Comparison of the i-gel with the cuffed tracheal tube during pressure-controlled ventilation

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Background. The i-gel (Intersurgical Ltd) is a novel device that differs from other supraglottic airway devices 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, ASA I–II, 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 H2O) 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 significant difference between the leak fractions of the i-gel and the tracheal tube at 15 and 20 cm H2O PCV. At 25 cm H2O, 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.

Conclusions. We suggest that the i-gel can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures.


Keywords: equipment, airway; ventilation, mechanical

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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 with the conventional tracheal tubes.1 The i-gel (Intersurgical Ltd, Wokingham, UK) is a novel supraglottic airway device (SAD) 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 perilyngeal 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 with insertion of other SADs.3 4

Furthermore, there is evidence to suggest that it is easier to train non-anaesthetists how to correctly insert i-gels, compared with the conventional SADs, 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 performed 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 undergoing elective surgery that involved tracheal intubation were recruited to the study. Most of our participants underwent abdominal hysterectomy or laparoscopic cholecystectomy. Patients, ASA I–II, age 16–70 yr, who had the ability to give informed consent, were included in the study. The exclusion criteria were presence of any significant acute or chronic lung disease, pathology of the neck or upper respiratory tract, potential difficult intubation, an increased risk of aspiration (hiatus hernia, gastroesophageal reflux, full stomach), pregnant women, BMI > 35 kg m⁻² and patients unable to communicate in English.

We used the Datex-Ohmeda Aestiva/5 anaesthetic machine (GE Healthcare) with its built-in pressure gauge and spirometer attachment 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 μg kg⁻¹ and a target control infusion (TCI) of propofol to achieve a target plasma concentration of propofol to 4–7 μg ml⁻¹. On loss of verbal contact, 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 <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 H₂O) using PCV at a rate of 10 bpm and an inspiratory-to-expiratory ratio of 1:2 with no positive end expiratory pressure. Inspired and expired tidal volumes (ETVs) 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 performed. 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 H₂O.

- 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 ETV was used to calculate leak volume (LV), i.e. LV = ITV – ETV. The primary endpoint 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 ITV (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. We chose a value of 0.20 following a survey in our institute in which the majority of anaesthetists considered <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 LMA-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

Twenty-five patients were recruited; five were excluded from analysis of primary endpoint because of calibration errors of spirometer. The mean (sd) age, weight, and BMI of the participants are 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$_{2}$O PCV ($P=0.61$ and $P=0.60$, respectively). At 25 cm H$_{2}$O PCV the median difference in leak fraction was 0.02 (95% CI 0.002–0.057; $P=0.014$). Two of the 20 patients who were analysed had a difference in leak fraction of more than 0.20. This difference was observed at all the pressures used during PCV (Fig. 1). The volume of gas leak in 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$_{2}$O.

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$_{2}$O was not statistically different between the two groups ($P=0.11$ and $P=0.67$, respectively). At 25 cm H$_{2}$O PCV the median difference in leak volume was 26.5 ml (95% CI 4.5–62; $P=0.006$).

Table 1 Patient characteristics. Values are expressed as mean (sd) or actual number

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</table>

Discussion

There are several well-established advantages of using an SAD compared with a tracheal tube. The major ones include lower incidence of sore throat,$^{13}$ less haemodynamic 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 an 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 suggest that compared with a tracheal tube there

The median [IQR] airway leak pressure for the i-gel was 28 [20–35.5] cm H$_{2}$O using the auscultation method and 28 [20.5–36] cm H$_{2}$O 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$_{2}$O.

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.
is no significant difference in the gas leak when using an i-gel during PCV with moderate airway pressures. 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 outliers. In the analysis, we included these two outliers 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 outlier 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 with this gold standard. We assumed that differences between inspired and ETVs 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 an 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 pressure of 28 cm H\(_2\)O, which is higher than those of the conventional LMA (20 cm H\(_2\)O) and similar to those of Proseal LMA.\(^{20}\)

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 the 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 fibroptic 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 randomized, 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\(_2\)O that can be associated with laparoscopic procedures.

Our study supports the use of the i-gel for PCV provided pressures can be limited to 25 cm H\(_2\)O, although there can be large gas leaks for a small proportion of patients. Attempts should be made to recognize these soon after insertion using spirometry, and if the gas leaks are excessive, the i-gel should be replaced with an alternative device.

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