

# Implantation of a self-expandable metallic inverted Y-stent to treat tracheobronchial stenosis in the carinal region: initial clinical experience

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## Introduction

Tracheobronchial stenoses or fistulas caused by benign or malignant diseases are life-threatening and present as respiratory distress symptoms. Airway stent insertion is an effective and widely used method to manage this condition. When the stenoses or the fistulas exist in the lower trachea, main carina, and main-stem bronchi, the insertion of one hinged stent or angled stent,<sup>1-3</sup> or two straight stents, does not provide complete lesion coverage. Thus, the placement of a Y-stent in these patients is often required for successful palliation.<sup>4</sup>

The most commonly used Y-stent in the carinal region is the silicone Dumon stent.<sup>5-7</sup> Hauck et al.<sup>8</sup> described the use of two self-expanding nitinol stents to create a Y-configuration, which requires the bronchoscopic creation of an opening in one stent using a laser to allow the second stent to be placed. The use of a custom-made, self-expanding, metallic, inverted Y-stent, which is inserted under fluoroscopic guidance, has not been previously reported. During 2006, the authors designed a system (Micro-Tech, Nanjing, China) specialized for delivery and deployment of the self-expandable, metallic, inverted Y-stent in the carinal area. The purpose of this study was to evaluate the initial clinical feasibility and efficacy of an expandable metallic inverted Y-stent to treat complex tracheobronchial stenoses in the carinal region.

## Materials and methods

### Patients

From April 2006 to October 2006, five consecutive patients with complex tracheobronchial stenoses involving a carinal bifurcation region were treated with a self-

expandable metallic inverted Y-stent (Micro-Tech, Nanjing, China). The patients were two men and three women, aged 49-79 years (mean 67.6±11.65 years). Demographic and clinical presentations of these patients are summarized in the Table 1. Stenoses were caused by lung cancer in two cases and oesophageal carcinoma in three. The patients' tumours were histologically staged as at least T4 N1 M0 using the TNM classification. The interval between the onset of dyspnoea and stent placement was 6.4 ±4.98 weeks (range 2-14 weeks). The patients presented with respiratory symptoms of dyspnoea, cough, orthopnoea, and/or haemoptysis. Pre-operative arterial blood oxygen saturation (SaO<sub>2</sub>) in all patients was under 90%, and arterial partial pressure of oxygen (PaO<sub>2</sub>) was under 80%.

Diagnoses of stenoses were established by reviewing patient history and examining findings at computed tomography (CT) and bronchoscopy examinations. The diameter of the normal trachea and bronchus, and the stenotic site and size were measured using multidetector CT [three-dimensional (3D) reconstructions] and bronchoscopy. The choice of stent was determined by the interventional radiologist according to the multidetector CT images. The stenoses were located in the trachea and left main bronchus (n=1); the trachea and right main bronchus (n=1); the trachea and bilateral main bronchus (n=3).

### Stents and delivery systems

The self-expandable, metallic, inverted Y-stent was woven from a single thread of 0.16 mm diameter highly elastic nitinol wire, which consisted of three parts: the body and two bronchial limbs. The body (tracheal stent) was in a tubular configuration: 18-25 mm in diameter when fully

expanded and 30-50 mm long. The two bronchial limbs were also in a tubular configuration, both 11-14 mm in diameter, but had different lengths: 10 and 30 mm. Precise stent placement was facilitated by four radio-opaque markers, one at the proximal end of the tracheal stent, at the distal ends of the two bronchial stents, and one at the bifurcated portion (Fig.1). The Y-stent was covered with polyethylene to prevent tissue hyperplasia or tumour infiltration extensively through the stent wires. The stent was constructed by a manufacturer (Micro-Tech) according to the authors' specifications.

The Y-stent delivery system had been developed by both our institute and MicroTech. It was specifically designed to place the self-expandable, metallic inverted Y-stent in the tracheal carina and was composed of a three-tier structure, as shown in Fig. 2. First, the inner tier consists of four parallel guiding tubes, two long and two short. Guide-wires pass through the two longer guiding tubes and binding threads traverse the shorter ones. The tips of the two longer tubes are guiding tips (short arrows in Fig. 2b) in a fusiform configuration. One guiding tip is bigger and in an outer position, and the other is smaller and concealed proximal to the introducer sheath (long arrows in Fig. 2b). The proximal long tubes cross the bronchial and tracheal stents, and the body of the two tubes is situated in the pusher catheter (arrowheads in Fig. 2b). The body of the two shorter guiding tubes is also located in the pusher catheter, and the tails (Fig. 2c) extend out of the back of the pusher catheter by about 5 cm. The two bronchial stents are bound by the two binding threads and are fixed on the proximal side of the two guiding tubes. When pulling back the two retaining threads, the two bronchial stents are deployed in a proximal to distal direction. Second, the middle-tier is a pusher catheter with a diameter of 25 F (8.33 mm) and contains the four guiding tubes. Finally, the outer-tier is an 27 F (9 mm) introducer sheath with a ring radio-opaque marker at its proximal end and a lateral tube for ventilation at the distal end. For implantation under fluoroscopic guidance, the inverted Y-stent was mounted in a compressed state on the two guiding tubes by the introducer sheath (Fig. 2).

### Stent placement techniques

Informed consent was obtained from each patient, and the university committee on human investigation approved this study.

The patient was placed in the right anterior oblique or supine position with the neck extended and the stenosis

was identified by an injection of 3-5 ml of 30% diluted nonionic contrast medium

(Ultravist 300; Schering, Guangzhou, China; Fig. 4a). Fig. are exchanged using catheters (insert type of catheter used here) for two 0.035" super-stiff guide-wires (THSF; Cook, Bloomington, IN, USA); these are passed through the guiding tubes within the 27 F delivery system, which is then advanced down to the level of the tracheal carina (Fig. 3b). The whole stent system within the introducer sheath is then advanced further so that the bronchial stents pass over the guide-wires into the right and left main-stem bronchi (Fig. 3c). The two bronchial stents are deployed by retracting their retaining threads (Fig. 3d,e). Finally the tracheal stent is deployed by withdrawing the introducer sheath thus completely releasing the inverted Y-stent (Fig. 3f). Contrast medium was injected through the catheter into the tracheal stent to assess correct placement and expansion of the stent after the procedure (Fig. 4b).

After the procedure, all patients continued to be treated with appropriate antibiotics (levofloxacin injection) for 3e5 days to control infection. In addition, aerosol inhalation (50 ml of 0.9% normal saline + 5 ml of 30% lidocaine + 8000 U chymotrypsin + 0.2 g amikacin + 5 mg dexamethasone DMX) was administered once a day for 7-14 days after the procedure to dilute sputum (chymotrypsin), reduce tissue hyperplasia (DMX), abate local oedema, eliminate local inflammation, and alleviate retrosternal pain and cough.<sup>1</sup> Patients were followed up as outpatients for a mean of 16.6±4.93 weeks (range: 12-24 weeks). Chest radiography was obtained 3 and 7 days after stent placement to verify the state of pulmonary expansion and position of the stent. Contrast enhanced multidetector CT and bronchoscopy were performed to evaluate the efficacy of the stent placement and patency or migration of the stent 2 weeks after the procedure, and then at 2 or 3 months after the procedure. If the follow-up examination at the outpatient clinic was not practical, the patients or their families were contacted by telephone by one of the authors every 1e2 months for the remainder of the patient's life. Information was obtained concerning coughing, dyspnoea, haemoptysis, and complications such as pain, bleeding, and stent-related complications.

## Results

### Technical and initial clinical results

Stent placement in the carinal areas was technically successful and well tolerated in all patients, with no

procedure-related complications. Initially, all patients required the placement of only one inverted Y stent. Contrast medium injected through the catheter after the procedure demonstrated that the stenoses had disappeared completely. All patients had immediate relief of respiratory symptoms of dyspnoea, or cough, and postoperative SaO<sub>2</sub> increased by 95% and PaO<sub>2</sub> by 80%. Three patients felt dull chest pain for 1-5 days after stent placement.

#### Follow-up data

During follow-up (mean survival 16.6±4.93 weeks; range 12-24 weeks), all stenoses were resolved without stent-related complications, and the general physical health of all the patients (patients 2 and 3 were followed by telephone) improved with no occurrence of obvious dyspnoea or bleeding. All patients accepted follow-up healthcare after having the stents inserted and are alive with no evidence of dyspnoea at the time of this report.

#### Discussion

This study evaluated the efficacy of an expandable metallic inverted Y-stent to treat complex tracheobronchial stenoses in the carinal region. Initial results were positive in that the stenoses were completely eradicated in all patients tested and follow-up studies revealed that no deaths occurred and patients were generally healthy. These results suggest that an expandable, metallic, inverted Y-stent deployed via our delivery system is a feasible and effective way to treat tracheobronchial stenoses in the carinal areas.

The most commonly used non-metallic Y-stent is the silicone Dumon stent, which is inserted using a bronchoscope under general anaesthesia. This stent has been used to successfully manage patients with tracheobronchial stenoses or fistulas in carinal region.<sup>5-7</sup> Like the silicone Dumon Y-stent, the expandable, metallic, inverted Y-stent also provides sustained improvement in the quality of life in patients with this condition and relieves

the acute dyspnoea associated with complete tracheal obstruction.

The expandable metallic inverted Y-stent has advantages over the silicone Dumon Y-stent. First, the insertion of the inverted Y-stent only requires topical anaesthesia for the optimal calibration of the tracheobronchial lumen and then a guide-wire is inserted periorally into the trachea or bronchus under fluoroscopic guidance. For a Dumon Y-stent, the first step requires recanalization of the obstructed central airways by either mechanical or photoablative means, which often takes longer.<sup>6,9</sup> The insertion of the inverted Y-stent is easy and simple, and is almost identical to the technique used for implanting conventional expandable metallic stents; the procedure often takes less than 10 min. Once in position the inverted Y-stents are released by withdrawing the introducer sheath and threads, they gradually expand to a predetermined shape that matches the intraluminal contour of the tracheobronchial tree; the metal stents require minimal routine care. Furthermore, the metallic inverted Y-stent minimizes the risk of recurrent infectious complications related to tracheo-oesophageal or broncho-oesophageal fistulas and contact with the mucosa limiting granuloma formation and tumour infiltration due to polyethylene covering.

This study has the following limitations. First, it is not a comparative study, and the patient population was small and no control group was included. The goal of the present study was merely to provide details of the techniques, and early results of the use of the expandable, metallic, inverted Y stent in our practice. Second, the covered stent may impede mucociliary clearance, thereby fostering sputum retention.

In conclusion, although further clinical trials and expanded follow-up studies are needed, the preliminary results indicate that using the self-expandable, metallic, inverted Y-stent for the treatment of stenoses involving the carinal proved to be a simple, safe, and feasible procedure.

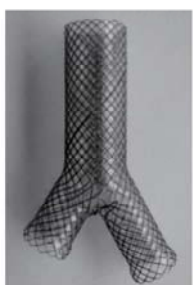


Figure 1 Schematic drawing of the self-expandable metallic inverted Y-stent.

Note: the stent sizes and angles should be adjusted to fit the patient.

Table 1 Summary of characteristics of five patients with tracheobronchial stenoses

Patient no./ age / sex	Symptom and sign	Interval (week)	History	Location stenosis	Preoperation		Postoperation		Stent(mm)			Follow-up (weeks)	Outcome
					Sao2	Pao2	Sao2	Pao2	Trachea	LB	RB		
1/49/M	C,D,O,T	8	LC	Trachea,RB,LB	82%	72%	99%	96%	24 x 30	14 x 15	14 x 25	24	Ailive
2/75/M	C,D,H,O,T	14	LC	Trachea,RB	88%	76%	97%	95%	22 x 40	13 x 10	13 x 25	19	Ailive
3/79/F	D,H,O,T	6	OC	Trachea,RB,LB	84%	72%	97%	97%	18 x 50	11 x 35	11 x 20	15	Ailive
4/65/F	D,H,O,T	2	OC	Trachea,LB,RB	76%	63%	98%	99%	20 x 50	24 x 40	14 x 20	13	Ailive
5/70/F	D,H,O,T	2	OC	Trachea,LB	81%	68%	99%	96%	22 x 50	12 x 30	12 x 20	12	Ailive

C, cough; D, dyspnoea; O, orthopnoea; H, haemoptysis; T, three concave sign; RB, right bronchus; LB, left bronchus; LC, lung cancer; OC, oesophageal carcinoma.

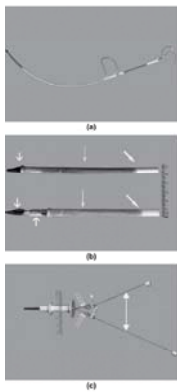


Figure 2 (a) Photograph of the entire Y-stent delivery system. (b) Photograph of the entire stent assembly. (c) Photograph of the tail of the delivery system. The entire delivery system consists of two guiding tips (short arrows in 2b), introducer sheath (long arrow in 2b), four guiding tubes (inside the assembly and, therefore, not visible), pusher catheter (arrowheads in 2b), and a compressed stent. Note also the tails of the two shorter guiding tubes (double arrow in 2c) and the two binding threads (bidirection arrow in 2c).

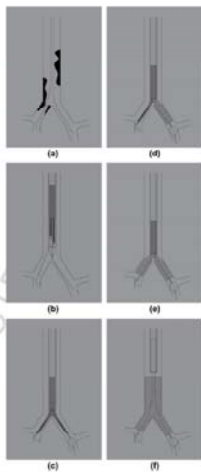


Figure 3 Schematic diagrams showing the steps used for placement of the self-expandable, metallic, inverted Y-stent.

(a) Complex stenoses involving the lower trachea, carina, and right main bronchus are delineated by the injection of a small amount of contrast medium. Two guide-wires are inserted into the right and left bronchi. (b) Two guide-wires are inserted into the right and left bronchi. (c) The inverted Y-stent is advanced using the pusher catheter so that the bronchial stents pass into the right and left bronchi. (d, e) The bronchial stents are deployed by retracting their retaining threads. (f) The introducer sheath is pulled back to deploy the tracheal stent.

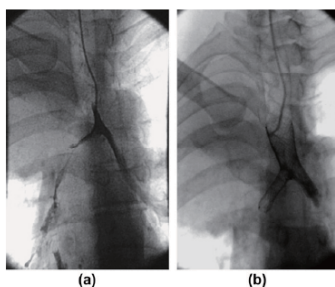


Figure 4 Complex stenoses in a 49-year-old man with lung cancer who presented with cough, dyspnoea, and haemoptysis of 1 months duration. (a) Contrast medium injected through the catheter confirms multiple stenoses located at the lower trachea, the main carina, and the right bronchus. (b) Contrast medium injected through the catheter immediately after stent placement demonstrates that the stenoses have disappeared with partial expansion of the stent.

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