Similar oropharyngeal leak pressures during anaesthesia with i-gel™, LMA-ProSeal™ and LMA-Supreme™ Laryngeal Masks

T. C. R. V. VAN ZUNDERT (*) and J. R. BRIMACOMBE (**)
the guided insertion technique is more frequently successful at first attempt than the digital technique without increasing insertion time or airway trauma.

In the following randomised, non-crossover three-way study, we tested the hypothesis that there are differences in performance among three EADs during spontaneous breathing anaesthesia. Our primary aim was to measure the oropharyngeal leak pressure. Secondary variables tested were the ease and success of the guided-insertion technique, effective airway time and anatomical position of the EAD.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Manufacturing specifications of i-gel, LMA-ProSeal and LMA-Supreme</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inventor</strong></td>
<td>i-gel®: Dr. Muhammed Nasir</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Intersurgical Ltd Wokingham Berkshire UK</td>
</tr>
<tr>
<td><strong>Use</strong></td>
<td>Single-use</td>
</tr>
<tr>
<td><strong>Manufacturing recommendations for choice of EAD size 3/4/5 based on weight</strong></td>
<td>30-60 kg / 50-90 kg / &gt; 90 kg</td>
</tr>
<tr>
<td><strong>Insertion Technique</strong></td>
<td>Not necessary to insert fingers into mouth</td>
</tr>
</tbody>
</table>

**Cuff**
- **cuff material**
  - i-gel®: Medical grade transparent thermoplastic elastomer SEBS (styrene ethylene butadiene styrene) with a soft durometer and gel-like feel
  - LMA-ProSeal®: Silicone
  - LMA-Supreme®: Clear medical grade polyvinyl chloride

- **inflatable cuff**
  - i-gel®: Absent
  - LMA-ProSeal®: Yes, enlarged high seal cuff with posterior extension
  - LMA-Supreme®: Enlarged inflatable cuff, highly airway seal cuff, reinforced tip

**Airway Tube**
- **form tube**
  - i-gel®: Curved longitudinally semi-rigid stem
  - LMA-ProSeal®: Straight/Flexible
  - LMA-Supreme®: Firm anatomical shaped semi-rigid fixed curved tube

- **cross section**
  - i-gel®: Elliptical
  - LMA-ProSeal®: Circular
  - LMA-Supreme®: Elliptical

- **airway channels, n**
  - i-gel®: 1 central
  - LMA-ProSeal®: 1 central
  - LMA-Supreme®: 2 lateral

- **likelihood accidental axial rotation tube**
  - i-gel®: Less likely
  - LMA-ProSeal®: More likely
  - LMA-Supreme®: Less likely

- **channel length**
  - i-gel®: 192 mm
  - LMA-ProSeal®: 155 mm
  - LMA-Supreme®: 150 mm

- **conduit for intubation (ID tube 13 mm) size EAD/ETT**
  - i-gel®: Via FOS guided ETT size 3 – 7.0 mm ETT size 4 – 7.5 mm ETT size 5 – 7.5 mm ETT
  - LMA-ProSeal®: Via FOS guided ETT size 3 – 6.0 mm ETT size 4 – 6.0 mm ETT size 5 – 6.0 mm ETT
  - LMA-Supreme®: No direct FOS exchange possible – need for airway exchange catheter Size 3/4/5 :14/16/18 Fr NGT

- **prevention of kinking tube**
  - i-gel®: Semi-rigid stem
  - LMA-ProSeal®: Position drain tube
  - LMA-Supreme®: Lateral grooves on airway tube Reinf orced tip

- **prevention of epiglottic downfolding/ obstruction laryngeal inlet**
  - i-gel®: Yes, epiglottis blocker
  - LMA-ProSeal®: No
  - LMA-Supreme®: Yes, epiglottic fins

<table>
<thead>
<tr>
<th>Gastric drain tube for passive drainage, suctioning, venting, and passage NGT</th>
</tr>
</thead>
</table>
| **second lumen**
  - i-gel®: Lateral to airway tube size 3 ID 5 mm 12Fr gauge
  - LMA-ProSeal®: Central in airway tube size 3 ID 8 mm 18Fr gauge
  - LMA-Supreme®: Central in airway tube size 3 ID 6 mm 14 Fr gauge

| **accommodates NGT (max size)**
  - i-gel®: size 4 ID 6 mm 12Fr gauge size 5 ID 6 mm 14Fr gauge
  - LMA-ProSeal®: size 4 ID 8 mm 18Fr gauge size 5 ID 8 mm 18Fr gauge
  - LMA-Supreme®: size 4 ID 6 mm 16 Fr gauge size 5 ID 6 mm 16 Fr gauge

| **Integral Bite Block**
  - i-gel®: Rigid bite block
  - LMA-ProSeal®: Rigid bite block
  - LMA-Supreme®: Manifold with integral bite block and fixation tab

NGT: nasogastric tube FOS: Fibreoptic scope.
**METHODS**

After obtaining Ethical Committee approval and written informed consent, we studied 150 consecutive patients (American Society of Anesthesiologists grade 1-2, aged 18-80 yr) scheduled for elective peripheral or superficial surgery in the supine position expected to last more than 30 minutes. Patients were randomly allocated into equal-sized groups for airway management with the i-gel, LMA-Supreme or LMA-ProSeal. Randomization was by computer-generated tables and the randomized device was revealed by opening an opaque, sealed envelope immediately before induction. Patients were excluded if they had a predicted or known difficult airway, mouth opening < 2.5 cm, airway or upper gastrointestinal pathology, were at risk of aspiration, or had a body mass index > 35 kg.m⁻².

A standard anaesthesia protocol was followed and routine monitoring applied. Anaesthesia was in the supine position with the patient’s head on a pillow 7 cm in height. After preoxygenation for 3 min, induction of anaesthesia was with fentanyl 1 µg.kg⁻¹ iv. and propofol 2-3 mg.kg⁻¹ iv. The lungs were manually inflated via a face mask and oral airway (if required) using sevoflurane 2-3% in oxygen 100% until conditions were suitable for insertion: loss of lash reflex, jaw relaxation, apnoea and lack of movement in response to jaw thrust (7). Additional boluses of propofol 0.5 mg.kg⁻¹ i.v. were given as required until an adequate level of anaesthesia was achieved. Maintenance of anaesthesia was with sevoflurane 2-3% in air/oxygen mixture. All patients underwent manually assisted ventilation until spontaneous ventilation resumed.

The airway device was inserted using a laryngoscope-guided, gastric tube-guided technique which involved 1) priming the lubricated airway device drain tube with an appropriate-sized gastric tube such that it protruded 15 cm beyond the distal end; 2) insertion of a laryngoscope to obtain a view of the pharynx; 3) advancing the gastric tube into the oesophagus; 4) removing the laryngoscope; 5) inserting the airway device with the head and neck in the sniffing position; and 6) advancing the gastric tube into the stomach. The i-gel and LMA-Supreme were inserted using a single-handed rotational technique; the LMA-ProSeal was inserted using the index finger to press it into and around the palatopharyngeal wall. Size selection was based on weight and the devices were fixed according to the manufacturer’s instructions.

The cuff of both LMA devices was inflated with air to 60 cm H₂O. The increase in intracuff pressure was measured in both LMA masks. Oropharyngeal leak pressure was measured when the patient was apnoeic, and 30 and 60 min after induction. Oropharyngeal leak pressure was measured using the technique of static equilibrium during apnoea and audible leak during spontaneous ventilation. The following data were also collected: ease of insertion, effective airway time, anatomical position and whether gastric tube placement was successful or not. Ease of insertion was scored as follows: grade 3 – insertion at first attempt without tactile resistance; grade 2 – insertion at first attempt but with tactile resistance; grade 1 – insertion at second attempt; and grade 0 – failed insertion at second attempt. A failed attempt was defined as withdrawal of the airway device from the mouth. If insertion failed after two attempts, the patient was intubated. Effective airway time was from picking up the airway device to detection of a square wave capnograph trace. The anatomical position was determined by passing a fiberoptic scope (Karl Storz, Tuttingen, Germany) to a position 1 cm proximal to the end of the airway tube and scoring the view: grade 4 – only vocal cords seen; grade 3 – vocal cords and epiglottis seen; grade 2 – only epiglottis seen; grade 1 – epiglottis not seen; and grade 0 - failed passage of fiberoptic scope or failed insertion of the airway device. Correct placement of the gastric tube was determined by aspiration of gastric fluid or an audible noise over the stomach during injection of 15 ml air. Heart rate, mean blood pressure, oxygen saturation and end-tidal CO₂ were recorded every five minutes. Any episodes of hypoxia (SpO₂ < 90%) or other adverse events were documented.

The airway device was removed at the end of surgery when the patient opened their mouth to command. The presence of blood, gastric content and/or pathology was noted, including any mouth, lip or tongue injury. A blinded observer asked the patients about sore throat, dysphagia and dysphonia two hours postoperatively, which were graded subjectively as mild, moderate or severe.

Sample size (N = 47) was based upon a pilot study of ten patients and a projected difference of at least 20% for a type I error of 0.05 and a power of 0.8 for the following primary variables: change in oropharyngeal leak pressure during spontaneous breathing, ease of insertion, effective airway time and anatomical position. Statistical analysis was with the T and Chi Squared tests. Significance was taken as p < 0.05.

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RESULTS

There were no differences in patient or surgical data among groups (Table 2). 150 patients were studied randomized into three groups, with mean anaesthesia duration of just over an hour. 53 i-gels were used in 50 patients. In three patients a larger size i-gel had to be used due to initial airway leakage. Results on oropharyngeal leak pressure are given for 47 i-gels. There were no differences in oxygen saturation, end-tidal CO₂ or hemodynamic data among groups. Airway management data are presented in Table 3. The LMA-Supreme was easier (P < 0.05) and quicker (P < 0.01) to insert than the LMA-ProSeal and i-gel. The first attempt success rates were 80% (i-gel), 84% (LMA-ProSeal) and 100% (LMA-Supreme). Anatomical position was better for the LMA-Supreme than the i-gel (P < 0.01), but was otherwise similar among groups. Oropharyngeal leak pressures were similar among groups during apnoea (1 min) and spontaneous ventilation (at 30 and 60 min). A small, but statistically insignificant, increase in intradevice oropharyngeal leak pressure was seen when comparing apnoea with spontaneous breathing at 30 and 60 min. There was a similar, but small increase in intracuff pressure for the LMA-Supreme and LMA-ProSeal. Gastric tube placement was successful in all patients. There were no differences in secondary variables (blood staining, airway trauma or airway morbidity) among groups (Table 4).

DISCUSSION

This is the first clinical study that compared three modern EADs (i-gel, LMA-ProSeal, LMA-Supreme) with separated ventilation and gastric channels, which combine features such as a high seal cuff, gastric access and bite block, intended to facilitate ventilation, airway protection and prevention of airway obstruction, and demonstrated that they are reliable airway devices, which are easy to use, producing high efficient oropharyngeal airway leak pressures (at 1, 30 and 60 min) with a very low incidence of trauma and airway morbidity, and no indications of regurgitation or aspiration at any time.

In three instances in our study, the i-gel appeared unexpectedly too small and had to be replaced with a larger size due to an unacceptable leak, despite successful placement. This was not an error according to the manufacturing size recommendations of the i-gel, but might be due to the fact that there is an 10 kilogram overlap between sizes 3 and 4 (Table 1, i-gel column). The choice of a size of the EAD should always be considered on a weight base in conjunction with the clinical assessment of the patient’s anatomy. Patients with cylindrical necks or wide thyroid/cricoid cartilages may require a larger size i-gel than would normally be recommended on a weight basis. CATTANO et al. (8) also found 3 patients in which the i-gel showed a poor seal and had to be replaced.

Table 2

Patient Characteristics (NS)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>i-Gel® N = 50</th>
<th>LMA-ProSeal® N = 50</th>
<th>LMA-Supreme® N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Intersurgical Ltd Wokingham, UK</td>
<td>The Laryngeal Mask Company Ltd Wooburn Green Bucks, UK</td>
<td>The Laryngeal Mask Company Ltd Wooburn Green Bucks, UK</td>
</tr>
<tr>
<td>Sex, male:female ratio, n</td>
<td>11:39</td>
<td>12:38</td>
<td>13:37</td>
</tr>
<tr>
<td>Age, years</td>
<td>41 ± 14 (18-75)</td>
<td>43 ± 15 (18-80)</td>
<td>41 ± 15 (19-78)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>170 ± 9 (152-188)</td>
<td>169 ± 8 (156-185)</td>
<td>171 ± 8 (160-185)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>71 ± 14 (50-100)</td>
<td>73 ± 13 (53-109)</td>
<td>74 ± 14 (53-120)</td>
</tr>
<tr>
<td>ASA Physical Status i/ii, n</td>
<td>39/11</td>
<td>27/23</td>
<td>59/11</td>
</tr>
<tr>
<td>Maximum mouth opening, mm</td>
<td>42 ± 6 (28-51)</td>
<td>43 ± 6 (32-60)</td>
<td>43 ± 7 (31-70)</td>
</tr>
<tr>
<td>Thyromental distance, mm</td>
<td>74 ± 6 (63-86)</td>
<td>75 ± 9 (62-100)</td>
<td>77 ± 9 (55-101)</td>
</tr>
<tr>
<td>Surgery Type</td>
<td>10:15:3:22</td>
<td>18:12:0:20</td>
<td>16:17:2:15</td>
</tr>
</tbody>
</table>

Data are given as numbers, or mean ± SD (range).
Kawashima (9) had 5 patients with gas leaks and Janakiraman et al. (10) even had to replace 14 out of 50 i-gels due to leakage of gas, rather than misplacement, which was easily corrected using a larger size. In the patients with the LMA-ProSeal and LMA-Supreme, none of the devices had to be replaced.

The LMA-Supreme was easier to insert and had a shorter effective airway time than the LMA-ProSeal and i-gel. The high first attempt success rate for the LMA-Supreme was also confirmed by others (11-16). The shorter effective airway time for the LMA-Supreme was primarily related to the high first attempt success. The first attempt success rates for the LMA-ProSeal in our study was lower (84%) than reported for bougie-guided insertion in other studies (14) with a 97% first attempt success rate. Kuppusamy and Azhar (17) reported that gum elastic bougie LMA-ProSeal insertion was successful in 96.7% of the patients in the first attempt, while LMA-ProSeal insertion using the digital technique was successful in 86.7% patients. Chen et al. (18) found a 100% first attempt success rate with the LMA-ProSeal and the introduction of a stylet (Flexi-Slip™) in the drainage tube than with the introducer (86%). Gasteiger et al. (6) showed a high first attempt success rate (99%) with the duodenal tube guided LMA-ProSeal insertion technique. Studies using the LMA-ProSeal (13) have shown the bougie guided technique to be superior to digital and introducer tool insertion. The guided technique reduces impaction at the back of the mouth and directs the distal portion into the hypopharynx. The difference found with our study is probably because the gastric tube is much softer than the gum elastic bougie making it more difficult...

### Table 3
**Anaesthetic Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>i-Gel® N = 50 (*)</th>
<th>LMA-ProSeal® N = 50</th>
<th>LMA-Supreme® N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of anaesthesia, min</td>
<td>65 ± 27</td>
<td>70 ± 31</td>
<td>66 ± 37</td>
</tr>
<tr>
<td>EAD size used, 3:4:5, n</td>
<td>3:40:7</td>
<td>0:38:12</td>
<td>1:34:15</td>
</tr>
<tr>
<td>Ease of Insertion 3:2:1:0, n</td>
<td>40:7:0:3</td>
<td>42:6:2:0</td>
<td>50:0:0:0</td>
</tr>
<tr>
<td>Effective airway time, s</td>
<td>44 ± 12</td>
<td>48 ± 16</td>
<td>32 ± 6*</td>
</tr>
<tr>
<td>Oropharyngeal leak pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– At 1 min (N = 47:50:50)</td>
<td>30 ± 11</td>
<td>33 ± 7</td>
<td>32 ± 6</td>
</tr>
<tr>
<td>– At 30 min (N = 47:50:50)</td>
<td>34 ± 9</td>
<td>36 ± 5</td>
<td>35 ± 5</td>
</tr>
<tr>
<td>– At 60 min (N = 28:27:26)</td>
<td>36 ± 4</td>
<td>36 ± 5</td>
<td>38 ± 3</td>
</tr>
<tr>
<td>Intracuff pressure increase, cm H₂O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– At 1 min (N = 47:50:50)</td>
<td>9 ± 14</td>
<td>7 ± 9</td>
<td></td>
</tr>
<tr>
<td>– At 30 min (N = 47:50:50)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– At 60 min (N = 28:27:26)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– At 90 min (N = 28:27:26)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intracuff pressure increase, cm H₂O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– At 1 min (N = 47:50:50)</td>
<td>14:32:3:1:0</td>
<td></td>
<td>23:27:0:0:0</td>
</tr>
</tbody>
</table>

Data are presented as numbers, or mean ± SD.

The LMA-Supreme was easier (P < 0.05) and quicker (P < 0.01) to insert than the LMA-ProSeal and i-gel and had a better anatomical position (P < 0.01) than the i-gel.

(*) 53 i-gels were used in 50 patients. In three patients a larger size i-gel had to be used due to the initial airway leakage. Results on oropharyngeal leak pressure are given for 47 i-gels.

### Table 4
**Trauma and airway morbidity data (NS)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>i-Gel®</th>
<th>LMA-ProSeal®</th>
<th>LMA-Supreme®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood staining at time of removal, n</td>
<td>5</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Mouth, lip or tongue injury, n</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Airway morbidity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sore throat, n</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Dysphagia, n</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Dysphonia, n</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

Data are given as numbers.
to place in the oesophagus and more easily displaced during railroading. The first attempt success rate in the i-gel patients was the lowest in our study (80%). Recent independent researchers (10) found a first attempt success rate with the i-gel as low as 54%, whereas others found a varying incidence between 78% and 98% (6, 16, 19-21).

Anatomical position was better for the LMA-Supreme than the i-gel. This suggests that the epiglottis was more frequently downfolded during insertion of the i-gel. We postulate that because the i-gel cuff cannot be deflated to form a fine leading edge it is less able to slip underneath the epiglottis during passage into the pharynx.

The mean oropharyngeal leak pressures in this study were high at insertion of the i-gel (30 ± 11 cm H2O) ; the LMA-ProSeal (33 ± 7 cm H2O) and the LMA-Supreme (32 ± 6 cm H2O). Our results with the i-gel show comparable results with the mean airway leak pressure in other studies (19, 21, 23-25), although still others (6, 10, 16, 26) only obtained mean oropharyngeal leak pressures of 20 cm H2O. Our results showed the highest mean oropharyngeal leak pressures with the use of the LMA-ProSeal, similar to others (6, 12-14, 17, 19, 27-29). Our results with the LMA-Supreme were somewhat higher than those found by others (11-13, 15, 16, 24, 25, 29), although Verghese and Ramaswamy (14) and Hosten et al. (29) found identical mean airway leak pressures in the LMA-ProSeal and LMA-Supreme airways, well above those in the LMA-Classic (19). Schmidbauer et al. (30) found in cadavers, a better seal of the oesophagus with the LMA-ProSeal than with the i-gel. The mean oropharyngeal leak pressures obtained in studies using the classic laryngeal mask (10, 27, 28) or the single use extraglottic airway (LMA-Unique) (8, 23, 31) are much lower (15 to 20 cm H2O) compared to the airways evaluated in this study. In principle, the higher seal of the three tested airway devices, may make them more suitable than the more classic types of airways for positive-pressure ventilation. However, interstudy comparisons are difficult as few studies attempt to look at the seal during spontaneous breathing.

Oropharyngeal leak pressures in the tested airways in this study were similar among groups during apnoea and during spontaneous breathing. This is not surprising as intracuff pressure changes were minimal for the LMA devices and the i-gel has a fixed volume cuff. Interestingly, intradevice oropharyngeal leak pressures were similar when comparing apnoea with spontaneous breathing at 30 min and mostly similar when comparing apnoea with spontaneous breathing at 60 min. Such comparisons must be treated cautiously as the measurement techniques were different, but it does hint that pharyngeal muscle tone contributes little to the seal.

Our study has several limitations: 1) these results may only apply to the gastric tube-guided technique, as success rates may be different with other guides and when a guide is not used; 2) the devices were inserted by experienced anaesthesiologists and may not apply to less skilled personnel; 3) the study was not sufficiently powerful to compare airway morbidity among groups; and 4) most of the data were collected unblinded, a possible source of bias.

Conclusion

Since the clinical introduction of the LMA-Classic® and similarly designed EADs of the first generation, several features have been added to improve the existing airway masks, to broaden the scope of their indication and to improve their safety by raising the oropharyngeal leak pressure and separating the gastrointestinal and respiratory tracts. We conclude that the LMA-Supreme is easier and quicker to insert than the LMA-ProSeal and i-gel using a gastric tube-guided technique and is associated with better anatomical positioning than the i-gel. Oropharyngeal leak pressures are similar among devices tested, but much higher than the first generation LMA-Classic type laryngeal masks.

References

7. Drage M.P., Nunez J., Vaughan R.S., Asai T., Jaw thrusting as a clinical test to assess the adequate depth of

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anaesthesia for insertion of the laryngeal mask, ANAESTHESIA, 51, 1167-1170, 1996.