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A prospective randomized controlled trial of the Baska® mask and the LMA Supreme® in patients undergoing laparoscopic cholecystectomy

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Abstract : *Objectives* : LMA Supreme® (LMA-S) mask is one of the most used and proved supraglottic airway devices (SADs) for laparoscopy. The Baska® mask is a relatively new SAD with an inbuilt drain channel and just a limited experience has been reported with this device. We compared these two SADs with regard to safety, efficacy, ease of use and incidence of adverse events for laparoscopic cholecystectomy.
Methods : Prospective, randomized, controlled study of two groups of 40 patients each, undergoing elective laparoscopic cholecystectomy. After induction of general anesthesia (maintained with 5% desflurane in 50% oxygen and air, remifentanil 0.2-0.5 µg kg-1 min-1 and rocuronium 0.6 mg kg-1), we evaluated, success rates, speed of insertion, ease of insertion of the drain tube, leak pressure, tidal volume and airway pressures (peak pressure and plateau pressure). We also recorded intraoperative adverse events and postoperative oropharyngeal discomfort.
Results : Success rate on first attempt insertion was higher for the LMA-S group than the Baska® mask group (97.5% and 60% respectively; $p < 0.001$). There was no difference in the median time taken for the insertion between groups ($p = 0.93$). Ease of insertion of the drain tube differed significantly and it was slightly easy inserted in the LMA-S group ($p = 0.04$). Leak pressure was similar between the groups ($p = 0.61$) and it was consistent with a similar tidal volume achieved ($p = 0.10$). Both devices showed equal sore throat scoring at 2 h postoperatively ($p = 0.24$).
Conclusions : We found that LMA-S was an easier device to insert than the Baska® mask, showing a better success rate on first attempt insertion. Insertion of the drain tube was also easier for the LMA-S group. Seal pressure and tidal volume achieved were similar between groups. Complication rates and postoperative OPD scoring are comparable for both devices.

Keywords : Baska® mask ; LMA Supreme ; oropharyngeal seal pressure ; laparoscopic cholecystectomy.

Introduction

The Baska® Mask (Proact Medical Ltd, Northants, UK) is one of the latest SAD incorporated to the clinical use. This device has a non-inflatable cuff, an esophageal drainage inlet and side channels to facilitate aspiration of gastric contents, as well as an integrated bite-block (1) (Fig. 1 and 2).

Recently, was introduced the Baska® FESS mask (Functional Endoscopic Sinus Surgery), a new variation of the BM designed for head and neck procedures, such as rhinoplasty and septoplasty (2, 3).

The BM have been reported as a good SAD for common uses in anesthesia, as demonstrated by some observational studies (4-6)and it was compared to the classic LMA (c-LMA) (7) and LMA Proseal (LMA-P) (8), proving to be an adequate device for general anesthesia. However, the utility of the BM has not been demonstrated to date in a comparative with LMA Supreme (LMA-S) and it has not been demonstrated at all for laparoscopic surgery. Consequently, the purpose of this study was to test the utility of the BM for patients undergoing laparoscopic cholecystectomy and compare

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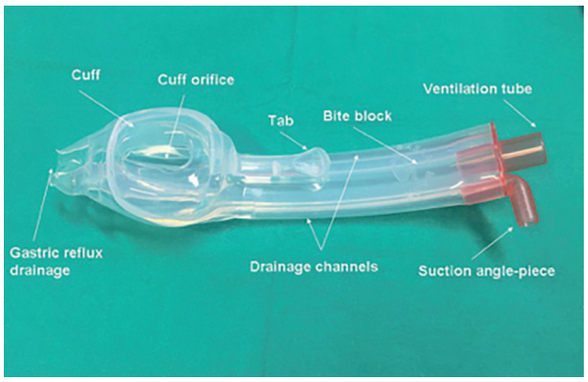

Fig. 1. — The Baska® Mask and its key features.

Fig. 2. — The Baska® Mask sizes 4 (yellow) and 5 (red).

it to LMA-S, one of the most used SADs when these devices are choosen for laparoscopy.

Some of the benefits for using a SAD instead an endotracheal intubation (ETI) for laparoscopy are: SADs can be accomplished without muscle relaxants and laringoscopy, they cause a lower hemodynamic response and upper airway morbidity, SADs have reported lower anesthetic requirements than ETI and a lower incidence of adverse events, such as, coughing or laryngoespasm as well as postoperative sore throat, dysphagia or dysphonia (4-6).

As far as we know, this is the first study in patients undergoing elective laparoscopic cholecystectomy, comparing the use of the BM and the LMA-S, 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 and dysphonia. Our primary outcomes were to measure oropharyngeal seal pressure (OSP), speed of insertion and success rates. Our secondary outcomes were to evaluate tidal volume, ventilation pressures and adverse events.

Materials and methods

This study was approved by the Complutense University Hospitals Research Ethics Committee (Madrid, Spain) on 16 December 2016 (Chairperson: Prof. M.C Gasco, Plaza Ramón y Cajal s/n, Madrid, Spain, Internal reference: HSE-008-2016, EudraCT number: 2016-001944-08). Written informed consent was obtained from all participants, recruitment started on 20 December 2016 and ended on 30 October 2017. We enrolled 84 adult patients scheduled for elective laparoscopic cholecystectomy. The following were excluded from the trial: ASA physical status 4 or higher, BMI ≥ 40 kg m^{-2}, a mouth opening of < 2.5 cm or were at risk of aspiration of gastric contents.

Eighty patients were randomized to any of the two groups (BM and LMA-S) of 40 each, using a computer-generated randomization list. Allocation concealment was maintained with opaque sealed envelopes.

A standardized general anesthetic technique was employed. Each device was inserted by an experienced anesthesiologist in the use of SADs. Patients were pre-oxygenated prior to induction of anesthesia with propofol 2-3 mg kg -1 and remifentanil 0.3 µg kg-1 min-1. We did not use neuromuscular blocking drugs at this time. Once an adequate depth of anesthesia was achieved (relaxation of the jaw, loss of eyelash reflex and onset of apnea), allocated SAD was inserted.

The sizing of both, BM and the LMA-S was based on manufacturer´s weight-based guidelines (size 3 for patients < 50 kg, size 4 for patients 50-70 kg and size 5 for patients > 70 kg). The cuff of LMA-S was completely deflated and dorsal surface of both devices was lubricated with jelly. In the case of the BM, the entire body of the mask was lubricated.

The SADs were inserted with the patient´s head and neck in neutral position, for LMA-S insertion, a single-handed technique was used. BM was inserted according to the manufactures´ instructions: the mask was decreased in size by compressing the proximal, firmer part of the mask below the airway tube, between the thumb and two fingers. If necessary, when the device was fully within the mouth, the tab (unique feature of the BM) was pulled to help negotiate the palate-pharyngeal curve.

Cuff of LMA-S was inflated to an intra-cuff pressure of 60 cm H^2O. After insertion, the device was connected to a closed-circuit breathing system under volume-controlled ventilation (TV of 8 ml kg-1, RR of 12 breaths min-1, I: E ratio of 1:1.5 and fresh gas flow 3 L min-1). If the device did not function effectively (poor capnographic curve,

inadequate tidal volume < 7 ml kg-1 or an audible leak was detected), jaw thrust was performed and the device was slightly moved up and down (in case of LMA-S cuff volume was also re-adjusted). If the mask failed to ventilate effectively despite these maneuvers, it was removed and device´s size was changed (depending on the problem detected; larger device when large leak was detected and smaller device when device size was deemed too large, respectively). If insertion failed after three attempts, it was considered a failure and endotracheal intubation (ETI) was performed. Successful ventilation was defined as the presence of normal chest movements, an adequate square-wave capnograph trace with normal end-tidal CO_2 ($EtCO_2$) values and bilateral auscultation of the chest. The time required for successful insertion was defined as the time from removing the face mask to the first square capnogram.

A lubricated gastric tube was passed through the gastric channel (16 FG for all devices) and ease of insertion was scored (easy to insert, minor difficulty to insertion and difficult to insert). A non-blinded independent observer recorded the number of attempts, time needed for the SAD´s insertion, the easy of insertion (graded as very easy, easy, intermediate or difficult by the attending anesthesiologist) as well as easy of the drain tube´s insertion.

Anesthesia was maintained with 5% desflurane in 50% oxygen and air, remifentanil 0.15-0.5 µg kg-1 min-1 and rocuronium 0.6 mg kg-1. A "seal test" in order to measure oropharyngeal sealing pressure (OSP) was assessed by closing the expiratory valve of the circuit and allowing a fresh gas flow of 3 L min-1 to build airway pressure until an audible leak was heard over the mouth (not permitted to exceed 40 cm H2O). We conducted a preliminary pilot study (n=19) to determine mean OSP ± SD as our primary outcome.

Ventilatory variables were recorded before and after the pneumoperitoneum (including peak and plateau airway pressure, $EtCO^2$), intra-abdominal pressure was held constant at 12 mm Hg and head-up tilt was limited to 30º. Peritoneal insufflation time and anesthetic time were also recorded. The procedure was performed by 2 surgeons, a total of 12 surgeons were involved in the study and the mean experience of this group was 8 ± 4 years.

Ventilatory parameters were monitored continuously (Picis Care Suit Anesthesia Manager, Picis Ltd, USA) and adapted to give a SpO2 > 95% and EtCO2 = 35-45 mmHg.

During emergence and removal, airway complications were monitored (laryngospasm, bronchospasm, regurgitation, aspiration, cough or hypoxia) and the presence of blood or lip damage were also recorded. Additionally, all patients were interviewed at discharged from the PACU by an assessor blinded to the allocation group, about the presence of sore throat, dysphagia and hoarseness. It was assessed using a 10 points verbal rating scale (VRS; 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) i.v, analgesic requirements were comparable between both groups.

Statistical analysis

In our earlier pilot study, we found mean OSL of 27 ± 6 cm H2O for the BM (n=9) and 28 ± 4 cm H2O for the LMA-S (n=10). To detect similar clinically difference in the means with 80% power ($1 - \beta = 0.80$) and a two-sided type 1 error 0.05, a sample size of 68 was calculated using DSS Research (www.dssresearch.com). A total of 84 subjects were consented for potential patients drop out. We analyzed the data with R-statistics version 3.3.3 (The R Project for Statistical Computing, Vienna, Austria) (7).

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 $\chi 2$ test for nominal data. For airway complications (laryngospasm, bronchospasm, regurgitation, aspiration, cough or hypoxia) and the presence of blood, $\chi 2$ test was performed. Data are mean (± SD) unless otherwise stated. A p value less than 0.05 was considered significant.

Results

We recruited 84 patients and data were excluded from four randomized patients, two of them after the surgical approach changed from laparoscopy to open surgery (1 BM and 1 LMA-S), one more patient for a protocol violation (wrong sized device in BM group) and in another patient (BM) gastric tube could not be inserted and had to be intubated for safety reasons. The results of 80 patients (40 LMA-S and 40 Baska® mask) were finally analyzed. The groups were comparable for demographic and surgical data (Table 1).

Success rate on first attempt insertion was significantly higher for the LMA-S group compared to BM (97.5% and 62.5% respectively; $p < 0.001$). LMA-S group needed only a second attempt in 3

Table 1
Demographic and surgical data

	LMA-S (n = 40)	BM (n = 40)	P
Gender (Females/Males)	22/18	19/21	0.43
Age (years)	50.2 ± 15	48.8 ± 35	0.39
Weight (kg)	71 ± 7.7	73 ± 6.4	0.55
Height (cm)	165 ± 35	167 ± 51	0.19
BMI (kg m^{-2})	25.5 ± 4.5	28.2 ± 4.9	0.97
ASA 1/2/3	20/19/1	22/15/3	0.70
Surgical time (minutes)	72.85 ± 32	78.56 ± 25	0.37
Peritoneal insufflation time (minutes)	57.52 ± 30	59 ± 20	0.79
Duration of anaesthesia (minutes)	100 ± 7.2	99 ± 8.3	0.58

Values are presented as mean ± SD or numbers.

Table 2
Seal, ventilatory and efficacy parameters, incidence of complications and postoperative sore throat data

	LMA-S	**BM**	**P**
Seal and Ventilatory parameters			
Oropharyngeal sealing pressure (cm H_2O)	28.9 ± 4.15	29.36 ± 4.12	0.61
Mean peak airway pressure before carboperitoneum (cm H_2O)	17.5 ± 3.42	16.73 ± 3.23	0.3
Mean plateau airway pressure before carboperitoneum (cm H_2O)	15.6 ± 3.52	15.27 ± 3.31	0.66
Mean peak airway pressure after carboperitoneum and reverse Trendelenburg (cm H_2O)	22.17 ± 3.71	22.41 ± 3.33	0.75
Mean plateau airway pressure after carboperitoneum and reverse Trendelenburg (cm H_2O)	20.33 ± 3.74	21.21 ± 3.28	0.25
Maximum tidal volume (ml)	553.98 ± 54.35	571.7 ± 42.18	0.1
Efficacy parameters			
First attempt success rate (%)	97.5	62.5	< 0.001*
Time taken for insertion (seconds)	11.7 ± 4.71	11.75 ± 2.23	0.93
Ease for gastric tube insertion (easy/ minor difficulty/difficult)	37/3/0	27/11/2	0.04*
Complications			
Cough (%)	1	1	1
Blood on mask (%)	4	5	0.9
Postoperative Sore Throat			
At 2 h (mean in a 0-10 Visual Analog Scale)	0.57 ± 0.8	0.83 ± 0.9	0.24

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

patients and no third attempts were reported, whereas in BM group a second attempt were needed in 13 patients and 2 third attempts were reported. Although there was no difference in the median time taken for the insertion between groups (p = 0.93) (Table 2).

We found statistical differences in ease of insertion of the drain tube. It was proved to be easier to insert in the LMA-S compared with the Baska mask (p =0.04). In LMA-S group, the drain tube was easy to insert in 92.5% compared to 67.5% of BM group. Facility for gastric tube insertion in BM group was scored as minor difficulty in 11 patients and difficult to insert in 2 patients (Table 2).

There were no significant differences in OSP (BM 29.36 ± 4.12; LMA-S 28.90 ± 4.15 cm H2O, p = 0.61), or TV (BM 571.70 ± 42.18; LMA-S 553.98 ± 54.35 ml, p = 0.1). We found no differences regarding airway pressures (peak pressure and plateau pressure or EtCO2) between groups, even during pneumoperitoneum condition (Table 2).

No differences were found between groups relating intraoperative complications. 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 = 1 and p = 0.9, respectively).

There were no differences relating incidence of postoperatively sore throat (ST), dysphagia (D) or hoarseness (H) at discharge from the PACU (2h) between groups: BM (ST ≥ 1 = 19; D = 2; H = 1) and LMA-S (ST ≥ 1 = 17; D = 2; H = 0), (p = 0.24).

The incidence of postoperatively sore throat during this period was very low for both devices (Table 2).

Discussion

We only found a few studies regarding the Baska® mask when reviewing literature (3,8-12),

most of them are observational and a case report (13). This is the first study comparing the use of BM and LMA-S in patients undergoing laparoscopic surgery.

In our study, we found LMA-S easier to insert, in terms of number of attempts, compared to BM (first attempt insertion 97.5% and 62.5% respectively; $p < 0.001$), although mean insertion time was similar between groups This result concurs with Foo et al (3), they found LMA-S was easier and faster to insert than Baska® FESS (the Functional Endoscopic Sinus Surgery variant of the Baska® mask very useful for nasal, facial and eye surgery). Other authors found that the BM required more insertion attempts and took longer to insert than the c-LMA (11), meanwhile Al-Rawahi et al. concluded that the BM was faster to insert compared to LMA-P (12).

The special anatomically shape and rigidity of LMA-S makes it a perfect device for an easy insertion, as it has been proved by several authors when comparing LMA-S to other devices, so it explains our results (14, 15, 17, 18).

Gastric tube was easier to insert in the LMA-S group compared to the BM ($p = 0.04$). This is consistent with the results drew by other authors, finding that the gastric tube was easier and faster to insert in the LMA-S compared to BM FESS (3). The more rigid, centered and smoother gastric drain channel of LMA-S may facilitate the insertion of the drain tube. In addition, LMA-S showed an easier of insertion of the drain tube device when compared to other gastric access supraglottic devices (14-17).

Seal pressure was similar between devices. Our OSP values measured for the BM (29.36 ± 4.12 cm H_2O) are variable to those reported previously. Seal pressure was chosen as the primary outcome, because this is the most important measure to determinate the viability of a SAD to perform a laparoscopic procedure safely. If airway peak pressure exceeds the OSP value, airway may be unprotected against a broncho-aspiration. On the one hand, our results in terms of mean OSP are similar to Al-Rawahi et al. (12), who observed a sealing pressure higher for the BM (29.98 ± 4.54 cm H_2O) compared to the LMA-P, but on the other hand, other authors measured different mean OSP values: Lopez AM et al. (10); 33 ± 7 cm H2O, Van Zundert T et al. (9); OSP was above 30 cm H2O in all patients and 40 cm H2O was achieved in 82% of the patients and Alexiev et al. measured a mean OSP of 35.7 ± 13.3 cm H_2O and 40 (IQR= 34-40, range= 16-40) respectively (8-11).

We are not able to explain why other authors found higher mean OSP values than us, but our results are consistent with the only study that compares two SADs with drain tube (12), the other works are observational studies (8-10) or a comparative between the BM and the c-LMA, a different and older device (11). Maybe more studies are needed to determinate the seal pressure that the BM can achieve.

Anyway, the mean OSP ± SD observed in our study is comparable to the results recorded by other authors when using the most common SADs with drain channel for laparoscopy. These OSP values are appropriate to perform a laparoscopic procedure with these two devices and it permits to maintain a safe airway for an adequate ventilation of the patient and broncho-aspiration protection.

Regarding intraoperative complications, both devices were similar, we found very few adverse events and it is comparable to the rest of the studies, only one study reported an increased rate of minor blood staining on the BM after removal (11).

We found no differences relating incidence of postoperatively sore throat, dysphagia or hoarseness when discharged from the PACU (2h) between groups, this is the first time comparing the BM and the LMA-S, but other authors did not find differences when comparing the BM with the c-LMA (11) or the LMA-P (12).

Our study has some 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 devices had less experience with the Baska® Mask than using other SADs, because the BM is a relatively new device.

We conclude that BM and LMA-S are comparable regarding seal pressure in anesthetized patients undergoing laparoscopic cholecystectomy. We found better first-time success rate and ease of the drain tube´s insertion for LMA-S. Both devices were similar regarding intraoperative and postoperative adverse events. Therefore, the Baska® Mask has no benefits over the LMA-S, but it is a good device for patients undergoing laparoscopic cholecystectomy under general anesthesia, it provided an enough seal pressure to perform a laparoscopy in a safe condition, but it is a more difficult device to insert when compared to LMA Supreme.

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