Randomised crossover comparison between the i-gel and the LMA Unique in anaesthetised, paralysed adult patients

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Summary

Background. The i-gel differs from other supraglottic airway devices in that it has a softer and a non-inflatable cuff. This study was designed to compare the performance of the i-gel and the LMA Unique when used during anaesthesia in paralysed patients.

Methods. The devices were studied in 39 anaesthetised, paralysed patients by randomized crossover trial. The primary outcome was airway leak pressure. Secondary outcomes included the time for insertion, the number of insertion and reposition attempts, leak volumes and leak fractions.

Results. There was no significant difference between the airway leak pressures of the two devices (median [IQR] values, i-gel 25 [22-30] cm H_2O and LMA Unique 22 [20-28] cm H_2O; $p = 0.083$). The median [IQR] insertion time for the i-gel (12.2 [9.7-14.3] s) was significantly less than for the LMA Unique (15.2 [13.2-17.3] s; $p = 0.007$). All the LMA Uniques and 38/39 i-gels were inserted at the first attempt. The number of manipulations required after insertion to achieve a clear airway was same in both the groups (four in each). There were no statistically significant differences in the leak volumes or leak fractions during controlled ventilation.

Conclusions. We were unable to demonstrate any difference in efficacy of seal and success rate of first-time insertion between the i-gel and the LMA Unique although the insertion times for the i-gel are significantly shorter when compared to the LMA Unique. We conclude

that the i-gel provides a reasonable alternative to the LMA-U for controlled ventilation during anaesthesia.

Keywords: equipment, airway; equipment, masks, laryngeal; ventilation, mechanical

The i-gel (Intersurgical Ltd, Wokingham, UK) is a relatively new, single use supraglottic airway device (SAD) designed for use during anaesthesia.[1] Unlike the conventional LMAs it does not have an inflatable cuff. The i-gel is made from a soft, gel-like, and transparent medical grade thermoplastic elastomer (Styrene Ethylene Butadiene Styrene). The cuff has been designed to create a non-inflatable anatomical seal by a shape which is a mirror impression of the supraglottic anatomy. A studies performed on manikins showed that the insertion of the i-gel was significantly easier when compared with insertion of other SADs.[2] 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.[3-5] Recent studies show that the i-gel provides a good seal during anaesthesia for spontaneously breathing patients as well as for controlled ventilation.[6–8] We are unaware of any published studies performed on live humans which have compared its performance with other well established SADs for controlled ventilation. LMA Unique (LMA-U; Intavent Orthofix, UK) is the single-use form of the LMA classic. This study was designed to compare the adequacy of seal and ease of insertion of the i-gel and the LMA-U during anaesthesia in paralysed patients.

Methods

After obtaining approval from the Local Research Ethics Committee and written informed consent, we recruited 40 adult patients to a prospective randomised crossover clinical trial. Patients undergoing elective surgery that involved tracheal intubation were recruited to the study. 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, gastro-oesophageal reflux, or 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 manufacturer's guidelines. Intravenous access was secured and standard monitoring, including a peripheral nerve stimulator, was attached. After preoxygenation, 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 $microgram.ml^{-1}$. 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 patients were randomly allocated to one of the two groups using sequentially numbered sealed opaque envelopes naming the airway device to be evaluated first. The insertions were

performed by a single user (SG) who had an experience of more than 1000 insertions of any type of SAD including more than 90 i-gel insertions and more than 200 LMA-U insertions. The i-gel was inserted 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. Similarly for the LMA-U we followed a weight based algorithm recommended by the manufacturers: size 3 was used for patients <50 kg, size 4 was used for those between 50 and 70 kg, and size 5 was used for those over 70 kg. The cuff of the LMA-U was inflated to two-thirds of the maximum recommended volume as this usually provides most effective seal.[9] Therefore size 3, 4 and 5 LMA-U were inflated with 13, 20 and 26 ml of air respectively. We did not measure cuff pressures using an aneroid cuff pressure gauge as this does not reflect our usual clinical practice.

The time taken to insert the SAD was noted, this was defined as the time from picking up the SAD to first breath made by manual ventilation. Adequate placement of the SAD 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. Two attempts were allowed before device use was considered a failure. In the event of adequate ventilation not achieved using either SAD, the protocol was that the trachea of participant would be intubated using a standard tracheal tube and the participant would be excluded from the study. The number of manipulations and abandonment of the device after insertion and during maintenance of anaesthesia were recorded. 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 pressure-controlled ventilation (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 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 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 first SAD was removed and any visible blood on the SAD was noted. The second SAD was then inserted after rechecking neuromuscular blockade and the previous measurements were repeated.

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 leak fraction was defined as leak volume divided by ITV (i.e. leak fraction=LV/ITV).

The primary outcome for the study was the airway leak pressure of the two SADs. For sample size calculation, we consider a 5 cm H_2O to be a clinically significant difference.[10] A

previous study with the LMA-U showed the average airway leak pressure to be 19 cm H_2O with a standard deviation of 5 cm H_2O.[11] A two sample study design, using a t-test for comparison of group means, would therefore require a total of 34 patients for 80% power at a significance level of 5% (nQuery Advisor® 4.0). Our study used a crossover design and should have greater power to detect discernable differences between the devices. However, there was no data available on the within-subject variability of the primary endpoint, so it was unclear whether within-patient differences would follow a normal distribution, as would be assumed in a paired t-test. We therefore decided to recruit 40 patients to allow for the imprecision in the power calculation and to allow for some loss of patients from the study. Patients were randomised to one of the two possible orderings of the devices in equal proportion, in random permuted blocks of 4 and 6.

Airway leak pressures, insertion times, leak volumes and leak fractions were not normally distributed. However the differences between airway leak pressures of the two SADs were normally distributed (Kolmogorov-Smirnov test). Therefore the former were analysed using the Wilcoxon sign-rank test and the later was analysed using a paired t-test. Fisher's exact test was used to assess whether the first time success rates, number of manipulations and trauma rates were different between the two devices. Statistical analysis was performed using MINITAB 15.1 Statistical Software (Minitab Inc., State College, USA).

Results.

Forty patients were recruited to the study; one patient was excluded from analysis because of calibration error of spirometer. The mean (SD) age, weight, and BMI of the participants are shown in Table 1. Majority of participants underwent gynaecological surgery (22/39), followed by general surgery (15/39) and orthopaedic surgery (2/39). The results of the study are summarised in Table 2

The mean [SD] difference in the airway leak pressure between the two devices was 2.8 [8.0] cm H_2O in favour of the i-gel (95% CI -0.32, 4.88 cm H_2O; p=0.084). The median [IQR] difference in the insertion time between the two devices was 2.3 [0.2-4.4] seconds again in favour of the i-gel (95% CI 1.05, 3.40 s; p=0.007). The difference between leak volumes and leak fractions was not significant between the groups. There were 3 cases of difficult insertion in the i-gel group and one difficult insertion in the LMA-U group. On analysis using Fisher's exact test the incidence of difficult insertions between the groups was statistically not different (p = 0.358). Number of manipulations required to achieve a clear airway was same in both the groups (four in each group). An acceptable airway could be achieved for all the study patients with both the SADs. Airway leak pressure above 40 cm H_2O was achieved for three patients in each group. None of the participants in our study tested positive for gastric insufflations by auscultation over epigastric area using either of SADs. There were no adverse events such as regurgitation or aspiration during the study.

Discussion

Since its introduction to the UK market in January 2007, the i-gel has been widely used as a SAD during anaesthesia and cardiopulmonary resuscitation. Apart from a soft, non-inflatable cuff, which may make its insertion easy and less traumatic, it has several design features which make it a useful SAD. It has a gastric channel which may allow early recognition of regurgitation of gastric contents and passage of a drainage tube. It has an epiglottic ridge which is designed to rest on the base of tongue and may prevent upward and outward movement. It has a ridged flattened stem to aid insertion and may reduce risk of axial rotation. Most of these designed features have not been tested in humans. An observational study evaluating its performance found the i-gel as a promising SAD.[6] However, we were unable to identify any published trials comparing the performance of the i-gel with its likely competitors for use during controlled ventilation. LMA-U is a commonly used single use SAD which has been shown to have similar clinical performance to the reusable LMA classic.[12]

Comparing the two SADs we found that the median insertion time for the i-gel (12.2 s) was significantly shorter than the LMA-U (15.2s). This difference although statistically significant may not be clinically important but is an indication of ease of insertion. It is quite likely that this time difference might be a reflection of the time need for the cuff inflation of

the LMA-U. Bamgbade et al in an evaluation study of 300 i-gel insertions reported that in 290 patients the i-gel could be inserted within 5 s, but they did not specify how they defined insertion time.[13] This is very different to others studies which show median insertion time for the i-gel and the LMA-U as 15 s and 24 s respectively.[6, 11] Shorter insertion times in both the groups in our study may be related to the experience of the user. High first time insertion rate, low failure rate and low incidence of mucosal trauma in our study may be because of the same reason. A recent study showed that the experience had no effect on insertion but that study was done on manikins and the conclusion may not apply to live subjects.[5]

There was no statistical difference between the median airway leak pressure achieved with the i-gel (25 cm H_2O) and the LMA-U (22 cm H_2O). The values of airway leak pressure found in our study are similar to those in previous studies. The median airway leak pressure for the i-gel has been quoted as 24-28 cm H_2O,[6,8] whereas the values for the LMA-U have been shown to be 18-25 cm H_2O.[14-15] No significant differences in the airway leak pressures, leak volumes and leak fractions suggest that the efficacy of seal provided by both devices is equivalent.

There was no evidence of gastric insufflation, regurgitation, or aspiration while using any of the SAD during our study. The incidence of regurgitation and aspiration with the use of the i-gel is not known. Three cases of regurgitation of which one of them had a confirmed aspiration have been reported.[16] In all these cases the gastric channel allowed early identification of the regurgitation. The incidence of clinically detectable gastric insufflations and regurgitation with the use of LMAs in general is 0-0.3% and 0.07% respectively.[17] The incidence of aspiration with LMAs in fasted patients is 0.012%.[17]

As in our previous study, we used pressure-controlled mode instead of volume-controlled mode for controlled ventilation.[8] This is because 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] Similarly we did not assess the anatomical position of the device in relation to vocal cords with fibreoptic bronchoscope as it has been shown that there is no correlation between fibreoptic scores and airway leak pressures.[19-20]

Our study has several limitations. Firstly, the data was collected by an unblinded observer so we cannot exclude an element of bias, although by the use of a crossover design we were able to limit the influence of interpatient variability during the comparison. Secondly, both the devices were inserted by a single experienced user and our results may not be applicable to inexperienced users. Finally, because of the crossover design, we were unable to determine which SAD has higher airway morbidity. This needs a larger non-crossover or an observational study.

In summary, we were unable to demonstrate any difference in efficacy of seal and success rate of first-time insertion between the i-gel and the LMA-U. The insertion time for the i-gel was marginally shorter. We conclude that the i-gel provides a reasonable alternative to the LMA-U for controlled ventilation during anaesthesia.

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Table 1 Patient characteristics. Values given as mean (SD) or absolute numbers

Parameters	n = 39
Sex; Males: Females	2:37
Age; (years)	47.8 (12.2)
Weight; (Kg)	70.3 (11.9)
Body Mass Index; kg m^{-2}	26.3 (4.1)

Table 2 Values are expressed as median (IQR) or actual number (n=39). * p = 0.007

	i-gel	**LMA Unique**
Ease of insertion		
Insertion times; s	12.2 (9.7-14.3)	15.2 (13.2-17.3)*
Insertion attempts; First/ Second	38/ 1	39/ 0
Failed insertions	0	0
Efficacy of seal		
Airway leak pressure; cm H_2O (Manometer method)	25.0 (22.0-30.0)	22.0 (20.0-28.0)
Airway leak pressure; cm H_2O (Auscultation method)	25.0 (22.0-30.0)	22.0 (20.0-28.0)
Leak Volume; ml		
15 cm H_2O PCV	30 (20.0-61.0)	21 (13.0-36.0)
20 cm H_2O PCV	34 (21.0-126.0)	28 (20.0-50.0)
25 cm H_2O PCV	43 (23.0-178.0)	48 (23.0-165.0)
Leak Fraction		
15 cm H_2O PCV	0.07 (0.03-0.15)	0.04 (0.02-0.09)
20 cm H_2O PCV	0.04 (0.03-0.13)	0.04 (0.02-0.08)
25 cm H_2O PCV	0.04 (0.02-0.16)	0.05 (0.02-0.17)
Mucosal trauma		
Visible blood (first device)	1	0