ORIGINAL ARTICLE

Comparison of the i-gel™ and the LMA Proseal™ in anesthetized patients undergoing laparoscopic cholecystectomy: a prospective, randomized clinical trial

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ABSTRACT

Background: LMA Proseal™ (LMA-P) and i-gel™ are two of the most used supraglottic airway devices (SADs) with an inbuilt drain channel. We compared these devices regarding efficacy, safety, ease of use and incidence of adverse events.

Methodology: We randomized 140 patients undergoing elective laparoscopic cholecystectomy to have either i-gel or LMA-P. We evaluated speed of insertion, success rates, ease of insertion of the drain tube, leak pressure and tidal volume. We also recorded postoperative oropharyngeal discomfort based on sore throat, dysphagia and dysphonia.

Results: I-gel had a lower leak pressure and achieves a lower tidal volume compared to the LMA-P (28.3 ± 3.3 cmH_2O versus 30.9 ± 2.6 cmH_2O; p = 0.027), as well as a lower tidal volume provided (562.6 ± 41 ml versus 584.8 ± 44 ml; p = 0.025). Insertion times were lower for i-gel compared with LMA-P (10 ± 1.7 versus 11.7 ± 2 s; p = 0.004). Insertion success rate on first attempt as well as drain tube insertion were comparable between groups. I-gel group complained about a slightly higher sore throat scoring at 2 h postoperatively (p = 0.025).

Conclusions: We found that i-gel had a lower leak pressure and achieves a lower tidal volume compared to the LMA-P in anesthetised patients undergoing laparoscopic cholecystectomy. Although i-gel was quicker to insert than LMA-P, it reported higher sore throat scoring at 2 h postoperatively.

Key words: LMA Proseal; i-gel; Laparoscopic cholecystectomy; Airway, leak pressure

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INTRODUCTION

The Laryngeal Mask Airway Classic™ (LMA-C) is the most widely studied supraglottic airway device (SAD) and since it was introduced, several devices have been incorporated in order to improve the SAD´s indications, some of them with gastric access incorporation.

A far as we know, there are seven SADs with a drain tube available in the market at this moment: Laryngeal Tube Suction™ (LTS or LTS-D if disposable), LMA Proseal™ (LMA-P), LMA Supreme™ (LMA-S), i-gel™ and recently The Guardian CPV™ , the Baska Mask™ and the Ambu AuraGain™ . LMA-P and i-gel are two of the most commonly used devices with gastric access in clinical anesthesia.

These devices are a reasonable choice when performing anesthesia for procedures accompanied by high peak airway pressure, such as laparoscopy. In addition, the drain channel helps to identify the correct tip position just after insertion.[1] Over the last ten years, some studies have been performed in order to establish the safety of SADs with gastric access for this purpose. In that sense, a number of studies have been performed with LMA-P[2,3] and LMA-S[4-7] , but we only found a few articles evaluating i-gel for laparoscopic procedures.[5,8,9]

We present a prospective and randomised study of 140 patients undergoing elective laparoscopic cholecystectomy, comparing the use of i-gel and LMA-P and evaluating in detail their safety, efficacy and ease of use. We also compared the incidence of adverse events, focused on postoperative rate of sore throat, dysphagia or dysphonia.

Our primary outcomes were to measure leak pressure, speed of insertion and success rates. Our secondary outcome was to evaluate the postoperative oropharyngeal discomfort during the patients´ stay in the Postanesthesia Care Unit (PACU).

METHODOLOGY

Local Research Ethics Committee of the Hospital Universitario del Sureste, Arganda del Rey, Madrid, Spain (Chairperson Dr. F.J. Yuste, registration number: HUSE 2012-3) approved this study on 11 October 2012. Written informed consent was obtained from all participants and recruitment ended on 10 June 2013. We prospectively randomized 140 adult patients scheduled for elective laparoscopic cholecystectomy. Patients were excluded if they presented ASA physical status 4 or higher, BMI $\geq$ 40 kg m^{-2}, severe gastro-esophageal reflux disease or known risk of aspiration.

Patients were randomly assigned using computer generation random numbers to one of the two groups, to be managed with either i-gel or LMA-P as SAD.

Midazolam 0.03 mg/kg and remifentanil 0.1 μg/kg/min intravenously were used as premedication and standard anesthetic monitoring was attached. Airway management was performed by four senior anesthesiologists experienced in the use of SADs .

After preoxygenation, anesthesia was induced with intravenous remifentanil 0.3 μg/kg/min and propofol 2-3 mg/kg. We did not use neuromuscular blocking drugs at this time. After optimum conditions for SAD insertion were achieved (relaxation of the jaw, loss of eyelash reflex and onset of apnea), either i-gel or LMA-P was introduced.

Size chosen was based on manufacturer´s recommendations according to the patient´s weight. All the devices were lubricated and the cuff of LMA-P was completely deflated.

The SADs were inserted with the patient´s head in the "semi-sniffing" position using a digital technique. The cuff of LMA-P was inflated to a pressure of 60 cmH_2O using a manometer. After insertion, the device was connected to a closed-circuit breathing system under volume-controlled ventilation (TV of 8 ml/kg, RR of 12 breaths/min, I: E ratio of 1:1.5 and fresh gas flow 3 L/min). Successful placement was defined as a square-wave tracing on the capnography with normal end-tidal CO_2 ($EtCO_2$) values. After three failed attempts, insertion was considered a failure and endotracheal intubation (ETI) was performed. The time required for successful insertion was defined as the time from removing the face mask to the first square capnogram. In case of ineffective ventilation [hypoventilation (TV < 6 ml/kg) or hypercarbia (> 45 mmHg)], despite a successful placement, the device was removed and reinserted performing correctives maneuvers. If ventilation continued ineffective after repositioning the SAD, it was considered a ventilation failure and ETI was performed.

A suction gastric tube was introduced via the drain tube (12 FG for i-gel and 16 FG for LMA-P) and ease of insertion was scored (easy to insert, minor difficulty to insertion and difficult to insert). A non-blinded observer who was not involved in the study recorded the number of attempts and time needed for the SAD´s insertion as well as ease of the drain tube´s insertion.

Anesthesia was maintained with 6% desflurane in 50% oxygen and air, remifentanil 0.15-0.5 μg/kg/min and rocuronium 0.6 mg/kg. After obtaining and effective and stable airway, leak pressure (LP) was assessed by closing the circuit and allowing a fresh gas flow of 3 L/min to built airway pressure until an audible leak was heard over the mouth (not permitted to exceed 40 cmH_2O) [10] .

Ventilatory variables were recorded before and after the pneumoperitoneum, intra-abdominal pressure was held constant at 13 mm Hg and head-up tilt was limited to 30º. Peritoneal insufflation time and anesthetic time were also recorded.

Maximum expiratory tidal volume was recorded over one minute after pneumoperitoneum was established, based on the expiratory tidal volume showed by the ventilator. This measurement corresponds to the maximum expiratory TV value observedoverthatminuteunderpneumoperitoneum condition. During emergence and removal, airway complications (laryngeal stridor, laryngospasm, bronchospasm, regurgitation, aspiration, cough or hypoxia) and the presence of blood on device were recorded. Aspiration of gastric contents was defined as either the presence of bilious secretions or particulate matter in the tracheobronchial tree. All patients were closely followed up during anesthesia period, especially when we detected regurgitation of gastric contents observed at the gastric tube. Patients also were followed up at PACU in order to find a clinically detectable pulmonary aspiration and we performed a chest radiograph to discard the presence of infiltrates when clinical suspicion.

Additionally, all patients were interviewed at 2 hours postoperatively by an assessor blinded to the allocation group, about the presence of sore throat, dysphagia and hoarseness. It was assessed using a VAS (0 = no sore throat, dysphagia or dysphonia, 10 = worst sore throat ever, total dysphagia or dysphonia).

Patients received a standard postoperative analgesic regime of dexketoprofen (50 mg) and paracetamol (1 g) IV, analgesic requirements were comparable between both groups.

Statistical analysis: Published data on leak pressure were used to calculate the necessary sample size. Assuming a mean OLP of 26 cmH_2O for the i-gel[11] and 25 cmH_2O for the LMA-P,[12] and assuming a standard deviation of 5 cmH_2O for all devices, 66 patients per group were needed to detect a clinically significant difference of 10% between the groups with 90% power ($1 - \beta = 0.90$) and a significance level of 0.05 (two tailed). A total of 146 patients were consented to account for a 9% dropout rate.

We analysed the data with SPSS version 17 (SPSS Inc., Chicago, Illinois, USA).

The distribution of data was determined using Kolmogorov-Smirnov analysis. Statistical analysis was performed with paired t test, one way ANOVA for repeated measurements and χ^2 test for nominal data. Data are mean (± SD) unless otherwise stated. A p-value less than 0.05 was considered significant.

RESULTS

We recruited 146 patients and data were excluded from six randomized patients, four of them after the surgical approach changed from laparoscopy to open surgery, one more patient for a protocol violation (wrong sized i-gel device) and in another patient (LMA-P) gastric tube could not be inserted and had to be intubated for safety reasons. The results of 140 patients (71 LMA-P and 69 i-gel) were finally analyzed

The groups were comparable for demographic and surgical data (Table 1).

The mean leak pressure with i-gel group was significantly lower than in the LMA-P group (28.3 ± 3.3 cmH_2O versus 30.9 ± 2.6 cmH_2O; p = 0.027). This finding was consistent with a lower tidal volume achieved with i-gel (562.6 ± 41 ml versus 584.8 ± 44 ml; p = 0.025) (Table 2).

I-gel showed shorter mean time to insertion compared with LMA-P (10 ± 1.7 versus 11.7 ± 2 s), and it proved to be inserted 1.7 s quicker than LMA-P (p = 0.004) (Table 2).

There were no significant differences in success rate on first attempt insertion between groups: 80% for i-gel versus 74% for LMA-P (p = 0.09). No failed insertions were recorded in either group.

Both groups were comparable regarding ease of insertion of the drain tube, 78% of i-gel and 72% of LMA-P were graded as "easy to insert" (p = 0.07).

No differences were found between groups relating intraoperative complications and no episodes of laryngeal stridor, laryngospasm, bronchospasm, hypoxia, regurgitation or aspiration were seen. Frequency of coughing and visible blood at removal of the device were comparable in both groups (p = 0.804 and p = 0.593, respectively).

There was a higher incidence of postoperative sore throat in i-gel group compared with LMA-P group (p = 0.025). Patients from i-gel group suffered more sore throat (0.25 more points at the VAS scale) than LMA-P group during their stay at the PACU. In addition, VAS values by categories (VAS=0 / VAS=1-3 / VAS≥4) were: i-gel = 53% / 47% / 0% and LMA-P = 77% / 23% / 0%. Four patients reported dysphagia (two in LMA-P and two in i-gel groups) and one patient complained of dysphonia (i-gel) at that time.

Table 1: Demographic and surgical data

Parameter	LMA-P (n = 71)	i-gel (n = 69)	p
Gender (F/M)	41/30	38/31	0.45
Age (yr)	52 ± 2	49 ± 3	0.35
Weight (kg)	70 ± 2	73 ± 3	0.54
Height (cm)	165 ± 3	164 ± 4	0.36
BMI ($kg.m^{-2}$)	25 ± 4	27 ± 4	0.60
ASA 1/2/3	31/30/10	25/37/7	-----
Surgical time (min)	75 ± 5	70 ± 4	0.60
Peritoneal insufflation time (min)	55 ± 3	53 ± 5	0.09
Duration of anesthesia (min)	100 ± 7	98 ± 8	0.53

Values are presented as mean ± SD or numbers

Table 2: Safety and efficacy parameters, incidence of complications and postoperative sore throat data

Parameters	i-gel	LMA-P	p-value
Safety/Feasibility parameters			
Leak pressure (cmH_2O)	28.3 ± 3.3	30.9 ± 2.6	0.027*
Mean peak airway pressure before carboperitoneum (cmH_2O)	18 ± 3	19 ± 4	0.75
Mean peak airway pressure after carboperitoneum (cmH_2O)	25.5 ± 3	24.1 ± 3.5	0.15
Mean peak airway pressure after carboperitoneum and reverse Trendelenburg (cmH_2O)	25.3 ± 3	25 ± 3.4	0.17
Tidal volume (ml)	562.6 ± 41	584.8 ± 44	0.025*
Efficacy parameters			
First attempt success rate (%)	80	74	0.09
Time taken for insertion (s)	10 ± 1.7	11.7 ± 2	0.004*
Ease for gastric tube insertion: easy/ minor difficulty/difficult/impossible (%)	78/20/2/0	72/23/5/0	0.07
Complications			
Cough (%)	8.5	10	0.80
Blood on mask (%)	4	7	0.59
Postoperative Sore Throat At 2h (mean in a 0-10 VAS)	0.5 ± 0.6	0.25 ± 0.5	0.025*

Values are presented as mean ± SD, numbers or percentage. * $p < 0.05$.

DISCUSSION

A significant portion of current literature studying the use of SADs with gastric access in laparoscopy focuses on comparisons between LMA-P, LMA-S and i-gel. Most of the studies compared these SADs for gynaecological laparoscopic procedures and just a few authors compared the use of these devices in patients undergoing laparoscopic cholecystectomy.

Leak pressure test is commonly performed to qualify the airway seal when a SAD is used. Leak pressure is significant to indicate the success of positive pressure ventilation and the degree of airway protection. It is regarded as the most important value when testing how suitable a SAD is for laparoscopy use.[3,13]

LMA-P recorded a better LP than i-gel, it may have been due to its bigger and inflatable double cuff, the deeper bowl, the proximal wedge shape of the cuff and its corresponding larger surface area in comparison to i-gel. This last device has smaller cuffless bowl made of a thermoplastic elastomer called SEBS (Styrene Ethylene Butadiene Styrene).

The LP values that we found were consistent with a

lower tidal volume achieved with i-gel compared to LMA-P.

Our results are similar to Sharma et al., who found that LMA-P achieved higher LP than i-gel for laparoscopic cholecystectomy while the dynamic compliance was higher for i-gel.[8] Woo et al reported that LP did not vary significantly between these two groups; however, their work was performed in females undergoing gynecological laparoscopy.[9]

We found that i-gel was 1.7 sec quicker to insert than LMA-P. Other authors also found a shorter time to insertion for i-gel as compared with LMA-P, although these studies were performed in non-laparoscopic procedures.[14-16] However, this little difference found is clinically irrelevant and due to this fact no differences were found by other authors.[8,9]

The success rate on the first attempt was not significantly different between the groups. Most of the published data did not report differences regarding first-time success rate.[8,9,14] Although two studies reported that i-gel was easier to insert, using an insertion of the device scoring.[15,16]

Ease of insertion of the gastric tube was comparable between i-gel and LMA-P in our study, as showed by the majority of authors. In fact, i-gel has a narrower drain access which only allows the introduction of a smaller sized gastric tube when compared to LMA-P, but it had no clinical significance.

With regard to intraoperative adverse events, no differences were found, in this sense no episodes of laryngospasm, bronchospasm, hypoxia or regurgitation were seen. Only coughing and visible blood at removal of the device were reported and they were comparable in both groups ($p = 0.804$ and $p = 0.593$, respectively). Our findings are similar to the results obtained by other authors.[8,14,16]

Incidence of postoperative discomfort during the first 2 hours after anesthesia, showed significant differences between devices, so that i-gel group experienced higher sore throat at that moment.

Most of the studies did not find differences concerning postoperative sore throat or other complaints among devices during postoperative period.[8,9,14,16]

We observed a significant statistical difference ($p = 0.025$) related to sore throat during the first 2 hours in PACU, whereas dysphagia and dysphonia were comparable between groups. Actually, this result is difficult to explain, despite our findings suggest that i-gel may be a more injuring device than LMA-P regarding airway morbidity, there is not enough argument to draw a conclusion. In any case, we have to consider that a mean difference about 0.25 points in VAS is clinically insignificant with respect to the incidence of postoperative sore throat, which has no clinical relevance. Consequently, more studies are needed in order to explain the small differences that we found.

LIMITATIONS

Our study had a number of limitations. Firstly, the observer who measured the insertion times and events was not blinded to the type of device. Postoperative outcome assessors were blinded to the group assignment in order to mitigate that limitation. Secondly, the anesthesiologist who inserted the device, had less experience with i-gel than using LMA-P, due to the late market appearance of i-gel.

CONCLUSION

We conclude in this randomised study, that i-gel had a lower leak pressure and achieves a lower tidal volume compared to the LMA-P in anesthetised patients undergoing laparoscopic cholecystectomy. I-gel was more rapidly placed than LMA-P, although we found not differences in first time success rate and ease of the drain tube´s insertion. Our study showed that i-gel reached a slightly higher sore throat scoring during 2 h-postoperative period.

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Conflict of interest: None

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AV: Study conception and design, analysis and interpretation of data, drafting of manuscript and critical revision.

CG: Acquisition of data, drafting of manuscript and critical revision.

JY: Drafting of manuscript and critical revision

AK: Drafting of manuscript and critical revision

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