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Original Article

A prospective randomized study for the placement of flexible laryngeal airway mask with two-step jaw-thrust technique by both hands for adults

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Abstract: Objective: A prospective, randomized, and controlled study was conducted to investigate the effect of two-step jaw-thrust technique on the placement of flexible laryngeal mask (FLMA) with both hands. Methods: Between November 2019 and January 2020, 160 patients scheduled for functional endoscopic sinus surgery with general anesthesia were enrolled in this study and were divided into two groups (*n*=80 each) using a random number table method: control group (group C) and test group (group T). After the induction of general anesthesia, the traditional method was applied to insert the flexible laryngeal airway mask in patients of group C, and the two-step jaw-thrust technique with both hands by the nurse was applied to help place the laryngeal mask in patients of group T. The success rate, alignment status by fibroscope (FOB) score, oropharyngeal leak pressure (OLP) of the laryngeal mask, oropharyngeal cavity soft tissue injury and postoperative sore throat, and the incidence of adverse airway event were compared between the two groups. (The registry of clinical trial: Chinese Clinical Trial Register, ChiCTR2100053017, https://www.chictr.org.cn). Results: 78 patients in group C and 79 patients in group T were in includedfinal analysis. The success rates of the first placement of flexible laryngeal masks in patients of group C and group T were 73.81% and 97.52%, respectively. The final success rates were 97.52% and 98.81%, respectively. The success rate of first placement in group T was significantly higher than that of group C. There was no significant difference in the final success rate between the two groups (P=0.561). The alignment score showed that the placement of group T was significantly better than that of group C. The OLP of group T (25.43±3.82 cm) was significantly higher than that of group C (22.13±2.62 cm). The incidences of mucosal injury and postoperative sore throat in group T were 2.52% and 5.01%, which were significantly lower than those of 23.02% and 16.72% in group C. There was no adverse airway event in each group. Conclusion: The two-step jaw-thrust technique with both hands can improve the success rate of the first placement of the flexible laryngeal mask and the positioning of the laryngeal mask, increase the sealing pressure of the laryngeal mask, and reduce the incidence of oropharyngeal soft tissue injury and postoperative pharyngeal pain.

Keywords: Flexible laryngeal mask, traditional technique, two-step jaw-thrust technique with both hands, oropharyngeal leak pressure, sore throat

Introduction

In the practice of anesthesia, endotracheal intubation (ETI) is considered the standard method of airway management, especially when surgeons use the airway in operations. Laryngeal mask airway (LMA) is increasingly used in anesthesia because it is placed above the larynx and causes less direct mechanical stimulation of the airway. Studies have shown that the use of LMA in children undergoing adenoidectomy can achieve a safe airway [1, 2]. In addition to ensuring airway safety, LMA application does not involve the use of muscle relaxants which usually cause laryngospasm, bronchospasm, or breath-holding, and allows early intubation. Therefore, LMA applications have been found to be superior or at least not inferior to ETI in terms of respiratory complications. However, when using classic LMA, in terms of perioperative airway complications, the safe airway management of adenoidectomy is still controversial, such as the displacement of LMA, and gas leakage during surgical positioning [3]. Flexible laryngeal mask airway (FLMA) is more advantageous in general anesthesia in facial features. Its simple operation can reduce hemodynamic fluctuations during intubation, reduce adverse airway events during extubation, and speed up surgical turnover. Compared with the classic laryngeal mask, the FLMA has a longer catheter end and can be far away from the operation area. The tube can be bent and resistant to compression. The head and neck are not easy to move when rotating, which is convenient for the operator to operate [4, 5]. A well-positioned FLMA can provide a suitable oropharyngeal sealing pressure and fully protect the glottis and lower respiratory tract from blood and surgical irrigation fluid contamination [6, 7]. However, the long and flexible catheter is not conducive to the force transmission, and it is prone to rotation and misalignment during traditional single placement. Therefore, the success rate of ventilation with a flexible laryngeal mask is slightly lower than that of classic laryngeal masks [8, 9]. In addition, the use of classic LMA is an important reason for insufficient surgical vision in some gland resections. There is a significant difference between the diameters of classic LMA and FLMA. The advantages of using FLMA during adenoidectomy include better surgical visibility after the plug is placed and preventing the LMA tube from being compressed or kinked under the plug. Because of these advantages, FLMA is significantly better than traditional LMA in airway management during operations such as adenoidectomy and adenoid tonsillectomy [10].

The purpose of this study was to compare the effects of traditional laryngeal mask placement methods and the two-step jaw-thrust technique with the participation of itinerant nurses on laryngeal mask success rate, alignment, closure pressure, and soft tissue injury. This study was the first to explore the effect of applying this technology on the improvement of adult pharyngeal cavity and postoperative sore throat under general anesthesia. In addition, this study also explored the improvement of laryngeal mask placement conditions, which has guiding significance for the wide application of this technology in clinical practice in the future.

Materials and methods

Normal information

A total of 157 patients, aged 18-65 years, under the American Society of Anesthesiologists (ASA) grade I-II, who were scheduled to undergo elective endoscopic sinus in Beijing Tongren Hospital affiliated to Capital Medical University from September 2019 to January 2020, were recruited in this prospective, randomized, and controlled study. The estimated time for the operation was within 4 hours. Patients with contraindications to the use of laryngeal masks or severe obese with a body mass index (BMI) greater than 35 were excluded from this study, and patients with mouth opening less than 2.5 cm were also excluded. Patients were divided into a control group (C group) and an experimental group (T group) by using a random number table. There were 78 and 79 cases in C group and T group, respectively. This study was approved by the Ethics Committee of Beijing Tongren Hospital affiliated to Capital Medical University (ethics number: TRECKY2019-061), and informed consent form was signed by the patients.

Anesthesia method

All patients were strictly prohibited from drinking water before operation. The blood pressure, heart rate, pulse oxygen saturation and end-expiratory carbon dioxide (ETCO2) of patients were monitored. After oxygen is given and nitrogen is exhausted through mask, atropine (Harbin Pharmaceutical Group, China) 0.5 mg, midazolam (Humanwell healthcare, China) 0.03 mg/kg, cisatracurium (Humanwell healthcare, China) 0.15 mg/kg, sufentanil (Humanwell healthcare, China) 0.2 g/kg and propofol (Harbin Pharmaceutical Group, China) 1.5-2 mg/kg were intravenously administered. After patients' consciousness disappeared and muscle relaxation improved, the appropriate model of flexible laryngeal mask (disposable use of laryngeal mask airway catheter, Tianjin Medidis Medical Products Company, China) was placed in the patient's oropharynx after applying Obucaine gel on the tip and back. The laryngeal mask was placed by an experienced anesthetist who has worked for more than 3 years. The model of the flexible laryngeal mask was selected based on the weight of patient: for the body weight ≥70 kg, the No. 5 laryngeal mask was used, for the body weight <50 kg, the No. 3 laryngeal mask was used, and the No. 4 laryngeal mask was used for the rest. After three failed trials of laryngeal mask ventilation, it was changed to tracheal intubation. Anesthesia was maintained by intravenous injection of pro-

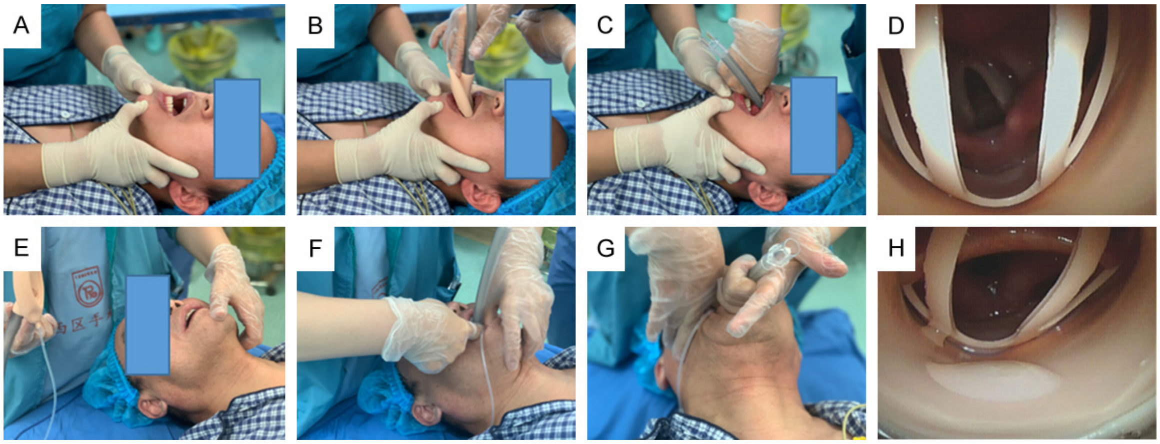

Figure 1. Two-step of jaw-thrust technique by both hands (A-D): The process of opening the oral cavity (A), placing the FLMA into the oral cavity (B), placing the FLMA into the pharyngeal cavity (C), and the alignment effect of FLMA under FOB (D). Traditional technique (E-H): An anesthesiologist opening the oral cavity (E), placing the FLMA into the oral cavity (F), and placing FLMA into the pharyngeal cavity (G), and the alignment effect of FLMA under FOB (H).

pofol 6-8 mg/kg/h and remifentanil (Humanwell healthcare, China) 0.1-0.2 μg/kg/min, and intermittent injection of cisatracurium 0.05 mg/kg. During the operation, the patients inhaled pure oxygen and ventilated with positive pressure. The tidal volume was 6-8 ml/kg, the inspiratory-expiratory ratio was 1:2, and the respiration frequency was adjusted to keep ETCO2 at 35-40 mmHg. After the operation, the blood and secretions in the patient's mouth were fully sucked out. After the patient was fully awake, the laryngeal mask was removed, and the patient was sent to the anesthesia recovery room (PACU) for observation. Before leaving the PACU, the patient was scored by visual simulation method (VAS, 0-10 points), and a score greater than 3 was defined as the occurrence of throat pain.

Method and positioning of laryngeal mask placement

Patients in group C were treated with traditional FLMA placement. The patients were placed with their head in a backward position. The anesthesiologist opened their mouth with the left hand, lifted the chin with the thumb, and placed the right index finger between the laryngeal mask bag and the ventilation tube. The anesthesiologist placed it along the posterior wall of the oropharynx from the median approach until there was significant resistance in the pharynx. For the patients in group T, the nurse stood on the right shoulder side of the patient, holding the mandibular angle of the patient while holding the patient's head back with both hands, and opening the patient's mouth as far as possible with both thumbs backward and downward. At the same time, the anesthesiologist fixed the top of the patient's head with his left hand and put the laryngeal mask body into the mouth cavity with his right hand. While holding the mandibular angle, the tour nurse lifted the mandibular angle upward, opened the pharyngeal cavity. Then, while holding the mandibular angle, the nurse lifted the mandibular angle upward to open the pharyngeal cavity. The anesthetist placed the laryngeal mask along the posterior pharyngeal wall with the index finger of his right hand. When opening the pharyngeal cavity while lifting the mandibular angle, it is necessary to keep the mouth open to prevent accidental injury to the fingers of the anesthesiologist after lifting the posterior teeth of the mandible. The operation process is shown in **Figure 1**. After the two groups of laryngeal masks were inserted, the cuff pressure was inflated to 60 mmHg, then the laryngeal mask and the anesthesia machine line were connected, and manual control breathing was performed to judge the position of the laryngeal mask: (1) Observe the effectiveness of ventilation: When the tidal volume was controlled at 6 ml/kg, the neck for murmurs was auscultated and the peak airway pressure was observed. If there was no murmur and the peak airway pressure was less than 20 cm H_2O, continue to measure the maximum air leakage pressure. Otherwise, it was considered as the failure of laryngeal mask

Table 1. Comparison of general data between the two groups of patients

Group	Gender (Male/Female)	Age (Year)	Height (cm)	Weight (kg)	BMI (kg/m^2)	Operation time (min)	Mask type (4#/5#, n)
C (n=78)	45/35	41±13	167.62±8.82	69.82±14.02	24.62±4.02	83.21±28.53	57/21
T (n=79)	48/32	39±15	169.11±8.73	67.73±13.84	23.61±3.35	78.72±27.26	59/20
t/χ^2 value	0.231	0.704	1.062	0.953	1.792	1.021	0.053
P value	0.631	0.494	0.295	0.352	0.087	0.318	0.819

placement and needed to be replaced. (2) Oropharyngeal leak pressure (OLP): Close the valve of the anesthesia machine, and the flow rate of fresh gas was 5 L/min. Observe the rise of airway pressure in the curve of the respiratory volume loop. The airway pressure at the time when the peak airway pressure in the curve no longer rose or there was a leak in the mouth was taken as OLP. (3) Positional scoring of fiber laryngoscope (FOB): 1 point indicated only seen in the larynx; 2 points indicated visible vocal cords and posterior epiglottis; 3 points indicated visible in the larynx and epiglottis overlapped on the fence of the laryngeal mask; 4 points indicated epiglottis prolapse, and the larynx was not visible. (4) Pharyngeal injury: fiber laryngoscope was placed through the oral cavity to observe whether there was mucosal injury and bleeding in the way of laryngeal mask placement.

Observation index

General conditions of the patients, such as gender, age, height, weight, type of laryngeal mask used, and operation time were recorded. The baseline status, mean arterial pressure (MAP) and heart rate (HR) were recorded 1 min before and 1 min after laryngeal mask placement in both groups. The one-time and final success rates of laryngeal mask placement, the corresponding scores of OLP and FOB after placement were determined [11]. The OLP is an indicator of airway protection degree to evaluate whether successful placement is achieved. The complications related to laryngeal mask such as pharyngeal injury and pharyngalgia were recorded in both groups. Airway adverse events during anesthesia and recovery, including reflux aspiration, bronchospasm, laryngospasm, and hypoxemia (oxygen saturation below 91% for more than 1 minute) were recorded.

Statistical methods

Statistical analysis was performed using SPSS 23.0. Normally distributed measurement data was expressed as mean ± standard deviation ($\bar{x}$±sd). Two-sample independent t-test was used for the comparison of measurement data between groups, rank-sum test was used for rank data, and chi-square test was used for count data. $P<0.05$ indicates statistically significant differences.

Results

Comparison of general situation between two groups

As shown in **Table 1**, there was no significant difference between the two groups in general conditions such as gender, age, height, weight, BMI, operation time and the proportion of different types of laryngeal mask used ($P>0.05$).

Operating procedure of two-step jaw-thrust technique by both hands

As shown in **Figure 1**, two-step jaw-thrust technique by both hands was used in the operation, which was divided into the multiple steps.

Comparison of hemodynamic changes between the two groups

There were no significant differences in basal blood pressure, heart rate and changes of blood pressure and heart rate before and after laryngeal mask placement between the two groups ($P>0.05$, **Table 2**) (**Figure 2**).

Comparison of success rate, alignment and OLP of laryngeal mask placement between the two groups

The first successful rate of laryngeal mask placement in patients of group T was significantly higher than that in patients of group C ($P<0.001$). One case in group T and 2 cases in group C were changed to endotracheal intubation because of three times of failure. There was no significant difference in the final successful rate of laryngeal mask placement between the two groups ($P=0.561$). No leakage

Table 2. Baseline state and hemodynamic changes before and after laryngeal mask placement in the two groups

Group	Baseline state		Before 1 min		After 1 min	
	Blood pressure (mmHg)	Heart rate (Time/min)	Blood pressure (mmHg)	Heart rate (Time/min)	Blood pressure (mmHg)	Heart rate (Time/min)
C (n=78)	94.02±8.12	76.21±9.64	74.31±9.43	67.14±10.74	74.92±8.63	66.63±10.42
T (n=79)	91.81±11.23	76.62±10.12	75.01±10.05	68.52±10.13	74.51±9.01	68.42±11.51
t/χ^2 value	1.124	0.201	0.332	0.553	0.212	0.821
P value	0.262	0.833	0.745	0.581	0.836	0.413

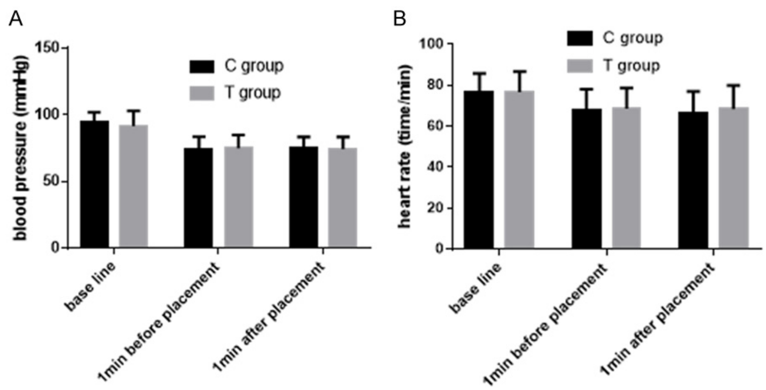

Figure 2. The basic state of the two groups and the hemodynamic changes before (A) and after (B) implantation of the laryngeal mask.

or displacement of laryngeal mask occurred in both groups during the operation. Group T experienced significantly higher FOB position score than group C (*P*<0.001). OLP in group T was significantly higher than that in group C (**Table 3**).

Comparisons of complications between the two groups

As shown in **Table 4**, the incidence of mucosal injury and postoperative pharyngalgia in group T was significantly lower than that in group C (P<0.001). There were 3 cases of soft palate injury, 1 case of palatal arch injury, 14 cases of posterior oropharyngeal wall abrasion, and 13 cases of postoperative pharyngalgia in group C. In group T, there were 2 cases of abrasion on the posterior wall of the oropharynx and 4 cases of postoperative pharyngalgia. No airway adverse events such as reflux aspiration, bronchospasm, laryngeal spasm and hypoxemia occurred during the anesthesia and recovery phase in both groups.

Discussion

The traditional method of bendable laryngeal mask placement is that the anesthesiologist's left hand supports the mandible and the right hand pushes the index finger through the median approach while keeping the patient's head back [12, 13]. However, the operation success rate is lower than other types of laryngeal mask placement. The main reason is that single person cannot fix the head and keep the patient's head back simultaneously, and the lack of laryngoscope support makes it difficult to ensure a satisfactory mouth opening. The soft catheters have no support force and thus cannot overcome resistance. In recent years, there have been many improvements in the placement of bendable laryngeal masks, such as the 90-degree rotation method and the addition of laryngeal mask guides [14, 15]. However, the operation is complicated, irritating, and clinically not popular. In addition, repeated insertion of the laryngeal mask and the violent operation can cause damage to the soft tissue of the oropharynx and increase the incidence of postoperative sore throat [16]. In this study, we found that the two-step jaw-thrust technique by both hands had little stimulation and no significant effect on hemodynamics. The success rate of the first intubation with a flexible laryngeal mask can be improved by two-hand approach, which is consistent with previous reports of mandibular support assisted by anesthetic nurses [17]. When the anesthesiologist placed the laryngeal mask on the head side of the patient with a backward position and the right hand operated downward and forcefully toward the foot side in the oral cavity, it was difficult to maintain the head in the backward position. The three-dimensional finite element model reconstructed by NMR found that the minimum cross-sectional area of the upper

Table 3. Comparison of success rate, alignment, airtight pressure, oropharyngeal injury and postoperative pharyngalgia between the two groups

Group	First-time success rate (%)	Final success rate n (%)	FOB position score (1/2/3/4), n	Air leakage pressure (cmH_2O)
C (n=78)	59 (73.81)	78 (97.52)	41/33/2/2	22.13±2.62
T (n=79)	78 (97.52)	79 (98.81)	58/19/3/1	25.43±3.82
t/χ^2 value	18.333	0.342	111.125	4.516
P value	<0.001	0.561	<0.001	<0.001

Table 4. Complications of the two groups of patients

Group	Soft palate injury	Palatal arch injury	Oropharyngeal wall abrasion	Postoperative pharyngalgia
C	3/78	1/78	14/78	13/78
T	0/79	0/79	2/79	4/79
Total	3/157	1/157	16/157	17/157
P value		<0.001		0.018

airway was larger in the head-back supine position than in the supine position, whether in normal or difficult airways. Clinical studies have also found that hyperextension of the head can elevate the hyoid bone and laryngeal inlet, increase the anterior and posterior diameters of the pharyngeal space, and flexion of the head can lead to a decrease in the anterior and posterior diameters of the pharyngeal cavity, and even partial airway obstruction [18, 19]. Therefore, the maximum volume of the pharyngeal cavity can be ensured during the placement of the laryngeal mask with the fixed head in the backward position, which is conducive to the smooth placement of the laryngeal mask [20, 21]. Itinerant nurses use their thumbs to open the oral cavity forcefully, which is helpful for the anesthetist to smoothly place the mask body along the midline, and it is not easy for the laryngeal mask to rotate. Supporting the mandibular angle while lifting the mandible at the same time is beneficial to fully open the pharyngeal cavity and increase the space within the pharyngeal cavity so that the tongue surface of the laryngeal mask can be smoothly laid on the mucosa of the pharyngeal cavity and placed down smoothly along the posterior pharyngeal wall [22, 23]. Putting it close to the posterior wall of the pharynx, on one hand, can avoid the occurrence of air leakage caused by wrinkles on the tongue surface of the laryngeal mask, on the other hand, it can ensure that the tip of the mask is located at the entrance of the esophagus, rather than rising upward to block the entrance of the glottis. The observation results showed that the laryngeal mask was better positioned, and the sealing pressure was higher. During nasal endoscopic surgery, blood, fluids, secretions, etc. will flow into the pharynx. The higher the airtight pressure is, the higher the safety is.

It is worth noting that the incidence of pharyngeal cavity injury and pharyngalgia in group T was significantly lower than that in group C in this study. We found that soft palate injury in group C resulted in nasopharyngeal hemorrhage and palatal arch injury, which were associated with greater resistance, repeated placement and violent manipulation [5, 24, 25]. One patient with palatal arch injury presented with persistent severe pharyngalgia after surgery, requiring additional antibiotics and aerosol therapy. The T group all had only slight posterior pharyngeal wall abrasion, which may be related to the high success rate of the first insertion and no obvious resistance to catheterization. Therefore, improving the method of laryngeal mask placement can increase the success rate of laryngeal mask placement for the first time to avoid severe soft tissue injury and postoperative sore throat.

However, our study had several limitations. First, the sample size was relatively small. Second, the lack of an ETI and a classic LMA groups for comparison with the use of FLMA is the main limitation of our study. Future studies of FLMA using two-step jaw-thrust technique by both hands or classic method, and comparison of FLMA, LMA and ETI with larger sample sizes may clarify this topic. We also believe that our research and clinical experience can guide clinicians in this field.

In summary, two-step jaw-thrust technique by both hands can increase the success rate of the first placement of the flexible laryngeal mask, improve the positioning of the laryngeal mask and increase the sealing pressure of the laryngeal mask, and reduce the incidence of oropharyngeal soft tissue injury and postoperative sore throat. Its operation is simple and easy, and it is worthy of widespread promotion in the clinic.

Disclosure of conflict of interest

None.

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