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Original Article

Application of a novel gastro-laryngeal mask in upper gastrointestinal endoscopy surgery: A pilot randomized clinical trial

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ABSTRACT

Background: The Gastro-Laryngeal Mask (Jcerity Endoscoper™ Airway) is a new airway management technique utilized in patients undergoing upper gastrointestinal endoscopy surgery under general anesthesia, but evidence of its effectiveness and safety is scarce.
Objective: To assess the success rate of insertion, cardiovascular response, airway pressure, time taken for placement, nausea or vomiting, pharyngodynia, and other complications of using the new type of back-open gastroscopy laryngeal mask.
Methods: We screened 1401 patients; 105 were ineligible, and 40 declined to participate. Participants were randomly allocated into the Jcerity Endoscoper™ Airway (JEA) group and the endotracheal tube (ET) group. Among them, 1266 patients were randomly assigned to receive endotracheal intubation (n = 633) or JEA (n = 633).
Results: Compared with the ET group, the JEA group had a significantly shorter insertion time and less cardiovascular response during insertion. The time taken for extubation after anesthesia and residence time in PACU in the JEA group was shorter than in the ET group. Especially, the incidence of pharyngodynia in the JEA group was lower than that in the ET group. The satisfaction of endoscopists with the JEA reached 99.4%.
Conclusions: This study showed that the back-open JEA can not only provide a safe and effective airway guarantee for patients but also provide convenience for gastroenterologists to carry out endoscopic operations.
Trial Registration: The trial was registered before patient enrollment at the Chinese Clinical Trial Registry Center (ChiCTR2100046864, principal investigator: Yunqi Lv, date of registration: 2021-05-29). The study was conducted in the painless diagnosis and treatment center of the First Affiliated Hospital of Zhengzhou University from June 2021 to October 2023 (Date of enrolment of the first research participant:2021-06-01).

Introduction

The wide application of electronic endoscopes, magnifying endoscopes, and ultrasonic endoscopes has greatly improved the level of diagnosis and treatment of digestive diseases [1,2]. Compared with surgery, endoscopic treatment has the advantages of less trauma, lower cost, fewer complications, and rapid recovery, which makes it convenient for patients to recover earlier. Endoscopic treatment often needs to be completed under deep sedation or general anesthesia because of the long procedural time and certain trauma [3,4]. Altogether, these bring challenges to airway management during operation, especially for patients with obesity, a short jaw, obstructive sleep apnea, a potentially difficult airway, and so on. If patients are given deep sedation or anesthesia without a safe airway, the incidence of respiratory complications is high. Therefore, the choice of airway management is an important issue related to patient safety [5,6]. Appropriate depth of anesthesia and establishment of a stable airway can also make endoscopists pay more attention to the treatment process to improve the complete resection rate of the tumor, and the success rate of ERCP, and shorten the operation time [7,8].

General anesthesia with endotracheal intubation is often used in digestive endoscopic treatment, while endotracheal intubation often requires a deeper anesthesia depth, and the incidence of

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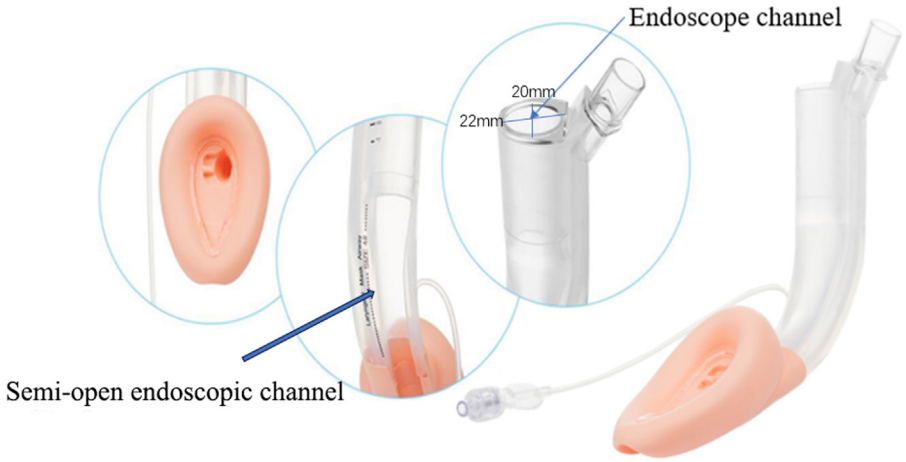

Fig. 1. Illustration of a back-open gastroscopy laryngeal mask JEA (Reprinted from http://www.jenstonmed.com/product/210.html).

postoperative airway injury is high. In addition, coughing during extubation can lead to gastrointestinal mucosal tears, bleeding, perforation, and other related risks. Laryngeal masks, as a simple, safe, and effective airway management method, have been widely used in the airway management of various operations [9]. However, attention and research on gastroscopy laryngeal masks specially used for digestive endoscopy are limited at present, and there are only a few related reports [8,10–14].

As a new type of gastroscopy laryngeal mask, compared with the LMA-Gastro™ Airway, the back-open Jcerity Endoscoper™ Airway (Zhejiang Jiancheng Medical Technology Co., Ltd., Huzhou, China. Patent number: ZL 201920081516.1) has a larger and wider endoscope channel, and its endoscope channel innovatively adopts a semi-open design. The semi-open endoscopic channel has a large enough space (20 by 22 mm) (Fig. 1), which reduces the friction with the endoscope (Generally, the outer diameter of the gastroscope is 5.4/8.9/10.2/13.2 mm, etc., and rarely exceeds 13.2 mm), and this innovative design makes it more convenient for endoscopic insertion and flexible operation [15,16]. In addition, the Jcerity EndoscoperTM Airway (JEA) cuff adopts a low-pressure, high-capacity design, which means it can automatically attach to the posterior pharyngeal wall of the patient and form an effective sealing area in the pharynx to ensure safe and effective ventilation. Its improved design structure provides a novel anesthetic airway management for painless endoscopic diagnosis and treatment. Based on this, the purpose of this study is to comprehensively evaluate the role of the back-open JEA in upper gastrointestinal endoscopic treatment through a large-sample prospective study.

Methods

As a prospective, randomized controlled clinical trial, this trial was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University in June 2019 (Approval No. 2019-KY-276), and each participant signed a written informed consent before the study. The trial was registered before patient enrollment at the Chinese Clinical Trial Registry Center (ChiCTR2100046864, principal investigator: Yunqi Lv, date of registration: 2021-05-29). The study was conducted in the painless diagnosis and treatment center of the First Affiliated Hospital of Zhengzhou University from June 2021 to October 2023.

Study procedures

A biostatistician independent of data management and statistical analysis used SAS 9.4 software (SAS Institute, Cary, NC) to generate random numbers (with a ratio of 1:1). The results of the randomization were sealed in sequentially numbered envelopes and stored at the research site until the end of the study. According to the randomized results, patients who met the inclusion criteria were divided into the JEA group or the ET group. The specific research procedures were as follows: Thirty minutes before the start of anesthesia, 0.1 $mg.kg^{-1}$ penehyclidine hydrochloride (anticholinergic agent to reduce oral and airway secretions) was administered intravenously to all patients. After entering the operating room, the left lateral recumbent position was taken, and ECG, SpO_2, non-invasive blood pressure, end-expiratory carbon dioxide, and EEG bispectral index (BIS) were routinely monitored for all patients. Before induction, the patient was preoxygenated (6 L/min) for at least 3 minutes. The induction drugs were as follows: propofol (2 $mg.kg^{-1}$), sufentanil (0.3 $\mu g.kg^{-1}$), cisatracurium besilate (0.1 $mg.kg^{-1}$) or succinylcholine (1 $mg.kg^{-1}$). Then, the JEA or endotracheal tube was placed, respectively, according to the randomization situation. Since endoscopic treatment of the upper digestive tract is mostly performed in the left lateral recumbent position, to shorten the preoperative preparation time and reduce the possible complications of postural changes after anesthesia, we performed endotracheal intubation in the left lateral decubitus position. Both groups were mechanically ventilated with a tidal volume of 6–8 $mL.kg^{-1}$, and the respiratory rate was adjusted to maintain the end-expiratory CO_2 at a level of 35–45 mmHg. During the operation, continuous administrations of sevoflurane, propofol, and remifentanil were used to maintain the BIS between 40 and 60. Depending on the length of the operation, additional cisatracuramide may be added if necessary. Pressure-volume curves were recorded throughout the procedure. All anesthesiologists and endoscopists participating in this trial had more than 5 years of experience in airway management or endoscopic operation. They must follow standardized operation procedures and successfully operate at least 50 cases to ensure the consistency of operating techniques.

Standardized JEA insertion process

The JEA size was selected according to the manufacturer's instruction manual. In brief, size 3 is for a body weight of 30–50 kg, and size 4 is for all patients weighing more than 50 kg (since size 4 can meet the needs of all patients weighing more than 70 kg, the manufacturer did not design size 5 or above). All laryngeal masks were fully deflated and lubricated with a water-soluble gel. The anesthesiologist stood on the left side of the

patient. When the BIS value was less than 60, he gently pressed the patient's lower jaw with the left hand to open the mouth, then slid the lubricated laryngeal mask into the mouth along the tongue and hard palate with the right hand and completely inserted the cuff of JEA until resistance was felt. If necessary, the assistant should lift the lower jaw and help open the pharyngeal space to avoid oral injury caused by excessive force. The anesthesiologist then filled the cuff with the appropriate amount of air and observed the pressure indicator or airbag. The pressure of the cuff should not exceed 60 cmH_2O. If the lungs could not be ventilated, he attempted another insertion or chose another size. If he was still unable to ventilate, the anesthesiologist gave up the laryngeal mask and changed to endotracheal intubation. The gastric endoscope was lubricated before starting the endoscopic operation.

Outcomes

The differences between the JEA group and the ET group were recorded in detail by independent observers. The primary endpoint was the first-attempt insertion success rate, which was defined as the first-attempt insertion success of a JEA or endotracheal tube by a skilled anesthesiologist after induction of anesthesia.

The secondary endpoints included the number of attempts to insert an endotracheal tube or laryngeal mask, the time taken for intubation or insertion (including the total time to insert JEA, to check the quality of the ventilation, and to tape-fix it), cardiovascular response (mean arterial pressure (MAP) and heart rate (HR) variation range) during intubation or laryngeal mask insertion and removal, airway pressure 5 minutes after the insertion, the time taken for extubation (time from endoscopic withdrawal to extubation of tracheal intubation or laryngeal mask), and complications related to airway management (reflux aspiration or regurgitation, choking cough during extubation, postoperative pharyngodynia, dental or mucosal trauma, dysphagia or dysphonia, etc.). Cardiovascular response to endotracheal intubation or laryngeal mask insertion was defined as the amplitude of MAP and HR changes immediately after intubation or laryngeal mask insertion compared to 3 minutes after induction (before intubation or laryngeal mask insertion). The cardiovascular response to extubation was defined as the change in amplitude of MAP and HR immediately after extubation and 5 minutes before extubation. Additional prespecified endpoints of JEA included difficulty degree of insertion (easy/difficult), quality of ventilation (1/2/3), seal pressure, fiberoptic bronchoscope (FBS) view of vocal cords (VC) (optimal/suboptimal), complications associated with JEA insertion (blood staining degree of the laryngeal mask (mild/moderate/severe), pharyngodynia, postoperative oral bleeding, dysphagia, laryngeal nerve injury or vocal cord paralysis, arytenoid cartilage dislocation, maxillary hematoma and others (lingual nerve paralysis, etc.).

Definition of specific indicators

Difficulty degree of insertion (easy/difficult): As a subjective indicator, we tried to standardize it. First-attempt insertion success was defined as easy, and difficulty was defined as requiring two or more insertions or the assistance of an aid to hold the jaw [10].

Quality of ventilation: The JEA ventilation quality was scored on a 3-point scale [17]: (1) optimal ventilation was defined as normal thoracic expansion, a normal pressure-volume curve, and a square wave diagram without air leakage; (2) ventilation difficulty was defined as peak airway pressure >25 cm H_2O or severe air leakage related to mechanical ventilation failure. If ventilation difficulty was managed by adjusting the insertion depth, changing the head and neck position, or adjusting the cuff volume, the score was recorded as 2 points. (3) After all attempts to ventilate failed, the case was changed to endotracheal intubation.

Airway seal pressure [17]: It was measured by closing the expiratory valve of the anesthesia machine and observing the balanced airway pressure at a fresh air flow rate of 3 $L.min^{-1}$. When the peak airway pressure did not rise or there was air leakage in the mouth, the airway pressure at this time was the maximum leakage pressure. If the maximum air leakage pressure was less than 15 cm H_2O, the JEA was replaced. If there was gas leakage in the mouth, we opened the expiratory valve to avoid alveolar trauma. If the maximum pressure reached 40 cm H_2O, we recorded 40 cm H_2O as the airway sealing pressure. Airway sealing pressure was recorded at four time points (T1: immediately after JEA insertion; T2: 3 min after T1; T3: 10 min after T1; and T4: at the end of the operation).

FBS view of VC [17]: When JEA was successfully inserted, a 4.0 mm fiberoptic bronchoscope (FBS) (F1-10RBS, Pentax, Japan) was introduced near the end of the laryngeal mask through its airway channel by the same anesthesiologist familiar with FBS. If a resistance was encountered, we operated the tip of the FBS and classified the laryngoscope view.

Blood staining degree of the laryngeal mask (mild/moderate/severe): The criteria for determining the degree of blood staining of the laryngeal mask were as follows: if a small amount of blood was detected on the removed laryngeal mask, it was recorded as "mild"; if the blood was limited to one-quarter of the surface of the laryngeal mask, it was classified as "moderate"; if the blood covered more than a quarter of the laryngeal mask surface, it was classified as "severe". If there was more than moderate blood staining, a visual laryngoscopy should be performed 6 hours after surgery to observe the damage to the oral mucosa.

After one hour in the recovery room, a structured interview was conducted to investigate the patient's pharyngodynia, which was recorded by a blinded observer. Three hours after the operation, the complications related to the insertion of a laryngeal mask were followed up by a blinded observer (postoperative oral bleeding, dysphagia, laryngeal nerve injury or vocal cord paralysis, arytenoid dislocation, maxillary hematoma, vocal cord paralysis, etc.).

Sample size

The primary outcome was the first successful insertion rate. In the operating room, the first success rate of tracheal intubation under the guidance of direct classic laryngoscopy was 97% [18]. In our previous experiment, the first success insertion rate of the back-open JEA was about 91%. The sample size of the test group and control group was calculated according to the proportion of 1:1 and calculated to detect a 10% margin, which was considered clinically relevant in this scenario. For a type I error of 0.05 and a type II error of 0.1, using the non-inferiority test, considering a 5% missed follow-up rate, 632 patients were required for each group. Because the missed follow-up rate was less than 5%, we finally collected 631 effective cases in the JEA group and 624 cases in the ET group.

Statistical analysis

Statistical analysis was performed using the Student's t-test for unpaired quantitative variables and the χ^2 test or Fisher's exact tests for qualitative variables as required. Statistical analyses were done on SPSS 24.0 software (SPSS, Chicago, IL) or GraphPad Prism version 8 (GraphPad Software, La Jolla, CA), and *p*-values less than 0.05 were considered to have statistical significance.

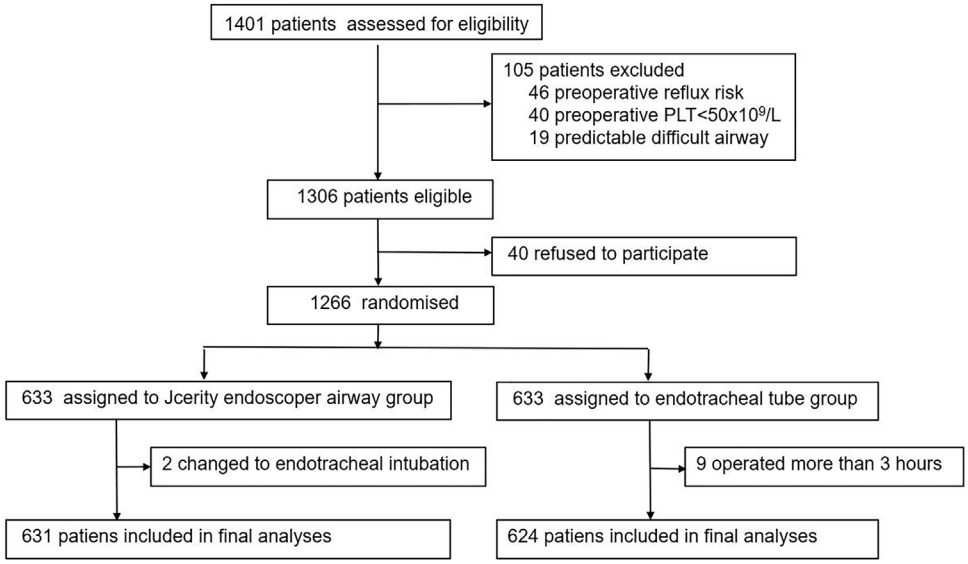

Fig. 2. The CONSORT flow diagram.

Results

From June 2021 to October 2023, 1401 patients undergoing gastrointestinal endoscopy were screened to participate in the study. Among them, 1266 patients were enrolled in the study and randomly assigned to receive endotracheal intubation (ET group, n = 633) or JEA insertion (JEA group, n = 633) (Fig. 2). There were 2 cases in the JEA group who dropped out of the trial due to the change of operation (Tracheo-esophageal fistula or esophago-mediastinal fistula occurred during the operation), and there were 9 cases in the ET group withdrew from the trial since the operation time was more than 3 hours. Finally, there were 631 effective cases collected in the JEA group and 624 cases in the ET group. Overall, the two groups were well-matched for baseline and perioperative variables. There were no differences between the groups regarding age, gender, body mass index (BMI), ASA classification, Mallampati classification, or comorbidities (Table 2).

Table 1 lists the types of endoscopic treatment and size of airway management tools under general anesthesia included in this study. The time taken for insertion of JEA was 17.2 [SD3.4]s (Table 2), which was significantly shorter than the ET group (30.1[SD8.3]). The first successful insertion rate for the JEA group was lower than that of the ET group, but the difference was not

Table 1
Baseline demographic and clinical characteristics of study participants.

Characteristic	(n = 1255)
Procedure	
ESD	108(8.6%)
EMR	122(9.7%)
Endoscopic ultrasonography	503(40.1%)
EVL	165(13.1%)
EIS	113(9.0%)
Peroral endoscopic myotomy	25(2.0%)
OGD with oesophageal dilatation	56(4.5%)
Peroral endoscopic cardial constriction	22(1.8%)
Extraction of esophageal foreign body	12(1.0%)
Implantation of stents in the digestive tract	14(1.1%)
Others(Pyloroplasty, etc.)	115(9.2%)
JEA size	
Size number 3	287(22.9%)
Size number 4	344(27.4%)
Endotracheal intubation size	
Size number 6.5	264(21.0%)
Size number 7.0	360(28.7%)

ESD: endoscopic submucosal dissection; EMR: endoscopic mucosal resection; EVL: endoscopic esophageal varix ligation; EIS: endoscopic injection sclerosis; OGD: oesophagogastroduodenoscopy.

Table 2
Intraprocedural characteristics. Results are presented as number (%) or mean (SD).

Variable	JEA(n = 631)	ET(n = 624)	*P*
Age (yr)	54.9 ± 10.6	55.6 ± 11.2	0.23
Sex (F/M)	349/282	360/264	0.43
Body mass index ($kg.m^{-2}$)	22.0 ± 2.0	22.2 ± 2.1	0.22
ASA Classification (I/II/III)	4/231/396	6/262/356	0.11
Mallampati Classification (I/II/III)	4/277/350	8/294/322	0.23
Comorbidities			
Current smokers	169(26.8%)	191(30.6%)	0.13
Respiratory disease	10(1.6%)	7(1.1%)	0.48
Coronary artery disease	10(1.6%)	4(0.6%)	0.11
Diabetes mellitus	47(7.5%)	53(8.5%)	0.49
CVA	3(0.5%)	5(0.8)	0.47
Cirrhosis	87(13.8%)	67(10.7%)	0.10
Management Details			
Insertion			
Time (s):	17.2 ± 3.4	30.1 ± 8.3	<0.01
No. attempts(1/2/3):	588/33/10	590/29/5	0.39
First attempt success rate:	93.2%	94.6%	0.35
Cardiovascular response(insertion)			
MAP variation range	8.8 ± 4.8	10.6 ± 7.1	<0.01
HR variation range	10.8 ± 3.0	19.2 ± 9.7	<0.01
Cardiovascular response(extubation)			
MAP variation range	6.1 ± 3.2	7.5 ± 4.6	<0.01
HR variation range	8.5 ± 5.7	15.0 ± 5.8	<0.01
Procedure duration (min)	31.5 ± 17.2	32.7 ± 15.5	0.20
Airway pressure (cmH_2O)	21.4 ± 3.4	20.4 ± 2.3	<0.01
Time taken for placement of endoscope(s)	12.7 ± 7.7	12.7 ± 6.6	0.86
Time taken for extubation (min)	8.4 ± 6.2	11.5 ± 8.4	<0.01
Residence time in PACU(min)	19.9 ± 7.6	23.1 ± 9.0	<0.01
Complications			
Nausea or vomiting	15(2.4%)	9(14.4%)	0.23
Cough during extubation	25(4.0%)	73(11.7%)	<0.01
Pharyngodynia	55(8.7%)	136(21.8%)	<0.01
Dental or mucosal trauma	5(0.8%)	2(0.3%)	0.26
Regurgitation	0	0	
Hoarseness	0	0	

ASA: American Society of Anesthesiologists; CVA: cerebral vascular accident; JEA: Jcerity Endoscoper™ Airway; ET: endotracheal intubation; MAP: mean arterial pressure; HR: heart rate; PACU: postanesthesia care unit. Results are presented as number (%) or mean (SD).

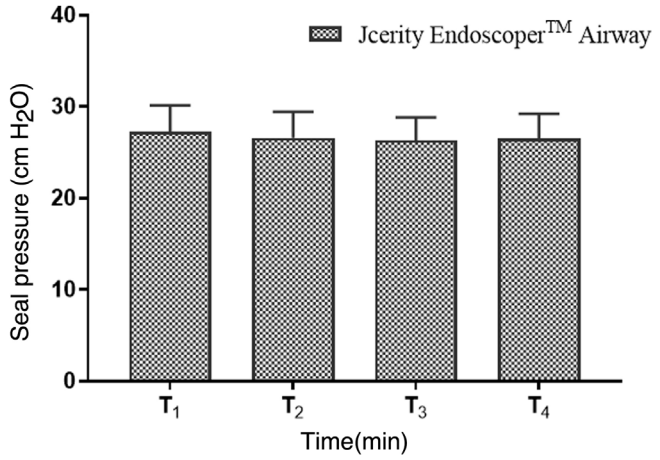

Fig. 3. Seal pressure of JEA at various points.

Table 3
Efficacy and safety evaluation of JEA. Results are presented as number(%).

	JEA group (n = 631)
The success rate of endoscopic treatment	100%
First attempt success rate	98.7%
Ease of insertion (easy/difficult)	628/3(99.5/0.5%)
Operation convenience (easy/difficult)	626/5(99.2/0.8%)
Satisfaction level of endoscopist (satisfactory/ average/unsatisfactory)	627/3/1(99.4/0.5/0.2%)
Difficulty degree of insertion (easy/difficult)	588/43(93.2/6.8%)
Quality of ventilation (1/2/3)	610/21/0(96.7/3.3/0%)
FBS view of VC (optimal/suboptimal)	561/32(88.9/5.1%)
Associated complications	
Degree of blood staining (mild/moderate/severe)	9/2/0(1.4/0.3/0%)
Pharyngodynia	55(8.7%)
Postoperative oral bleeding	0
Lingual frenulum injury	1(0.2%)
Dysphagia	0
Vocal cord paralysis	0
Arytenoid dislocation	0
Palate hematoma	2(0.3%)
Other (Lingual nerve paralysis, etc.)	0

statistically significant (93.2 *vs.* 94.6%, $P = 0.35$). As for the effect on the circulation during endotracheal intubation/laryngeal mask insertion, MAP increased more significantly during endotracheal intubation than JEA (10.6 [SD7.1] *vs.* 8.8 [SD4.8]%, $P < 0.01$), and HR also increased more (19.2 [SD9.7] *vs.* 10.8 [SD3.0]%, $P < 0.01$). Additionally, the changes in HR (bpm = beats per minute) and MAP during extubation in the JEA group were significantly less than those in the ET group (8.5 [SD5.7] *vs.* 15.0 [SD5.8]%, $P < 0.01$; 6.1 [SD3.2] *vs.* 7.5 [SD4.6]%, $P < 0.01$).

Compared with the JEA group, there was a significant difference ($P < 0.01$) in the airway pressure of the ET group 5 minutes after intubation (21.4 [SD3.4] *vs.* 20.4 [SD2.3] cmH_2O, $P < 0.01$). However, there was no significant difference in gastroscopy laryngeal mask airway sealing pressure at different time points during anesthesia (Fig. 3). There was no significant difference in the successful insertion of the endoscope between the two groups. The time taken for removal after anesthesia in the JEA group was 8.4 [SD3.4] min, which was significantly shorter than that in the ET group (11.5 [SD8.4] min). In terms of residence time in PACU, the JEA group was significantly shorter than the ET group (19.9 [SD7.6] *vs.* 23.1 [SD9.0] min, $P < 0.01$). As for the complications related to ET or JEA, the choking cough response in the JEA group during extraction was significantly less than that of the ET group (4.0 *vs.* 11.7%, $P < 0.01$). Especially, the incidence of pharyngodynia in the JEA group was 8.7%, which was significantly lower than that of the ET group (21.8%) (Table 2). However, there was no significant difference in the incidence of hoarseness, nausea and vomiting, dental or mucosal trauma, or regurgitation.

To further evaluate the effectiveness and safety of the back-open JEA, we conducted a more detailed observation (Table 3). 93.2% of the patients were successfully inserted with the back-open JEA for the first time, and the remaining patients were successfully inserted after 2 or 3 attempts. 96.7% of the patients could get the best ventilation effect after JEA insertion. Only 3.3% of the patients needed to re-adjust the position of the laryngeal mask again to get the best ventilation effect, and there was no need to change to ET because of ventilation. Further confirmation by FBS revealed that 88.9% of the laryngeal masks were in optimal position under FBS. Although some were in suboptimal positions under FBS, they still had good ventilation quality. There were few blood stains on the JEA body after the operation, and most of the blood stains observed in the study came from the endoscopic channel. In addition, we also observed two patients with palate hematoma after an operation, one of whom had moderate mask body blood staining when the laryngeal mask was removed, and lingual frenulum injury could be seen under direct classic laryngoscopy (Table 3).

We observed that the first-attempt insertion success rate of gastroscope placement through the endoscopic channel of the laryngeal mask was 98.7%, and all endoscopic treatment or examination could be completed through the JEA endoscopic channel after two or more attempts. In five cases, the endoscopes were inconvenient to operate through the JEA endoscopic channel, mainly during the endoscope in and out manipulation, and the rotation was not smooth, but the operation could be completed by adjusting the position of the laryngeal mask or lubricating the endoscopic body and the endoscopic channel of the laryngeal mask. In general, the satisfaction of the endoscopist with the back-open JEA was 99.4% (Table 3).

Discussion

In the present study, we observed that the insertion time of the well-lubricated back-open JEA was shorter than ET and didn't require special equipment or assistance, which made it more convenient and rapid than ET guided by direct classic laryngoscopy [19]. The removal time after anesthesia with JEA was also significantly shorter than in the ET group, which was possibly related to the need for fewer muscle relaxants and a shallower depth of anesthesia with a laryngeal mask airway. It was also confirmed that the selection of JEA can significantly shorten the time of the artificial airway's establishment and removal in the anesthetic management of endoscopic therapy, which could distinctly improve the operation turnover and enhance the efficiency of the operating room. Compared with the ET group (94.6%), the first-attempt success rate of JEA insertion was 93.2%; the difference was not statistically significant. However this result was lower than the gastroscope laryngeal mask insertion reported by Terblanche *et al.* (98%) [10], and the first attempt success rate of ET was 94.6%, which was lower than the 97% reported in the literature [18]. This may be related to the fact that we performed intubation and inserted the laryngeal mask in the left lateral position (since upper gastrointestinal endoscopic treatment surgeries are mostly performed in the left lateral decubitus position, to shorten the preoperative preparation time and reduce possible complications from position changes after anesthesia, we use the methods of induction and tracheal intubation in the left lateral decubitus position).

Since the treatment under an endoscope is minimally invasive, it does not require excessive anesthesia depth and analgesia intensity, so the doses of the anesthetic drugs needed in the induction process are less than those in general surgery, and the cardiovascular response during intubation/laryngeal mask insertion needs particular attention. Our study found that compared with JEA insertion, MAP and HR increased significantly during endotracheal intubation ($P < 0.01$). In particular, HR can increase by 19.2 [SD9.7]% in the ET group, while in the JEA group, it was controlled at 10.8 [SD3.0]% (Table 2). Ensuring perioperative circulation stability is particularly important for patients to recover quickly, reduce cardiovascular accidents, and shorten the length of hospitalization. This result proved that JEA may have more advantages than ET in maintaining the stability of the patient's circulatory system and also confirmed the substitutability of ET to some extent, especially for patients with serious cardiovascular diseases [20,21].

The airway sealing pressures of well-fixed JEA at different time points during anesthesia were not statistically significant (Fig. 3), which meant that JEA could provide a stable and safe airway for patients in the process of endoscopic treatment.

There was no significant difference in the time taken for the placement of the endoscope between the two groups. As for the complications, the choking cough response in the JEA group during extubation was significantly less than that of the ET group (4.0 *vs.* 11.7%, $P < 0.01$). Choking cough during extubation could not only induce cardiovascular adverse events in patients with cardiovascular disease but also lead to gastrointestinal mucosal tears, bleeding, and perforation, which increases the risk of airway obstruction and asphyxia. All of these affected the patient's rapid recovery and prolonged the duration of post-operative nursing and hospitalization [22].

It was particularly noteworthy that the incidence of pharyngodynia in the JEA group was 8.7%. It was significantly lower than the ET group (21.8%) (Table 2), which also confirmed the superiority of JEA as an airway management tool in gastro endoscopy [22,23]. Previous studies have shown that although laryngeal mask insertion could avoid direct stimulation and injury to the glottis and trachea, it could cause damage to the soft tissue of the mouth, pharynx, and larynx. Pharyngodynia and bleeding were still common postoperative complications [9], and pharyngodynia's incidence in a traditional gastroscope laryngeal mask was about 37% [10]. In this study, the use of back-open JEA greatly reduced this probability, which may be related to the particularity of its material and structure: The main lumen adopted a fixed angle and streamlined design, and the head end of the cuff was a semi-open buffer sheet structure, which minimized the resistance damage to the oropharynx and the mucosa around the glottis during insertion (Fig. 1); Some studies had also shown that postoperative pharyngodynia incidence was not only related to the insertion trauma but also to the long-term compression of the laryngeal mask [24]. The large-capacity inflatable cuff of the JEA was made of silica gel material with high elasticity and softness. It had low inflation pressure, which not only fitted the anatomical curve of each patient to form an effective sealing area in the throat but also avoided pharynx and larynx injury caused by excessive inflation and compression. Of course, the relationship between postoperative pharyngodynia and endoscopic operation also cannot be denied. The residence time in PACU in the JEA group was lower than that in the ET group, which could significantly speed up operation turnover and improve the efficiency in the operating room. It was also observed that there was no significant difference in the incidence of hoarseness, nausea and vomiting, tooth injury, or reflux aspiration between the two groups.

This study also found that the insertion of a JEA was easy to learn, and all trained anesthesiologists could perform it skillfully. Most JEAs had high ventilation quality after insertion, and the FBS view of VC was ideal, which proved that this back-opening JEA was easy to insert and position (Table 3). In addition, the blood staining degree of JEA after operation was low, and most of the laryngeal mask blood stains observed in the study came from the endoscopic lumen, which may be related to long-term endoscopic invasive treatment. In addition, we also observed two cases of palate hematoma after an operation, and one patient had moderate blood staining on the JEA when pulling out the laryngeal mask, and the injury and bleeding of the lingual frenulum could be seen under visual laryngoscopy, which may be related to the insufficient depth of anesthesia and the fact that the operation was not gentle enough.

In this study, the success rate of endoscopic treatment in the JEA group reached 100%. At the same time, gastroenterologists were highly satisfied with the smooth operation through the JEA endoscopic lumen (Table 3). The evaluation of endoscopists also confirmed the effectiveness and convenience of JEA, and there was no significant difference between the JEA group and the ET group (Table 2). This may be related to the unique design of JEA. It had a large enough endoscopic examination channel (20 by 22 mm) [15], which was larger than the examination channel with the largest inner diameter of 14 mm [11] in South Korea and 16 mm introduced by M. Skinner [10,25]. More importantly, its innovative design is that the endoscopic examination channel was not completely closed, which reduced the friction between the inner wall of the JEA and the endoscope, making it more convenient for endoscopic placement and flexible operation.

Limitations of the study

Of course, if patients have a history or indication of difficulty in intubation, a risk of reflux aspiration (such as Achalasia, esophageal obstruction, intestinal obstruction, or pyloric obstruction), or airway instability factors (such as a tracheoesophageal fistula) during operation, a safer airway management method (such as ET) should be used instead of a gastroscopic laryngeal mask. Moreover, with the extension of the operation time, the secretion gathered around the laryngeal mask increased, and the probability of laryngeal mask displacement and laryngospasm became greater. Therefore, we do not recommend the use of JEA in endoscopic therapy for more than 3 hours. Based on the above reasons, before selecting an airway, it is necessary to make a full preoperative evaluation and communicate with the gastroenterologist, anesthesiologists, and endoscopists should consider various factors and carefully formulate individualized anesthesia airway management. In addition, this study was a domestic single-center clinical study, and some characteristics of this study may be different from those of patients in other countries. Therefore, the conclusions of this study need to be verified by further multicenter studies.

Conclusions

This study showed that the back-open JEA can not only provide a safe and effective airway guarantee for patients but also provide convenience for gastroenterologists to carry out endoscopic procedures. It is a convenient and safe airway management tool that can replace ET under certain conditions.

Trial registration

Chinese Clinical Trial Registry | Registration No.ChiCTR2100046864 | Type of study: A Pilot Randomized Clinical Trial (http://www.chictr.org.cn/).

Human and animal rights

The authors declare that the work described has been carried out in accordance with the Declaration of Helsinki of the World Medical Association revised in 2013 for experiments involving humans as well as in accordance with the EU Directive 2010/63/EU for animal experiments.

Informed consent and patient details

The authors declare that this report does not contain any personal information that could lead to the identification of the patient(s).

The authors declare that they obtained a written informed consent from the patients and/or volunteers included in the article. The authors also confirm that the personal details of the patients and/or volunteers have been removed.

Disclosure of interest

The authors declare that they have no known competing financial or personal relationships that could be viewed as influencing the work reported in this paper.

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Author contributions

Yunqi Lv and Jian-jun Yang had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: Yunqi Lv. Acquisition, analysis, or interpretation of data, Drafting of the manuscript: Junfei Zhou and Lu Li. Statistical analysis: Chang Xu. Supervision: Erxian Zhao.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.accpm.2024.101456.

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