


# Clinical study of multifunctional laryngeal mask in airway interventional therapy

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## Abstract

**Objective:** This study is conducted to evaluate the efficacy and safety of using multifunctional intubation laryngeal masks with normal frequency jet ventilation in airway interventional therapy.

**Methods:** A total of 200 patients receiving airway interventional therapy were enrolled in this retrospective study and were divided into 2 groups (group M and group P) by doctors in our hospital to compare the effect of different laryngeal masks. Group M used common laryngeal masks and an anesthesia machine for positive pressure ventilation while group P took multifunctional intubation laryngeal masks and used a jet ventilator for normal frequency jet ventilation. The patients' mean arterial pressure, heart rate, arterial oxygen partial pressure (PaO<sub>2</sub>) and arterial carbon dioxide partial pressure (PaCO<sub>2</sub>), and the operation time, recovery score and the patients' and doctors' satisfaction levels were compared between the 2 groups.

**Results:** Both groups were hemodynamically stable, and their PaO<sub>2</sub> levels were significantly higher before the operation than that during and after the operation ( $P < .05$ ). Compared with group M, the PaCO<sub>2</sub> level of group P was more stable both during and after the operation, and this difference was statistically significant ( $P < .05$ ). There was no statistically significant difference in terms of the 2 group's operating time, recovery score, and patients' satisfaction levels ( $P > .05$ ). However, the satisfaction levels of doctors in group P were higher than that in group M, and this difference was statistically significant ( $P < .05$ ).

**Conclusion:** As statistics show, the intraoperative hemodynamics and PaO<sub>2</sub> and PaCO<sub>2</sub> levels were stable, and patients, surgeons and anesthesia operators were satisfied. Therefore, it is feasible to apply multifunctional intubation laryngeal masks with normal frequency jet ventilation in airway interventional therapy and it is a safe and ideal way to ensure ventilation.

**Abbreviations:** HFJV = high-frequency jet ventilation, PaCO<sub>2</sub> = arterial carbon dioxide partial pressure, PaO<sub>2</sub> = arterial oxygen partial pressure, SpO<sub>2</sub> = pulse oximetry.

**Keywords:** airway interventional therapy, jet ventilation, laryngeal mask, normal frequency

## 1. Introduction

With the development of bronchoscopy, fiberoptic bronchoscopy has become a widely used method in the diagnosis and treatment of respiratory diseases.<sup>[1-3]</sup> And due to high stimulation intensity and strong patient discomfort, it is more common for this operation to be practiced with general anesthesia in recent years.<sup>[4,5]</sup> However, general anesthesia under spontaneous breathing may cause severe consequences such as moving, choking, tracheospasm or even hypoxia.<sup>[6,7]</sup> And applying laryngeal masks is possibly the only way known to help effectively control airways in bronchoscopy operations. Because of the curvature of common laryngeal masks, air cannot effectively reach the lungs, for which high-frequency jet ventilation is necessary. Compared to it, the size and curvature of the cavity at the end of the multifunctional intubation laryngeal masks have been improved, which facilitates air movement and jet ventilation. In this study, these 2 types of laryngeal masks - multifunctional

intubation laryngeal masks and common laryngeal masks - were used. As mentioned above, the former type used jet ventilators while the latter one used an anesthesia machine for positive pressure ventilation. And the 2 types were compared to evaluate their effectiveness and safety in airway interventional therapy and hope our study can provide a reference for future clinical application.

## 2. Materials and methods

### 2.1. General information

A total of 100 patients who used multifunctional intubation laryngeal masks under general anesthesia in bronchoscopy from December 2018 to December 2019 were randomly selected and named group M. This group consisted of 51 males and 49 females, aged 18 to 71 years old, with an average age of (42.75 ± 8.53). And A total of 100 patients who

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

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used common laryngeal masks with jet ventilators in the same period were selected and named group P, including 53 males and 47 females, aged 19 to 67 years old, with an average age of  $(43.77 \pm 9.19)$ . Statistics show no significant statistical difference in comparison of gender, age, or other general information between these 2 groups' patients ( $P > .05$ ). Inclusion criteria: general anesthesia airway intervention was considered necessary through clinical manifestations, body signs and examinations. Exclusion criteria: patients with benign airway stenosis treated with balloon dilation, received lobectomy, with tracheal or main bronchial stenosis greater than 50% or invasive pulse saturation of peripheral oxygen ( $SpO_2$ ) less than 90%. By retrospectively analyzing the effect of different laryngeal masks used by doctors in our hospital who observed these 2 groups, there was no statistically significant difference in the comparison of general data between the 2 groups ( $P > .05$ ). The present study was approved by the Ethics Committee of our hospital, and prior informed consent of the patients was obtained.

## 2.2. Methods

The patients were prohibited from drinking for 4 hours and feasting for more than 6 hours before the operation. After entering the operation theater, their upper limb veins were opened and they were connected to a multifunctional monitor which monitors noninvasive blood pressure, electrocardiogram, pulse oximetry ( $SpO_2$ ), end-tidal carbon dioxide, and bispectral index. Radial artery puncture and catheterization were performed under local anesthesia with 0.5 mL of 2% lidocaine. And both group P and group M were given a slow intravenous injection of 0.1 mg/kg of dezocine 15 minutes preoperatively.

Induction medication: Both group P and group M were given a slow intravenous injection of 2 mg/kg of propofol and 0.6 mg/kg of rocuronium before surgery with mask-assisted ventilation. After the disappearance of spontaneous breathing, group M was given a common laryngeal mask and an anesthesia machine for positive pressure ventilation (the parameters were adjusted accordingly). And group P was placed in a patented multifunctional intubation laryngeal mask with a jet ventilator (Jiangxi Teli Anaesthesia & Respiratory Equipment Co., Ltd., Jiangxi, China; Model TKR-400 (T) high-frequency jet ventilator) to ensure normal frequency jet ventilation (inhaled oxygen concentration 100%, jet ventilation frequency 20 to 25 times/min, inhalation-expiration ratio 1:1, jet pressure 0.09 MPa). During the operation, 4 to 8 mg/kg/h propofol was continuously pumped, and 0.05 to 2  $\mu$ g/kg/min remifentanyl was used to maintain anesthesia. The dosage was adjusted according to the patient's vital signs to maintain the bispectral index range of 40 to 60. If the patient had  $SpO_2 < 90\%$  during the operation, the operator was instructed to withdraw the bronchoscope and perform pressurized oxygen in a closed environment. After the operation, the patient was admitted to the hospital's post anesthesia care unit for observation.

## 2.3. Observation indicators

The mean arterial pressure and heart rate before anesthesia (T0), 10 minutes after the bronchoscope had passed the glottis (T1), 20 minutes after the bronchoscopy had passed the glottis (T2), and 5 minutes after the operation (T3) and arterial blood gases ( $PaO_2$ ,  $PaCO_2$ ) were recorded. The number of patients with hypoxemia ( $SpO_2 < 90\%$  who withdrew from bronchoscopy and underwent pressurized oxygen operation) during the operation was recorded. And the operating time was noted. After the patient woke up, the Steward awakening score was performed. (The Steward awakening score range from 0 to 6: awakesness – 2 points for fully awake, 1 point for responding to stimuli, and 0 point for non-response to stimuli. Airway patency – 2 points for coughing according to the doctor's instructions, 1 point for maintaining the airway unobstructed without any support, and 0 point for maintaining the airway unobstructed with support. Limb mobility – 2 points for conscious limb activity, 1 point for unconscious limb activity, and 0 point for limb inactivity). The patient was asked whether there was intraoperative awareness and about his/her satisfaction levels with anesthesia. And the surgeon was asked about his/her satisfaction levels during the operation.

## 2.4. Statistical methods

Data analysis of this study was conducted with SPSS 25.0, a statistical software. The categorical data are expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ), and 2 sample *t* tests were used for comparison between the 2 groups. And the numerical data is expressed as  $\chi^2$  tests, with a *P*-value of  $< .05$  implying a statistically significant difference.

## 3. Results

### 3.1. Baseline information

Group P: 47 cases of primary tumors or metastases in the lung were reviewed and cleared, 34 cases were reviewed after airway stents insertion, 19 cases were treated with photodynamic therapy, 16 cases were combined with hypertension, and 9 cases were combined with coronary artery disease (atherosclerotic heart disease).

Group M: 53 cases of primary tumors or metastases in the lung were reviewed and cleared, 30 cases were reviewed after airway stents insertion, 17 cases were treated with photodynamic therapy, 13 cases were combined with hypertension and 7 cases were combined with coronary artery disease (atherosclerotic heart disease).

### 3.2. Hemodynamics

The mean arterial pressure and heart rate levels of the 2 groups were recorded before anesthesia (T0), 10 minutes after the bronchoscopy passed the glottis (T1), 20 minutes after the bronchoscopy passed the glottis (T2), and 5 minutes (T3) after the operation show no statistically significant difference ( $P > .05$ ), as shown in Table 1.

**Table 1**

Life characteristics of the patients in both groups ( $\bar{x} \pm s$ ).

Group	Group M		Group P		t(MAP/HR)	P(MAP/HR)
Case number	100		100			
Observation item	MAP (mm Hg)	HR (time/min)	MAP (mm Hg)	HR (time/min)		
T0	89.95 $\pm$ 6.98	73.74 $\pm$ 6.43	89.63 $\pm$ 5.95	74.29 $\pm$ 6.44	0.266/0.469	0.791/0.640
T1	90.12 $\pm$ 7.56	72.08 $\pm$ 5.58	90.47 $\pm$ 6.71	71.2 $\pm$ 5.84	0.266/0.840	0.791/0.403
T2	88.97 $\pm$ 5.58	73.65 $\pm$ 5.22	88.04 $\pm$ 5.40	74.45 $\pm$ 5.76	0.926/0.806	0.356/0.422
T3	89.02 $\pm$ 7.32	73.15 $\pm$ 5.62	88.76 $\pm$ 6.55	73.38 $\pm$ 6.19	0.197/0.211	0.844/0.833

1 mm Hg = 0.133 kPa, HR = heart rate, MAP = mean arterial pressure.

### 3.3. Arterial blood gas

The PaO<sub>2</sub> levels of the 2 groups recorded 10 minutes (T1) after the bronchoscopy passed the glottis, 20 minutes (T2) after the bronchoscopy passed the glottis, and 5 minutes (T3) after the operation increased compared with that before the anesthesia (T0), and the difference is statistically significant (*P* < .05). However, the difference between the 2 groups at the above time points is not statistically significant (*P* > .05) (Table 2). In terms of group M, the PaCO<sub>2</sub> collected at 20 minutes (T2) after the bronchoscopy through the glottis and 5 minutes (T3) after the operation are lower than those before anesthesia (T0), and the difference is statistically significant (*P* < .05).

The PaCO<sub>2</sub> of group P collected at 20 minutes (T2) after the bronchoscopy passed the glottis and 5 minutes (T3) after the operation were compared with those of group M, and the difference is statistically significant (*P* < .05), as shown in Table 2.

### 3.4. Other

As Table 3 shows, there is no statistically significant difference between the 2 groups' operating time, recovery score, and patients' satisfaction levels (*P* > .05). However, the difference in satisfaction levels of the surgeons of the 2 groups is statistically significant (*P* < .05). No patient in either group appeared with hypoxemia or intraoperative awareness.

## 4. Discussions

Airway interventional therapy is vital in the diagnosis and treatment of benign and malignant lung diseases.<sup>[8,9]</sup> And jet ventilation is of great significance in helping airways unobstructed in interventional therapy under general anesthesia.<sup>[10]</sup> High-frequency jet ventilation (HFJV) is a commonly used mode, in which frequency ranged from 60 to 600 times/min, and tidal volume ranged from 1 to 3 mL/kg. The tidal volume includes the volume of jet gas and the Venturi effect. It is less than the total amount of the anatomical dead space and the equipment dead space. The body's oxygenation maintenance mainly depends on the direct diffusion of gas in the alveolar cavity, Taylor diffusion, swing breathing, etc.<sup>[11,12]</sup>

Sütterlin et al<sup>[13,14]</sup> used a pig model without respiratory diseases and found that when the HFJV frequency reaches 300 beats/min in the absence of airway obstruction, sufficient oxygen supply cannot be guaranteed. In the severe airway stenosis (75% obstruction) model, the frequency of HFJV needs to be set to <150 times/min to ensure the supply of oxygen and an effective carbon dioxide emission.<sup>[15]</sup>

Several studies focused on the application of HFJV technology in airway interventional therapy in China and beyond. We also considered the application. However, our preliminary experiments have shown that it is unreasonable to follow the previous studies completely.<sup>[16,17]</sup> First, HFJV often uses a low tidal volume, which may lead to carbon dioxide accumulation in long-term application.<sup>[18-20]</sup> We have tried to perform HFJV with a common laryngeal mask at a respiratory rate of 60 to 150 breaths/min, and fix the HFJV catheter opening 2 to 3 cm in the mouth of the laryngeal mask catheter. However, numerous patients could not maintain good oxygenation. And due to the curvature of the lumen of a common laryngeal mask, HFJV cannot effectively reach the lungs. But if the HFJV catheter is bound with the bronchoscope and enters the subglottis for jet ventilation,<sup>[21,22]</sup> even though the patient's airway blockage is <50%, the soft fiber bronchoscope placed in the airway will reduce the area to one-third of its original and lead to airway obstruction.<sup>[23,24]</sup> Moreover, for patients with tumor or stent implantation, it is likely to cause respiratory infections and affect the respiratory system. Although these can be improved by the intermittent withdrawal of the fiberoptic bronchoscope, and oxygenation can be maintained to a large extent, jet ventilation still has a

Group	Group M				Group P			
	PaO <sub>2</sub> (mm Hg)	PaCO <sub>2</sub> (mm Hg)	PaO <sub>2</sub> (mm Hg)	PaCO <sub>2</sub> (mm Hg)	PaO <sub>2</sub> (mm Hg)	PaCO <sub>2</sub> (mm Hg)	t(PaO <sub>2</sub> /PaCO)	P(PaO <sub>2</sub> /PaCO)
Case number	100				100			
Observation item								
T0	84.9 ± 11.11	37.1 ± 2.69	83.4 ± 14.46	37.6 ± 2.47	0.652/1.109	0.516/0.270		
T1	307.8 ± 64.69*	36.2 ± 1.97	308.1 ± 69.72*	37.7 ± 2.52	0.022/3.633	0.983/0.000		
T2	296.5 ± 73.49	33.5 ± 3.03*	297.8 ± 64.08*	39.0 ± 2.96**	0.100/9.964	0.921/0.000		
T3	231.4 ± 55.84*	34.5 ± 3.40	250.3 ± 52.28	38.9 ± 2.05**	1.906/8.558	0.059/0.000		

PaO<sub>2</sub> = arterial blood oxygen pressure; PaCO<sub>2</sub> = arterial blood carbon dioxide pressure.  
 \**P* < .05 compared before anesthesia.  
 \*\**P* < .05 compared with M group.

**Table 3****Operating time, awakening score, and patient physician satisfaction between the 2 groups.**

Group	Example number	Operate time (min)	Awakening score (points)	Patient satisfaction (Example%)	Physician satisfaction (Example%)
M组	100	32.32 ± 3.73	5.5 ± 0.5	65 (100%)	52 (80%)
P组	100	32.80 ± 3.86	5.6 ± 0.5	55 (100%)	55 (100%)
t/χ <sup>2</sup>		0.730	1.212	*	12.336
P		0.467	0.228	*	0.000

Comparison with group M, \*P &lt; .05.

disadvantage. It interferes with ultrasound imaging, which will severely influence the operation of the surgeon.

Therefore, our team independently developed a multifunctional intubation laryngeal mask. The size and curvature of the cavity at the end of this laryngeal mask were improved, which is more conducive for the passage of ultrasound bronchoscopy. And this mask is equipped with a soft inner tube. The tube has an inner diameter of 1 cm and can be inserted into the subglottis with the ultrasonic bronchoscope. It will not affect the operation of the ultrasonic bronchoscope but opens up the airway and the entry and exit of jet gas. There are 2 openings in the upper section of the lumen of the laryngeal mask, namely the jet ventilation inlet and the oxygen inlet, which can supply oxygen during jet ventilation, increasing the oxygen concentration of the gas involved in the Venturi effect and further improving oxygenation. After the operation, the inner tube can be returned to the glottis without stimulating the respiratory tract during extubation. Meanwhile, considering the risk of carbon dioxide accumulation, we set the normal frequency injection ventilation at 20 to 25 times/min. Normal-frequency jet ventilation provides a long-time air jet and a larger tidal volume, and its gas reaches farther, which is beneficial to the gas exchange in the alveoli and reduces the functional shunt in the lungs. Besides, it allows the alveoli and chest wall to return to their appropriate position within enough period, which ensure normal oxygen partial pressure and carbon dioxide emission.<sup>[16,20]</sup>

In this study, the hemodynamic indicators of the 2 groups were very stable, suggesting that when applying laryngeal masks for ventilation without spontaneous breathing, the PaO<sub>2</sub> of the 2 groups during and after the operation significantly increased compared with that before anesthesia. This indicates that the application of laryngeal masks in the interventional treatment can help the airway establishment, and hence the reduction of hypoxia. There was no statistically significant difference in the PaO<sub>2</sub> levels of group P and group M at each time point, which proved that this patented laryngeal mask can function as an anesthesia machine for positive pressure ventilation in terms of ensuring oxygenation. Compared with group M, the PaCO<sub>2</sub> levels of group P during and after the inspection were more stable and almost the same as that before the operation, which means that this mask combined with regular-frequency jet ventilation can effectively prevent the carbon dioxide accumulation caused by long-term high-frequency jet ventilation, and thereby reduces hypercapnia and helps maintain the balance of the entire internal environment. Statistics of group M show that as the ventilation time grows, the possibility of over-ventilating increases, which further proves the difficulty in ensuring effective ventilation during the positive pressure ventilation brought by an anesthesia machine with the laryngeal mask due to a leakage of gas. This issue needs further research. Apart from this, since the inner tube of the patented laryngeal mask is soft and can be retreated to the glottis after the operation, no complaints of sore throat or hoarseness appeared, and the hemodynamics of the extubation is stable after the laryngeal mask is removed, for which the patients were highly satisfied with it. In this study, 6 endoscopists in group M faced difficulty in entering the corner of the inner mouth of the laryngeal mask with an ultrasound bronchoscope, but none in group P. For patients with severe

airway stenosis, even when their main airway stenosis is > 90%, good oxygen and an effective discharge of carbon dioxide<sup>[25]</sup> can be provided. No statistically significant difference was observed in the recovery time between the 2 groups of patients. Since the operation time is relatively short, we believe that mild carbon dioxide accumulation has no severe effect on the postoperative recovery time of patients. But similar to Barker et al's<sup>[26]</sup> study results, our although mild carbon dioxide accumulation may not impact patients' safety, it is necessary to monitor the end-tidal carbon dioxide partial pressure to avoid severe hypercapnia. As the mask improves the size and curvature of the cavity at the end of the laryngeal mask, it is easier for the passage of the ultrasound bronchoscope, and this improves the satisfaction levels of the endoscopist during the operation. In addition, since it reduces the frequency for anesthesiologists in group P to adjust the parameters of the ventilator during the operation, they can pay more attention to the patient and the operation, and hence improves the safety of the patient.

Overall, it is feasible to apply multi-functional intubation laryngeal mask in airway interventional therapy if it works with regular-frequency jet ventilation. It can provide stable hemodynamics during the operation, effective oxygenation, avoid hyperventilation and carbon dioxide accumulation, reduce hypercapnia, and effectively stabilize the internal environment. And it can help not only control patients' ventilation but also the operation of the surgeon. It improves the safety and comfort of patients, as well as the satisfaction levels of anesthesia and surgery. Therefore, it is an ideal ventilation method and is recommended for clinical use.

### Author contributions

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