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RESPIRATION AND THE AIRWAY

Randomized crossover comparison between the i-gel and the LMA-Unique in anaesthetized, paralysed adults

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

Methods. Both devices were studied in 39 anaesthetized, paralysed patients in a randomized crossover trial. The primary outcome was airway leak pressure. Secondary outcomes included time to 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) leak pressures 25 (22–30) *vs* 22 (20–28) cm H_2O for the i-gel and LMA-U, respectively; $P=0.083$, 95% CI of the mean difference -0.32 to 4.88 cm H_2O]. The median (IQR) insertion time for the i-gel was significantly less than for the LMA-U [12.2 (9.7–14.3) *vs* 15.2 (13.2–17.3) s; $P=0.007$]. All the LMA-U devices and 38 of 39 i-gel airways were inserted at the first attempt. The number of manipulations required after insertion to achieve a clear airway was the same in both the groups (four in each). There were no statistically significant differences in leak volumes or leak fractions during controlled ventilation.

Conclusions. We found no difference in leak pressures and success rate of first-time insertion between the i-gel and the LMA-U. Time to successful insertion was significantly shorter for the i-gel. We conclude that the i-gel provides a reasonable alternative to the LMA-U for controlled ventilation during anaesthesia.

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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. The i-gel has several other useful design features including a gastric channel (which may allow early recognition of regurgitation of gastric contents and passage of a drainage tube), an epiglottic ridge (designed to rest on the base of tongue and resist upward and outward movement), and a ridged

flattened stem to aid insertion and reduce the risk of axial rotation. A study performed on manikins showed that the insertion of the i-gel was significantly easier in comparison with the insertion of other SADs.[2] There is evidence suggesting 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 and for controlled ventilation.[6-8] However, 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 randomized crossover clinical trial. Patients undergoing elective surgery who required neuromuscular block but not necessarily tracheal intubation were recruited to the study. The exclusion criteria were the 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, i.v. access was secured and standard monitoring, including a peripheral nerve stimulator, was sited. After preoxygenation of the patients' lungs, anaesthesia was induced with fentanyl 1 μg kg^{-1} and a target-controlled 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 hand-ventilation with a facemask was possible. A bolus dose of rocuronium 0.5 mg kg^{-1} was then administered. Neuromuscular block was confirmed using a train-of-four stimulation count of zero. TCI propofol with inspired oxygen-enriched air was used for maintenance of anaesthesia during data collection.

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 (S.G.) who had experience of more than 1000 insertions of any type of SAD, including >90 i-gel insertions and >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 (weight <50 kg: i-gel size 3; 50–90 kg: size 4; and >70 kg: size 5). Similarly for the LMA-U, we followed a weight-based algorithm recommended by the manufacturers: weight <50 kg: LMA-U size 3; 50–70 kg: size 4; and >70 kg: size 5. The cuff of the LMA-U was inflated to two-thirds of the maximum recommended volume as this usually provides the most effective seal.[9] Therefore, size 3, 4, and 5 LMA-U devices 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 defined as the time from picking up the SAD to time at first manually ventilated breath. Adequate placement of the SAD was assessed by gently squeezing the reservoir bag and observing the end-tidal CO_2 waveform and movements of the chest wall. If ventilation was deemed 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 tracheal intubation would be performed 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.

Once a clear airway was established, patients' lungs were ventilated at three different applied pressures (15, 20, and 25 cm H_2O) using pressure-controlled ventilation (PCV) at a rate of 10 min^{-1} and an inspiratory-to-expiratory ratio of 1:2 with zero PEEP. 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 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 reading stabilized (i.e. the airway pressure at which the leak was in equilibrium with fresh gas flow).

After completion of these tests, the first SAD was removed and the presence of visible blood on the SAD was noted. The second SAD was then inserted after rechecking neuromuscular block and the previous measurements were repeated.

Leak volume (LV) was calculated as the difference between inspired tidal volume (ITV) and expired tidal volume (ETV) (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. A previous study showed the mean (SD) average airway leak pressure with the LMA-U to be 19 (5) cm H_2O.[10] For sample size calculation, we considered 5 cm H_2O to be a clinically significant difference.[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 discernible differences between the devices. However, there were no available data on the within-subject variability of the primary endpoint, so it was unclear whether within-patient differences would follow a normal distribution. 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 randomized to one of the two possible orderings of the devices in equal proportion, in randomly permuted blocks of 4 and 6.

Airway leak pressures, insertion times, leak volumes, and leak fractions were not normally distributed and were analysed using the Wilcoxon sign-rank test. Differences between airway leak pressures of the two SADs were normally distributed (Kolmogorov–Smirnov test) and were analysed using a paired *t*-test. Fisher's exact test was used to compare first-time success rates, number of manipulations, and incidence of oropharyngeal mucosal trauma. All statistical analyses were performed using MINITAB 15.1 Statistical Software (Minitab Inc., State College, PA, USA).

Results

Forty patients were recruited to the study; one patient was excluded from the analysis because of a calibration error of the spirometer (Table 1). The results of the study are summarized in Table 2.

Table 1 Patient characteristics ($n=39$) expressed as mean (range), mean (SD) or absolute numbers

Gender (M:F)	2:37
Age (yr)	47 (19–70)
Weight (kg)	70.3 (11.9)
Body mass index (kg m^{-2})	26.3 (4.1)
Type of surgery: gynaecological/general/orthopaedic	22/15/2

Table 2 Leak volumes, pressures, and insertion data, 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$_2$O (manometer method)	25.0 (22.0–30.0)	22.0 (20.0–28.0)
Airway leak pressure; cm H$_2$O (auscultation method)	25.0 (22.0–30.0)	22.0 (20.0–28.0)
Leak volume (ml)		
15 cm H$_2$O PCV	30 (20.0–61.0)	21 (13.0–36.0)
20 cm H$_2$O PCV	34 (21.0–126.0)	28 (20.0–50.0)
25 cm H$_2$O PCV	43 (23.0–178.0)	48 (23.0–165.0)
Leak fraction		
15 cm H$_2$O PCV	0.07 (0.03–0.15)	0.04 (0.02–0.09)
20 cm H$_2$O PCV	0.04 (0.03–0.13)	0.04 (0.02–0.08)
25 cm H$_2$O PCV	0.04 (0.02–0.16)	0.05 (0.02–0.17)

The mean (SD) difference in the airway leak pressure between the two devices was 2.8 (8.0) cm H$_2$O lower for the i-gel (95% CI −0.32, 4.88 cm H$_2$O; $P=0.084$). The median (IQR) difference in the insertion time between the two devices was 2.3 (0.2–4.4) s again in favour of the i-gel (95% CI 1.05–3.40 s; $P=0.007$). The differences between leak volumes and leak fractions were not significant between the groups. There were three cases of difficult insertion in the i-gel group and one difficult insertion in the LMA-U group ($P=0.358$, Fisher's exact test). The number of manipulations required to achieve a clear airway was four in each group. An acceptable airway was achieved for all the study patients using both SADs. Airway leak pressure above 40 cm H$_2$O was reached in 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, and no adverse events were noted.

Discussion

In this study, we found that airway leak pressures, leak volumes, and number of attempts at insertion were similar between the LMA-U and the i-gel when used by an anaesthetist experienced in the use of both SADs. However, median insertion time for the i-gel (12.2 s) was significantly shorter than the LMA-U (15.2 s). Although this difference may not be clinically important, it may reflect ease of insertion or the time needed for the cuff inflation of the LMA-U. Bamgbade and colleagues[12] in an evaluation 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 insertion time was defined. In contrast, other studies have reported a median insertion time for the i-gel and the LMA-U as 15 and 24 s, respectively.[6 10] Shorter insertion times in both the groups in our study may be related to the experience of the user, as may the high first-time insertion rate, low failure rate, and low incidence of mucosal trauma.

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$_2$O,[6 8] whereas the values for the LMA-U have been shown to be 18–25 cm H$_2$O.[13 14] The similarities in 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 gastric aspiration during our study. The incidence of regurgitation and aspiration with the use of the i-gel is not known. Three cases of regurgitation, including one confirmed gastric aspiration, have been reported.[15] 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.[16]

The incidence of aspiration with LMAs in fasted patients is 0.012%.[16]

We used pressure-controlled mode instead of volume-controlled ventilation, 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 an SAD.[17] Similarly, we did not assess the anatomical position of the device in relation to vocal cords with the fibreoptic bronchoscope as it has been shown that there is no correlation between fibreoptic scores and airway leak pressures.[18 19]

Our study has several limitations. First, the data were 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 inter-patient 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 found no significant difference in efficacy of seal and first-time successful insertion rate 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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