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A Randomised Comparison of the Supreme Laryngeal Mask Airway with the i-gel During Anaesthesia

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Abstract

Objective: The i-gel and LMA Supreme are second-generation supraglottic airways. We performed a comparison of the two with the primary endpoint of first insertion success by experienced anaesthetists.

Methods: With Ethics Committee approval, patients were randomised to insertion of either device. Anaesthesia was maintained with sevoflurane and patients were not paralysed. Data was collected on insertion, oropharyngeal leak pressure, fibreoptic view via both airway and drain tube, adequacy of controlled ventilation, clinicians' subjective assessments of airway performance and complications at each stage from insertion to the first post-operative day.

Results: Data from 97 patients were analysed. The primary outcome was insertion success on first attempt, which was 78% for i-gel and 87% with SLMA (p=0.4). There were no statistically significant differences between the two devices' performances: >92% overall insertion success, >98% of airways rated "good" after insertion, >90% optimal ventilation, minimal complication rates during insertion, maintenance and removal, and low rates of post-operative sequelae, >90% of which were mild. Both devices performed safely, with no episodes of aspiration or long term sequelae.

Conclusions: We have conducted a rigorous comparison of the i-gel and SLMA in a European population receiving sevoflurane anaesthesia, without muscle relaxation. Performance of the two devices is very similar.

Trial Registry Number

The trial received LREC approval on 5th March 2007 (REC reference number 07/Q2001/14). Patient enrolment began prior to 1st January 2009; therefore this trial is not registered in a public trials registry.

The i-gel (Intersurgical, Wokingham, UK) and LMA Supreme airway (SLMA, Teleflex, Old Amersham, UK) are supraglottic airways devices (SAD) for use during anaesthesia. The i-gel is similar in design to a laryngeal mask but is made of an elastomer and lacks an inflatable cuff. The SLMA is made of PVC. When the airways are inserted, they lie along the length of the tongue with the distal tip in the upper oesophagus. Both are single use devices, incorporating an elliptical bite block to minimise axial rotation and a small drain tube to enable gastric tube placement and prevent gastric inflation during ventilation. Both can be considered to be second-generation SADs [1].

When this study was conceived, there were no published trials comparing the SLMA and i-gel. We intended to study the devices in a randomised controlled, unblinded trial to compare insertion characteristics and performance throughout anaesthesia.

The main aim of the study was to assess the utility of the devices during controlled ventilation (unparalysed) and spontaneous ventilation, and directly compare the i-gel and SLMA. Our hypothesis was that there would be no difference in the frequency of successful insertion with the devices. Secondary outcomes of interest were seal pressure, incidence of blood on the device, and post-operative sore throat.

Methods

The Local Research Ethics Committee approved the study. All subjects received a patient information leaflet and a face-to-face explanation of the study with the chance to ask questions prior to signing a consent form.

We recruited adult patients (American Society of Anaesthesiology physical status 1-3) undergoing elective surgery in the supine or lithotomy position. Following a pre-operative assessment which included an airway assessment; patients were excluded if there was pathology of the neck, increased risk of pulmonary aspiration of gastric contents or other contraindications to the use of a classic laryngeal mask airway. All investigators involved in the study were experienced in the insertion of LMAs and were required to have inserted a minimum of 10 i-gels and 10 SLMAs before recruiting patients.

Randomisation was as follows. Pieces of paper indicating the group allocation (SLMA or i-gel) were shuffled and blindly placed in sealed opaque envelopes, which were then sequentially numbered. The envelopes were allocated to patients in order and were opened when the patient arrived in the anaesthetic room.

Prior to anaesthesia, patient monitoring consistent with the Association of Anaesthetists of Great Britain and Ireland recommendations was applied [2]. A firm pad or pillow was placed under the patient's occiput. After pre-oxygenation, anaesthesia was induced with propofol 2-4.0 mg kg^{-1} intravenously, supplemented with fentanyl 1 mcg kg^{-1} and maintained with sevoflurane at an end-tidal concentration of approximately 1 Minimum Alveolar Concentration in oxygen and air.

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Before the airway device was inserted, adequate depth of anaesthesia was determined by loss of patient response to voice and the absence of response to jaw thrust [3]. The allocated device was then inserted, selecting a size determined by manufacturers' guidelines. In the SLMA group, size 3 was used for patients weighing less than 50 kg, a size 4 for patients between 50 and 70 kg, and a size 5 for patients weighing more than 70 kg [4]. The posterior of the mask was lubricated and after insertion, the cuff was inflated using a cuff inflator (VBM GmbH, Sulz, Germany) until the intracuff pressure reached 60 cmH$_2$O. In the i-gel group, size 4 i-gel was used in the majority of patients, with a size 3 used for patients weighing below 50 kg and a size 5 for those weighing more than 90 kg [5]. The back and sides of the i-gel were lubricated and then the mask was placed by the method described in the manufacturer's instruction manual. Once inserted, the allocated device was secured by tying.

The number of attempts at insertion was recorded. Ease of insertion was scored into four grades: easy (single pass without manipulations or significant resistance), moderately difficult (single pass with up to two manipulations or one complication), difficult (more than two attempts, more than two manipulations or more than one complication) and impossible (three failures or complications leading to abandonment of further attempts). The number of airway manipulations to establish an airway (predefined as neck extension, chin lift, neck flexion, jaw thrust and in/out movements) and any complications of insertion (pre-defined as soft tissue damage, hypoxia defined as desaturation to a $S_pO_2<92\%$, gagging, dental damage, failure to establish or maintain an airway, laryngospasm, coughing, bleeding, wheeze, stridor, loss of airway, regurgitation, pulmonary aspiration, hiccough and movement) were also noted. If it was not possible to insert the device or ventilate through it, two more attempts at placement of the device were allowed. If placement had failed after three attempts, the study was abandoned and the other device was used. If this alternative device failed on first attempt, a classic LMA or tracheal tube was used based on clinical judgement. Time for insertion of the airway (starting from removal of the facemask to attachment of the breathing system to the test device) was measured in patients in whom it was possible to ventilate through the device.

After fixation of the device and attachment of the breathing system, airway leak pressure was determined. Gas was administered at 5 l min^{-1} with the airway pressure-limiting valve closed; airway pressure was monitored until it peaked or an audible leak was heard. Airway pressure was not allowed to exceed 40 cm H$_2$O.

Adequacy of controlled ventilation was assessed with an inspired tidal ventilation of 7 ml kg^{-1} and I:E ratio 1:2 and with respiratory rate adjusted to maintain the end-tidal carbon dioxide concentration within the normal range. Adequate ventilation was recorded if four tests were passed 1) adequate chest movement, 2) an expired tidal volume of at least 7 ml kg^{-1}, 3) stable oxygenation and 4) normal capnography trace. Tidal ventilation was increased up to 10 ml kg^{-1} if necessary to achieve an expired tidal volume of 7 ml kg^{-1}. Following assessment of controlled ventilation patients were allowed to breathe spontaneously.

The anatomical position of the airway device was examined with a fibrescope positioned with the tip just exiting the bowl of the airway. The view was scored as follows: grade 1, vocal cords visible; grade 2, only arytenoids visible; grade 3, only epiglottis visible and grade 4, no laryngeal structures visible [6] The view through the drain tube was also recorded: as larynx, mucosa, open oesophageal orifice or closed oesophageal orifice. Up to two attempts were made to pass an appropriately sized orogastric tube (OGT) via the drain port.

During the maintenance phase of anaesthesia any airway manipulations to maintain the airway (neck extension, neck flexion, chin lift and jaw thrust) and the lowest recorded oxygen saturation were recorded. The quality of the airway was judged as clear throughout, intermittent partial obstruction, intermittent complete obstruction or complete obstruction. Removal of the device and predefined airway complications (as above) were recorded.

At the end of operation, anaesthetic agents were discontinued while the device was left in place. The device was removed after the patient has regained consciousness, and had responded to verbal command to open the mouth. However, if necessary (such as airway obstruction or retching occurred), it was removed before this point. The cuff on the SLMA remained inflated for its removal. After removal, the device was examined for the presence or absence of blood. Any complications (defined as above) that occurred during removal were recorded.

Postoperatively in recovery or on the ward within one hour, each patient underwent a structured interview to detect sore throat (constant pain, independent of swallowing), dysphagia (difficulty in, or pain provoked by, swallowing), sore jaw, dysphonia (difficulty in, or pain on, speaking), numbness of the tongue or the oropharynx, vomiting, lip or tongue swelling, hearing changes, neckache or mouthache. Each complication was graded as none, mild, moderate and severe. The same information was also sought directly or by phone at 24 hours.

For each airway used, the anaesthetist documented their subjective opinion of a) the quality of the airway during maintenance, b) ease of hands free anaesthesia and c) overall usefulness of the device in this patient; assessed on a 5-point Likert scale from inadequate to excellent.

Statistical Analysis

Experience with the SLMA suggested successful first-time insertion in approximately 90% of cases [7]. Our hypothesis was that there would be no difference in the frequency of successful first-time insertion with the devices. A clinically relevant difference would be a reduction to 75%. Power analysis using a two-sided binomial power test indicated that 224 patients were required to detect this difference with 80% power and 0.05 significance [8].

For each analysis we included only those devices remaining in use at that assessment stage: all airways were included for assessment of insertion success, but only successfully inserted devices for performance after insertion etc. Performance of secondary devices was not evaluated.

Data were analysed using Microsoft Excel (Microsoft Corporation, Redmond, WA, 98052-6399, USA) and Analyse-it (Leeds University, UK, 2012). Continuous variables (e.g. insertion time and leak pressure) were analysed using the Mann Whitney U test. Categorical variables (e.g. success rate, complications) were analysed using Fisher exact test (2x2 tables) or Chi^2 testing (2x>2 tables) as appropriate. All tests were two-sided and we determined statistical significance when $p<0.05$.

Results

Slow recruitment led to curtailment of the trial at 97 patients. This was due to the changing casemix at the hospital and the decision was made to stop the trial. The two groups had similar baseline characteristics (Table 1). In a small number of cases data collection was incomplete and this is indicated where applicable.

Insertion and ventilation

There were 51 patients in the i-gel group and 46 in the SLMA group. There were no statistically significant differences between groups in

	i-gel (n=51)	SLMA (n=46)
Surgical specialty		
Orthopaedics	22	15
General	18	18
Gynaecology	5	3
Urology	4	9
ENT	1	0
Not stated	1	1
Duration of surgery; min	45 (25-60) [5-200]	40 (22.8-50) [5-120]
Patient		
Gender f:m: not recorded	26:24:3	22:23:1
Age; years	54 (42-64) [19-83]	57 (42-66.5) [21-76]
Weight; kg	75 (69-88) [52-109]	73 (66-88) [47-106]
Height; m	1.7 (1.63-1.80) [1.53-1.85]	1.73 (1.65-1.8) [1.49-1.96]
BMI; kg m^{-2}	26.5 (23.6-29.4) [19-37.7]	25.9 (23-29.4) [15.9-38.9]
ASA 1:2:3:not recorded	26:22:0:3	24:17:2:3
Mallampati class: 1:2:3:not recorded	28:14:5:4	32:13:0:1
Anaesthetic variables		
Size of device 3:4:5	7:40:4	3:32:11
Grade of anaesthetist; consultant: other	40:11	34:12

Table 1: Patient and procedure details. Continuous data presented as median (interquartile range) [range].

first-time insertion success rate (i-gel 78%, SLMA 87%, p=0.4), number of insertion attempts (p=0.54), or failure of insertion: four i-gel failures and three SLMA failures (p=0.8).

There were no statistically significant differences between groups in time taken to establish a patent airway (p=0.87), the number of manipulations required to establish a patent airway (p=0.12), the number of complications of insertion (p=1.0), the number of patients experiencing complications (p=0.65), operator assessment of ease of insertion (p=0.12) or the initial airway quality (p=1.0). An attempt was made to pass an orogastric tube in 42 cases in the i-gel group and 40 in the SLMA group: success rates did not show statistically significant differences (p=0.39),

Fibreoptic inspection was attempted via the airway and drain tube as follows: i-gel 46, 41 respectively and SLMA 40, 41 respectively. There were no statistically significant differences between groups in the fibreoptic view of the airway (p=0.24) or via the drain tube (p=0.12).

	i-gel (n=51)	SLMA (n=46)	P value
Insertion			
Extra propofol	8	3	0.27
Insertion attempts; 1:2:3	40:6:5	40:3:3	0.54
Insertion success; y: n	47:4	43:3	0.80
Ease of insertion; 1:2:3	40:6:5	40:1:2	0.12
Time for insertion; s	15 (10-24) [4-120]	17 (11-21) [4-120]	0.87
Total manipulations needed (patients)	17 (11)	8 (7)	0.12 (0.6)
Complications of insertion (patients)	7 (7)	6 (4)	1.0 (0.65)
Initial airway			
Quality of airway (good: poor: inadequate; not recorded)	46:1:0:0	40:0:0:3	1.0
Fibreoptic laryngeal view; 1:2:3:4	41:4:1:0	30:5:4:1	0.24
Fibreoptic drain tube view; (larynx: mucosa: open oesophagus: closed oesophagus)	3:21:10:6	1:31:4:5	0.12
Gastric tube success	35:5	40:2	0.39
Ventilation			
Chest movement; yes: no	46:1	43:0	1.0
Vt >7 ml kg^{-1} ; yes: no	45:2	42:1	1.0
Stable oxygenation; yes: no	47:0	42:1	0.96
Normal capnography; yes: no	44:3	42:1	0.69
All measures of ventilation good; yes: no	43:4	42:1	0.42
Airway leak pressure, cm H$_2$O	22.5 (17-29) [7-40]	25.5 (20-30) [3-30]	0.46
Maintenance			
Manipulations required (patients)	2 (2)	0 (0)	0.55 (0.55)
Quality of airway; patent; intermittent obstruction; obstructed	45:1:0	43:0:0	1.0
Lowest oxygen saturation %	98 (96-99) [92-99]	98 (99-98.5) [89-99]	0.97
Complications (patients)	1 (1)	0 (0)	1.0 (1.0)
Failure (patients)	0 (0)	0 (0)	1.0 (1.0)
Emergence and removal			
Not tolerated during emergence; yes: no	44:1	41:0	1.0
Problems with secretions; yes: no	2:43	1: 40	1.0
Blood on the airway; yes:no	5:40	1:40	0.25
Complications at removal (patients); yes:no	0: 45 (0)	1: 40 (1)	0.95 (0.95)

Table 2: Device performance. Continuous data presented as median (interquartile range) [range].

	i-gel (n=45)	SLMA (n=40)	P value
In recovery			
Sore throat; none: mild: moderate: severe	40:4:0:1	32:7:1:0	0.33
Other complication; none: mild: moderate: severe	40:4:1:0	36:4:0:0	0.63
Total number of complications	10	12	0.49
Number of patients experiencing complication; 0:1:2:3	37:7:0:1	32:5:2:1	0.49
At 24 hours			
Sore throat; none: mild: moderate: severe	37:8:0:0	34:6:0:0	0.96
Other complication; none: mild: moderate: severe	40:5:0:0	36:4:0:0	0.87
Total number of complications	13	10	0.88
Number of patients experiencing complication; 0:1:2:3	34:9:2:0	32:6:2:0	0.83

'Other' includes: nausea or vomiting, tongue swelling or numbness, ear pain, hearing change, pain on swallowing, jaw or neck pain, pain on speaking, any areas of numbness. All asked individually and (when present) rated as mild, moderate or severe.

Table 3: Post-operative sequelae.

The laryngeal inlet was visible (grade 1 view) via 89% of i-gels and 75% of SLMAs.

There were no statistically significant differences between groups in individual or combined tests of ventilation (chest movement, tidal volume >7 ml kg^{-1}, stable oxygenation and normal capnography waveform, all p>0.05). All four tests of ventilation were passed with the i-gel in 91% of uses and with the SLMA in 98% (p=0.42). Despite this, two i-gels were removed shortly after these tests due to poor airway seal or suboptimal ventilation.

There were no statistically significant differences between groups in airway leak pressures (i-gel 22.5 cm H_2O and SLMA 25.5 cm H_2O, p=0.46) (Table 2).

Maintenance

Forty-five patients in the i-gel group and 43 patients in the SLMA group were studied. There were no failures reported during maintenance. One patient in the i-gel group developed hiccoughs during maintenance and there were no other complications in either group. There was no statistical significant difference in the quality of the airway between groups (p=1.0), manipulations required (p= 0.55), in the number of complications (p=1.0) or patients experiencing complications (p=1.0) (Table 2).

Emergence and recovery

Forty-five patients in the i-gel group and 43 patients in the SLMA group finished anaesthesia with their allocated airway device: in two patients in the SLMA group no data was collected at emergence. Both devices were tolerated well during emergence with one of 45 i-gels and none of SLMAs poorly tolerated (p=1.0). None of the measures of quality of emergence and recovery showed any statistically significant differences between groups (Table 2).

Post-operative sequelae

Post-operative data was collected from 45 patients in the i-gel group and 40 in the SLMA group. Post-operative sequelae were frequent and generally mild: in recovery, 13% patients in the i-gel group and 20% in the SLMA group reported a complication and at 24 hours, 23% in the i-gel group and 20% in the SLMA group. In the i-gel group, complications other than sore throat were (mild unless stated) in recovery: vomiting (1), dysphagia (1, moderate), dysphonia (1) and numbness (2); and at 24 hours vomiting (1), ear pain (1) and dysphagia (3). In the SLMA group, complications other than sore throat were (mild unless stated) in recovery: dysphagia (3) and dysphonia (1) and at 24 hours tongue swelling (1), dysphagia (2) and dysphonia (1). There were no statistically significant differences between groups in the number of patients experiencing complications, the severity of complications or the total number of complications either in recovery or at 24 hours (all p>0.05) (Table 3).

Clinical assessments

Clinician ratings did not differ statistically significantly between groups. All failures were regarded as 'inadequate'. I-gels, of which 88% were used for the entire operation, were rated as an excellent performance for 76-86% of measures. SLMAs were used for the whole case 93% of the time and were rated as performing excellently in 87-89% of measures (Table 4).

Discussion

This study has shown considerable similarities between these second-generation SADs: in performance and post-operative sequelae. Both devices performed well achieving: >92% overall insertion success, >98% of successfully inserted airways rated 'good' after insertion, >90% optimal ventilation, minimal complication rates during insertion, maintenance and removal, and low rates of post-operative sequelae, >90% of which were mild in nature. These results are consistent with many other studies [7,9-11]. Both devices performed safely, with no episodes of failure during surgery or major complications such as regurgitation, aspiration or numbness persisting >24 hours. We found no statistically significant difference in any of the outcomes measured in this study.

The primary outcome was insertion success on first attempt, which was similar in both groups (i-gel 78%, SLMA 87%) and not statistically significantly different between groups. We recruited fewer patients than intended because of a changing case-mix in our hospital; had we recruited our intended sample size (n=224) with the same proportionate results, then the difference in insertion success rate would still not have been statistically significant (Fisher test, p=0.166).

Our results can be considered both in their own right and in the context of previous similar studies. Our study indicates that there are no major differences in performance between the SLMA and the i-gel

	i-gel (n=51)	sLMA (n=46)	P value
Quality of airway during maintenance	41:3:1:0:6	40:3:0:0:3	0.49
Quality of hands free anaesthesia	44:1:0:0:6	41:2:0:0:3	0.83
Overall quality of airway device	39:5:1:0:6	40:2:1:0:3	0.27

Table 4: Anaesthetists' subjective assessments of performance. All rated excellent: good: fair: poor: inadequate.

when used for controlled and spontaneous ventilation by experienced anaesthetists during volatile-based anaesthesia; indeed, their performance is remarkably similar. Even if our small study has missed performance differences that would have statistical significance in a larger trial, the clinical importance of such differences would appear rather small given the almost identical performance of devices within this study.

A recently published meta-analysis of the performance of the i-gel and SLMA included 10 randomised controlled trails (RCTs) [12]. Seven meta-analyses were performed, each including between 290 and 784 patients. Overall, the meta-analysis reported similar performance between devices with the only statistically significant differences being ease of gastric tube insertion (17% more likely to succeed via the SLMA) and sore throat (i-gel less than half the incidence of sore throats). Our results are notably in agreement with the meta-analysis, both in their (lack of) statistical significance and numerical findings (e.g. first attempt success rates: meta-analysis pooled results i-gel 83%, SLMA 84%, our results i-gel 78%, SLMA 87%).

The question then arises as to whether there is a need for studies such as ours when 10 RCTs and a meta-analysis are already published? We believe the answer is yes. The 10 RCTs included in the meta-analysis are variable in size, purpose and many other factors. While our study was closed early it is notable that only one RCT studied more patients with each airway device than we did: 60 participated in a crossover study of simulated difficult airway [13]. Seven studies included fewer patients than we did. Six studies used airway leak pressure as their primary outcome measure [14-19]. The studies included in the meta-analysis were diverse: five RCTs studied Asian patients [15-19] and five European patients; [13,14,20-22] four studies were performed during laparoscopic surgery; [16-19] several used muscle paralysis; [16,18-20] one study was performed with the patient restrained in a neck collar; [13] in one the purpose of the study was to examine mucosal airway pressures; [20] one study looked at novice insertion; [21] several used total intravenous anaesthesia [13,14,19-21] and two studies used non-standard insertion techniques [20,22]. The studies were self-evidently heterogeneous. The resulting meta-analyses also showed significant statistical heterogeneity (Chi^2 <0.05 and I^2 >0.5) for analyses of first attempt insertion success, device insertion time, airway leak pressure and fibreoptic view. Only the, perhaps less important, outcomes of ease of OGT insertion, blood on device at removal and post-operative sore throat did not show such heterogeneity. The timing of sore throat was not described.

The current study adds to the literature in several ways. Our study was performed in non-paralysed patients undergoing a mixture of surgical procedures and was performed during maintenance with volatile anaesthesia; its results will be applicable to the setting in which these devices are used most commonly. This study is the most thorough of all similar studies, examining and comparing performance between devices at all phases of anaesthesia, during recovery and into the first post-operative day. Therefore, it provides a useful broad examination of overall performance in a pragmatic clinical setting.

There are limitations to this study. First, as outlined above, we did not enrol as many patients as intended. Nevertheless, our study groups are similar in size or larger than all comparable published trials. Like all such studies the study was not, and could not be, blinded.

In conclusion, we have conducted a rigorous comparison of the i-gel and SLMA in a European population receiving sevoflurane anaesthesia, without muscle relaxation. The performance of the two devices was very similar which is in keeping with a recent meta-analysis comparing studies of the two devices. This study adds to the existing, but heterogeneous, data.

Acknowledgement

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