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A Clinical Study on the Application of Multi-Functional Intubating Laryngeal Mask Airway in EBUS-TBNA Technique

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Abstract

Objective: To observe the effectiveness and safety of the multi-functional intubating laryngeal mask airway (LMA) under a jet ventilator applied in EBUS-TBNA technique.

Methods: A total of 60 patients who received painless EBUS-TBNA were randomly divided into two groups, M and P, out of which group M patients used a normal laryngeal mask supplemented with positive pressure mechanical ventilation, while in group P, a multi-functional intubated laryngeal mask was placed along with a jet ventilator for regular jet ventilation. Mean Arterial Pressure (MAP), Heart Rate (HR), arterial blood gas levels (PaO and PaO), operation time, WAKE score, patient and surgeon satisfaction were compared between the two groups.

Results: Although the hemodynamics of both groups were stable, the intraoperative and postoperative PaO levels were significantly higher postoperatively than in preoperative assessment ($p<0.05$) while the intraoperative and postoperative PaO levels of group P were more stable than group M which was statistically significant ($p<0.05$). While there were no statistically significant differences in the operation time, WAKE score or patient satisfaction between the two groups ($p>0.05$), the surgeon satisfaction in group P was greater than the group M which was statistically significant ($p<0.05$).

Conclusion: The application of multi-functional LMA in EBUS-TBNA is a safe and ideal ventilation method, with stable intraoperative hemodynamics, PaO and PaO levels, as well as both patient and surgeon satisfaction.

Keywords: Laryngeal mask airway; Jet ventilation; Constant frequency; Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration (EBUS-TBNA)

Introduction

Lung cancer is the most common cancer and a leading cause of mortality worldwide which can be divided into two categories: Small Cell Lung Cancer (SCLC) and Non-Small Cell Lung Cancer (NSCLC) [1,2]. NSCLC accounts for 75%–80% of all lung cancer cases with high morbidity and mortality rates and can be classified into squamous cell carcinoma, adenocarcinoma, and large cell lung cancer according to its differentiation degree, morphological and biological characteristics [3]. Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration (EBUS-TBNA), first developed in 2002, has emerged as a new diagnostic tool for facilitating the diagnosis of peripheral lung lesions and was recommended by the National Comprehensive Cancer Network (NCCN) along with the American College of Chest Physicians (ACCP) in 2007 as a novel diagnostic technology for preoperative lymph node staging of lung cancer and as a routine mediastinal and hilar lymph node biopsy method [4] and was introduced to China in 2008. Presently, EBUS-TBNA has proven to be an effective and minimally invasive tool for diagnosing mediastinal lymph node staging in pulmonary malignant tumors as well as the lung and mediastinal space-occupying lesions along with the diagnosis of unexplained hilar and mediastinal lymph node enlargement [5] while in China; this operation is mostly performed either in local anesthesia or local anesthesia combined with intravenous (IV) drug sedation, as the relative general anesthesia methods are slightly inadequate. This study aimed to assess the self-developed and patented multi-functional intubated laryngeal mask (Patent No.: ZL 2019 2 2309568.2) (hereinafter referred to as the patent laryngeal mask) in the Normal Frequency Jet Ventilation (NFJV) and its application to EBUS-TBNA for observing its effectiveness and safety, which are now reported as follows.

Materials and Methods

Normal information

A total of 60 patients (aged 33–72 years) who received painless EBUS-TBNA in Xiamen Respiratory Disease Hospital between December 2018-December 2019 were selected, including 38 males and 22 females, weighing 49–77 kg, BMI 19.1–30.8 kg/m2, American Society of Anesthesiology (ASA) grade score II–III, and cardiac function grade 1–2. Although, the patients had no drug allergy history, severe chronic obstructive pulmonary disease, severe restrictive lung disorders, no obvious abnormality was found in the three major preoperative routine laboratory investigations, namely, liver and kidney function, coagulation function, and Electrocardiogram (ECG) examination. All 60 patients were randomly divided into two groups, 30 cases in each group: group M was considered a positive pressure ventilation group with anesthesia machine using common LMA, while group P was a jet ventilation group with patented LMA; no statistically significant difference in general information was observed between the two groups ($p>0.05$), indicating that they were comparable with each other's characteristics. This study was approved by our Medical Ethics Committee, and informed consent forms were signed by all the patients before the study commenced.

Methods

Anesthesia: After eight hours of fasting, patients were forbidden to drink two hours before the operation. After the proper patient placement, the upper limb veins were opened and connected to a multi-function monitor to perform non-invasive Blood Pressure (BP), ECG, pulse oximetry (SpO_2), End-Tidal Carbon Dioxide ($PETCO_2$), and Bispectral Index (BIS) monitoring. Radial artery puncture and catheterization were performed under local anesthesia with 2% lidocaine (0.5 ml), and both groups were given a slow IV injection of dezocine (0.1 mg/Kg) 15 min before the operation. Both groups were also given slow IV injections of propofol (2 mg/Kg) and rocuronium (0.6 mg/Kg) before the surgery, with mask-assisted ventilation. After the spontaneous breathing disappeared, group M was placed in an ordinary laryngeal mask, and an anesthesia machine was utilized for positive pressure mechanical ventilation; the parameters were adjusted constantly according to the ventilation situation while the group P was given a patented laryngeal mask and a jet ventilator was corporated (produced by Jiangxi Teli Anesthesia and Respiration Equipment Co. Ltd.), Model TKR-400T high-frequency jet ventilator) containing NFJV (inhaled oxygen concentration 100%, jet ventilation frequency 20–25 times/min, inhalation-expiration ratio 1:1, jet pressure 0.09MPa). After successful anesthesia induction and assessment of any untoward occurrence, the lymph node puncture location was determined according to the eighth edition of the lung cancer staging system (TNM classification) published by the International Association for the Study of Lung Cancer (IASCL) in 20176. During the operation, propofol (4–8 mg/kg/h) was continuously pumped while remifentanil (0.05–2 μg/kg/min) was used to maintain anesthesia along with intermittent dose adjustment according to the patient's vital signs for maintaining the BIS value at (40–60). If the patient's SpO_2 was less than 90% during the operation, the operator withdrew the bronchoscope and gave hyperbaric oxygen therapy in a closed environment followed by admission into PACU for postoperative observation.

Observation index: The MAP and HR were recorded just before anesthesia (T0), ten minutes after the bronchoscope passed through the glottis (T1), 20 min after the bronchoscope passed through the glottis (T2), and five minutes postoperatively (T3) along with arterial blood gas levels (PaO_2, PaO_2) while the number of hypoxic patients (SpO_2<90%) who, after withdrawal from bronchoscopy, underwent hyperbaric oxygen therapy during the operation as well as the total operating time was recorded. In patients who recovered from consciousness, the Steward recovery scoring system was performed (total score: 6 points: Consciousness; 2 points for fully awakened, 1 point for responding to stimuli, 0 point for non-response to stimuli; Airway patency-2 points for coughing according to instructions or crying, unobstructed airway maintenance, equivalent to 1 point, the airway needs to be supported, equivalent to 0 point; limb mobility-2 points for intended limb activities, 1 point for unintended limb activities, absence of activity, equivalent to 0 point). Patients were also asked about intraoperative awareness and anesthesia satisfaction which was evaluated by the surgeon during the operation.

Statistical analysis

Statistical software (SPSS19.0) was used for data analysis; measurement data were expressed as mean ± standard deviation (±s) whereas a two-sample t-test was used for comparison between groups, Chi-square test (c2) was used for assessing count data, and p<0.05 indicated that the difference was statistically significant.

Results

Hemodynamics

The MAP of the two patient groups measurement just before anesthesia (T0), ten minutes after the bronchoscope passed through the glottis (T1), 20 min after the bronchoscope passed through the glottis (T2), and five minutes postoperatively (T3) along with the difference in HR was not statistically significant (p>0.05), as mentioned in Table 1.

Group	Number of cases	Observation item	T0	T1	T2	T3
Group M	30	MAP(mmHg)	90.4 ± 11.4	91.8 ± 13.3	89.1 ± 9.8	89.9 ± 12.9
		HR(/min)	74.1 ± 10.8	73.7 ± 9.6	75.0 ± 10.1	72.4 ± 10.2
Group P	30	MAP(mmHg)	88.8 ± 11.8	89.9 ± 12.8	87.6 ± 10.1	89.3 ± 11.1
		HR(/min)	73.6 ± 11.2	73.9 ± 10.2	75.2 ± 10.3	73.4 ± 10.8

Table 1: Vital signs of the two groups of patients (±s)

Note: MAP: mean arterial pressure; HR: heart rate; 1mmHg = 0.133 kPa.

Arterial blood gas levels

The PaO_2 levels of both the groups at ten (T1) and 20 (T2) minutes after the passing of bronchoscope through the glottis as well as five minutes after the end of the operation (T3) increased when compared to the preanesthetic stage (T0) while the difference was statistically significant (p<0.05), while the difference between the two groups at the above-mentioned time points was not statistically significant (p>0.05), as is seen in Table 2. The group M findings revealed that the PaO_2 levels at 20 min after the bronchoscope passed through the glottis (T2) and five minutes postoperatively (T3) decreased as compared to the preanesthetic stage (T0), which was statistically significant (p<0.05); when both groups P and M were compared, the difference in PaO_2 level, at 20 min after the bronchoscope passed through the glottis (T2) and five minutes postoperatively (T3) was statistically significant (p<0.05), as depicted in Table 2.

Group	Number of cases	Observation item	T0	T1	T2	T3
Group M	30	PaO2(mmHg)	84.3 ± 19.4	299.7 ± 109.8a P=0.000	302.1 ± 116.5a P=0.000	237.0 ± 102.7a P=0.000
		PaCO2(mmHg)	37.8 ± 4.9	36.8 ± 4.4	34.9 ± 5.1a P=0.027	34.8 ± 5.0a P=0.024
Group P	30	PaO2(mmHg)	82.3 ± 25.4	298.1 ± 121.5a P=0.000	297.4±111.9a P=0.000	269.4 ± 118.2a P=0.000
		PaCO2(mmHg)	37.6 ± 4.9	38.7 ± 4.9	39.7 ± 4.3b P=0.000	39.7 ± 3.8b P=0.000

Table 2: Arterial blood gas of two groups of patients（±s）

Note: Compared with the same group before anesthesia, a: $P<0.05$; compared with M group, b: $P<0.05$; PaO_2: arterial oxygen partial pressure; $PaCO_2$: arterial carbon dioxide partial pressure.

Other findings

There was no significant difference between the two patient groups in terms of operating time, recovery score, and patient satisfaction ($p>0.05$), as is seen in Table 3, while the difference in satisfaction between the two surgical groups performing the procedure was statistically significant ($p<0.05$), mentioned in Table 3. None of the patients in the two groups developed hypoxemia or its awareness during the procedure.

Group	Number of cases	Operating time (min)	Awakening score (min)	Patient satisfaction (case%)	Doctor satisfaction (case%)
Group M	30	32.9 ± 6.2	5.9 ± 0.3	30（100%）	24（80%）
Group P	30	33.4 ± 6.1	5.8 ± 0.4	30（100%）	30（100%）

Table 3: Operation time, wake-up score, and patient's doctor satisfaction in the two groups.

Note: Compared with M group, b: $P<0.05$.

Discussion

Although Conventional Transbronchial Needle Aspiration (C-TBNA) has been widely used for more than 30 years, with sensitivity close to 70%-80% [7], the introduction of EBUS-TBNA, a recently developed endoscopic technique, is now mainly being used for the diagnosis of lung tumors, cancer as well as evaluation of preoperative staging and diagnosis of unexplained mediastinal or hilar lymphadenopathy. Despite the fact that C-TBNA examination is still one of the most conventionally used techniques for preoperative examination and diagnosis of lung cancer, it's possible replacement by EBUS-TBNA, an approach that displays more useful diagnostic adequacy, is still ambiguous [8].

As EBUS-TBNA displays the vascular loop and the outer bronchial wall lesions in real-time visualization and eludes inadvertent vascular injury or puncture marks, there is a vast improvement in the diagnosis rate; while the sensitivity of the lung cancer diagnosis and mediastinal lymphadenopathy is 82%-97%, along with the specificity of 82%-97%, thereby implying that due to nearly 100% diagnostic accuracy, it has become an effective approach for lung cancer diagnosis and mediastinal staging [9,10]. An ultrasonic bronchoscope is a device comprising of an ultrasound probe attached with a special suction biopsy needle in front of the bronchoscope, which is used for transbronchial needle aspiration biopsy under real-time ultrasound guidance and helps in confirming the blood vessel's position and preventing its accidental penetration. The ultrasonic bronchoscope has a 6.5 mm diameter, which is thicker than ordinary bronchoscopes, but creates a greater stimulation when passing through the glottis, however as EBUS-TBNA, during the examination requires repeated biopsy near the carina or on the bronchial tube wall that causes great irritation to the carina and surrounding tracheal mucosa; thus, causing great difficulty in tolerating and cooperating with the examination without anesthesia. EBUS-TBNA is usually performed under local anesthesia or local anesthesia combined with IV drug sedation, while the commonly used local anesthesia is 7% lidocaine aerosol that can be sprayed locally in the oral, nasopharyngeal cavity and airway or a local spray with 2% lidocaine (5–10 ml). Operating under simple local anesthesia often has several disadvantages like choking, suffocation, nausea, and vomiting experienced by the patients making them quite difficult to cooperate. Moreover, it can also damage the respiratory tract's mucous membranes and the vocal cords while causing cardiovascular and cerebrovascular accidents and Post-Traumatic Stress Disorder (PTSD) in the whole body. At the same time, due to the requirement of multiple biopsies of lymph node sets, the time for each investigation varies depending on the lymph node location, which inevitably increases the amount of local anesthetic being used and greatly increases the risk of local anesthetic poisoning if the inspection time is extended. Yehong X et al. reported that 7% lidocaine aerosol (3–5 mL) was sprayed on the throat, 2% lidocaine (2 mL) orally, and midazolam (2 mg) was used for sedation in patients, whereas Jiayuan S et al. added Dulan Ding (25–50 mg) intramuscularly; when compared with local anesthesia, the patient's comfort and acceptance was greatly improved, hence the local anesthetic dosage might be reduced simultaneously in such cases. Propofol sedation, commonly in combination with dexmedetomidine or remifentanil, is used clinically to maintain anesthesia, as dexmedetomidine is a highly selective α2 adrenergic receptor agonist with good sedative and analgesic effects and does not cause any respiratory depression, unlike other sedatives11. Although the above-mentioned anesthetic agents are short-acting and have less accumulated effect, their combined usage along with inherent drug synergistic effects promote hemodynamic stability as well as safe airway management in the concerned patients [12,13] reported that a remifentanil infusion at a rate of 0.075 µgkg−1 min−1 can provide adequate sedation for Awake Fiberoptic Bronchoscopy Intubation (AFOI), which was further validated by the finding of [14] that the maintenance dose of remifentanil is 0.02～0.08 μgkg–1min–1 for an adequate response. Another study conducted on the sedative effect in the AFOI process [15] revealed the maintenance dose of dexmedetomidine as 0.1 ～ 0.7 μgkg–1h–1. Additionally, the remifentanil and dexmedetomidine dosage in the present study were determined based on the above-mentioned studies, which depicted that due to usage of patient appropriate dose, decreased choking was observed along with a significant reduction of the body movement and a greater improvement in the postoperative analgesic effect and satisfaction. However, the general anesthetic agents' application in IV anesthesia can greatly increase the possibility of patients experiencing posterior tongue fall, respiratory depression, and sharp fluctuations in BP and HR, simultaneously, the airway obstruction with the bronchoscope makes it more difficult for anesthesiologists to manage airway patency whereas, in some instances, many EBUS-TBNA patients are elderly patients afflicted with cardiopulmonary diseases, and have poor tolerance to hypoxia. Therefore, optimizing the anesthesia induction along with proper airway management and avoiding avoid complications such as intraoperative hypoxemia is essential for a positive patient outcome during anesthesia.

In addition to local anesthesia induction, using local anesthesia combined with IV sedation preserves spontaneous breathing while employing general anesthesia with (LMA)-assisted ventilation in some cases is also used in painless bronchoscopy, which effectively reduces the occurrence of intraoperative hypoxemia. Another factor affecting the anesthetic output is the usage of fiberoptic bronchoscopy that usually occupies the entire airway as well as affects breathing and is in accordance with another study that the stimulation and obstruction of the fiberoptic bronchoscope can reduce the patient's PaO_2 level by 8–20 mmHg [16]. Although a thicker tube and usage in tracheal intubation makes an ultrasonic bronchoscope very inconvenient for entering and exiting while operating, so on this basis, a precise management model was developed for positive pressure mechanical ventilation of the anesthesia machine, including the application of laryngeal mask after general anesthesia induction in EBUS-TBNA. However, there were still some drawbacks that hampered the smooth functioning during the operation, like, firstly, the outer mouth of the laryngeal mask should be permitted for entering and exiting during the bronchoscopy procedure, but due to incomplete closure, it resulted in gas leakage. Also, the parameters displayed by the anesthesia machine truly did not reflect the effective tidal volume due to the occurrence of certain conditions like insufficient ventilation, excessive ventilation, or excessive tidal volume that might cause barotrauma risk due to high airway pressure; and as the operation progressed, anesthesiologists adjusted the anesthesia machine parameter constantly, that increased the workload with undue distractions.

Presently, there are numerous High-Frequency Jet Ventilation (HFJV) technologies applied to the conventional bronchoscopy procedure; the steps for airway patency are enumerated as follows:

1. The ventilation catheter is inserted directly into the other side of the nostril.

2. Thereafter, the urinary tube is inserted through the other side of the nasal cavity to the middle of the trachea and connected via the urethral tube to the high-frequency ventilator.

3. The optimal placement for the HFJV needle tube is 2–3 cm near the mouth of the laryngeal mask tube.

4. The needle tube enters the bronchoscope's suction hole and is further inserted 5 cm down and is connected to the endoscope mask.

5. The sputum suction tube gets attached to the bronchoscope, making the opening end of the suction tube 7–8 cm away from the end of the bronchus lens.

6. Initiation of HFJV results in micro catheter being tethered at the front end of the bronchoscope, along with a simultaneous supply of oxygen during the entire procedure that makes it efficacious, nevertheless further research should be ensured so that we use this novel modality in the best possible way.

Since high-frequency vibration accelerates the gaseous diffusion as well as produces bias flow due to the gaseous movement back and forth in the bronchus, resulting in the expansion of lung tissue asynchronously, that is conducive to oxygenation while avoiding carbon dioxide retention and hypercapnia [17]. Henceforth, for smooth procedural functioning, HFJV technology application in EBUS-TBNA has also been in consideration for a while; however, several preliminary experiments have proved that some HFJV features are not suitable for adapting to EBUS-TBNA working mechanism namely, HFJV often uses a low tidal volume with an inherent risk of carbon dioxide accumulation in the long-term use[18,19] reported that the HFJV mode incorporating I-gel laryngeal mask was utilized for mechanical ventilation in the EBUS-TBNA operation, which must be further supplemented by the inclusion of intermittent manual ventilation for reducing hypercapnia adequately. Moreover, in our study, HFJV was used in conjunction with a common laryngeal mask at a breathing rate of 60–150 breaths/min while the HFJV catheter opening was adjusted 2–3 cm further into the mouth of the laryngeal mask catheter, although the smaller tidal volume, faster frequency, along with a low airway pressure (7~10 cm H2O) and the exhalation resistance which might not induce barotrauma20 and cause the least interference to the cardiac blood flow while undergoing the operation [21,22]. However, a considerable number of patients cannot maintain good oxygenation; as a result, HFJV often uses a low tidal volume, causing a risk of carbon dioxide accumulation in the long-term application due to the inability of HFJV to reach the lungs owing to improper lumen curvature of a common laryngeal mask. Consequently, if the HFJV catheter [23] employed in the bronchoscopy enters the subglottis for jet ventilation, the resultant jet ventilation might interfere with the ultrasound imaging and adversely affect the procedure's outcome despite good oxygenation levels.

In our study, a multi-functional intubation laryngeal mask was independently developed thus, improving the size and curvature of the cavity at the laryngeal mask tip, which made it more conducive to the passage of ultrasound bronchoscopy. The laryngeal mask was equipped with an inner tube having an inner diameter of one cm and was soft in texture and could be extended till the subglottis with the ultrasonic bronchoscope along with opening up the respiratory tract for making it more conducive for the gaseous diffusion entering and exiting the mask. Additionally, the mask lumen's upper section was provided with two openings, one for the jet ventilation inlet and the other one was for the oxygen inlet, which could supply oxygen while the jet ventilation, increased the oxygen concentration involved in the venturi mask device, which further improved oxygenation. After the commencement of the operation, the inner tube returned to the glottis without irritating the respiratory tract during extubation, while NFJV (20–25 times/min) was chosen after considering the long operating time of EBUS-TBNA and the carbon dioxide accumulation issue since NFJV takes a long time for each jet, a larger tidal volume, and the long-distance covered by gas is instrumental to the alveolar gaseous exchange that reduces the functional shunt in the lungs. At the same time, the alveoli and chest wall have enough time to return to the appropriate position; thus, the NFJV can ensure partial pressure of oxygen and carbon dioxide emission for a better outcome.

Our study results reported that the hemodynamic indicators of both the groups were extremely stable, suggesting that EBUS-TBNA, along with the incorporation of the laryngeal mask ventilation without spontaneous breathing, can effectively inhibit the drastic BP and HR fluctuations caused by the operation without the usage of anesthesia or in conjunction with local anesthesia. Since reducing the incidence of adverse cardiovascular events is a safer and precise way of giving a prompt anesthetic response, the PaO_2 levels of the two patient groups both during the operation and after the operation were significantly higher than the preanesthetic stage, suggesting that the application of the laryngeal mask in EBUS-TBNA ensured the airway patency while reducing the airway obstructions that could further lead to hypoxia. It was also observed that there was no statistically significant difference in PaO_2 levels between the groups P and M at specific time points, which proved that this patented laryngeal mask is comparable to positive pressure ventilation provided by an anesthesia machine in terms of ensuring prompt oxygenation levels. When compared with group M, the PaO_2 levels of the group P during and after the inspection were more stable and had the same value before the operation, which proved that this patented laryngeal mask, when combined with RFJV, can effectively resolve the persisting issue of carbon dioxide accumulation caused by long-term HFJV that might later reduce hypercapnia and help in maintaining the entire internal environment balance. Our study results denoted that with an increase in ventilation time, group M developed a tendency to over ventilate, which further established that the differences in the positive pressure ventilation of the anesthesia machine under the laryngeal mask occurred due to the partial leakage of the gas; thus, implying that the effective ventilation volume limitations are difficult to manage and require further research to seek an amenable working mechanism. Since the inner tube of the patented laryngeal mask was soft and retreated to the glottis after the operation, no complaint of sore throat or hoarseness after the removal of the laryngeal mask was registered thereby stating that the hemodynamics of the extubation was stable along with higher patient satisfaction. Our study results revealed that six endoscopists in group M had difficulty in entering the corner of the laryngeal mask's inner mouth with the ultrasound bronchoscope whereas three patients experienced sore throat after extubation which might be due to the blind placement of the laryngeal mask as well as a tracheal tube that caused damage to the throat mucosa. No such case occurred in group P because the usage of a patented laryngeal mask that improved the size and curvature of the cavity at the head end of the laryngeal mask was more favorable for the ultrasound bronchoscope passage, which further improved the endoscopist satisfaction level during the procedure. Moreover, due to these above-mentioned advantages, the anesthesiologists in group P did not frequently adjust the ventilator parameters during the operation, and could focus more on observing the patient response as well as the operation procedure, that improved the safety of the patient.

Conclusion

To conclude, the multi-functional intubation type regular frequency jet ventilation applied to EBUS-TBNA can provide stable hemodynamics during the operation, effective oxygenation, avoid hyperventilation and carbon dioxide accumulation, as well as reduce hypercapnia by effectively stabilizing the internal environment as it is not only advantageous for the patient ventilation control, but also to the operating surgeon thus, providing a better diagnostic yield than the conventional methods. Usage of the EBUS-TBNA technique greatly improves the safety and comfort of the patient, as well as imparts satisfaction to the anesthesiologists and the operating surgeon. It is now considered an ideal ventilation method and is recommended for clinical use as it demonstrates excellent diagnostic accuracy and a positive patient outcome.

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