R. Comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. *Br J Anaesth* 1999; **82**: 286-7.

20. Brimacombe J, Keller C, Fullekrug B et al. A multicenter study comparing the ProSeal and Classic laryngeal mask airway in anesthetized, nonparalyzed patients. *Anesthesiology* 2002; **96**: 289-95.

21. Parker MR, Day CJ. Visible and occult blood contamination of laryngeal mask airways and tracheal tubes used in adult anaesthesia. *Anaesthesia* 2000; **55**: 388-90.

22. Tordoff SG, Scott S. Blood contamination of the laryngeal mask airways and laryngoscopes-what do we tell our patients? *Anaesthesia* 2002; **57**: 505-6.

23. Inagawa G, Okuda K, Miwa T, Hiroki K. Higher airway seal does not imply adequate positioning of laryngeal mask airways in paediatric patients. *Paediatric Anaesthesia* 2002; **12**: 322-6

24. Van Zundert A, Brimacombe J, Kamphuis R, Haanschoten M. The anatomical position of three extraglottic airway devices in patients with clear airways. *Anaesthesia* 2006; **61**: 891-5.

Table 1 Demographic data. Values are expressed as mean (SD) or actual number

Parameters	n=20
Sex; M: F	4:16
Age; years	45.2 (10.5)
Weight; kg	74.1 (12.2)
Body Mass Index; $kg.m^{-2}$	27.6 (4.1)

Figure 1 Leak fractions. Box shows the median, 25^{th} and 75^{th} percentiles (box boundaries), and range (whiskers). * out-lier cases. The difference between the pairs at 15 cm H_2O PCV (NS), 20 cm H_2O PCV (NS), 25 cm H_2O PCV significant (p=0.014)

Figure 2 Leak Volumes. Box shows the median, 25^{th} and 75^{th} percentiles (box boundaries), and range (whiskers). * out-lier cases. The difference between pairs at 15 cm H_2O PCV (NS), 20 cm H_2O PCV (NS), 25 cm H_2O PCV significant (p=0.006)