Journal of Anesthesia & Clinical Research
ISSN: 2155-6148

Bosley et al., J Anesth Clin Res 2014, 5:11
DOI: 10.4172/2155-6148.1000459

Research Article Open Access

A Randomised Comparison of the Performance of ProSeal® Laryngeal Mask Airway with the i-gel® for Spontaneous and Controlled Ventilation during Routine Anaesthesia in European Population

Bosley NJ*, Burrows LA, Bhayani S, Nworah E and Cook TM

Department of Anaesthesia, Royal United Hospital, Coombe Park, Bath BA1 3NG, UK

Abstract

Study objective: The aim of the study was to determine if there is a clinically significant difference in the performance (Ease of insertion, manipulations, ventilator performance, leak pressures and complications) of two second generation supraglottic airways (LMA ProSeal® (Intavent Direct, UK) and the i-gel® (Intersurgical, Wokingham, UK) in non-paralysed European patient population group, during routine anaesthesia with spontaneous and controlled ventilation.

Methods: Ninety-eight American Society Anaesthesiologists physical status class I-III patients, undergoing elective surgical procedures, judged suitable for general anaesthesia with a classic LMA were recruited for the trial. Patients were randomised to have either the LMA ProSeal® or the i-gel® group as the supraglottic airway for spontaneous and controlled ventilation during routine anaesthesia prior to induction.

Measurements: The primary outcome was first attempt insertion success and time to insertion of either the LMA ProSeal® or i-gel®. Secondary outcomes were, ease of insertion, manipulations to establish patent airway, fibre optic view of larynx, complications during anaesthesia, emergence, recovery, and anaesthetist assessment of device performance.

Results: First time insertion success rate was 86% in the LMA ProSeal® group and 78% in the i-gel® group (P=0.61). The number of insertion attempts did not differ between the two groups (P=0.31). The ease of insertion (P=0.64), time to establish a patent airway (P=0.06), number of manipulations (P=0.97) and anatomical positioning of the device (P=0.36) and ventilator performance were similar between the two groups. The number of patients reporting post-operative sequelae and the total number of complications were similar between devices in recovery (P=0.72) and at 24 hours (P=1.0). The leak pressure was significantly higher in the group LMA ProSeal® (28 cmH_2O) compared to i-gel® (22 cmH_2O) (P=0.002).

Conclusion: The LMA ProSeal® and i-gel® have comparable performance characteristics during routine general anaesthesia in non-paralysed patients. The LMA ProSeal® has a higher airway seal that is statistically significantly different and may be clinically important.

Keywords: ProSeal® LMA; i-gel® LMA; Anaesthesia; Insertion; Ventilation

Introduction

The LMA ProSeal® (Intavent Direct, Maidenhead, UK) is a reusable supraglottic airway device (SAD) with both an airway lumen and a drain tube. It achieves high-pressure seals for both the airway and the oesophagus [1,2]. The drain tube reduces gastric inflation and enables drainage of regurgitant matter or decompression of the stomach. The median airway seal is above 30 cm H_2O [1]. The LMA ProSeal® is a reliable device for airway maintenance and ventilation of the lungs [1].

The i-gel® (Intersurgical, Wokingham, UK) is a single use SAD made of a medical grade thermoplastic elastomer. It also has a drain tube running alongside the airway tube. The mask design aims to achieve easy insertion and stability once inserted, effective airway and oesophageal seals and avoidance of compression and trauma to the airway [3,4]. The i-gel® has a lower airway seal and oesophageal seal than the LMA ProSeal® [2,3]. Both devices have design features intended to reduce the risk of aspiration of gastric contents and can be regarded as second generation SADs [5].

There are a number of comparisons of the two devices in various clinical settings [6-13]. Each of these provides some information on specific aspects of performance however there are limitations to each study. No other study has compared the two devices during both controlled and spontaneous ventilation in non-paralysed patients. We designed this study to evaluate the LMA ProSeal® and i-gel® performance using standard insertion techniques in non-paralysed patients undergoing controlled and spontaneous ventilation anaesthesia in a European setting.

Method

The study was approved by the Institutional Review Board Local

***Corresponding author:** Bosley NJ, Department of Anaesthesia, Royal United Hospital, Coombe Park, Bath BA1 3NG, UK, Tel: +447989669329; E-mail: nicolabosley@yahoo.co.uk

Received July 21, 2014; **Accepted** November 04, 2014; **Published** November 14, 2014

Citation: Bosley NJ, Burrows LA, Bhayani S, Nworah E, Cook TM (2014) A Randomised Comparison of the Performance of ProSeal® Laryngeal Mask Airway with the i-gel® for Spontaneous and Controlled Ventilation during Routine Anaesthesia in European Population. J Anesth Clin Res 5: 459. doi:10.4172/2155-6148.1000459

Research Ethics Committee at The Royal United Hospital Bath in February 2007 (Prior to clinical trial registration date, therefore no registration number). All patients were given an information leaflet and face-to-face explanation of the study with the opportunity to ask questions prior to giving written consent.

We studied American Society of Anaesthetists physical status 1-3 patients judged suitable for classic LMA® (cLMA) anaesthesia undergoing elective surgery in the supine or lithotomy position. Patients were randomised to anaesthesia with either the LMA ProSeal® or i-gel® by selection of a pre-shuffled sealed opaque envelope.

All patients had a pre-operative assessment including an airway assessment prior to anaesthesia. Exclusions included pathology of the cervical spine, upper respiratory or alimentary tract, increased risk of gastric reflux or pulmonary aspiration, body mass index >40 $kg.m^{-2}$ or any contraindications to use of a cLMA. All anaesthetists had experience of inserting both LMA ProSeal® and i-gel® SAD in manikins and patients. They were required to have inserted at least 10 of each device in clinical practice before recruitment started.

On arrival in the anaesthetic room the patient was allocated to either the i-gel® or LMA ProSeal® group by randomly selecting and opening a numbered sealed opaque envelope containing the name of the device to be used. The envelopes had been shuffled three times before numbering them prior to commencement of the trial.

Standard monitoring equipment (Electrocardiogram, pulse oximeter, blood pressure cuff) as recommended by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines were in place prior to induction of anaesthesia [14]. A firm pillow was placed under the patient's occiput and they were pre-oxygenated with 100% oxygen. Anaesthesia was induced with intravenous fentanyl 1 μg/kg followed by a dose of propofol 2-4 mg/kg and maintained using Sevoflurane at MAC values 1-1.5 in a mixture of air and oxygen achieving FiO_2 of 0.4, through a circle anaesthetic circuit. Once the patient was anaesthetised, adequacy of depth of anaesthesia for SAD insertion was determined by the absence of response to jaw thrust [15].

The manufacturer's guidelines were followed for sizing and insertion method of each device [16,17]. For the LMA ProSeal® a size 5 was used in males >70 kg, size 4 in males or females 50-70 kg and size 3 in females 40-50 kg. The LMA ProSeal® cuff was inflated to a pressure of 60 cmH_2O after insertion. A size 4 i-gel® was used in most cases except for patients weighing <50 kg or >90 kg. A different size of either SAD could be chosen if judged clinically indicated.

Once the airway was inserted it was connected to the breathing system, and the adequacy of manual ventilation was judged by observation of chest movement, capnography, airway pressure waveforms and spirometry. The number of attempts at insertion to achieve an adequate airway was recorded. After up to three failed attempts at insertion the anaesthetist was able to use the other study device once or to withdraw the patient from the study as judged appropriate. Once inserted the SAD was secured by tying.

Insertion

The ease of insertion was evaluated:

- Easy: single pass without manipulations or significant resistance
- Slight difficulty: single pass with up to 2 manipulations or 1 complication
- Difficult: ≥ 2 attempts or >2 manipulations or >1 complication
- Impossible: three failures

The need for, and number of, predefined manipulations (additional jaw thrust, chin lift, head extension or flexion, in/out movements) were recorded.

The presence and number of predefined complications of insertion were recorded at insertion (soft tissue damage, dental damage, bleeding, loss of airway, hypoxia (SpO_2<92%), failure to establish or maintain airway, regurgitation, aspiration, laryngospasm, wheeze, hiccough, gagging, coughing, stridor, gross movement, other).

Time for insertion was taken from the first point of removal of the facemask to the point at which the breathing system was attached to the airway device. Time was recorded in seconds using the timer on the anaesthetic machine. If multiple attempts were required to achieve an adequate airway the timer kept running between attempts so as to measure the total time taken to secure the airway. Maximum time allowed was 120 seconds. Failed insertions were recorded as taking 120 seconds.

Adequacy of controlled ventilation

Volume controlled ventilation using the Datex AS2 anaesthetic machine, was started with an inspired tidal volume of 7 $ml.kg^{-1}$, inspiration: expiration ratio of 1:2 and respiratory rate of 10-14 per minute to maintain normocapnia. Tidal volume could be increased up to a maximum of 10 $mg.kg^{-1}$ if required. Successful ventilation was judged to have been achieved when the following criteria were met:

- Adequate bilateral chest inflation
- An expired tidal volume of 7 $ml.kg^{-1}$
- Stable oxygenation as measured by pulse oximetry
- A square wave capnograph

The quality of the airway was recorded as clear, partially obstructed or obstructed. Once the tests of controlled ventilation were completed the patient was allowed to breathe spontaneously.

Airway position

Airway position was confirmed by

- Inspection of the front of the neck (symmetrical bulging on insertion) and the device (adequate depth of insertion absence of axial rotation)
- Adequacy of lung ventilation
- Fibre optic inspection via the SAD with the view recorded with the tip of the fibrescope positioned at the entry to the device bowl, without manipulation of the scope. The view recorded on a scale of 1-4 [18] grade 1, clear view of vocal cords; grade 2 only arytenoids visible; grade 3 only epiglottis visible; grade 4 no laryngeal structures visible.

Airway leak pressure

Airway leak pressure was tested with fresh gas flows set at 5 $l.min^{-1}$ and the adjustable pressure leak valve closed to 40 cmH_2O. The airway pressure was monitored until it plateaued and the seal pressure was recorded. Airway pressure was not allowed to rise above 40 cmH_2O.

Leak pressures were classified as follows

- Excellent, no air leak at airway pressure >20 cmH_2O

- Good, air leaked between 12-20 cmH_2O
- Poor, air leaked below 12 cmH_2O
- Failure, failed insertion or failed ventilation

Maintenance

The duration of anaesthesia (induction to end of surgery) was recorded in minutes. The need for, and number of, airway manipulations (as defined above) or airway complications during maintenance (as defined above) was recorded. The patency of the airway during maintenance was recorded (patent, partially obstructed, intermittent obstruction, continuous obstruction) as defined clinically by the anaesthetist. The lowest oxygen saturation during the procedure was recorded.

Emergence and recovery

At the end of the operative procedure sevoflurane was discontinued. The patient was recovered in the supine position and recovery staff removed the airway device once the patient had regained consciousness in the recovery room. The presence and number of airway complications during emergence (as defined above) was recorded. Recovery staff documented visible blood on the device, excess secretions and whether the device was well tolerated up to the point of removal. Any complications of removal (predefined) were also recorded.

Post-operative sequelae

Each patient was seen in recovery or within an hour of emergence and the presence of sore throat, dysphonia, and numbness of tongue or oropharynx elicited by structured questionnaire. Each confirmed complication was graded by the patient as mild, moderate or severe. The same procedure was repeated at 24 hours, if necessary by telephone.

Anaesthetist assessment of performance

For each device used, the anaesthetist recorded their subjective opinion of i) the quality of the airway during maintenance, ii) ease of hands free anaesthesia and iii) overall usefulness of device in this patient, each judged on a 5-point Likert scale from inadequate to excellent.

Statistical analysis

The study was initially planned to be larger than that which was performed: a power analysis based on a first time insertion success rate for the LMA ProSeal® of 99% and powered to detect a reduction in success rate to 70% with a power of 80% and a type 2 error of 5% led us to plan to study 204 patients [19]. However due to slow recruitment the study was curtailed at 100 patients. Statistical analysis was performed using the Analyse-it (Leeds University, UK, 2012). All analyses included only those devices still in use at that stage of assessment: e.g. all devices were included for assessment for insertion success but only those successfully inserted for performance after insertion etc. All device failures were recorded as having taken 120 seconds for insertion and as 'inadequate' for subjective assessments of performance. Secondary devices used after failure of the primary device were not analysed. All 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) of Chi^2 testing (2×>2 tables) as appropriate. All tests were two sided and statistical significance was denoted by P>0.05.

Results

One hundred patients were studied: two data collection forms were incomplete and were excluded. A total of 98 patients were included in the study. The patient characteristics were similar between the groups and are shown in table 1. Patients for whom the LMA ProSeal® was used were a little heavier than those for whom an i-gel® was used and insertion was less frequently performed by a consultant.

Insertion and ventilation

First time insertion success rate was LMA ProSeal® 86% and i-gel® 78% (P=0.61) and the number of insertion attempts did not differ between groups (P=0.31). Overall insertion success after three attempts (LMA ProSeal® 98%, i-gel® 91%) did not differ between groups (P=0.3). There were four failures in the i-gel® group and one in the LMA ProSeal® group. Of the four failures in the i-gel® group two size 4 i-gel® had large leaks when gentle manual ventilation was applied: no size 5 i-gel® was available at the time. In one i-gel® failure both a size 4 and size 3 i-gel® failed before a patent airway was established using a LMA ProSeal® size 4. One PLMA insertion failed despite three airway manipulations to correct the position and a size 4 i-gel® was successfully used as an alternative airway (Table 2).

Both devices performed well in measures of ease of insertion (no or minimal resistance LMA ProSeal® 94%, i-gel® 89%, p=0.64) and time taken to establishing a patent airway (mean time LMA ProSeal® 12 seconds, i-gel® 17 seconds, P=0.06). The number of manipulations required to establish a patent airway was similar between the groups (LMA ProSeal® 24 in 21 patients, i-gel® 22 in 16 patients, P=0.97). There were no reported complications of insertion in either group.

Both airway devices achieved good quality airway in all patients after successful insertion. The fibre optic view down the device did not differ between groups either via the airway tube (p<0.36) or the drain tube (P=1.0). A grade 1 view of the larynx was seen via 78% of LMA ProSeal® and 85% of the i-gel®.

The four tests of ventilation – chest movement, tidal volume >7 $ml.kg^{-1}$, stable oxygenation and normal capnography - were achieved in 100% LMA ProSeal® group and 95% in the i-gel® group. There was no statistical difference between the two devices with respect to individual measures of adequacy of ventilation (all P>0.4) or overall performance

	i-gel® (n=47)	LMA ProSeal® (n=51)
Specialty of surgery		
Orthopaedics	25	21
General	13	16
Gynaecology	6	6
Urology	3	7
ENT	0	1
Duration; mins	45 (30-61) [12-160]	40 (29-58) [10-123]
Patient		
Gender f:m	26: 21	23:28
Age; yrs	45.5 (34-63.5) [17-88]	46.5 (37.3-61) [19-77]
Weight; kg	72 (65-80) [50-97]	79 (69.5-89) [41-115]
Height; m	1.7 (1.63-1.75) [1.5-1.88]	1.72 (1.63-1.8) [1.5-1.97]
BMI; $kg.m^{-2}$	25.6 (23.0-27.5) [20-38]	26.7 (23.6-30) [16.5-40.3]
ASA 1:2:3:not stated	31:13:1:1	31:16:2:2
Mallampati class: 1:2:3:4	27:18:2:0	22:21:8:0
Anaesthetic variables		
Size of device 3:4:5	4:33:10	3:26:24
Grade of anaesthetist; consultant: other	9:38	2:49

Table 1: Patient and procedure details.

	i-gel® (n=47)	LMA ProSeal® (n=51)	P value
Insertion			
Extra propofol	6	8	0.9
Insertion attempts; 1:2:3	37:8:2	43:4:4	0.31
Success: failure	43:4	50:1	0.31
Ease of insertion; 1:2:3	42:1:4	48:1:2	0.64
Time for insertion; seconds	17 (10-39) [4-240]	12 (8-23.5) [5-120]	0.057
Total manipulations needed (patients)	22 (16)	24 (21)	0.97
Complications of insertion (patients)	0 (0)	0 (0)	1.0
Initial airway			
Quality of airway (Good: poor: inadequate)	43:0:0	50:0:0	1.0
Fibreoptic laryngeal view; 1:2:3:4	40:2:0:1	40:5:1:0	0.36
Fibreoptic drain tube view; mucosa: other	43:0	46:0	1.0
Ventilation			
Chest movement; yes: no	42:1	47:0	0.96
Vt>7 ml.kg^{-1} ; yes: no	41:2	47:0	0.45
Stable oxygenation; yes: no	43:0	47:0	1.0
Normal capnography; yes: no	43:0	47:0	1.0
All measures of ventilation good; yes:no	41:2	47:0	0.45
Leak pressure, cm.H_2O	22 (17-24) [6-37]	28 (22-32) [11-40]	0.002*
Maintenance			
Manipulations required (patients)	1 (1)	1 (1)	1.0
Quality of airway; patent; intermittent obstruction; obstructed	43:0:0	47:0:0	1.0
Lowest oxygen saturation	98 (97-98) [90-99]	98 (97-99) [94-100]	0.75
Complications (patients)	1 (1)**	0 (0)	0.96
Failure (patients)	1 (1)	0 (0)	0.96
Overall failures	5	1	0.17
Emergence and removal			
Not tolerated during emergence; yes: no	1	0	0.91
Problems with secretions; yes: no	1	2	1.0
Blood on the airway:	1	2	1.0
Complications at removal (patients)	1 (1) ***	0 (0)	0.91

*Mean difference 6 cm.H_2O (95% confidence interval 3.0-9.0 cmH_2O)

**patient intubated because of laryngospasm

***analysed by number of patients experiencing complication

Table 2: Device performances.

(p=0.45) Airway leak pressure was higher in the LMA ProSeal® group (LMA ProSeal® 28 cm.H_2O, i-gel® 22 cm.H_2O, difference 6.0 cm.H_2O, 95% confidence interval 3.0-9.0 cmH_2O, P=0.002).

Maintenance

During maintenance of anaesthesia one LMA ProSeal® group and one i-gel® group required manipulation to re-establish a patent airway. One i-gel® was removed due to laryngospasm and the patient was intubated. There were no other complications reported at this stage (Table 2).

Emergence and recovery

Both devices were tolerated well during emergence with just one of 43 in the i-gel® group and none in the LMA ProSeal® group being poorly tolerated prior to removal and only one complication during removal (with an i-gel®) (both P=0.91). Two in the LMA ProSeal® group and one in the i-gel® group (P=1.0) were noted to have excessive secretions and the same numbers to have blood on the airway but these did not cause any problems (Table 2).

Post-operative sequelae

The number of patient experiencing post-operative reported complications were similar in recovery (22% LMA ProSeal® group and 26% i-gel® group) and at 24 hours (22% in LMA ProSeal® group and 21% in i-gel® group). All were rated mild (>80%) or moderate (>20%) except one severe sore throat at 24 hours in the i-gel® group. There was no statistically significant difference in the number of patients experiencing complications in the initial recovery period or the severity of complications. Similar numbers in each group complained of mild or moderate sore throat in recovery (P=1.0) and similar but smaller numbers at 24 hours (6 (12%) in LMA ProSeal® group, 5 (12%) in the i-gel® group, P=0.4). The number of patients reporting complications and the total number of complications were similar for each device in recovery (all p>0.57) and at 24 hours (all p>0.4) (Table 3).

Anaesthetist assessment of performance

There was no statistically significant difference in the anaesthetists' ratings between devices, though there was numerical superiority in the LMA ProSeal® group. LMA ProSeal® of which 98% were used for the whole case, were rated as performing excellently in 92-98% of measures. I-gel® of which 89% were used for the whole case, were rated as performing excellently in 77-83% of measures (Table 4).

Discussion

Overall this study has shown notable similarity in performance and post-operative sequelae between these two second generation SADs. Both devices performed well achieving: close to 90% overall insertion success: >90% easy insertion; 100% of airways rated 'good' after insertion; >90% sited directly over the larynx: >95% optimal ventilation: <5% intraoperative failures: minimal complication rates during insertion, maintenance or removal; and low rates of post-operative sequelae, almost all of which were mild in nature. These results are consistent with many other studies and suggest the performance of the researchers was broadly consistent with experts [1,3,20,21]. Both devices performed safely. There were no episodes of gastric inflation, regurgitation or aspiration.

Our primary outcome measure was insertion success on first attempt and this was similar in both groups (i-gel® 78%, LMA ProSeal® 86%) and not statistically significant. We recruited fewer patients than intended: assuming our findings are extrapolated to a larger sample, had we recruited our intended sample size (n=204) the difference in insertion success rate would still not be statistically significant (Fisher test P=0.37). Indeed had we studied 500 patients with the same proportionate results the observed difference remains statistically non-significant (Fisher test P=0.14).

The only statistically significant difference between performances of the two devices was that the LMA ProSeal® achieved a significantly higher airway leak pressure than the i-gel®. The difference of 6 cm.H_2O (95% CI 3.0-9.0) is potentially clinically significant as the better seal allows higher tidal volumes with less gas leak. This is particularly important in the setting of an increasingly obese population, and is consistent with other studies of non-paralysed patients [6].

We are aware of eight other studies comparing the LMA ProSeal® and i-gel®. Six of the studies were performed on Asian populations [7-10,12,13]. Patients in these studies are notably smaller than the patients studied in the current study (mean weight 60 kg vs approx. 80 kg). In four of these studies the patients received neuromuscular blockade [7-9,12]. Overall these Asian studies show either slightly faster, more

	i-gel® (n=42)	LMA ProSeal® (n=50)	P value
In recovery			
Sore throat; none: mild: moderate: severe	33:7:2:0	41:8:1:0	0.75
Other complication; none: mild: moderate: severe	35:3:2:1	45:5:1:0	0.57
Total number of complications	15	15	0.72
Number of patients experiencing complication; 0:1:2:3	31:9:2:0	39:8:2:1	0.74
At 24 hours			
Sore throat; none: mild: moderate: severe	37:3:1:1	44:6:00	0.40
Other complication: mild: moderate: severe	36:3:2:1	42:5:3:0	0.69
Total number of complications	11	14	1.0
Number of patients experiencing complication; 0:1:2:3	31:7:2:0	39:9:1:1	0.70

'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.

	i-gel® (n=47)	LMA ProSeal® (n=51)	P value
Quality of airway during maintenance	39:0:2:1:5	47:1:0:0:1	0.055
Quality of hands free anaesthesia	38:1:3:0:5	49:1:0:0:1	0.08
Overall quality of airway device	36:3:2:1:5	48:2:0:0:2	0.11

All rated excellent: good: fair: poor: inadequate

Table 4: Anaesthetists' subjective assessments of performance.

reliable and less traumatic insertion of the i-gel® than the LMA ProSeal®, [8,10,13] or close equivalence [7,9,12]. Several of the studies are small in size, [12] or study only limited aspects of performance [7]. Most studies report a higher airway leak pressure in the LMA ProSeal® group [7-10,12]. In one study showing superior performance of the i-gel® the intracuff pressure of the LMA ProSeal® was allowed to rise to >90 cmH_2O (more than 50% above the manufacturer's recommendation) and high rates of difficulty passing a gastric tube raises the possibility of incorrect placement [1]. In one study the statistical results do not appear to be reproducible [8].

There are only two studies comparing the LMA ProSeal® and i-gel® in a non-Asian setting. Both studies used a non-standard insertion technique [22]. Gasteiger et al. studied 151 patients in an combination of European and Australian settings and compared insertion characteristics when LMA ProSeal® and i-gel® were inserted using a laryngoscope and gastric tube guided technique [6]. They reported very high first attempt insertion success rates (LMA ProSeal® 99%, i-gel® 97%) and very similar performance characteristics between devices [6]. Oropharyngeal seal pressure was 7 $cm.H_2O$ higher in the LMA ProSeal® group. Van Zundert et al., studied 150 patients in a European setting (50 each LMA ProSeal®, i-gel® and Supreme LMA) using the same insertion technique [11]. LMA ProSeal® and i-gel® performance were entirely equivalent during insertion and spontaneous breathing anaesthesia.

The current study therefore adds to the literature in a number of ways. It is the first evaluation of LMA ProSeal® and i-gel® using standard insertion techniques in a European setting. Second, as it was performed in non-paralysed patients its results will be applicable to the commonest setting in which these devices are used. Third, it is arguably the most thorough of all similar studies, examining and comparing performance between devices at all phases of anaesthesia and into recovery. It therefore provides a usefully broad examination of overall performance in a pragmatic clinical setting. Finally, as 90% of all device insertions were performed by trainee anaesthetists and the results are in line with similar studies, they are likely to be widely reproducible.

The LMA ProSeal® and i-gel® have some structural differences and performance characteristics that were not studied in the current study. The LMA ProSeal® not only has a higher oropharyngeal leak pressure than the i-gel® but also a notably higher oesophageal leak pressure [23]. This may provide greater protection against regurgitation progressing to aspiration, though provided the drain tube performs its function this risk should be mitigated [2].

Notwithstanding the fact we did not study as many patients as we intended, the study was not (and was not designed to be) powered to reliably detect clinically important differences in many of our secondary outcomes. For most outcomes, particularly performance once inserted quality of emergence and post-operative sequelae the results are as similar between groups as to suggest that even a considerably larger study would not show statistically significantly different performance. However there are several outcomes in which the LMA ProSeal® was numerically favoured and these include attempts at insertion, number of failures of insertion and subjective assessments of performance. None of these comparisons were statistically significant [24].

A larger trial or meta-analysis of multiple studies might further explore potential differences, which might be clinically relevant.

Two of the i-gel® failures were the result of air leaking around the device; both were size 4.0 i-gel® at a time when alternative sizes were not immediately available. The manufacturer recommends that an alternate size be tried if there is a poor airway seal. Inadequate (light) anaesthesia is always a potential cause of insertion failure and the larger second generation SADs may need higher doses of drug to facilitate insertion than the cLMA [1].

There are several limitations to this study. First as described above we did not recruit as many patients as originally intended. Of note our study included as many patients in each group as all other comparable studies with the exception of van Zundert et al., which only studied insertion success [11]. Second it could be argued that we should have used a laryngoscope and gastric tube guided insertion technique, as this maximises correct positioning. This technique is more invasive than standard insertion techniques, is necessary only in <1% of LMA ProSeal® insertions and is not routine practice for most SAD users. On two occasions lack of alternative sizes of i-gel® prevented an attempt with an alternative size after initial failure (with the manufacturer's recommended size). We can only speculate whether additional attempts would have been successful. Finally, like all such studies the study was not, and could not be, blinded.

In conclusion we have conducted a rigorous comparison of the LMA ProSeal® and i-gel® in a European population without muscle relaxation during both spontaneous and controlled ventilation. Performance of the two devices has been very similar. The study confirms the improved airway seal achieved with the LMA ProSeal®.

Declaration of Interests

Dr Tim Cook has been paid (>5 years ago) for lecturing for the LMA Company and Intavent Orthofix who, distributed laryngeal mask airways. The department has received free or at cost airway equipment for evaluation or research from Intavent Orthofix and Intersurgical (who respectively make the LMA ProSeal® and i-gel®) and other companies. None of the equipment used in this study was gifted.

Acknowledgement

Anaesthetics Department at Royal United Hospital Bath who funded the trial. Dr Tim Cook who designed the study and assisted with statistical review and manuscript preparation.

References

1. Cook TM, Lee G, Nolan JP (2005) The ProSeal laryngeal mask airway: a review of the literature. Can J Anaesth 52: 739-760.
2. Schmidbauer W, Bercker S, Volk T, Bogusch G, Mager G, et al. (2009) Oesophageal seal of the novel supralaryngeal airway device I-Gel in comparison with the laryngeal mask airways Classic and ProSeal using a cadaver model. Br J Anaesth 102: 135-139.
3. Gatward JJ, Cook TM, Seller C, Handel J, Simpson T, et al. (2008) Evaluation of the size 4 i-gel airway in one hundred non-paralysed patients. Anaesthesia 63: 1124-1130.
4. Wharton NM, Gibbison B, Gabbott DA, Haslam GM, Muchatuta N, et al. (2008) I-gel insertion by novices in manikins and patients. Anaesthesia 63: 991-995.
5. Cook T, Howes B (2011) Supraglottic airway devices: recent advances. Cont Ed Anaesth Crit Care & Pain 11: 56-61.
6. Gasteiger L, Brimacombe J, Perkhofer D, Kaufmann M, Keller C (2010) Comparison of guided insertion of the LMA ProSeal vs the i-gel. Anaesthesia 65: 913-916.
7. Sharma B, Sehgal R, Sahai C, Sood J (2010) PLMA vs. I-gel: A Comparative Evaluation of Respiratory Mechanics in Laparoscopic Cholecystectomy. J Anaesthesiol Clin Pharmacol 26: 451-457.
8. Singh I, Gupta M, Tandon M (2009) Comparison of Clinical Performance of I-Gel with LMA-Proseal in Elective Surgeries. Indian J Anaesth 53: 302-305.
9. Shin WJ, Cheong YS, Yang HS, Nishiyama T (2010) The supraglottic airway I-gel in comparison with ProSeal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. Eur J Anaesthesiol 27: 598-601.
10. Chauhan G, Nayar P, Seth A, Gupta K, Panwar M, et al. (2013) Comparison of clinical performance of the I-gel with LMA proseal. J Anaesthesiol Clin Pharmacol 29: 56-60.
11. Van Zundert TC, Brimacombe JR (2012) Similar oropharyngeal leak pressures during anaesthesia with i-gel, LMA-ProSeal and LMA-Supreme Laryngeal Masks. Acta Anaesthesiol Belg 63: 35-41.
12. Jeon WJ, Cho SY, Baek SJ, Kim KH (2012) Comparison of the Proseal LMA and intersurgical I-gel during gynecological laparoscopy. Korean J Anesthesiol 63: 510-514.
13. Hayashi K, Suzuki A, Kunisawa T, Takahata O, Yamasawa Y, et al. (2013) A comparison of the single-use i-gel with the reusable laryngeal mask airway Proseal in anesthetized adult patients in Japanese population. Masui 62: 134-139.
14. Association of Anaesthetists of Great Britain and Ireland (2007) Recommendations for standards of monitoring during anaesthesia and recovery, (4th Edn) London: AAGBI.
15. Drage MP, Nunez J, Vaughan RS, Asai T (1996) Jaw thrusting as a clinical test to assess the adequate depth of anaesthesia for insertion of the laryngeal mask. Anaesthesia 51: 1167-1170.
16. ProSeal LMA instruction Manual.
17. I-gel how to use.
18. Verghese C, Berlet J, Kapila A, Pollard R (1998) Clinical assessment of the single use laryngeal mask airway--the LMA-unique. Br J Anaesth 80: 677-679.
19. Fleiss JL, Tytun A, Ury HK (1980) A simple approximation for calculating sample sizes for comparing independent proportions. Biometrics 36: 343-346.
20. Theiler L, Gutzmann M, Kleine-Brueggeney M, Urwyler N, Kaempfen B, et al. (2012) i-gelâ„¢ supraglottic airway in clinical practice: a prospective observational multicentre study. Br J Anaesth 109: 990-995.
21. Cook TM, Gibbison B (2007) Analysis of 1000 consecutive uses of the ProSeal laryngeal mask airway by one anaesthetist at a district general hospital. Br J Anaesth 99: 436-439.
22. Brimacombe J, Keller C, Judd DV (2004) Gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway is superior to the digital and introducer tool techniques. Anesthesiology 100: 25-29.
23. Brimacombe J, Irving S, Keller C (2004) Ease of placement of LMA Proseal with a gastric tube inserted. Anesth Analg 2004 98: 1817.
24. Gibbison B, Cook TM, Seller C (2008) Case series: Protection from aspiration and failure of protection from aspiration with the i-gel airway. Br J Anaesth 100: 415-417.