A Comparison of the New Double-tube Laryngeal Mask and the Endotracheal Intubation for Gastroesophageal Reflux Radiofrequency Ablation under General Anesthesia:A Randomized, Prospective, and Controlled Clinical Trial

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Abstract

Bsckground Stretta radiofrequency ablation therapy is a minimally invasive endoscopic anti-reflux procedure, which used to treat patients with gastroesophageal reflux.The operation has a longer time, greater stimulation, and higher requirements for anesthesia.The purpose of this trial To compare the safety and efficacy of the laryngeal mask airway and the endotracheal intubation in radiofrequency therapy under general anesthesia with GERD in adults. Methods 30 patients (ASA grade I-II) with gastroesophageal reflux disease receiving radiofrequency therapy were randomly divided into the laryngeal mask group (L group) and the tracheal intubation group (T group). After pre–oxygenation, routine intravenous anesthesia was induced, the PLMA or ETT inserted, the cuff inflated. The proper depth of anesthesia was maintained during the operation. The time of successful placement of the radiofrequency catheter, MAP, HR, SPO2, PetCO2 and airway pressure at six time points, operation time, extubation time (time from the end of surgery to the extraction of the mask), endoscopic physician, patient satisfaction, the incidence of reflux aspiration, and the postoperative sore throat were recorded. Results The success rate of laryngeal mask catheterization was 100%. The successful placement time of radiofrequency catheter in the LMA group was significantly shorter than that in the ETT group. In the LMA group,the operation time and postoperative extubation time or the time to pull out laryngeal mask was shorter than in the ETT group. The satisfaction scores of patients and endoscopy doctor in the LMA group were better than in the ETT group. The HR and MAP in the ETT group were significantly higher than in the LMA group at T1 time point. The incidence of the postoperative sore throat was higher in the LMA group than in the ETT group. There was no significant difference in ventilation oxygenation between the two groups, and no adverse events such as reflux and aspiration occurred. Conclusions PLMA has the characteristics of simple operation, stable hemodynamics, and proper airway sealing function, can significantly shorten the operation time, and improve the perioperative comfort of patients and the satisfaction of endoscopists. It can effectively and safely replace ETT in the radiofrequency treatment of gastroesophageal reflux disease.

Background

Gastroesophageal reflux disease (GERD) is a chronic disease characterized by reflux of gastric contents. It is one of the most common esophageal diseases in the world. Its typical clinical manifestations are heartburn and reflux. Some patients also have extraesophageal symptoms, including asthma, chronic cough, hoarseness and globus hysteria, etc. Some patients eventually may have complications such as esophageal stenosis and Barrett's esophagus, which severely affect the quality of life of patients[1,2,3]. Epidemiological data show that the incidence of GERD in the world is increasing year by year[4,5].

Stretta radiofrequency ablation therapy is a minimally invasive endoscopic anti-reflux procedure, which acts on the lower esophageal sphincter (LES). Patients who have been treated can reduce or discontinue the drug. Compared with other anti-reflux procedures, Stretta radiofrequency therapy has a longer duration and can be used repeatedly if necessary. More and more studies have confirmed the safety and effectiveness of radiofrequency therapy[6,7]. However, there is still room for improvement in the perioperative period of Stretta operation.

Compared with general endoscopic anesthesia, endoscopic micro-radiofrequency surgery has a longer time, greater stimulation, and higher requirements for anesthesia. In addition to ensuring the safety of patients and preventing reflux, aspiration and hypoxia, it is also necessary to ensure adequate sedation, analgesia and smooth breathing[8]. Up to now, endotracheal intubation has been considered the gold standard for providing a safe glottic seal[9]. It is an excellent choice for Stretta surgery with the risk of reflux aspiration. However, with the advent of the third generation laryngeal mask, a large number of studies have reported that LMA has successfully replaced tracheal tube for daytime surgery, laparoscopic surgery and even cardiac surgery [10,11,12]. There is no report of using laryngeal mask

for Stretta surgery. And the third generation of the laryngeal mask has added the drainage tube in addition to the snorkel, which may be more conducive to the operation of Stretta while ensuring patient safety. The purpose of this study was to compare the safety and efficacy of the laryngeal mask airway (LMA) and the endotracheal intubation (ETT) in radiofrequency ablation under general anesthesia with GERD in adults, and thus to optimize the surgical plan by optimizing the anesthesia.

Methods

Participants

This study was a prospective, randomized, and single-blind clinical trial. It was approved by the Medical Ethics Committee of the Second Affiliated Hospital of Chongqing Medical University and registered in the China Clinical Trial Center. All patients signed the informed consent. We strictly enforced the inclusion criteria: (1) age 40 to 65 years old, regardless of gender; (2) body mass index (BMI) 18 ~ 30kg / m2; (3) ASA classification I ~ II; (4) Mallampati classificationI ~ III. Exclusive criteria: (1) age < 40 years old or > 65 years old, regardless of gender; (2) ASA grade III or above; (3) Mallampati grade IV, mouth opening < 2.5 cm; (4) contraindications for anticholinergic drugs such as narrow-angle glaucoma, pyloric obstruction, benign prostatic hyperplasia, severe cardiovascular disease and allergies; (5) history of narcotic drug allergy; (6) long-term addiction and dependence on opioids or hypnotics, or long-term alcoholics; (7) those who do not cooperate, are unable to communicate or have neuropsychiatric diseases; (8) preoperative sore throat; (9) pregnant women who are in the process of breastfeeding;(10) serious heart, lung, liver and kidney dysfunction; (11) preoperative respiratory tract infection and asthma attack.

Randomization

Acording to the method of table of random number,thirty patients who underwent endoscopic micro-RF treatment of endoscopic gastroesophageal reflux disease in our hospital were randomly assisgned into the laryngeal mask group (L group) and the tracheal intubation group (T group). The experiment was conducted by two anesthesiologists, one anesthesiologist (clinical experience > 5 years) was responsible for anesthetic management, the other anesthesiologist data collection.The same group of doctors performed all procedures for both groups of patients.

Anesthesia

Patients were routinely fasted for 8 hours before surgery, and forbidden for 4 hours, with no preoperative medication. After entering the room, the peripheral venous access was opened, and the left lateral position was performed. The Mindray BeneView T8 monitor was connected to routinely monitor the patient's heart rate, blood pressure, electrocardiogram, respiratory rate, pulse oxygen saturation, and bispectral electroencephalogram. We chose the appropriate laryngeal mask according to body weight, (30 ~ 50kg # 3, 50 ~ 70kg # 4, >70kg # 5), selected the tracheal tube according to gender (male 7.5 female 7.0), and applied paraffin oil to the back of the laryngeal mask and tracheal catheter to lubricate. Then we checked the cuffs for air leaks. After pre-oxygenation, anesthesia induction was initiated. We further injected midazolam 0.05 mg/kg, fentanyl citrate 1.5 ug/kg, propofol 1.5-2.0 mg/kg, and vecuronium bromide 0.08-0.1mg/kg until the disappearance of patient's consciousness and eyelash reflex and the mandibular relaxation. Bis value was maintained between 40 and 60. In group T, the tracheal tube was inserted through oral cavity under the visual laryngoscope, while in group L, the laryngeal mask was placed blindly until there was a sense of resistance in the bottom of pharynx. The airbag with 20 mL of air was injected. After ensuring correct position of the mask, adequate ventilation and no air leakage, we use the anesthesia machine Mindray WATO EX-55 to control the ventilation. The intraoperative oxygen flow rate is 2L/min, the tidal volume was 8

ml/kg, and the respiratory rate was 12-15 times/min. The surgery started after fixation. During the operation, propofol was continuously and intravenously pumped at a rate of 4-7 mg/kg/h. The dose of sedative and analgesic drugs was adjusted according to the depth of anesthesia, and the BIS was maintained between 40 and 60. 0.1 mg Fentanyl was added at the beginning of the treatment, and 5 mg Dizocine was given before the end of the operation. Propofol of 0.5-1.0 mg/kg (20-50 mg) were added during the operation in case of facial pain, a sudden increase of heart rate, elevated blood pressure, or limb twitching. Patients with intraoperative systolic blood pressure (SBP) < 70% or 80 mmHg before the operation, or with diastolic blood pressure < 40 mmHg, were supplemented with 200 ml intravenous Ringer's lactate solution quickly , and dopamine was injected 1-2 mg each time if necessary. If there is a sinus bradycardia, HR < 50 times/min, appropriate amount of atropine can be intravenously injected. At the end of the operation, the drug was discontinued, and the tracheal tube or the laryngeal mask was removed when the patient's breathing, consciousness and swallowing reflex were restored. SpO2 (>95%) was maintained for about 5 minutes without oxygen inhalation. When the Aldrete improvement score is more than 9 points, the recovery standard after anesthesia is considered.

Surgery

An electrode plate was placed between the shoulder blades of the patient, and the other end of the electrode plate was connected with the Stretta therapeutic apparatus; the distance between the dentate line and the incisor was measured under the endoscope. In the tracheal intubation group, the Stretta guide wire was introduced into the duodenum through the gastroscopic biopsy hole, the gastroscope withdrew, the Stretta catheter introduced into the esophagus along the guide wire, and the guide wire withdrew, whereas in the laryngeal mask group, Stretta catheter was directly introduced into the esophagus through the working passage of the laryngeal mask. At 1.5cm, 1cm, 0.5cm above the dentate line, at the dentate line, 0.5cm, 1cm, 1.5cm below the dentate line, the air sac at the front end of the catheter was dilated with a syringe respectively, and propelled to the appropriate pressure to push the stimulator at the end of the Stretta catheter, so that the four click needles on the basket outside the balloon were inserted into the muscular layer of the esophageal wall. The screen display resistance of the Stretta system dropped rapidly. After confirming that the resistance and temperature were normal, we initiated the treatment. Each site was treated twice at 0 degrees and 45 degrees of dextral rotation, and each time lasted 60 seconds. Then the catheter balloon was pushed into the stomach, and we injected 25 ml and 22 ml into the balloon respectively. Then the catheter was pulled out to the appropriate resistance. Each plane was treated three times at 0 degrees, 30 degrees dextral and 30 degrees left. During the course of treatment, the tissue resistance should not exceed 1000 Ω, the myometrial temperature should be 80-90℃, and the surface temperature of the mucosa should not exceed 45 ° C. The mucosal surface was cooled by a pre-cooled water scouring system. If temperature or resistance exceeded the normal range, the treatment would be automatically stopped.

Outcome measures

We recorded the time of successful placement of the RF (radiofrequency) catheter, MAP, HR, SPO2, PetCO2 and airway pressure at seven time points(pre-anesthesia (T0), laryngeal mask/tracheal catheter placement (T1), start of surgery (T2), 10 minutes after surgery (T3), end of surgery (T4), removal of the laryngeal mask/tracheal catheter(T5), and 5 min after the removal of the laryngeal mask/tracheal catheter (T6)), operation time (from Gastroscope entered to Gastroscope withdrw), postoperative extubation time or the time to pull out laryngeal mask (time from the end of surgery to the extraction of the mask), endoscopic physician and patients satisfaction (scored 1-10 points from extremely dissatisfied to very satisfied), postoperative sore throat. We also recorded circulatory respiratory events (i.e., abnormal blood pressure, abnormal heart rhythm, abnormal position of the mask, hypoxia, etc.) and the incidence of reflux aspiration.

Statistical analysis

SPSS 22.0 software was used for data analysis. The measurement data were expressed as mean ± standard deviation（±s). The normal distribution data were compared using independent sample t-test (e.g., age, BMI), while the non-normal distribution data were compared using Wilcoxon rank sum test (e.g. catheter placement time, anesthesia time, operation time). Repeated measurement data group was analyzed by repeated measures analysis of variance (such as BP, RR, Sp02 at each time), and independent sample t-test was used for comparison between groups. Counting data were expressed as constituent ratios or rates (e.g. the incidence of the sore throat and airway accidents). Fisher's exact probability method was used for inter-group comparisons, and the result was statistically significant ($P < 0.05$).

Results

1 Comparison of general data between the two groups: There was no significant difference in age, gender composition ratio, ASA grade and BMI between the two groups ($P>0.05$). As shown in Table 1.

2 Comparison of MAP, HR, RR, PETCO2 and SpO2 at each time point in the two groups: At the T1 time point, the HR and MAP of the T group were significantly higher than those of the L group ($P<0.05$), and airway pressure in T1, T2, T4, L group were significantly higher than those in T group ($P < 0.05$); there was no significant difference between the two groups at the other time points ($P>0.05$).As shown in Table 2.

3 The comparison of the indexes of the operation between the two groups: The operation time, the time of removing the mask and the time of radiofrequency catheter placement in group L were significantly shorter than those in group T ($P < 0.05$). As shown in Table 3.

4 Comparing the incidence of postoperative sore throat and satisfaction between the two groups: group L had more sore throat than group T, and group L had higher scores of endoscopic physician satisfaction than group T （$P<0.05$）.There was no significant difference between the two groups.（$P>0.05$） As shown in Table 4.

5 Adverse events: One patient in the LMA group had difficulty inserting a laryngeal mask. After repeated operations for 3 times, there was a slight bleeding in the throat, and the intraoperative airway pressure was higher during the operation, but within the acceptable range (<26 cmH2O). There were no obvious hemodynamic fluctuations in the two groups, and no reflux aspiration was observed. All of them had poor ventilation. There was no laryngeal mask displacement due to surgical operation in the LMA group.

Discussion

The mechanism of endoscopic radiofrequency therapy for gastroesophageal reflux disease is that radiofrequency heat can promote collagen tissue proliferation of the esophageal sphincter, thicken the sphincter, increase the pressure, destroy the vagus nerve in the wall of gastric cardia, reduce the occurrence of transient lower esophageal sphincter relaxation, and reduce the symptoms outside the esophagus[13]. Compared with conventional endoscopy, radiofrequency therapy requires multiple placements of gastroscopes and radiofrequency catheters, which can prolong the operation time, stimulate a large number of gastrointestinal secretions, secretions or gastric flushing water, easily cause reflux and aspiration, and even induce asthma attacks. In addition, during the radiofrequency treatment process, the treatment plane is located according to the results of the gastroscope measurement. If the patient's breathing amplitude is too large, the positioning accuracy may be affected, and the treatment effect may be affected. Therefore, endoscopic radiofrequency anesthesia is highly demanding. In addition to ensuring stable vital

signs of patients and ensuring the anesthesia effect, it is also necessary to prevent reflux, aspiration, and hypoxia. Previous intravenous anesthesia with propofol, midazolam, and fentanyl has basically satisfactory anesthesia effect, but there are still some adverse reactions. Injection pain, respiratory depression, excessive breathing and limb movement are the most common ones that affect the operation. Some patients with obvious body motion or intraoperative asthma attacks need to terminate treatment temporarily. In addition, intravenous anesthesia is not easy to control the depth of anesthesia and cannot provide safe airway protection[14,15,16].Tracheal intubation general anesthesia can undoubtedly avoid the adverse reactions of intravenous anesthesia, better protect the airway, andmaintain a proper depth of anesthesia to ensure the smooth operation of the operation. However, the operation process is relatively complicated, and the patient has a significant stress response during intubation, which can induce serious reactions such as respiratory and circulatory responses.

As a kind of supraglottic aspiration device, the laryngeal mask can simplify the operation and need no additional instruments, which can improve the airway management speed and hemodynamic stability during anesthesia. Approved by the Food and Drug Administration (FDA) in 1991, the LMA has been successfully used in various surgical operations in pediatrics. Laryngeal masks also have potential effects on patients with difficult airways, including those with limited mouth opening. Cases of laryngeal masks used in maxillofacial surgery have been reported in the literature, including adenoidectomy, cleft palate repair, and alveolar surgery. The LMA also plays an essential role in acute airway management in trauma or anesthetic emergency[17]. When the patient can neither intubate nor ventilate, the LMA can be used to establish airway control. It can be seen that with the continuous renewal of the laryngeal mask, its clinical application is more and more extensive, including clinical anesthesia, emergency resuscitation, intensive care, difficult airway treatment and so on.

At present, there have been a large number of comparative studies on the LMA and the ETT. Compared with tracheal intubation, the LMA placement for beginners is less complicated and has a higher success rate. In short general anesthesia operation, the use of the laryngeal mask is less frequent than the tracheal intubation anesthesia induction of muscle relaxant dosage to facilitate early postoperative recovery of spontaneous breathing. Even if the position of the LMA is not ideal, it can maintain the airway. The LMA is well tolerated and has a lower incidence of reported respiratory adverse events (such as a cough, laryngeal spasm, breath holding) than endotracheal catheterization. The LMA reduces complications associated with intubation because it does not impact the anatomical location of the trachea and vocal cords. Compared with endotracheal tubes, the LMA has a lower incidence of a sore throat and hoarseness afterwards[18,19,20,21]. During anesthesia induction and recovery, hemodynamic stability was improved, intraocular pressure decreased, oxygen saturation increased during anesthesia recovery, the incidence of postoperative pharyngalgia in adults also decreased. Some studies have shown that the airway sealing pressure of multi-functional laryngeal mask is (28.69 + 3.10) cm H2O, which is higher than that of Supreme laryngeal mask. The LMA has high airway tightness and can effectively prevent the risk of backflow and aspiration[22].The LMA ventilator used in this study is more closely matched to the anatomy of the throat and has better sealing. The distal end of the laryngeal mask is located in the esophageal orifice, well fixed, and not easily displaced.No regurgitation occurred in all patients during the operation. In addition, it has a ventilating channel for respiratory management. An esophageal passage can be used for the placement of the digestive endoscope, which facilitates the operation of the surgeon while facilitating the anesthesiologist to manage the airway.Fig3

It has been pointed out that the use of the laryngeal mask has little effect on hemodynamics, and even elderly patients with hypertension are more suitable for using the laryngeal mask[23,24]. The results of the study showed that the anesthesia induction of the two groups was based on body weight. At the T1 time point (when placeing the laryngeal mask/tracheal tube), the HR and the MAP of the T group were significantly higher than that of the L group

(P<0.05), indicating that the patient's stress response was more significant when using the tracheal tube than using the laryngeal mask during tracheal intubation.At T5 time (when removing the laryngeal mask/tracheal catheter), there was no significant difference in the HR and the MAP between the two groups, but when the tracheal tube was taken out in the T group, the MAP increased significantly compared to the scores before anesthesia. The hemodynamics of the two groups were stable for the rest of time, and no adverse events such as significant fluctuations occurred. During the whole operation, some patients with severe reflux in both groups were treated with additional treatment points, or endoscopic gastric polypectomy was performed after radiofrequency treatment because of their own history of gastric polyps, but the total operation time ofthe L group was significantly shorter than that of the T group (P < 0.05). In the L group, the time from the end of the operation to the removal of the laryngeal mask/tracheal catheter was significantly shorter than that in the T group (P < 0.05), and the patient's tolerance to the laryngeal mask was better than to the tracheal catheter. In addition, compared with the endotracheal tube, laryngeal masks make it possible for endoscopy physicians to insert an incident frequency catheter directly through the esophageal orifice of the laryngeal mask without using a guide wire. This method simplifies the operation procedure, significantly shortens the time for successful placement of the radiofrequency catheter, and saves the operation cost for the patient. At the same time, it avoids the throat injury caused by multiple placements of incident frequency catheter due to the unsuccessful guide wire. The satisfaction scores of endoscopic physicians in the L group was significantly higher than those in the T group(P<0.05).

In this study, the airway pressure at T1, T2 and T4 time points in the L group was significantly higher than in the T group (P < 0.05), but the values were all within the safe range, and no ventilatory adverse events occurred. Patients with laryngopharyngeal pain after operation in the L group were more than those in the T group, the swallowing movements were more obvious, but they were tolerable, and the duration did not exceed 2 days, The prognosis of patients was good.

Conclusions

LMA has the characteristics of simple operation, stable hemodynamics, and proper airway sealing function, can significantly shorten the operation time, and improve the perioperative comfort of patients and the satisfaction of endoscopists. It can effectively and safely replace ETT in the radiofrequency treatment of gastroesophageal reflux disease.

Abbreviations

LMA:Laryngeal mask airway;ETT:endotracheal intubation;ASA:American Society of Anesthesiologists; BMI: Body mass index;EtCO2: End-tidal carbondioxide partial pressure; HR: Heart rate; MAP: Mean arterial pressure; SpO2: Pulse oxygen saturation;GERD:Gastroesophageal reflux disease;LES:lower esophageal sphincter;Bis:Bispectral index

Declarations

Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of the Second Affiliated Hospital of Chongqing Medical University as it was inaccordance with the current guidelines of the institution. This study was alsoregistered at chictr.org (ChiCTR1800016139).Written informed consent was obtained from all subjects participating in the trial.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

XW helped design the study,collect,analyze, interpret the data and write the manuscript.TR helped analyze the data and write the manuscript. WL helped design the study, interpret the data, and revise the manuscript. ZY helped design the study, conduct the study, and revise the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1 Comparison of general information between two groups of patients（n=30,±s）

projects	L	T
Gender composition ratio (male/female)	6/9	7/8
BMI（kg/m2）	22.94±2.02	22.72±1.76
Age(years)	55.27±6.75	54.87±5.54
ASA grade（）/（）	5/10	6/9

Table 2 Comparison of MAP, SpO2, HR and RR at each time point between the two groups（n=30,±s）

projects	group	T0	T1	T2	T3	T4	T5	T6
MAP	L	92.8±10.2	85.2±11.2a	98.7±10.1	93.6±9.1	93.7±8.1	93.5±8.0	93.4±8.0
（mmHg）	T	91.1±9.3	93±8.7	98.9±7.6	94.8±8.1	95.2±7.7	95.5±8.1	92.3±8.8
HR	L	76.2±10.4	79.3±11.3a	74.9±11.3	72.3±11.5	72.4±11.7	79.7±12.4	74.2±11.3
(Second /min)	T	75.5±9.2	87.4±8.5	81.1±8.9	74.8±8.7	74.3±9.1	80.9±9.6	75.8±8.3
airway pressure	L		18.5±2.2b	19.2±2.7b	20.2±3.0	18.5±2.0b		
CmH2O	T		16.9±0.8	17.4±0.8	18.5±1.1	17.2±0.8		
PET CO2	L		37.7±2.4	40.0±2.7	40.4±3.1	39.7±2.6		
（mmHg）	T		38.0±2.1	39.4±2.6	40.0±2.8	39.4±2.6		
SPO2	L	99.1±0.7	99.2±0.7	99.5±0.5	99.7±0.5	99.7±0.5	99.5±0.7	98.9±1.1
（%）	T	98.7±0.9	99.2±0.7	99.7±0.5	99.7±0.5	99.7±0.5	99.5±0.6	99.1±0.9

Note: compared with group T at T1 time point,a P<0.05, compared with group T at T1, T2, T4 time point,b P<0.05.

Table 3 Comparison of operative conditions between two groups of patients

projects	operation time （min）	pull out laryngeal mask time （min）	RF catheter successful placement time(s)
L	61.7±10.5	5.6±1.7	22.1±4.3
T	69.3±7.8	10.5±1.6	76±6.3

Table 4 Comparison of postoperative throat and satisfaction between the two groups（n=30,±s）

projects	Postoperative sore throat cases	Satisfaction of endoscopes	Patient satisfaction
L	10	9.5±0.6a	8.9±0.7
T	7	8.7±0.7	8.5±0.9

Note: satisfaction of two groups of endoscopesa a P<0.05（

Figures

Figure 1

The laryngeal mask used in this study not only has an airway for respiratory management, but also adds a drainage channel for the placement of digestive endoscopy to simplify surgical procedures.

Supplementary Files

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- supplement1.doc