Original Article

The efficacy of endobronchial valves for the treatment of bronchopleural fistula: a single-arm clinical trial

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Background: A bronchopleural fistula (BPF) is defined as communication between the bronchus and pleural cavity, and it is a dreaded complication of severe pulmonary disease. Surgical intervention, pleurodesis, and prolonged chest tube drainage have several disadvantages. To overcome these, many attempts have been made to treat BPF with bronchoscopy, especially with the insertion of an endobronchial one-way valve (EBV). Endobronchial valves for the treatment of BPF which had less trauma, relatively short operation time, better safety, and patients are more likely to accept this operation. If there is a definite efficacy, it should be widely used in later clinical practice. This study aimed to confirm the efficacy of endobronchial valves for the treatment of BPF.

Methods: We retrospectively reviewed data from 26 patients who were treated for BPF using an EBV between August 2017 and October 2020. This sample constitutes all patients treated in our hospital (Shanghai Pulmonary Hospital, Tongji University School of Medicine) for this condition and with this intervention during this timeframe. We collected general information about the patient, complications of the procedure, and chest tube indwelling to assess the efficacy and safety of the procedure.

Results: A total of 26 patients underwent EBV placement procedures; left upper lobe (LUL) was the most common lobe in which the valves were placed. The underlying etiologies for BPF were postoperative BPF (50%; n=14), pneumothorax (15%; n=4), non-tuberculosis mycobacteria (NTM) (19%; n=5), and tuberculosis (12%; n=3). Eleven patients underwent chest tube insertion. The average chest tube duration in the group of patients before receiving valves was 66 days (median, 65 days; range, 14–187 days). The average duration after which the chest tube was removed was 17.5 days after EBV placement (median, 7 days; range, 2–90 days). The effective rate of EBV for the treatment of BPF was 73.1%. Patients for whom the valves were not removed, there were no valve related complications.

Conclusions: EBV placement is a relatively mature procedure, which is safe and effective, and generates less trauma and fewer complications. And this intervention may be suitable for wide application in clinical practice.

Keywords: Bronchopleural fistula (BPF); endobronchial valve (EBV); air leak

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Introduction

A bronchopleural fistula (BPF) is defined as communication between the bronchus and pleural cavity, and it is a dreaded complication of severe pulmonary disease. Lung resection remains the leading cause of BPF with a prolonged pulmonary air leak, although refinements in surgical techniques have substantially reduced the incidence of BPF (1-3). Followed by invasive infectious or inflammatory etiologies, include aspergillus, tuberculosis, additional etiologies. Other causes of BPF including mechanical ventilation, pulmonary trauma, spontaneous pneumothorax, acute respiratory distress syndrome (ARDS), radiofrequency ablation, iatrogenic injuries, radiation (3,4). BPF is a relatively rare but worrying complication of several pulmonary diseases. BPF has high incidence and mortality rates and is associated with long-term hospitalization and high resource utilization. The treatment of BPF includes surgical procedures, medical therapy, and the interventional therapy with bronchoscopy. However, the success of existing treatments has been uneven, and the lack of consensus indicates that there is no optimal treatment available. The current interventions seem to be complementary and therapy should be individualized to improve success rates (4). The treatment of BPF remains a challenging and frustrating problem.

Surgical intervention, pleurodesis, and prolonged chest tube drainage have several disadvantages, and patients are not always suitable for major thoracic surgery because of various reason, therefore a variety of bronchoscopic methods have been tried to improve air leakage (5). Many bronchoscopic attempts have been made to treat BPF, including fibrin or tissue glue, spigots, silver nitrate, stents, vascular coils, gel foam, and an autologous endobronchial blood patch (6-12). To treat air leaks, the use of an endobronchial one-way valve (EBV) has been proposed.

In the presence of persisting peripheral air leaks, an EBV can be inserted. These valves were originally developed to reduce the bronchoscopic lung-volume in patients with emphysema. Because of these valves are one-way airway blockers, EBVs prevent air from entering into the affected segmental bronchus and allow mucus to be discharge. Therefore we thought this may be a promising minimal-invasive procedure that can treat peripheral BPF (13). We present the following article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-258/rc).

Methods

We retrospectively analyzed the data of 26 patients with a mean age of 54 years (range, 28–86 years) who were treated for BPF using an EBV between August 2017 and October 2020. This sample constitutes all patients treated in our hospital (Shanghai Pulmonary Hospital, Tongji University School of Medicine) for this condition with this intervention during this timeframe. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The need for ethical approval was waived by the Institutional Review Board of Shanghai Pulmonary Hospital as it is a retrospective observational study. Informed consent was previously obtained from each patient before any invasive procedures were performed. The outcomes of endobronchial valve placement for patients with BPF are summarized in *Table 1*.

Preoperative preparation and anesthesia

Patients were asked to fast (without eating or drinking water) for at least six hours before undergoing bronchoscopy. Patients with diabetes were asked to skip a dose of hypoglycemic drugs or insulin, and patients with hypertension were asked to take hypotensive drugs. The bronchoscopy was performed with general anesthesia. Patients were placed in the supine position on the table after entering the operating room. ECG (Electrocardiogram), pulse oxygen saturation, and blood pressure were monitored, and a peripheral or central venous access was established. Succinylcholine (1–1.5 mg/kg), sufentanil (0.4–0.6 μg/kg), and propofol (1.5–2 mg/kg) were intravenously injected to induce general anesthesia. After 1 minute, a laryngeal mask was placed on the patient (size number 5 was used for male patients, while size number 4 was used for female patients used). Mechanical ventilation was administered during navigation, and succinylcholine (3–5 μg/kg/min) and propofol (25–75 μg/kg/min) maintained anesthesia. Naloxone (0.2–0.4 mg) was administered at the end of the bronchoscopy, and the laryngeal mask was removed after the patient was completely awake (14).

Equipment

During EBV placement, a CLV-290SL Xenon light source (Olympus Corporation, Japan), a CLV-290SL image processing station (Olympus Corporation, Japan), and a

Table 1 Outcomes of endobronchial valve placement for BPF

Patient	Sex/age	Etiology	Chest tube duration before valve placement (days)	Endobronchial valve placement location	Chest tube duration after valve placement (days)	Complications	Prognosis of BPF
P1	M/60	NTM, bronchiectasis	25	LUL ×1; LUL ×1	5	Granulation proliferation	Improved
P2	M/59	NTM	N/A	LUL ×1	N/A	No	Improved
P3	M/30	Tuberculosis	187	LUL ×1; lingula ×1; LUL ×1; lingula ×1	30	Valve displacement	Improved
P4	F/56	NTM	35	LUL ×2; RLL ×1	7	No	Unhealed
P5	M/42	Aspergilloma; pulmonary lobectomy; bronchopleural fistula; postoperative empyema	65	RLL ×1; RLL ×1	2	No	Improved
P6	F/42	Aspergilloma; pulmonary fenestration	N/A	LUL ×1; LLL ×1	N/A	No	Improved
P7	M/73	Severe pneumonia; tuberculosis; aspergilloma	104	RLL ×1	90	Hemoptysis	Unhealed
P8	M/28	Bronchiectasis; pulmonary lobectomy	N/A	LLL ×1	N/A	No	Unhealed
P9	F/76	Bronchogastric fistula; partial gastrectomy	N/A	LLL ×1	N/A	No	Improved
P10	M/50	Bronchoesophageal fistula; esophagectomy	N/A	RLL ×1	N/A	No	Improved
P11	F/32	Pulmonary abscess; pulmonary lobectomy; bronchiectasis	N/A	RLL ×1; RLL ×1	N/A	No	Improved
P12	M/63	Carcinoma *in situ* of lung; pulmonary lobectomy	70	RLL ×1	30	No	Improved
P13	M/43	Postoperative empyema; obsolete pulmonary tuberculosis	N/A	RLL ×2	N/A	No	Improved
P14	F/59	NTM; bronchiectasis	N/A	RUL ×3	N/A	No	Improved
P15	M/53	Spontaneous pneumothorax; COPD	49	LUL ×3; lingula ×1	6	No	Improved
P16	M/86	Hydropneumothorax; COPD; Mediastinal emphysema, subcutaneous emphysema	26	LUL ×1	4	No	Improved
P17	M/74	Hydropneumothorax; COPD; postoperative lung cancer	15	LUL ×2	5	No	Unhealed (bullectomy of lung)
P18	M/69	Spontaneous pneumothorax; COPD; severe pneumonia	14	RLL ×2	7	No	Improved
P19	M/73	Bronchogastric fistula; partial gastrectomy	N/A	LLL ×1	N/A	No	Improved

Table 1 (*continued*)

Table 1 (*continued*)

Patient	Sex/age	Etiology	Chest tube duration before valve placement (days)	Endobronchial valve placement location	Chest tube duration after valve placement (days)	Complications	Prognosis of BPF
P20	M/51	Tuberculosis; pulmonary lobectomy	86	RLL ×1	4	No	Unhealed (pulmonary fenestration)
P21	F/33	Tuberculosis; tuberculosis destroyed lung	N/A	LUL ×1; lingula ×1	N/A	No	Unhealed
P22	M/68	Carcinoma *in situ* of lung; pulmonary lobectomy	99	Lingula ×1	9	No	Improved
P23	M/43	NTM	151	LLL ×2	80	No	Unhealed
P24	M/52	Lung malignant tumor; neoadjuvant posterior lobectomy +radical resection	58	RML ×1	36	No	Improved
P25	M/34	Tuberculous emphysema; exploratory thoracotomy and repair of visceral pleural leakage; tuberculosis	202	RLL ×1	98	No	Improved
P26	F/54	Pulmonary cyst with infection; excision of pulmonary cyst	222	LUL ×2	38	No	Improved

BPF, bronchopleural fistula; LLL, left lower lobe; LUL, left upper lobe; N/A, not applicable; RML, right middle lobe; RUL, right upper lobe; RLL, right lower lobe; NTM, non-tuberculosis mycobacteria; COPD, chronic obstructive pulmonary disease.

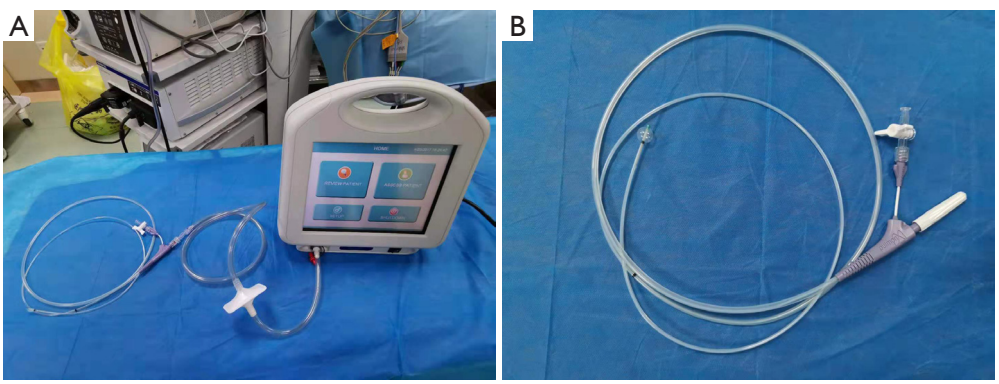

Figure 1 Chartis assessment system. (A) Chartis host. (B) Balloon catheter.

BF-1TQ290 flexible bronchoscope (Olympus Corporation, Japan) were used. The location of the BPF was identified using the Chartis system (Pulmonx SARL, CHARTIS CONSOLE, Switzerland; *Figure 1*) and a digital thoracic drainage system (Medela AG, Switzerland). The Emphasys Zephyr endobronchial valve (ZEBV, Pulmonx Inc. Neuchatel, Switzerland) was used; it is a second-generation device which is composed of a silicone 'duck bill' attached to a nitinol skeleton (*Figure 2*).

Endobronchial valve placement technique

The first step in the placement of an EBV was to localize the source of the BPF. Results of computed tomography

(CT) needed to be analyzed before any intervention took place. Then, routine bronchoscopy was performed to evaluate the airway condition. The Chartis assessment system consists of two parts. The first part is a balloon catheter which is inserted through the working channel of the bronchoscope. Balloon inflation blocks the airway, blocking the flow of inhaled air, so that the air can only flow out through the central lumen of the catheter. The second part is a console, which is used to display the flow and pressure readings in real time. If there is no collateral ventilation (CV) to supply the airway distal to the balloon, air flow from the lobe will gradually decrease. A continuous flow reading indicates the presence of CV in the target lobe (*Figure 3*) (15). A digital thoracic drainage system was also used to locate the site of BPF. When the balloon blocked the lobe, there was an immediate significant reduction in airflow visualized on the digital screen and flow-time graph. The processes were repeated to determine the segmental or subsegmental airway or airways that, when blocked, offered the greatest reduction in air leak rate. Then these airways were used as target airway for valve implantation

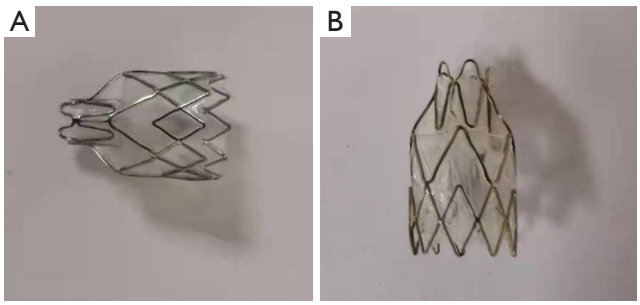

Figure 2 The Emphasys Zephyr endobronchial valve. (A) Zephyr® 4.0; functional size range: 4.0–7.0 mm. (B) Zephyr 5.5; functional size range: 5.5–8.5 mm.

Then, the EBVs were delivered to the target airway using a flexible catheter. A valve loader provided with the system compressed the valves into the distal tip of the delivery catheter. The delivery catheter was then passed via the working channel of a bronchoscope (3.0 mm inner diameter) and guided to the target airway. After placement in place, the valve was unfolded (16). The leak then decreased after placement of the valves.

Generally, the air leak of the lung lobe was detected first, followed by air leaks of lung segments. EBVs were first placed in segments that were difficult to access, then

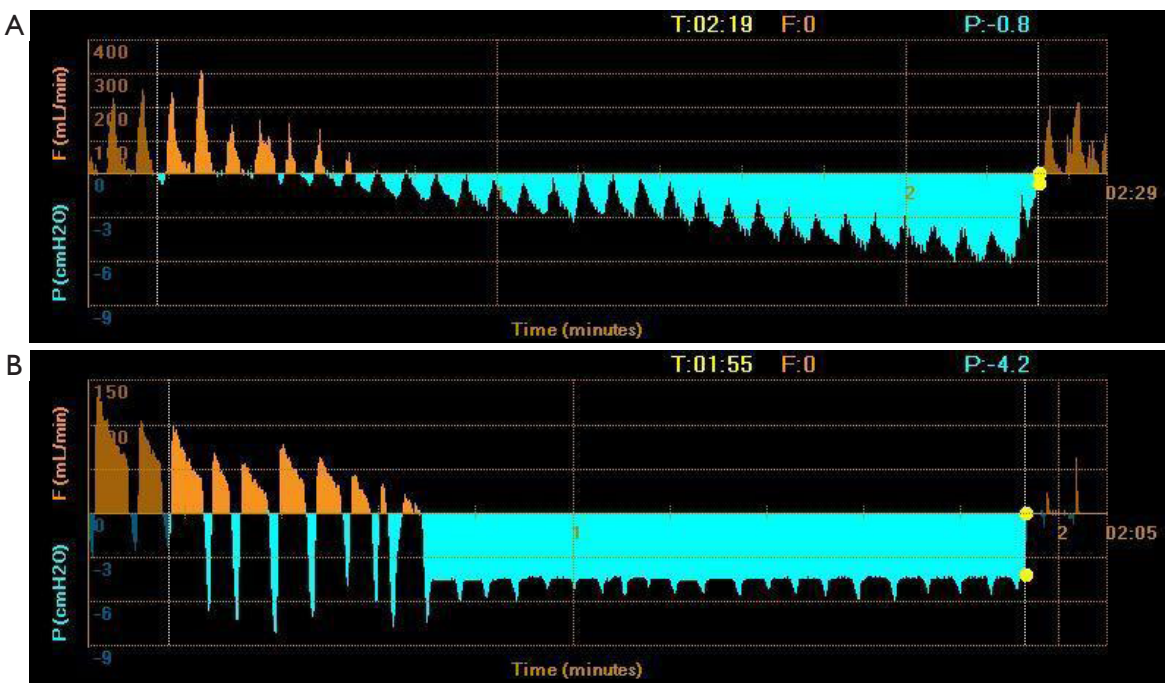

Figure 3 Graphic analysis of Chartis assessment system. "F" represents the airflow velocity of the corresponding bronchus blocked by the catheter; "P" represents the negative pressure of the catheter to block the corresponding bronchus. (A) Non-collateral ventilation. (B) Collateral ventilation.

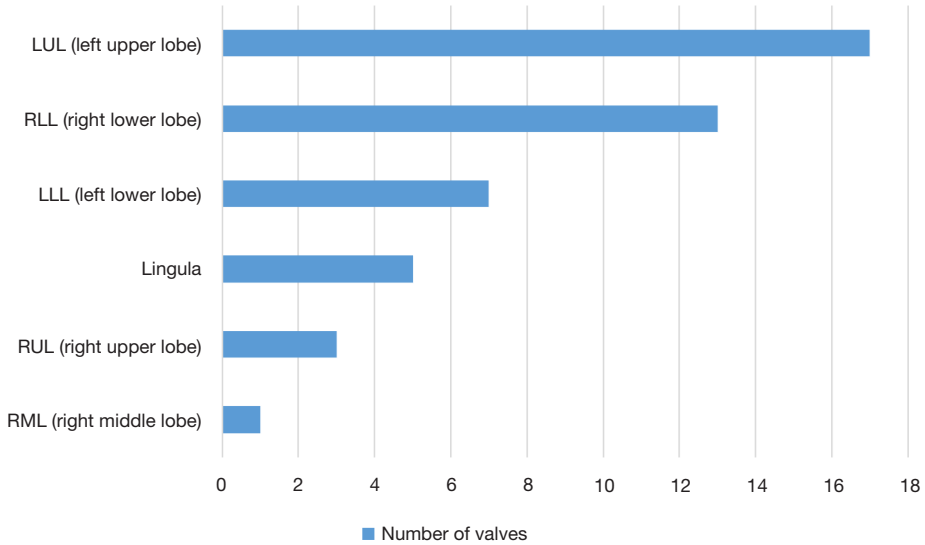

Figure 4 Lobes in which a one-way valve was placed. LUL, left upper lobe; RLL, right lower lobe; LLL, left lower lobe; RUL, right upper lobe; RML, right middle lobe.

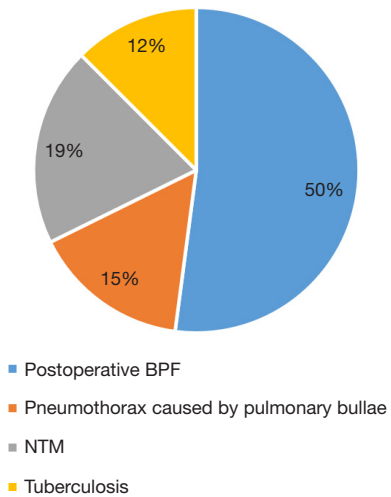

Figure 5 The underlying etiologies for BPF. BPF, bronchopleural fistula; NTM, non-tuberculosis mycobacteria.

into segments that were easier to access. The fewer valves placed, the better.

Statistical analysis

We used IBM SPSS Statistics 24 to perform all analyses. The measurement data conforming to the normal distribution shall be expressed as the mean, and those not conforming to the normal distribution shall be expressed as the median. The counting data is expressed by rate or composition ratio.

Results

A total of 26 patients underwent EBV placement procedures in the study; 19 were men, and 7 were women. The median age of all patients was 53.5 years (mean, 54 years; range, 28–86 years). A total of 46 valves were placed, with a median of 2 valves per procedure (mean, 1.8 valves; range, 1 to 4 valves). Left upper lobe (LUL) was the most common lobe in which valves were placed (*Figure 4*). The underlying etiologies for BPF were postoperative BPF (50%; n=14), pneumothorax caused by pulmonary bullae (15%; n=4), non-tuberculosis mycobacteria (NTM) (19%; n=5), and tuberculosis (12%; n=3). Previous postoperative BPF for the group as a whole included lobectomy (n=8), pulmonary fenestration (n=1), exploratory thoracotomy and repair of visceral pleural leakage (n=1), partial gastrectomy (n=2), esophagectomy (n=1), and excision of pulmonary cyst (n=1; *Figure 5*).

A total of 16 patients underwent chest tube insertion. Before receiving EBVs, the average chest tube duration in the group of patients was 88 days (median, 61.5 days; range, 14–222 days). The average duration after which patients had the chest tube removed was 28.2 days after EBVs placement (median, 7 days; range, 2–98 days). At the time of chest tube removal, close drainage equipment demonstrated zero flow

in these patients. The effective rate EBV for the treatment of BPF was 73.1%, and the condition of 19 patients with BPF was improved after treatment.

Patients were followed up for an average of 3–6 months after treatment. There were no adverse events related to the valve implantation procedure reported at the follow-ups. Six patients underwent valve removal using flexible bronchoscopy and grasping forceps under sedation and with spontaneous breathing, and there were no any further complications, while 20 cases did not have their valves removed. During bronchoscopy when valve removal happened, 1 patient had granulation tissue, 1 patient had valve migration, and 1 patient had a bronchial hemorrhage, which was improved after treatment with bronchial artery embolization. Patients for whom the valves were not removed, there were no valve related complications.

In addition to the placement of one-way valves, 5 patients also underwent other bronchoscopic procedures including the use of a silicone plug, lauryl alcohol, argon laser plasma coagulation, ventricular septal occluder, and umbrella occlude at a different time. After the poor effect of EBV, and remove the valve before surgeries, one patient underwent bronchial stump ligation and pulmonary fenestration, and one patient underwent a bullectomy of the lung.

Discussion

BPF represents abnormal communication between the pleural cavity and bronchial tree, which significantly increases incidence rate, mortality, and length of hospital stay. In this study, we reported on a consecutive series of 26 cases of EBV placement in a range of clinical scenarios for postoperative BPF, pneumothorax, NTM, and tuberculosis. Postoperative complications for pulmonary resection were the most common cause of BPF reported in our study. The underlying etiologies for BPF were postoperative BPF (50%; n=14) in our study. Tuberculosis and NTM are generally less common than BPF (4), but the two etiologies were frequent in our sample, which may be because our hospital is a pulmonary specialist hospital. The most common site of BPF was LUL, followed by RLL, and LLL, and the RML was the least common. This result may be related to the predilection sites of primary diseases.

Treatment of BPF includes surgical procedures and medical therapy, and a variety of interventional therapy with bronchoscopy have been previously reported, including instillation of ethanol, antibiotics, lead shots, albumin glutaraldehyde tissue adhesive and fibrin glue, and these endoscopic techniques were always for the treatment of long-term air leaks (15). Unfortunately, the infusion of these substances is often related to irreversible obstruction of target airways, significant foreign body reaction, or both. They play a role as airway or bronchial blockers. Furthermore, according to a recent report, they are also related to the risk of spigot migration and the incidence rate of lung disease, including atelectasis, lung abscess, and pneumonia (11).

The use of EBV placement for BPF is an increasingly recognized technique. EBVs were initially developed for lung volume reduction surgery in patients with severe emphysema. Research has confirmed the efficacy of endobronchial valves to manage a persistent air, including the management of a postoperative air leak and other clinical scenarios in which EBVs were effectively used to eliminate airflow from specific regions of the lung (17-30). In retrospect, the duration of chest tube placement, the length of stay, mortality, and anxiety of patients might have been reduced if EBV placement was considered earlier. EBV placement is a relatively mature procedure, which is safe and effective, and generates less trauma and fewer complications. Based on these advantages, an increasing number of doctors tend to choose this method to treat BPF. In our study, the effective rate of EBV for the treatment of BPF was 73.1%. There was only 1 case who had the complication of a bronchial hemorrhage, but this was improved after treatment with bronchial artery embolization. The primary disadvantage of an EBV lies in its cost. However, the cost can be offset by the multiple advantages, including that the treatment can be reversed by removing the EBV and that EBV placement is safe for critically ill patients who are unable to undergo surgical intervention (28).

There was 1 patient who underwent EBV placement for BPF, but for which the purpose of the EBV was also to reduce their lung volume. In addition to one-way valve placement, 5 patients underwent other bronchoscopic procedures, including use of a silicone plug, lauryl alcohol, argon laser plasma coagulation, and ventricular septal occlude. One patient also underwent bronchial stump ligation and pulmonary fenestration.

To be selected to undergo EBV placement, patients had to demonstrate a persistent continuous air leak, which was defined as an intrathoracic chest tube duration of more than 2 weeks even though they received conservative therapy, surgical therapy, or both. Postoperative BPF patients were also considered to be good candidates, but not all such

patients were suitable for EBVs placement. Their suitability depended on the length and diameter of the fistula. EBV placement was considered suitable if the surgical stump was long enough and the diameter of fistula was ≥3 and ≤8 mm.

The study is limited by its retrospective nature, the small sample size, and the lack of a control group. It is hoped that a large sample and multi-center research can be carried out in the future to further summarize indications of EBV placement and increase the success rate of this intervention.

Conclusions

The placement of EBVs is a simple, effective, and safe treatment of BPF in our study, and this intervention may be suitable for wide application in clinical practice.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-258/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-258/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-258/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The need for ethical approval was waived by the Institutional Review Board of Shanghai Pulmonary Hospital as it is a retrospective observational study. The written informed consent was obtained from each individual.

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