Cover Page

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RESEARCH PROTOCOL

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INTRODUCTION

Since supraglottic airway devices entered clinical practice in 1988 they have gained common popularity in anesthesia administration. Initially only entering use as an alternative to the face mask, additional new modifications have currently allowed them to enter the field of use of the endotracheal tube (ETT). A significant advantage of supraglottic airway devices is that they allow the possibility of securing the airway in cases with difficult ventilation for both tracheal intubation and mask. Additionally, the lack of neuromuscular blocker agent (NBA) requirement provides advantages leading to common use such as use in many outpatient surgical interventions and causing less stress response compared to endotracheal intubation, (1-5).

Initially the i-gel was produced in 2007 as a single-use supraglottic airway device. It includes a soft, gel-like, non-inflatable thermoelastic elastomer cuff, a flattened expanded stem and hard biting block. The biting block acts as a buccal stabilizer preventing axial rotation and sliding out of position. There is an esophagus ventilation channel allowing the passage of a gastric tube (8) (Figure 1).

The LMA-Supreme has similar characteristics to the i-gel. It has an esophagus ventilation channel allowing passage of a gastric tube and allows endotracheal intubation. Different to the i-gel it has an anatomic angle (Figures 2 and 3). The AuraGain is the only supraglottic airway device including a gastric channel, allowing endotracheal intubation and with an anatomic angle.

Many studies have found the i-gel is easily and reliably inserted, provides sufficient ventilation and is related to low morbidity rates (8). As a result during positive-pressure ventilation, it may be used as an alternative to endotracheal intubation.

Use of supraglottic airway devices in laparoscopic interventions

Contrary to the commonly held view, the use of supraglottic airway devices in gynecological laparoscopy does not increase the risk of pulmonary aspiration and ventilation failure (10,11,12). SGAD's are recommended as alternatives to ETT for spontaneous respiration and positive-pressure ventilation (13,36,37). Laryngeal mask application has gained popularity for gynecological laparoscopic procedures in the United Kingdom (12,14). Additionally many previous studies have shown that LM can be successfully used to ensure appropriate pulmonary ventilation in laparoscopic surgical interventions (12,14,15). Verghese and Brimacombe did not encounter pulmonary aspiration in 1469 elective gynecology cases (16), while Malins and Cooper did not encounter it in 3000 patients (17). Bapate et al. (14) researched the incidence of regurgitation in 100 patients undergoing LM elective gynecological laparoscopy surgery. This study confirmed that the incidence of regurgitation during laparoscopy with LM was very low and supported the view that LM can be reliably used during elective laparoscopy surgery.

Miller et al. (18) compared the use of ETT, LM-P and SLIPA during laparoscopic gynecology interventions and identified advantages of LMA use. The most important of these advantages is that insertion and use of supraglottic laryngeal devices for laparoscopic surgeries does not require neuromuscular blocker agents (NBA), contrary to tracheal tube technique. Thus, for outpatient laparoscopic surgeries they indicated that supraglottic laryngeal devices may be easily inserted without requiring muscle relaxants and reduce the duration spent in the operating room compared to ETT technique. Additionally the same study stated that there was less systolic blood pressure response and later less throat pain observed compared to ETT technique (18).

Thomas et al. (19) showed that administering NBA did not change incidence of throat pain difficulty swallowing, and voice loss when a supraglottic airway device was used during positive pressure ventilation and again they reported that neuromuscular blockage did not affect success rates for LMA insertion and ease of insertion. Successful airway opening and surgical procedures have been shown to be possible without using NBA in a variety of studies (with ETT or LM) in the literature (20,21). This technique is a successful alternative when NBA are contraindicated or unwanted. In routine practice many clinics do not use NBA unless clinically indicated (22). Especially for interventions where LM is used, the use of NBA, which are not necessary for LM insertion, can be avoided. Gynecological laparoscopic interventions are appropriate for this. As a result one of the advantages of supraglottic airway device use in laparoscopic gynecological interventions may be listed as not requiring NBA. 3

Williams et al. (23) compared gynecological laparoscopic interventions in an LM group without NBA and an ETT group with NBA. The CO2 insufflation volumes and pneumoperitoneum formation durations in both groups were similar. The researchers emphasized that due to the advantages, total anesthesia/surgery duration in the LM group without NBA was shorter and this was the main output of the study.

However in our literature search, we did not encounter any clinical study comparing the i-gel and LMS for laparoscopic interventions without NBA. There is a cadaver study comparing anatomic position and performance of i-gel, Ambu AuroGain and Laryngeal mask airway Supreme (LMA-Supreme) insertion. This study found that insertion of the Ambu AuroGain required manoeuvres, however the airway leak pressure was similar to other LMA-Supreme, and the nasogastric tube transfer was similar to LMA-Supreme (38).

There are studies comparing a variety of supraglottic airway devices with each other for laparoscopic gynecological surgeries. However, in all these studies neuromuscular blocker agents were used.

Many anesthetists choose not to use neuromuscular blocker agents unless necessary for surgical procedures in routine application. As the clinical view is generally based on personal experience, the use of both neuromuscular agents and the dose management of these agents may vary between clinicians.31 As a result making any specific recommendation is difficult. Chassard et al. evaluated 50 patients undergoing laparoscopic gynecological surgery with TIVA anesthesia management. In this study patients were divided into 2 groups as those given neuromuscular blocker agent (atracurium) and those not given it. In terms of operation conditions, an evaluation by surgeons found no difference between the two groups (32). The use of neuromuscular blockers in gynecological laparoscopy was found not to affect the majority of hemodynamic and respiratory changes due to pneumoperitoneum or operation conditions (33, 34).

Chen et al. (35) in a broad-series laparoscopic gynecological study (n=120) used ProSeal™ as SGAD and administered neuromuscular blocker agents to half of patients (rocuronium). The results of this study showed that both ventilation and surgical conditions were the same in both groups. The authors additionally noted that the use of neuromuscular blockers in laparoscopic gynecological surgeries was not beneficial as they did not reduce the operation and recovery times. In this study they emphasized the important point of easy insertion of laryngeal mask without neuromuscular blockers. Another study questioning the use of neuromuscular blockers in laparoscopic gynecological surgeries was completed by Swann et al.12. This study administered inhalation anesthesia for maintenance. The patients were divided into 2 groups. While spontaneous respiration and ventilation were ensured together without using neuromuscular blocker agents in the group with laryngeal mask inserted, controlled ventilation was

applied to the group with endotracheal intubation administered atracurium. There was no significant difference found between the groups in terms of intraoperative conditions; however a limitation of this study is the very short mean surgical duration (average < 15 min).

Williams et al. (23) compared an LM group without NBA and an ETT group with NBA for gynecological laparoscopic interventions. The CO2 insufflation volumes and pneumoperitoneum formation durations were similar in both groups. The researchers emphasized that the main outcome of the study was the shorter total anesthesia/surgical duration in the LM group due to the advantage of not using NBA.

However, there are some special situations where the use of neuromuscular blockers is definitely required for laparoscopic surgeries. Routine abdominal laparoscopy anesthesia is one of these special cases. In robotic surgeries extreme or deep neuromuscular blockage improves operation conditions and patient results (30).

In our literature scan of studies researching the oropharyngeal leak pressures, ventilation parameters and especially mean airway pressure values in anesthesia for laparoscopic gynecological surgery including lower pelvic region without the use of neuromuscular blocker agents, we did not encounter a study comparing i-gel with LMA-Supreme.

AIM

To compare the effects of i-gel and LMA-Supreme on ventilation parameters and surgical view during laparoscopic gynecological surgery in cases administered positive pressure ventilation without the use of neuromuscular agents.

MATERIAL AND METHOD

This study will be completed after receiving permission from "Dokuz Eylül University Faculty of Medicine Clinical Research Ethics Committee" and "Medical Device Study and Authorization Coordination Department", (Protocol No: 266-SBKAEK) with informed patient consent, as a prospective, randomized and double-blind study of 102 patients in ASA classification group I-II, aged from 18 to 65 years undergoing elective laparoscopic gynecological surgery.

Patients will be divided as

Group 1 => i-gel (51 patients) (control group)

Group 2 => LMA-Supreme (51 patients) (experiment group).

Patients and surgeons performing the operations will not be aware of the airway device used. Patients in the groups will be determined with the block randomization method. By looking at a simple random number table, 102 individuals will be divided into 2 groups of 51 by using 6 blocks of groups containing.

Before anesthesia induction patients taken to the operating room will have standard monitoring applied (non-invasive blood pressure measurements, electrocardiogram, peripheral oxygen saturation measurements). For preoperative sedation 0.02 mg/kg midazolam IV will be administered. Patients will be preoxygenized for 3 minutes with 6 L/min oxygen through a face mask. For anesthesia induction after 2 minutes of 0.2 μ/kg/min remifentanil and 6 mg kg st-1 propofol infusion, IV 1-2 mg kg-1 propofol will be administered. After induction patients will be ventilated with a face mask with 6 L/min 100% oxygen.

All patients will have bispectral index monitoring (BIS, ASPECT A-2000 BIS XP monitor) to standardize anesthesia depth. BIS values will be held between 40-60. BIS values will be kept within this interval by increasing or decreasing propofol infusion by 1 mg/kg after additional bolus dose of proprofol (1 mg/kg).

Airway device insertion will be performed by two researchers with more than 5 years experience.

During airway device insertion, if necessary depending on patient reaction additional doses of 0.5 mg/kg propofol will be administered.

Anesthesia maintenance will be ensured by 50% O2/air with 0.1-0.4 μ kg/min-1 remifentanil and 50-150 μ kg/ min-1 (4-10 mg/kg/hr) propofol IV infusion (29).

Before inserting the LMA-Supreme and i-gel, water-based K-YTM (*Johnson & Johnson Ltd. Maidenhead, UK*) gel, not containing local anesthetic material, will be spread on surfaces that will come in contact with the palate. Depending on body weight of patients LMA-Supreme numbered as follows will be inserted:

for < 50 kg: 3

50-70 kg: 4 6

70-100 kg: 5

Again depending on body weight of patients, i-gel numbered as follows will be inserted:

30-60 kg: 3

50-90 kg: 4

>90 kg: 5.

Successful insertion of LMA-Supreme or i-gel will be confirmed by square-shaped waves on capnogram, easy ventilation with respiration balloon and observation of chest movements. After confirming successful emplacement of airway device with fiberoptics, later to prevent observation of the device it will be covered. Larnygeal view will be assessed with points from 1 to 3 by the anesthesiologist (complete vocal cords view, non-obstructing epiglottis view and obstructed view).

For successful insertion duration (time from mouth-opening to first successful ventilation), number of attempts and ease of insertion will be recorded. Ease of insertion will be assessed as easy, difficult or unsuccessful (alternative airway management) by the anesthetist securing the airway (6,30).

In situations with 3 unsuccessful attempts at securing the airway, patients without LMA-Supreme or i-gel insertion will have airway management ensured with endotracheal intubation. **For oropharyngeal leak test** after shutting the expirium valve, air will be closed and O2 flow reduced to 3 L/min and the first pressure value when a leak sound is heard from the mouth will be recorded as oropharyngeal leak pressure. To prevent exposure of lungs to barotrauma, when peak inspiratory pressure (*peak*) of 40 cmH2O is reached the expiratory valve will be opened and the test ended (30). This test will be performed before peritoneal insufflation, 10 minutes later and immediately before desufflation and will be completed by a researcher blind to the type of airway device.

We considered the concept “margin on oropharyngeal leak pressure (OLP)” (MOLP), defined as the value for the margin of pressure between the highest PAW-pk during pneumoperitoneum and the maximum safety´s seal pressure value (SP). Our purpose is try to assess the “safety gap” on our patient´s airway (in terms of pressure) until it reaches the maximum PAW-pk permitted value under safety conditions (SP) (37).

Positive pressure respiration using a ring system will begin with 2-4 L/min fresh gas flow and FiO2 0.5 volume control with 6-8 ml/kg tidal volume and 10 respirations/min frequency.

PEEP will not be applied and I:E ratio will be 1:1,5. ETCO2 will be held from 35-45 mmHg, if necessary first respiration frequency will be increased, later tidal volume will be increased. For laparoscopic intervention, permission will be given for CO2 insufflation for peritoneal interior pressure of 15 mmHg.

Two minutes after insertion of LMA-Supreme or i-gel, before insufflation, 10 minutes after insufflation and trendelenburg position, immediately before peritoneal desufflation and before removing the airway device, ventilation parameters will be assessed.

Respiratory Measurements recorded: Tidal volume (TV), respiration rate (RR), peripheral oxygen saturation (SPO2), end-tidal carbon dioxide pressure (PETCO2), peak airway pressure (Ppeak), mean airway pressure (Pmean) and expiratory volume per minute (VE).

Hemodynamic Measurements recorded: (Simultaneous to the above measurements and additionally before induction) systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), and heart rate (HR).

Evaluation related to stomach probe: Immediately after the airway device is inserted, through the LMA-Supreme (14F for size 3 and 16F for sizes 4 and 5) and i-gel drainage tube a 12F orogastric tube will be advanced to the stomach and stomach contents aspirated. The ease of insertion of stomach probe and amount of aspirated fluid will be recorded. Ease of insertion of orogastric tube will be classified as very easy, easy, difficult or very difficult by the administrator (9). Gastric aspiration will be 200 cmH2O during 10 seconds by a suction; (connecting it later to a collection bag).

The number of interventions of verres needle, initial intra-abdominal pressure, time for intra-abdominal pressure to reach 15 mmHg, and volume of insufflated CO2 will be recorded. Sufficiency of pneumoperitoneum during operation (sufficient/insufficient), and quality of surgical view will be assessed with points from 1 to 4 by the surgeon blind to the airway device (24).

Stomach distension will be assessed on a scale of 0 to 10 (0= empty stomach, 10 distension obstructing view of the surgical field) by a surgeon blind to the airway device immediately after insertion of the laparoscope into the abdomen and immediately before the end of peritoneal insufflation and the difference between the scores at the start and end of surgery will be recorded (15). Operation table positioning (Trendelenburg) will be limited to a maximum 30º.

When the patient is cooperative, the LMA-Supreme or i-gel will be removed and total anesthesia duration and peritoneal insufflation duration will be recorded. Complications that may develop during airway device removal (cough, vomiting, laryngeal stridor, laryngeal spasm or airway intervention requirements) will be recorded.

After removing the SGAD, the presence of blood will be assessed as:

1: no blood

2: trace amounts of blood

3: clear amounts of blood

Conscious patients will be taken to the recovery unit and a blind researcher will evaluate throat pain, voice loss and difficulty swallowing in the 1st and 24th hours. For evaluation of throat pain, VAS-10 (visual analog scale) will be used.

Criteria:

Inclusion Criteria:

1.American Society of Anesthesiologists classification group I-II

2.between 18-65 years

3.undergoing elective laparoscopic gynecological surgery

Exclusion Criteria:

1.Those with any neck or upper respiratory tract pathology

2.Those at risk of gastric content regurgitation/aspiration (previous upper Gastrointestinal system surgery, known hiatus hernia, gastroesophageal reflux, history of peptic ulcers, full stomach, pregnancy)

3.Those with low pulmonary compliance or high airway resistance (chronic pulmonary diseases)

4.Obese patients (BMI >35)

5.Those with throat pain, dysphagia and dysphonia

6.Those with possible or previous difficult airway

7.Those with operations planned for longer than 4 hours

8.Conversion to laparatomy

9.Neuromuscular blocking agent used

Statistical Analysis

In a study that was conducted by Seet et al., power was calculated as 90% as a result of the power analysis that was made for laryngeal mask airway OLP=>21+/-5 cmH2O average values; and the number of the case was determined to be 40 for each group (30).

The data have been evaluated with the SPSS (Statistical Package for Social Sciences) 15.0 package program. The fitness of the variables to normal distribution was tested with the Kolmogorov Smirnov Test. The t-test was used to compare the two groups that fit normal distribution; and the Mann Whitney U-Test was used for those that did not fit normal distribution. The variables that were defined with numbers were evaluated with the Chi-Square Test and with the Fisher's Exact Test when needed; and the significance level was taken as $p<0.05$. The mean, standard deviation, median, min. and max. values of the continuous variables and their sub-groups were presented; and the frequency numbers and percentages of the class variables were presented.

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