Right Lower Lobe Bronchopleural Fistula Treated with a Novel, Y-shaped, Single-Plugged, Covered, Metallic Airway Stent

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Abstract: Background: Right lower lobe bronchopleural fistula is an infrequent but life-threatening complication after lobectomy. It serious influence patients quality of life. Purpose: To determine the feasibility and efficacy of using Y-shaped, single-plugged, covered, metallic stents to treat right lower lobe bronchopleural fistula. Material and methods: We designed the Y-shaped, single-plugged, covered, self-expandable, metallic airway stent to fit the specific anatomy of the right lower lobe bronchus. The stent had a main tube and two branches, resembling an inverted “Y.” One of the branches was closed (plugged) and bullet-shaped; the other was tubular and open. The entire stent was encased in a nitinol wire mesh. Stent size was individualized using Multi-Slice Spiral Computed Tomography (MSCT) measurements of the airway. Under fluoroscopic guidance, we implanted 10 Y-shaped stents in 10 patients who had right lower lobe bronchopleural fistula. Results: Stent insertion was successful in all patients. All fistulas were successfully closed immediately after stent placement. Follow-up was performed for 2–6 months. Positive clinical outcomes were seen in 9 of 10 patients. One patients died of intractable pulmonary infection and multiorgan failure. The fistula completely healed and the stent could be removed in seven patients; however, two of them were left with a small, aseptic, residual right lower lung cavity. Conclusion: The placement of Y-shaped, single-plugged, covered, self-expandable metallic airway stents seems to be a feasible and safe method for the treatment of bronchopleural fistulas involving the right lower lobe bronchus. This stent is a promising therapeutic alternative for bronchopleural fistulas involving the right lower lobe bronchus.

Key words: Right lower lobe bronchus; bronchopleural fistula; stent; single plugged; Y-shaped; interventional radiology.

Introduction
Right lower lobe bronchopleural fistula usually develop after right lower lobectomy. Its incidence has considerably decreased during the last few decades, reaching figures of <1% in lobectomies¹⁻³. Associated risk factors such as residual tumour on the bronchial stump, long bronchial stump, diabetes, steroids, neoadjuvant chemo or/and radiotherapy, infection, etc. are well known, so prevention is in part possible. Once diagnosis is made, proper management is paramount to reduce the associated mortality, reported to be between 25 and 71% ⁴⁻⁵. Surgical techniques with muscle or epiplon transposition to close the fistula and obliterate the empyema cavity, once sterilized, or completion of pneumonectomy in the case of previous lobectomy, It’s disability rate is high, and serious influence the quality of life of the patients¹. Transcatheter insertion of a bullet-shaped, covered stent can prevent the occurrence of bronchopleural fistulas involving the right lower lobe bronchus. We designed a Y-shaped, single-plugged, covered, metallic airway stent that fit the specific anatomy of the right lower lobe bronchus and could be used in patients with short bronchial stumps. Under fluoroscopic guidance, we implanted 10 stents in 10 patients with right lower lobe bronchopleural fistulas involving short, right lower lobe bronchial stumps. Here, we present our promising preliminary results.

Material and Methods

Clinical data

This study involved 10 patients who developed bronchopleural fistulas involving the right lower lobe bronchus after undergoing right lower lobectomy and were treated at the Interventional Center of The First Affiliated Hospital of Zhengzhou University between June 2010 and April 2012. The patients included 8 men and 2 women, with a mean age of 55.78 years (range, 32–75 years). Every patients had right lower lung cancer and underwent right lower lobectomy. The patients showed varying degrees of empyema, chest tightness, fever and fatigue. All patients had been clinically diagnosed with a right lower lobe bronchopleural fistula 5 days to 3 months after right
lower lobectomy. The lengths of the right lower lobe bronchial stumps were found to be 5–12 mm using chest MSCT scans (Fig 2a).

**Stent design**

This novel airway stent consisted of a main tube and two branches, forming an inverted “Y” shape (Fig. 1). The main tube was open at the top and bifurcated into two branches at the bottom. One of the branches had a blind end (plugged) and was bullet-shaped; the other branch was open at its distal end and had a tubular configuration. The entire stent was encased in a mesh of nitinol wire (diameter, 0.24 mm) and self-expandable.

The stent dimensions were individualized according to chest MSCT measurements of the airway. In general, the diameters of the main tube, the open branch, and the plugged branch were 15%–20% greater than those of their corresponding airway parts. The lengths of the main tube and open branch were 20–25 mm and 8–12 mm, respectively; the plugged tube was 2–3 mm shorter than the stump of the right lower lobe bronchus.

The technology used for loading, delivery and release of the stent was similar to that used for the integrated Y-shaped airway stent; the stent branches had a bundled loading and release mechanism, and the main tube had a push-type loading and release mechanism[6,7].

**Stent insertion and removal**

Digital subtraction angiography was performed with the patient in a supine position as follows. After the necessary preparations, including oxygen inhalation, ECG monitoring, spraying of the throat with anesthetic lidocaine, vacuum suctioning to clear the airway and oral secretions, the shoulder and neck of the patient were elevated, and the head was turned to the right.

Under fluoroscopic guidance, a multipurpose catheter was passed over a guide wire through the mouth, pharynx, larynx and trachea and then into the right main bronchus; the guide wire was then removed. A 3- to 5-ml bolus of 2% lidocaine was injected through the catheter, followed by 3- to 5-ml of 38% meglumine diatrizoate compound for airway imaging (Fig. 2a), and the location and size of the bronchial stump fistula were noted.

Another guide wire and catheter were inserted into the right middle bronchus; the guide wire was replaced with a strengthened guide wire, and the catheter was removed. The stump fistula was similarly cannulated with a guide wire and catheter, which were inserted further into the ipsilateral pleural cavity; the guide wire was exchanged with a strengthened guide wire.

The position of the two guide wires within the right middle bronchus (normal) and right lower lobe bronchus (affected) was confirmed. The Y-shaped, single-plugged, covered airway stent and its delivery system were introduced over the two guide wires into the right main bronchi, and the stent position was adjusted such that the open and plugged branches of the stent were placed within the right middle and lower lobe bronchus, respectively; the gold marker was present on both sides of the edge (Fig. 2b).

With the guide wire fixed in position using the back handle of the delivery system, the outer sheath was pulled back using the front handle to expose both stent branches. With the relative positions of the front and back handles fixed, the open and plugged branches were inserted into the right middle and lower lobe bronchus, respectively, over their guide wires (Fig. 2c).

And then, the stent-delivery system was fixed in position, and the tractive stent bundled silk released the plugged and open branches (Fig. 2d, e). Next, the back handle was fixed in position, and the front handle was pulled back to release the main tube (Fig. 2f). The stent delivery system and guide wires were slowly withdrawn. A drainage tube was inserted into the residual right thoracic cavity for subsequent suction and negative-pressure drainage therapy.

Airway imaging (Fig. 2g) and chest MSCT (Fig.3b, c) were performed postoperatively to observe the sealing of the fistula. After the procedure, the patients were administered aerosol inhalation with 10 ml saline, 5 ml lidocaine, 8000 U chymotrypsin, and 0.2 g amikacin to promote sputum discharge and reduce irritation due to the stent. Antibiotics were administered based on the results of bacterial cultures and sensitivity test to control lung infection. Anti-inflammatory, expectorant, and symptomatic treatment was also provided.

Follow-up contrast study, including chest MSCT and bronchoscopy, were performed to evaluate the efficacy of sealing the fistula and migration of the stent one weeks after the procedure and then every month after the procedure until the BPF was healed. The Pleural cavity drainage tube was removed if no signs of persistent fistula were detectable by air bubbles.

Retrieval of the stent was performed fluoroscopically using a retrieval set (Micro-Tech). This was performed after the BPF had healed or complications occurred. The set consisted of a 13F sheath, a 10F dilator, and a hook wire. The stent was grasped at the far end of the mesh stent within the Right middle bronchus part and gently pulled out.

**Results**

Ten patients with bronchopleural fistulas involving the right lower lobe bronchus underwent airway stenting with a Y-shaped, single-plugged, covered, metallic airway stent. The procedure was completed in 5–15 min, and all stents were successfully placed. The diameters of the main tube, and the open and plugged branches were 12–22 mm, 8–12mm, and
10–15 mm, respectively; their corresponding lengths were 20–25 mm, 8–12 mm, and 10–20 mm. No severe intra- or postoperative complications occurred, such as asphyxia, hemorrhage and airway rupture. Postoperative contrast study confirmed that all stump fistulas were completely blocked (no contrast extravasation).

Follow-up examination was performed for 2–6 months. One patients with successful fistula closure died of intractable pulmonary infection and multiorgan failure 2 weeks after stent insertion. In two patients, the fistula healed, and the stent was removed 2 months after placement, but a small, aseptic, residual lung cavity was seen in the right thorax. In seven patients, the fistula healed, the right residual cavity disappeared, and the stent was removed 2–3 months after placement. The patients’ quality of life has been greatly improved, although mild expectoration and coughing persist, without dyspnea, bleeding and other complications.

Discussion

Right lower lobe bronchopleural fistula is a serious complication of lobectomy. This condition has high morbidity and mortality and poses a difficult therapeutic challenge. Bronchoscopic management of bronchopleural fistula with intrabronchial instillation of glue has been reported[8]. At present, the treatment of bronchopleural fistulas rests on the following key strategies: the insertion of a drainage tube, drainage of any abscess to prevent pus flow into the normal lung and aggravation of lung infection, complete blockage of the fistula, and isolation of the normal lung from the abscess cavity. Plugged airway stents were invented by Professor Han Xin-wei and are suitable for the treatment of stump fistulas involving the left or right main bronchus, the right intermediate bronchus, and lower left bronchus when a long, residual bronchial stump is present; however, they are not suitable for fistulas of the right lower lobe bronchus, as this has a short bronchial stump[9,10].

The Y-shaped, single-plugged, covered, self-expandable, metallic stent has the following advantages: (a) the main tube, and the open and plugged branches of the stent are fixed together, which helps prevent stent migration; (b) the stent completely covers the Bronchial crotch, facilitating complete blockage of the fistula; (c) the stent is covered with polyethylene, which prevents granulation tissue formation and enables easy removal of the stent using a stent extractor under fluoroscopic guidance, in case of ill-fitting stents or temporarily placed stents; and (d) the main tube and open branch of the stent have an X-ray-opaque marker, enabling simple and accurate localization and release of the stent.

When a right lower lobe bronchopleural fistula has been diagnosed, efforts should be made to immediately block the fistula in order to prevent infection of the normal lung and multiorgan failure. One patients in this study developed severe lung and chest infections owing to a delay in treatment; they both died of multiorgan failure 2 weeks after the operation, even though the bronchopleural fistula was completely blocked. Chest MSCT data were used to individualize the size of the airway stents in order to ensure complete fistula blockage, eliminate the source of infection, and facilitate complete cure of empyema. The stent was released only after accurate positioning in order to prevent stent migration. Patients who had a residual lung cavity after the right lower lobectomy showed varying degrees of pulmonary infection and their tolerance to stent insertion and ability to breathe worsened; airway stenting should therefore be performed as soon as possible after the diagnosis of a bronchopleural fistula.

Figure 1: Y-shaped, single-plugged, covered, metallic airway stent.
Figure 2: **a.** Bronchial angiography images showing a fistula involving right lower lobe bronchial stump. **b.** Stent delivery system passed through the mouth and throat and into the right main bronchus. **c.** The open and plugged branches of the stent are introduced into the right middle bronchus and the stump of the right lower lobe bronchus, respectively, over two guide wires. **d.** The plugged branch is released in the residual right lower lobe bronchus by pulling the stent delivery handle. **e.** The open branch is released in the right middle bronchus by pulling the stent delivery handle. **f.** The main tube is released. **g.** A review angiography shows that stent expansion and location are appropriate, and the fistula is blocked completely.

Figure 3: **a.** Preoperative chest MSCT scan showing a bronchopleural fistula involving the right main bronchial stump. **b,c** Review chest MSCT scan obtained 1 week after stent insertion shows complete occlusion of the fistula and disappear of the right lower lung cavity.
In conclusion, the Y-shaped airway stent described in this study is easy to insert, safe, minimally invasive and repeatable. Insertion of this stent is associated with less pain and a quick recovery, especially in patients who are in poor health and cannot tolerate surgery and general anesthesia. Satisfactory results were obtained in this study, and this stent may be suitable for the clinical treatment of right lower lobe bronchopleural fistula. However, since this technology is in the preliminary stage, further studies are required to assess long-term efficacy, to shorten the time required for abscess healing, to develop a method for determining whether the fistula is closed and to determine the optimal time for stent removal.

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