Use of second generation supra-glottic airway devices during laparoscopic cholecystectomy: a prospective, randomized comparison of LMA Proseal™, LMA Supreme™ and i-gel™.

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Abstract: Introduction: Supra-glottic airway devices (SADs) with an inbuilt drain channel, such as the LMA Proseal™ (LMA-P), LMA Supreme™ (LMA-S) and i-gel™ (i-gel), have been used for laparoscopic cholecystectomy. We compared safety, efficacy, and ease of use, as well as the incidence of adverse events between these devices.

Methods: One hundred and eighty adult, ASA 1-3 patients scheduled to undergo elective cholecystectomy under general anesthesia were randomly allocated to one of three groups: LMA-P, LMA-S or i-gel. The primary outcome was to evaluate oropharyngeal leak pressure (OLP). Secondary outcomes were to evaluate speed of insertion, ease of insertion of the device and the drain tube, as well as the incidence of intraoperative adverse events and postoperative oropharyngeal discomfort (POPD).

Results: Mean OLP was significantly higher for LMA-P (LMA-P 30.87; i-gel 29.28; LMA-S 29.02 cm H2O, P = 0.007). OLP was correlated with a higher maximum tidal achieved volume (P = 0.025). Insertion times were shorter for the i-gel, which was 1.7 s faster to insert than LMA-P (P = 0.04). The success rate on first attempt was higher for the LMA-S (P = 0.004). The drain tube was easily inserted in the LMA-S group (p < 0.001). I-gel showed higher sore throat scoring 2 hours postoperatively (P = 0.008) and reported slower POPD decrease during that time (P < 0.001).

Conclusions: Among SAD’s, LMA-S is the easiest to insert (including the drain tube), LMA-P achieved the best leak pressure, and i-gel fastest to insert, although associated with the worst POPD scoring.

Key words: Supra-glottic airway device; LMA-Proseal; LMA-Supreme; i-gel; laparoscopic cholecystectomy.
pressure and the presence of a gastric drain tube (1-4). Later devices with an inbuilt drainage channel still await a prospective evaluation in that respect. In that respect, some studies have been performed using the LMA-S (4-8), while a few researches have been reported with i-gel (5,9,10).

We conducted a prospective, randomized and controlled study on 180 patients undergoing elective laparoscopic cholecystectomy, and compared the most common SADs with a gastric access (LMA-P, LMA-S and i-gel). We aimed at evaluating their safety, efficacy, and ease of use, as well as at determining the incidence of intraoperative adverse events and postoperative sore throat, dysphagia and dysphonia.

**METHODS**

Ethical approval for this study was provided by the Local Research Ethics and Investigation Committee on the 10th of January, 2012. The trial was also registered at the EU Clinical Trials Register (EudraCT identifier: 2014-002132-13). Written informed consent from each of the study participants was obtained and 186 patients (ASA 1-3) scheduled for elective laparoscopic cholecystectomy were recruited. Exclusion criteria were age less than 18 years, ASA class 4 or higher, body mass index of more than 40 Kg m⁻², symptomatic hiatus hernia, or severe gastro-esophageal reflux disease.

Patients were assigned to each group using a computer-generated randomization list, which resulted in 60 patients in each group (LMA-S, LMA-P, and i-gel) group. Allocation concealment was maintained with opaque sealed envelopes. Four senior anesthesia registrars with skills in placing SAD took care of all cases.

The size of the devices was determined according to the manufacturer’s recommendations based on weight. For the LMA-P and LMA-S, a size 3 was chosen for patients weighing 30 to 50 Kg, a size 4 for patients between 50 to 70 Kg, and a size 5 for patients over 70 Kg (11). For the i-gel, a size 3 was used in patients between 30 and 50 Kg, a size 4 between 50 and 90 Kg, and a size 5 for patients over 90 Kg. The posterior surface of the devices was lubricated with a water-soluble lubricant, and LMA-P and LMA-S devices were completely deflated to standardize the comparison between them.

Routine monitoring devices were attached before induction of anesthesia in accordance with the recommendations of the Spanish Society of Anesthesiology and Critical Care. Patients were premedicated using midazolam 0.04 mg Kg⁻¹ and remifentanil 0.1 μg Kg⁻¹.min⁻¹ intravenously. Anesthesia was induced with patients in the supine position and head resting on a gel head pad. Pre-oxygenation was carried out for 3 minutes and anesthesia was induced using intravenous remifentanil 0.3 μg Kg⁻¹.min⁻¹ and propofol 2-3 mg kg⁻¹. No muscle relaxant was used during induction of anesthesia. Patients were manually ventilated until optimum conditions for SAD insertion were achieved (relaxation of the jaw, loss of eyelash reflex, immobility, and apnea). Additional doses of propofol were administered at the anesthetist’s discretion to optimize conditions for insertion. The devices were inserted placing the patient’s head in the “semi-sniffing” position, using a single-handed technique in case of LMA-S, and a digital technique in case of LMA-P and i-gel, as suggested by the manufacturers. The cuff pressure for inflation of LMA-P and LMA-S was 60 cm H₂O, and checked using a hand manometer. Positive pressure ventilation was established using volume-controlled ventilation (tidal volume of 8 ml Kg⁻¹, respiratory rate of 12 breaths min⁻¹, inspiration/expiration ratio of 1:1.5, and fresh gas flow of 1 L min⁻¹). Successful ventilation was defined as a square-wave tracing on the capnography, with end-tidal CO₂ (EtCO₂) values ranging from 30 to 45 mmHg and normal thoracoabdominal movements. The number of insertion attempts was recorded. Three attempts were allowed before insertion was considered a failure. In that case, endotracheal intubation was performed. The time needed for insertion was defined as the time from removing the face mask to the first valid capnography reading.

When mechanical ventilation was ineffective (maximum expired tidal volume lower than 6 mL Kg⁻¹ or EtCO₂ higher than 45 mmHg), the cuff was deflated to zero (in case of LMA-P and LMA-P) and the SAD repositioned by gentle “up and down” or lateral movements. If ventilation continued to be suboptimal or ineffective after corrective maneuvers, intubation was performed.

We introduced a Salem sump gastric tube via the drain tube (#12 for the i-gel and #16 for LMA-P and LMA-S), and ease of insertion was recorded (easy to insert, minor difficulties to insertion, difficult to insert, and impossible to insert). Finally, we secured the SAD with adhesive tape. A second anesthesiologist was present as an independent observer, to record data.

Maintenance of anesthesia was achieved using sevoflurane (2% end-tidal) in 50% oxygen/air, and
remifentanil 0.15-0.5 μg Kg⁻¹ min⁻¹. Rocuronium 0.6 mg Kg⁻¹ was given to maintain neuromuscular blockade at one twitch of a train-of-four. Once stable ventilation and anesthesia had been obtained, the oropharyngeal leak pressure (OLP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L min⁻¹. The generated airway pressure was limited to a maximum of 40 cm H₂O, for safety reasons. When an audible hiss was heard from the mouth or with a stethoscope placed on the pharynx, the corresponding pressure was recorded (12).

Ventilatory parameters were recorded from the anesthesia system Fabius® GS (Dräger Medical AG & Co.KG, Lübeck, Germany). Peak airway pressures (PWA-pk) before and after the pneumoperitoneum, in the supine position, and in the reverse Trendelenburg position, were recorded in each patient. Peritoneal insufflation pressure was set at 13 mm Hg and head-up tilt was limited to 30°.

Ventilatory variables were monitored continuously and adjusted accordingly to maintain SpO₂ > 95% and EtCO₂ < 45 mmHg. Duration of both peritoneal insufflation and anesthetic procedure were recorded.

The independent observer recorded the occurrence of eventual complications, including cough, laryngeal stridor, laryngospasm, bronchospasm, regurgitation, aspiration, and hypoxia (<90%). All the SADs were evaluated for traces of blood to assess trauma to the pharynx caused by the device. After transfer of the patients to the Postoperative Acute Care Unit (PACU), a second assessor, blinded to the allocation group, assessed the patients for postoperative pain using a verbal questionnaire which evaluated the presence of sore throat, discomfort during swallowing and hoarseness at 10 minutes (min) and 2 hours (h) after anesthesia, using a 0-10 visual analogue scale (VAS). We considered 0 = no sore throat, dysphagia or dysphonia and 10 = worst sore throat ever, total dysphagia or dysphonia. All patients received a standard postoperative analgesic regime comprising intravenous paracetamol (1 g) and dexketoprofen (50 mg).

**Statistical analysis**

Our sample size was estimated based on published data on leak pressure. Assuming a mean OLP of 25 cm H₂O for the i-gel (13), 26 cm H₂O for the LMA-S (4) and 27 cm H₂O for the LMA-P (14), with a standard deviation of 5 cm H₂O for all devices. To detect a clinically significant difference of 10% between the groups, with α = 0.05 and power of 90% using a two-sided test, 51 patients...

![Fig. 1.— Consort Flow Diagram.](image-url)
per group were needed. To allow for potential dropouts, a sample size of 60 patients per group was chosen.

The data were analyzed using SPSS Statistics software version 17 (SPSS Inc., Chicago, Illinois, USA).

Statistical analysis was performed using one way ANOVA for continuous data with post hoc Bonferroni corrections for multiple comparisons. Categorical variables were analyzed using chi-squared tests ($\chi^2$).

For postoperative sore throat/dysphagia/dysphonia, test of within-subjects effects were performed, using the Greenhouse-Geisser adjustment.

Data are mean (± SD) unless otherwise stated. A P value less than 0.05 was considered significant.

RESULTS

We recruited 186 patients and the data from six randomized patients were excluded, four of them after the surgical approach changed from laparoscopy to open surgery, and two due to protocol violation (wrong sized device; one LMA-S and one i-gel). A total of 180 patients (60 per group) were finally included in the analysis (Figure 1). Demographic data and surgical characteristics were comparable between groups (Table 1). Post hoc test values are described on some of the studied variables (Table 2).

The mean OLP in the LMA-P group was significantly higher as compared to the other groups (LMA-P 30.87 ± 2.60; i-gel 29.28 ± 3.9; LMA-S 29.02 ± 3.83 cm H2O, P = 0.007). It was 1.85 and 1.58 cm H2O higher than the one of the LMA-S and i-gel group, respectively (Figure 2).

This finding was consistent with a higher maximum tidal volume (TVm) achieved with the LMA-P as compared to the LMA-S and i-gel (584.75 ± 43.61, 557.45 ± 51.06, and 562.58 ± 41.21 ml, respectively, P = 0.025). The LMA-P volume was larger of 27.30 mL and 22.16 mL than the LMA-S and i-gel volume, respectively.

New airway leaks occurring during surgical procedure were not reported.

Median insertion times were shorter for the i-gel (10.05 ± 1.75 s) as compared with the LMA-S (11.22 ± 4.15 s), and the LMA-P (11.75 ± 2.04 s). The i-gel was inserted 1.7 s faster than the LMA-P (P = 0.04).

Success rate on first attempt was higher for the LMA-S (96.6% as compared to 71.7% with the i-gel and 71.7% with the LMA-P, P = 0.004). There were no failed insertions in either group (Figure 3).

There were important statistical differences in ease of insertion of the drain tube. It was easier in the LMA-S group as compared with the LMA-P and i-gel group (P < 0.001). Insertion of the gastric tube was successful in all cases.

There were no between-group differences regarding intraoperative complications. No episodes of laryngeal stridor, laryngospasm, bronchospasm, or hypoxia were observed. Aspiration of gastric content was defined as either the presence of

| Table 1
Demographic and surgical data

<table>
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<th>LMA-P</th>
<th>LMA-S</th>
<th>i-gel</th>
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<td>39/21</td>
<td>37/23</td>
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<tr>
<td>BMI (kg.m⁻²)</td>
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<td>Peritoneal insufflation time (min)</td>
<td>56.2 ± 18.2</td>
<td>54.9 ± 25.9</td>
<td>56.6 ± 19.1</td>
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Values are presented as mean ± SD or numbers.
At the 2-hour postoperative interview, a statistical inter-group difference regarding sore throat was identified. The patients from i-gel group experienced a higher incidence of sore throat (at that moment) than the patients from the other two groups (P = 0.008). The i-gel group suffered more sore throat than the LMA-S group (0.28 more points on the VAS scale) and the LMA-P group (0.25 more points on the VAS scale). Mean VAS scoring on sore throat was 0.25 ± 0.47 for LMA-P, 0.22 ± 0.49 for LMA-S, and 0.50 ± 0.56 for i-gel. VAS values were graded according to the following three categories: VAS = 0, VAS = 1-3, and VAS ≥ 4. Percentages obtained for LMA-S were 82%, 18%, and 0% respectively, 33%, 65%, and 0% for LMA-P, and 53%, 47%, and 0% for i-gel. Although the i-gel reached lower rates of asymptomatic patients (VAS = 0), it finally revealed to be associated with a higher rate of patients with slight sore throat (VAS = 1-3). One patient experienced dysphagia, and no dysphonia was reported.

We applied a test of within-subjects effects (using the Greenhouse-Geisser adjustment) to analyze sore throat’s evolution during the studied time. There was a significant difference regarding sore throat’s trend during this period (P < 0.001). Indeed, patients receiving the i-gel device experienced a slight downward trend with respect to OPD, as compared with the notable downward tendency’s representation in the LMA-S and LMA-P group (Figure 4).

At the time of writing, the authors were unaware of the availability of this software. The analysis was performed using a standard statistical software (e.g., SPSS, R). The authors verified the accuracy of the data and methods used in the analysis. They also provided a detailed description of the statistical methods used in the analysis, including the significance level used (e.g., P < 0.05). The authors noted that the results were preliminary and further research is needed to validate the findings.
Differences between i-gel against neither LMA-S (5) or LMA-P (10). The higher seal pressure for the LMA-P is related to its double cuff design, as compared to the single cuff design of the LMA-S. This must be seen in addition to differences in constituting materials in terms of elasticity and adaptability (silicone and PVC, respectively). The semi-rigid curved airway tube of the LMA-S could be susceptible to movements, explaining in part the reported lower OLP as compared to the LMA-P’s elastic tube (20). The LMA-P had a better OLP than the i-gel as well. In addition to a larger and inflatable cuff, a deeper bowl, the shape of the proximal wedge of the cuff, and its corresponding larger surface area may explain the differences with the i-gel.

In our study, we found that i-gel was faster to insert than the LMA-P, although no differences were shown as compared to the LMA-S. Despite significant, it must be noted that this difference has no clinical relevance.

The success rate on the first attempt was higher in the LMA-S group. Our results are similar to previously published data (7,21) that compared LMA-P and LMA-S. However, the majority studies did not report any differences between i-gel against neither LMA-S (5) or LMA-P (10). The higher seal pressure for the LMA-P is related to its double cuff design, as compared to the single cuff design of the LMA-S. This must be seen in addition to differences in constituting materials in terms of elasticity and adaptability (silicone and PVC, respectively). The semi-rigid curved airway tube of the LMA-S could be susceptible to movements, explaining in part the reported lower OLP as compared to the LMA-P’s elastic tube (20). The LMA-P had a better OLP than the i-gel as well. In addition to a larger and inflatable cuff, a deeper bowl, the shape of the proximal wedge of the cuff, and its corresponding larger surface area may explain the differences with the i-gel.

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The success rate on the first attempt was higher in the LMA-S group. Our results are similar to previously published data (7,21) that compared LMA-P and LMA-S. However, the majority studies did not report any differences. The anatomically shaped and semi-rigid airway tube of the LMA-S makes it an ideal device for easy insertion. Success rates with the i-gel and the LMA-P were rather
low as compared to other publications (4,5,21). However, our results concur with those obtained by other studies (7,13,23). It may be due to the number of i-gel size 5 used in our study (for 13 patients weighing > 90 Kg). The i-gel size 5 is a very large device, which is sometimes difficult to insert.

The drain tube was easier to insert in the LMA-S group as compared to the LMA-P and i-gel group. These findings are comparable to Lee et al.’s study, who reported a shorter insertion time of the drain tube for LMA-S as compared to LMA-P. Similar to Teoh (5) and Fernandez’s (22) studies, in which the gastric tube was also longer to insert in an i-gel group of patients as compared to LMA-S group. This can possibly be explained by the more rigid, centered, and smoother gastric drain channel of the LMA-S when compared to LMA-P. Moreover, the narrower gastric channel of the i-gel only allows introducing a smaller sized gastric tube.

With regard to postoperative adverse events, a significant proportion of the current literature focuses on sore throat, dysphagia and dysphonia, all evaluated at a precise moment during the postoperative period. In addition to those data, we looked at the oropharyngeal discomfort (OPD) evolution during the studied period. During the immediate postoperative care (10 min), patients reported equal OPD scores between groups. Our findings are similar to the results obtained by other researchers comparing LMA-S and LMA-P (7,21). Postoperative OPD evaluated 2 hours after anesthesia showed significant differences between devices. The i-gel group experienced worse sore throat than the LMA-S and the LMA-P group. Published studies did not find differences concerning sore throat or other airway morbidity signs when comparing SADs during the first two postoperative hours (7,9,20,21). To our knowledge, this is the first time a higher postoperative sore throat scoring is demonstrated for the i-gel device, when compared with the LMA-S and LMA-P. However, we consider that a mean difference of 0.28 and 0.25 points on the VAS is clinically not relevant, and only indicates that the patients had a very mild sore throat. We observed a very significant statistical difference (P < 0.001) related to sore throat during the first 2 hours in the PACU. LMA-P and LMA-S patients reported higher sore throat scores than i-gel patients immediately after the anesthetic procedure, but the cuff-less device caused more discomfort than the other two SADs after 2 hours in the recovery room. Those two observations are actually the most unexpected results of our study. They must be, however, considered as clinically not relevant.

This study has some limitations. First, the observer who measured the insertion times and events was not blinded to the type of device. To mitigate this, postoperative outcome assessors were blinded to the group assignment. Second, the anesthesiologist inserting the SAD had less experience with the i-gel than with the other two devices (i-gel was introduced in our hospital 18 months after the other SADs).

In conclusion, we demonstrated that LMA-P had a higher OLP and allowed achieving a higher TVm, as compared to the LMA-S and i-gel, in patients undergoing general anesthesia for elective laparoscopic cholecystectomy. I-gel was more rapidly placed than the other devices. The success rate of the first insertion and the ease of insertion of the drain tube were higher for the LMA-S. I-gel device showed higher sore throat scoring 2 hours postoperatively and was associated with a slower OPD decrease during the 2 hour studied period.

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