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Customized airway stenting for bronchopleural fistula after pulmonary resection by interventional technique: single-center study of 148 consecutive patients

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Abstract

Background Bronchopleural fistula after pulmonary resection is a serious complication, with major impact on the quality of life and survival. This study aims to evaluate the efficacy and safety of customized airway stenting in the treatment of bronchopleural fistula.

Methods A series of airway stents for dedicated bronchopleural fistula occlusion were designed after taking into account the anatomical and pathophysiological features of post-pulmonary resection fistulas and the shortcomings of airway stents currently available. The fistulas were occluded with the bullet head or a special part of the covered airway stent. Successful stenting was defined as immediate cessation of air leak from the residual cavity after stenting. The results were retrospectively analyzed.

Results Airway occlusion stenting was successful on the first attempt in 143/148 (96.6%) patients with bronchopleural fistulas. In the remaining 5 patients, occlusion was successful only on the second try. At follow-up 30 days after stenting, 141 patients reported relief in symptoms. No choking, laryngeal edema, or airway rupture occurred in any patient during stent insertion or removal; 2 patients developed hemorrhage during stent removal.

Conclusions Airway occlusion stenting appears to be a feasible and effective technique for treatment of bronchopleural fistula.

Keywords Lung cancer · Pulmonary resection · Bronchopleural fistula · Stent · Interventional radiology

Bronchopleural fistula after pulmonary resection is a serious complication that occurs in 1.5–8% of patients; it is associated with a mortality rate of 13.4–67% [1, 2]. Improvements in surgical techniques and better understanding of the mechanism of bronchial stump healing in recent years have resulted in a decrease in the incidence of these fistulas, but it remains a major worry for the thoracic surgeon [3, 4].

Occasionally, a small bronchopleural fistula may heal with conservative management, but the vast majority of fistulas do not heal spontaneously, and long-standing chest and lung infection can severely debilitate the patient [5]. Bronchopleural fistula is commonly treated by thoracic drainage, fistula repair, omental flap, and thoracoplasty. However, this is a complex procedure that is associated with major trauma and a high failure rate. Besides, most patients with middle- and late-stage bronchopleural fistula are debilitated by long-standing infection and are not fit to withstand the stresses of a second surgery.

There have been occasional reports in the literature of non-surgical treatment of bronchopleural fistulas with the use of stents, tissue glue, coils, *N*-butyl cyanoacrylate glue, Amplatzer™ vascular plug, or other occluder techniques [6–11], but no large studies have been conducted. After studying the anatomical and pathophysiological features of bronchopleural fistulas after pulmonary resection, as well as the shortcomings of the airway stents currently available, we designed and patented a series of airway stents for dedicated bronchopleural fistula occlusion [12] (Fig. 1). We performed individualized airway stent implantation to treat 148 cases of bronchopleural fistulas. In this report we retrospectively

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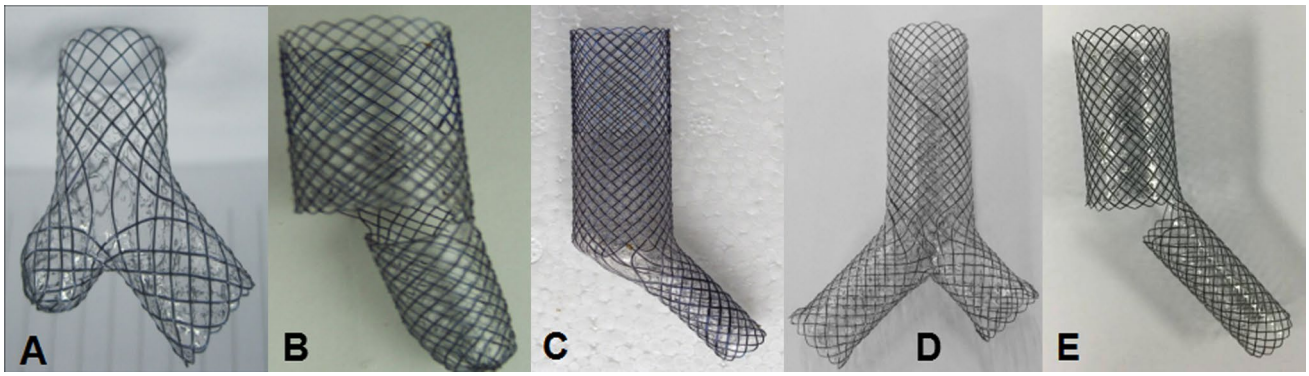

Fig. 1 **A** Y-shaped self-expandable covered metallic stent with a bullet head; **B** hinged self-expandable covered metallic stent with a bullet head; **C** L-shaped self-expandable covered metallic stent; **D** Y-shaped self-expandable covered metallic stent; **E** hinged self-expandable covered metallic stent

analyze the effect of the procedure and summarize our clinical experience.

Materials and methods

This was a retrospective–prospective analysis. The hospital records from January 1, 2008 to December 31, 2016 were searched manually to identify all patients who had been treated for bronchopleural fistula after pulmonary resection. Patients who had undergone treatment with the airway stenting method were eligible for inclusion in the study. Bronchopleural fistula was diagnosed on the basis of clinical manifestations, bronchoscopy, and chest CT examination. Bronchopleural fistula patients treated with conventional therapy, simple drainage tube placement, or by any method not involving airway stenting were excluded from this study. Bronchopleural fistulas diagnosed within 1 week of surgery were defined as "early stage"; those diagnosed within 1 week to 1 month of surgery were defined as "delayed stage"; and those diagnosed > 1 month after surgery were diagnosed as "late stage." Patients were followed up either through telephone calls or clinic visits; we defined a follow-up within 1 year as short term, 1–5 years as medium term, and > 5 years as long term.

Customization of the stent and the operation procedure

The stent used in each patient was customized on the basis of measurements derived from chest CT, bronchoscopy, and airway radiography (with water-soluble contrast injected via the catheter), if necessary. The stent was manufactured to our specifications by Micro-Tech Co., Ltd., Nanjing, Jiangsu, China. These novel covered airway stents had a bullet head or a special part that served to occlude the fistula. The diameters for the main body, branch portion, and bullet head of the stent were generally 15–20% larger than the diameter of the corresponding airway. Stent type was decided by the location and length of the bronchial stump (Fig. 2A–J; Table 1). A hinged self-expandable covered metallic stent with a bullet head was used for bronchopleural fistulas with bronchial stump length > 20 mm, a Y-shaped self-expandable covered metallic stent with a bullet head when the bronchial stump length was 5–20 mm, and an L-shaped self-expandable covered metallic stent when the bronchial stump length was < 5 mm. Due to the big difference in the diameter between the right main bronchus and the right middle bronchus, a stent with a thick proximal part and thin distal end branches was chosen for stenting in this area.

All procedures were performed with the patient supine and under conscious sedation, with tetracaine spray used for local anesthesia. Under fluoroscopic guidance, a 5F catheter over a wire was introduced transorally into the trachea. A transcatheter injection of 5 mL of 2% lidocaine was given first as local anesthesia and then 3 mL of water-soluble contrast was injected to confirm the site and size of the fistula. Interventional radiological techniques were employed to place or remove the stents. In all cases, insertion and removal of stents were performed by interventional radiologists [13–15]. After placement of the stent, its position and the success of occlusion were checked via tracheobronchography.

Bronchopleural fistula management

Under fluoroscopic guidance or DynaCT guidance, an external drainage catheter (8.5, 10.2, or 12F) with multiple side holes (Cook Medical Inc., Bloomington, IN, USA) was inserted into the thoracic cavity by percutaneous puncture using the Seldinger technique; the surgical chest tube was then removed. The chest drainage catheter

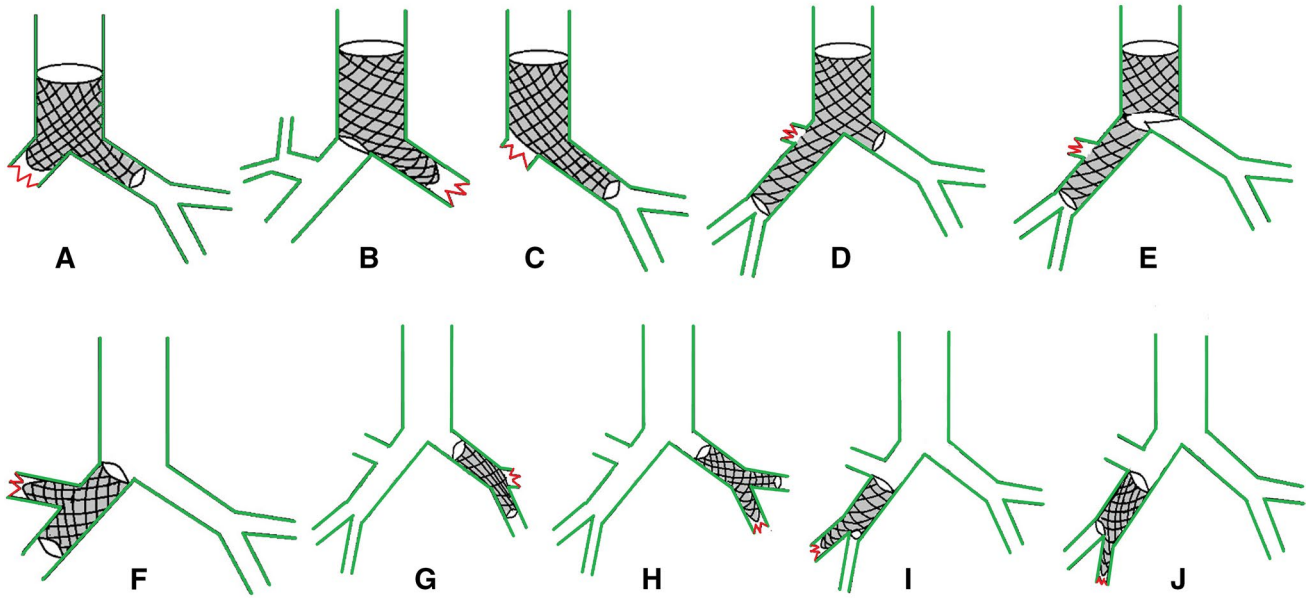

Fig. 2 **A** Schematic diagram of a Y-shaped self-expandable covered metallic stent with a bullet head occluding a right main bronchopleural fistula (bronchial stump length 5–20 mm). **B** Schematic diagram of a hinged self-expandable covered metallic stent with a bullet head occluding a left main bronchopleural fistula (bronchial stump length > 20 mm). **C** Schematic diagram of an L-shaped self-expandable covered metallic stent occluding a right main bronchopleural fistula (bronchial stump length < 5 mm). **D** Schematic diagram of a Y-shaped self-expandable covered metallic stent occluding a right upper bronchopleural fistula (right main bronchus short). **E** Schematic diagram of a hinged self-expandable covered metallic stent occluding a right upper bronchopleural fistula (right main bronchus long). **F** Schematic diagram of a small Y-shaped self-expandable covered metallic stent with a bullet head occluding a right upper bronchopleural fistula (right upper lobe bronchus long). **G** Schematic diagram of a small L-shaped self-expandable covered metallic stent occluding a left upper bronchopleural fistula (bronchial stump length < 20 mm). **H** Schematic diagram of a small Y-shaped self-expandable covered metallic stent with a bullet head occluding a left lower bronchopleural fistula (left lower bronchial stump long). **I** Schematic diagram of a small hinged self-expandable covered metallic stent with a bullet head occluding a right intermediate bronchopleural fistula. **J** Schematic diagram of a small hinged self-expandable covered metallic stent with a bullet head occluding a right lower lobe bronchopleural fistula

was connected to a syringe by a multidirectional stopcock. Continuous negative pressure of 10–20 mm Hg was applied by the syringe for thoracic drainage. Nebulization and antibiotic treatment (according to bacterial culture reports) were used to reduce phlegm and control infection. The shrinkage of the thoracic cavity was followed up by monthly (or more frequently if the patient was symptomatic) chest CT. The stent position and the airway patency were checked by monthly bronchoscopy. Before removing the stent, the presence of granulation tissue was looked for and, if necessary, ablated under bronchoscopy.

The stent was removed when (1) the patient was cured; (2) the stent was damaged (degradation of components due to wear and tear caused by respiration- and heart beat-induced movements); or (3) there was proliferation of granulation tissue severe enough to compromise the patient's breathing. The drainage catheter was removed after disappearance of the residual cavity. The drainage catheter was retained if the residual pleural cavity had not disappeared at the time of stent removal.

Successful stenting was defined as immediate cessation of air leak from the residual cavity after stenting. A patient was considered to be cured if the residual cavity had disappeared completely and the stent and chest drainage catheter had been removed. The primary outcome of this study was the technical success rate. The secondary outcome was the cure rate after stent removal.

The technical success rate, time to stent removal, short-term and long-term follow-up results, change in residual cavity drainage, and complications were analyzed.

Statistical analysis

Data were expressed as mean ± standard deviation (SD) and percentages. GraphPad Prism version 5.0 for Windows (GraphPad Software, San Diego, CA, USA; http://www.graphpad.com) was used for analysis. The Kolmogorov–Smirnov test was used to check for the normality of distribution of continuous variables. The change in variables over time (i.e., before stenting, 1 month after stenting, and

Table 1 Criteria for selection of stent

	Left main bronchopleural fistula	Right main bronchopleural fistula	Left upper bronchopleural fistula	Left lower bronchopleural fistula	Right upper bronchopleural fistula	Right middle bronchopleural fistula	Right lower bronchopleural fistula
Y-shaped self-expandable covered metallic stent with a bullet head	+	+	−	−	−	−	−
Small Y-shaped self-expandable covered metallic stent with a bullet head	−	−	+	+	+	+	+
Hinged self-expandable covered metallic stent with a bullet head	+	+	−	−	−	−	−
Small hinged self-expandable covered metallic stent with a bullet head	−	−	−	−	−	+	+
Y-shaped self-expandable covered metallic stent	−	−	−	−	+	−	−
Hinged self-expandable covered metallic stent	−	−	−	−	+	−	−
L-shaped self-expandable covered metallic stent	−	+	−	−	−	−	−
Small L-shaped self-expandable covered metallic stent	−	−	+	−	−	−	+

after stent removal) was analyzed using ANOVA; the Wilcoxon Rank Sum test was used for non-normally distributed data. Comparison between groups was based on the Bonferroni method. A 2×2 contingency table analysis was performed using the Chi-square test. $P < 0.05$ indicated statistical significance.

Results

A total of 148 patients with bronchopleural fistulas were treated with stenting (Table 2) (Fig. 3A–H). The mean age of the patients was 54 (range 7–78 years). The median time from lung resection to the diagnosis of bronchopleural fistula was 38 days (range 0 days–7 years). There were 55 (37%) patients with right pneumonectomy, 49 (33%) with left pneumonectomy, 14 (10%) with right upper lobectomy, 12 (8%) with left upper lobectomy, 9 (6%) with right middle and lower lobectomy, 7 (5%) with right lower lobectomy, and 2 (1%) with left lower lobectomy. All fistulas were from the bronchial stump and not from lung parenchyma. In 78 patients bronchopleural fistula was associated with aspiration pneumonia, while in 12 cases it was associated with different degrees of subcutaneous emphysema. A median of 3 (range 1–5) bronchoscopies were required per patient.

In 53 patients who had severe breathing difficulties and cough productive of large amounts of purulent sputum, spiral CT of chest showed contralateral severe aspiration

Table 2 Characteristics of patients and fistulas

Characteristic	Patients, $N=148$, n (%)
Sex	
Male	126 (85%)
Etiology	
Lung cancer	100 (68%)
Tuberculosis	21 (14%)
Bronchiectasis	9 (6%)
Traumatic lung injury	7 (5%)
Lung infection	8 (5%)
Hemoptysis	2 (1%)
Lung bullae	1 (1%)
Fistula staging	
Early stage	29 (20%)
Delayed stage	86 (58%)
Late stage	33 (22%)
Neoadjuvant therapy	
Chemotherapy	14 (9%)
Radiotherapy	35 (24%)
Chemoradiation	17 (11%)
Type of pulmonary resection	
Right pneumonectomy	55 (37%)
Left pneumonectomy	49 (33%)
Right upper lobectomy	14 (9%)
Left upper lobectomy	12 (8%)
Right middle and lower lobectomy	9 (6.%)
Right lower lobectomy	7 (5%)
Left lower lobectomy	2 (1%)

pneumonia. The cough and expectoration were relieved after chest tube placement and drainage of 300–800 mL of purulent fluid.

Stenting results

Bronchopleural fistula occlusion with stenting was successful on the first attempt in 143 patients—a technical success rate of 96.6% (Fig. 3A–H). In these cases, tracheobronchography showed complete fistula occlusion, with no gas spillovers in the chest drainage tube. In 5 patients, the first attempt at occlusion of fistula with airway stenting failed; these were immediately identified by airway radiography, with water-soluble contrast injected via the catheter. One of these patients, who had a left main bronchopleural fistula, was treated with a hinged self-expandable covered metallic stent with a bullet head, but post-procedure airway radiography showed contrast spillover. The stent was removed, and inspection revealed a manufacturing defect (a 1 mm hole in the stent bullet). Replacement with another hinged self-expandable covered metallic stent of the same type and size was sufficient for achieving successful fistula occlusion. In 2 patients with right main bronchial stumps of <20 mm length, the hinged self-expandable covered metallic stents failed to completely occlude the fistula; replacement with Y-shaped self-expandable covered metallic stents was sufficient to achieve good fistula occlusion. In the other 2 patients, the failure to achieve occlusion on the first attempt was due to the large difference between chest CT measurement and the actual size of the airway to be stented, which led to the selection of inappropriately sized stents; substitution with stents of the correct sizes provided good occlusion of the fistulas.

For 2 patients who had left main bronchopleural fistulas combined with middle esophagopleural fistulas, esophageal stents, and bronchopleural fistula occlusion stents were placed separately.

Short-term follow-up results (within 30 days of stenting)

At follow-up 30 days after the stenting, 141 cases reported relief in clinical manifestations; there was complete fistula occlusion, absence of gas spillover, normal body temperature, shrinkage of abscess cavity, change in drainage fluid from turbid to clear, better general health, and improved sense of well-being. Two patients with right lower lobe bronchus fistulas were treated with L-shaped self-expandable covered metallic stents, but 3–5 days later, the stents were found to have migrated as a result of severe coughing, and therefore had to be removed and replaced. Five patients with severe pulmonary infection and poor general health died within 5–25 days of stenting.

Medium- and long-term follow-up results (after 30 days of stenting)

Patients were followed up for periods ranging from 1 to 91 months, either through telephone calls or clinic visits, with a short term (median 3.5 months; IQR 2.5, 5.7), median term (median 34.40 months; IQR 18.4, 43.4), and long term (median 70.80 months; IQR 64.25, 84.2). Six (4.05%) patients did not attend follow-up. As of December 2015, there are 67 surviving patients. Among these, 26 (38.8%) patients had no residual cavities at the time of stent and chest drainage tube removal. Another 36 (53.7%) patients have significantly reduced residual pleural cavity size and daily drainage of 20–80 mL of purulent fluid. The remaining 5 (7.5%) patients have been stented for less than 3 months and therefore the chest drainage tube and stent are still in place. These patients have an irritating stent-induced cough with a little purulent sputum; however, the residual pleural cavity

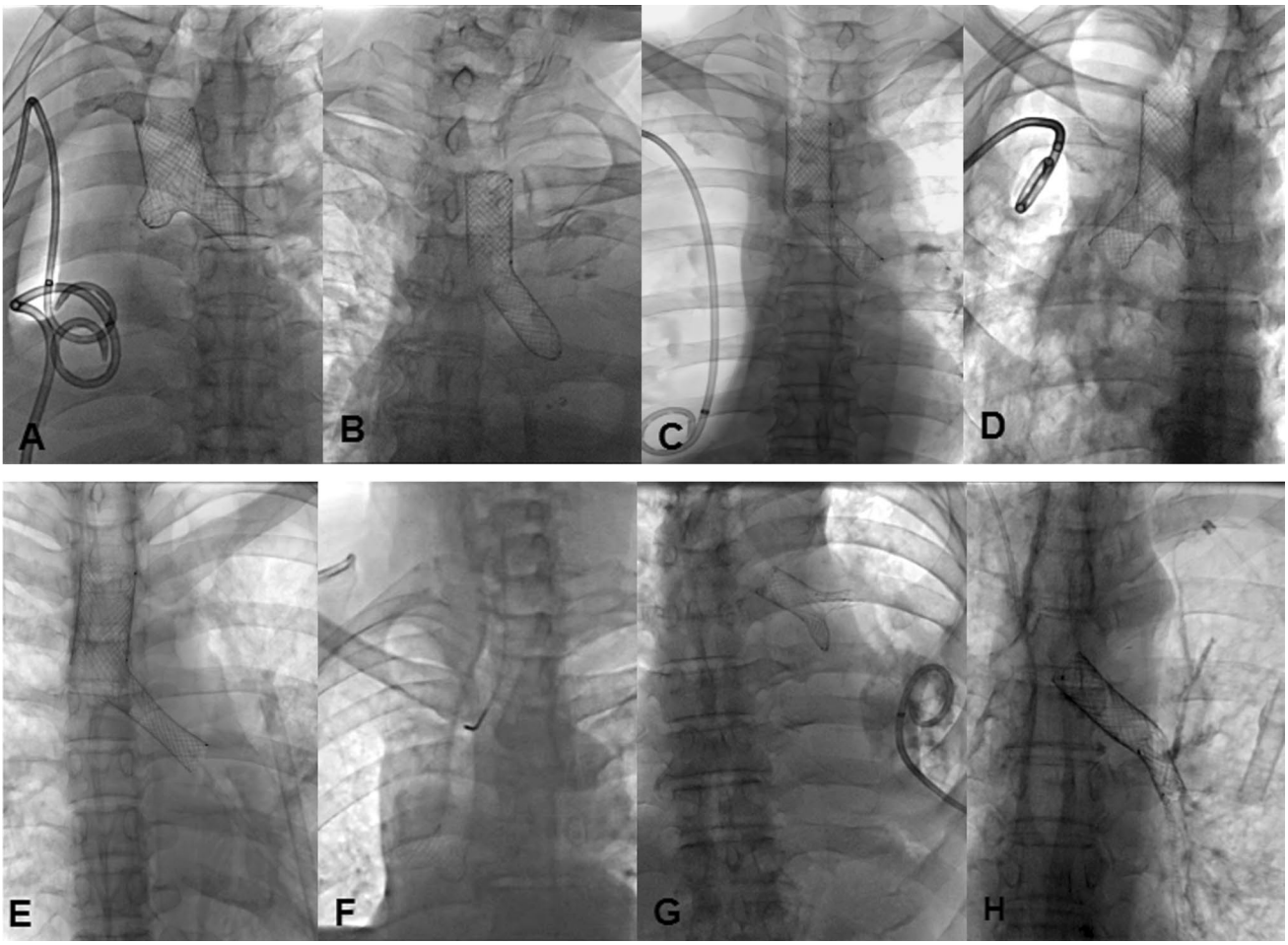

Fig. 3 **A** A Y-shaped self-expandable covered metallic stent with a bullet head occluding a right main bronchopleural fistula. **B** A hinged self-expandable covered metallic stent with a bullet head occluding a left main bronchopleural fistula. **C** An L-shaped self-expandable covered metallic stent occluding a right main bronchopleural fistula. **D** A Y-shaped self-expandable covered metallic stent occluding a right upper bronchopleural fistula. **E** A hinged self-expandable covered metallic stent occluding a left upper bronchopleural fistula. **F** A small hinged self-expandable covered metallic stent with a bullet head occluding a right upper bronchopleural fistula. **G** A small Y-shaped self-expandable covered metallic stent with a bullet head occluding a left lower bronchopleural fistula. **H** A small L-shaped self-expandable covered metallic stent occluding a left upper bronchopleural fistula

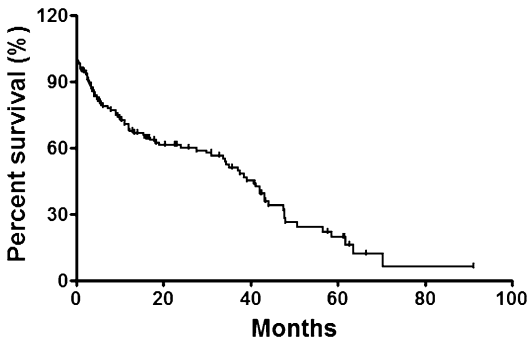

Fig. 4 Survival curve

is markedly reduced in size, and daily drainage of purulent fluid is only 60–150 mL.

In all, 75 patients died (Fig. 4); 39 (52.0%) died of lung infection and respiratory failure, 7 (9.3%) died of dyscrasias, 9 (12.0%) died following massive hemoptysis, 14 (18.7%) died as a result of progression of the tumor, and 6 (8.0%) died of cardio-cerebral vascular accidents.

Change in residual cavity drainage

The residual cavity drainage was 5–800 mL before stenting (median 90 mL; IQR 47.5, 200 mL), 5–300 mL after stenting for 1 month (median 60 mL; IQR 24, 122.5 mL), and 0–130 mL after removal of the stent (median 5 mL; IQR 0, 13.75 mL). Residual cavity drainage after removal of the stent was significantly lower than the drainage before

stenting ($P < 0.0001$) and that at 1 month after stenting ($P < 0.0001$).

The cavity size decreased after stenting; the transverse diameter decreased from 59.1 mm (IQR 40.5, 78.5 mm) before stenting to 37.1 mm (IQR 18.5, 56.5 mm) after 1 month of stenting ($P < 0.0001$), and to 35.3 mm (IQR 17.4, 48.4 mm) immediately after stent removal ($P < 0.0001$). The changes in the anteroposterior diameter and the vertical diameter were similar (Table 3). The pleural drainage catheter was removed during procedure of stent removal if the bronchopleural fistula had healed well; otherwise pleural drainage was continued until healing had occurred. The median time to removal of the pleural drain was 160 days (IQR of 144, 195 days).

At around 10 weeks (median 71 days; IQR 64–84 days) after stenting, 85% (34/40) of lobectomy patients versus 38% (39/102) of pneumonectomy patients were considered cured (i.e., had complete obliteration of the pleural cavity and removal of the chest tube); this difference was statistically highly significant ($P < 0.0001$).

Time to stent removal

In this study, 5 patients died within 1 month of stent placement and therefore their stents were not removed; 6 patients were lost to follow-up, who did not come for review, and could not to be contacted over the telephone; and 5 patients had their stents for less than 3 months and were still under observation. Thus, stents were removed in 132 of the 148 patients. The time to stent removal was 47–270 days (mean 112 ± 29 days). In 73 patients, the stents were removed following cure; in these patients the time to stent removal was 55–170 days (mean 110 ± 26). In 8 patients, the stents were removed because they were damaged; in these patients the time to stent removal was 47–150 days (mean 100 ± 37 days). In 51 patients, the stents were removed because of proliferation of granulation tissue severe enough to compromise breathing; the time to stent removal in these patients was 50–270 days (mean 116 ± 32 days).

The time to stent removal in bronchopleural fistulas of different stages

We examined whether the time to stent removal varied with the time of appearance of the fistula. Thus, we had three groups: early-stage fistulas were those that appeared < 7 days after pulmonary resection; delayed-stage fistulas were those that appeared 1 week–1 month after surgery; and late-stage fistulas were those that appeared > 1 month after surgery. As shown in Table 4, the time to stent removal was shorter in early-stage (< 7 days) bronchopleural fistula than in delayed-stage (7 days–1 month) fistulas. The time to stent removal in delayed-stage (> 1 month) bronchopleural fistula was shorter than that in late-stage fistula.

Complications

No choking, laryngeal edema, or airway rupture occurred in any patient during stent insertion or removal. A few patients had bloody sputum or hemoptysis because of injury to airway mucosa and granulation tissue during the process of stent implantation and removal, but they generally recovered without any specific treatment. However, 2 patients developed hemorrhage and dyspnea during stent removal. Tracheal intubation was done immediately by the interventional technique, and a suction catheter was used to remove blood from the airway; pituitrin was injected intravenously. Bleeding was controlled in all cases. Patients experienced different degrees of chest pain after stenting, but in all cases the pain disappeared after stent removal. Stent insertion often

Table 3 Change in residual cavity size after stenting

	Prior to stenting	At 1 month	Immediately after stent removal
Transverse diameter (mm)	59.1 (40.5–78.5)	37.1 (18.5–56.5)*	35.3 (17.4–48.4)**
Anteroposterior diameter (mm)	104.5 (67.1–133.9)	77.60 (34.7–100.4)*	64.90 (28.43–79.6)**
Vertical diameter (mm)	126.3 (85.4–153.9)	85.9 (60.0–124.9)*	83.75 (33.8–120)**

Data are presented as median values (IQR)

*$P < 0.0001$ (for comparison with diameter prior to stenting); **$P < 0.0001$ (for comparison with diameter prior to stenting)

Table 4 The time to stent removal in bronchopleural fistulas of different stages

	Number of patients	Number of stent removals	Median time to stent removal (days)	Interquartile range (days)
Early stage (< 7 days)	29	26	90	75–95
Delayed stage (7 days–1 month)	86	79	108	95–130
Late stage (> 1 month)	33	27	120	98–150

induced severe cough, but there was little sputum and the symptom was relieved with nebulizers. The cough was significantly relieved or even disappeared after stent removal.

In 18 patients with severe lung infection, poor general health, and weak cough reflex, the stents were blocked by tenacious sputum. These patients complained of chest discomfort and breathing difficulty. However, they improved with steam inhalations, nutritional support, and intermittent fiber-optic bronchoscopy suction to clear the airway. In 2 patients, L-shaped self-expandable covered metallic stents migrated due to severe coughing and had to be removed and reinserted.

In 101 patients, granulation tissue growth at the ends of stent caused airway stenosis, though breathing was not affected. In 6 patients, severe hyperplasia of granulation tissue caused airway stenosis with breathing difficulty; they were successfully treated with timely cauterization of granulation tissue and stent removal.

Discussion

In this study, airway occlusion stenting was successful on the first attempt in 143/148 (96.6%) patients with bronchopleural fistulas. In the remaining 5 patients, occlusion was successful only on the second try. At follow-up 30 days after stenting, 141 patients reported relief in symptoms.

The aim of treatment of bronchopleural fistula is to improve quality of life and survival time of the patients by repairing or occluding the fistula and eradicating the residual pleural cavity. In our series, fistula occlusion stenting showed good efficacy, especially over the short term, with patients showing progressive reduction in the size of the residual cavity and the drainage volume, as well as obvious relief in symptoms such as cough, hemoptysis, chest pain, and dyspnea.

Early bronchopleural fistula (i.e., developing in the first week after pulmonary resection) leads to a sensation of chest tightness and may be associated with subcutaneous emphysema, mediastinal swing (which seriously impairs the blood circulation), and contralateral lung infection. Delayed bronchopleural fistula (i.e., occurring 8–30 days after pulmonary resection) can lead to aspiration pneumonia and other chest infections, weight loss, and poor general health. Late bronchopleural fistulas generally occur 30 days after pulmonary resection, with patients presenting with weight loss, fatigue, poor general health, and progressive debilitation [16]. We found that the earlier the stent was placed, the sooner it could be removed.

Bronchopleural fistulas have been treated with various types of stents previously, but in these patients the stents were implanted permanently [17–22]. There are no reports in the literature describing airway stenting for treatment of upper or lower lobar bronchus fistulas. For lobar bronchus fistulas after lobectomy, the treatment has traditionally been a pneumonectomy; this approach, however, involves major trauma and results in increase in size of the residual pleural cavity and may also lead to the formation of a bronchopleural fistula again [23].

Bronchopleural fistula residual stump length, fistula location, and the associated anatomical relationships vary widely, which makes individualized choice of stent type and size advisable. In our series, the hinged self-expandable covered metallic stent with a bullet head was used for bronchopleural fistulas with bronchial stump length > 20 mm; in these cases, the bullet head can occlude the fistula effectively. However, it cannot occlude the fistula when the bronchial stump length is 5–20 mm, and so the Y-shaped self-expandable covered metallic stent with a bullet head was preferred in these cases. With bronchial stump length < 5 mm, only the L-shaped self-expandable covered metallic stent was applied. In 2 patients, inappropriate selection of stent type and size resulted in failure of the procedure. Therefore, stent selection should take into account individual anatomical variations, which should help improve success rates and decrease the incidence of complications.

Granulation tissue is the success-limiting step in patients undergoing this procedure. Therefore, it is necessary to study the mechanism of healing of the residual cavity and to identify methods to promote healing so that the stent can be removed as soon as possible. New types of stent material should also be developed that will help reduce proliferation of granulation tissue.

There are some drawbacks associated with airway stenting for bronchopleural fistula treatment. A stent in the airway acts as a foreign body and, despite improvements in airway stent materials and placement techniques, airway stent-related problems such as chest discomfort, expectoration difficulties, and granulation tissue formation cannot be totally avoided.

In summary, airway occlusion stenting is a novel treatment for bronchopleural fistula. The technology is still immature, and further research is needed to identify methods to shorten abscess healing time and to establish the ideal time for removal of the stent.

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Compliance with ethical standards

Disclosure Xinwei Han, Meipan Yin, Lei Li, Ming Zhu, Kewei Ren, Yu Qi, Xiangnan Li, and Gang Wu have no conflicts of interest or financial ties to disclose.

Ethical approval This study was approved by the Ethics Committee and Medical Records Management Department of the First Affiliated

Hospital of Zhengzhou University, Henan, China (Registration No. 2015-07).

Informed consent All patients gave written informed consent.

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