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Multiple Bifurcated Covered Self-Expanding Metallic Stents for Complex Tracheobronchial Fistulas or Stenosis

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Abstract

Objective We aimed to determine the safety and feasibility of bifurcated covered self-expanding stents for the treatment of complex tracheobronchial fistulas or stenosis.

Methods Twenty-eight patients were treated by multiple bifurcated covered airway stents (Micro-Tech Co. Ltd., Nanjing, China), including 18 cases of gastrobronchial or gastrotracheal fistula, 6 cases of bronchopleural fistula and 4 cases of severe tracheobronchial stenosis. The large bifurcated covered stent was placed at the main carina, and the small stents were inserted into primary right carina or secondary left carina. Clinical and imaging data were retrospectively analyzed.

Results Stents were successfully inserted in 27 patients at the first attempt. In total, 29 large bifurcated covered stents, 27 small bifurcated covered stents and 5 small bifurcated covered single-plugged stents were inserted. All patients with fistula could resume eating without coughing after the procedure. No perioperative death or severe complications occurred. Two patients underwent stent removal due to intolerance of stenting; the clinical success rate was 93% (26/28). Nineteen complications were found in 12 patients; 8 patients needed stent removal or replacement, for a major complication rate of 29% (8/28). Eight patients underwent successful stent removal due to complications. Fifteen patients died of tumors and one patient died of pulmonary infection. The median survival was 33 months. Fistula recurrence was found in one patient 5 months after stenting, and second small bifurcated covered stent was inserted.

Conclusions Multiple bifurcated covered metallic stenting is effective and safe for complex tracheobronchial fistulas or stenosis, with good symptom palliation.

Keywords Respiratory tract fistula · Tracheal stenosis · Stents · Fluoroscopy · Postoperative complications

Introduction

Tracheobronchial fistula or stenosis is severe and potential life-threatening complications often encountered after surgery for lung or esophageal carcinoma, endobronchial tuberculosis and thoracic trauma [1]. The mortality and disability rates are high; unfortunately, both medical and surgical treatments show a poor curative effect. Most of these patients may be too sick to undergo definitive open surgery or may not be successful in such cases [2]. Since first adoption of metallic stents to treat bronchial obstruction by Simonds et al. [3], the metallic stents placement has become an effective method for the treatment of tracheal

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fistula [4–7] or tracheal stenosis [8–13]. However, few studies have described the treatment of complex tracheobronchial fistula or stenosis, such as gastrotracheal fistula and gastrobronchial fistula caused by tumor recurrence and radiation necrosis [14–16]. Some investigators have used covered tubular airway stents to treat tracheal fistulas (e.g., esophago-tracheal fistula) or stenosis, but the bifurcated structure of the trachea causes a high rate of tracheobronchial leakage or stent migration [11, 14, 15]. Bifurcated covered metallic stents have been used for sealing tracheobronchial fistulas, such as bronchopleural fistula after lobectomy [15, 17]. However, in the case of complex tracheobronchial fistulas (e.g., thoracogastric bronchial fistula) or stenosis that involves the carina and/or the right or left main bronchus, a single tubular airway stent might not completely seal fistulas or dilate stenosis. In this study, we used the multiple bifurcated covered metallic stent to treat complex fistulas or stenosis that involved the carina and/or main bronchus. The aim of this study was to determine the safety and feasibility of multiple bifurcated covered metallic stents for the treatment of complex tracheobronchial fistulas or stenosis.

Materials and Methods

Patients

This retrospective study was approved by institutional review board of our university. All written informed consents were obtained from these enrolled patients. From February 2011 to June 2017, 28 patients were treated by multiple bifurcated covered airway stents in our department. This study included patients with complex tracheobronchial fistula or stenosis that involves the carina and/or the right or left main bronchus, such as gastrotracheal fistula, gastrobronchial fistula or bronchopleural fistula after lobectomy or caused by tumor recurrence and radiation necrosis. Bronchoscopy and chest spiral computed tomography (SCT) were used for the diagnosis of tracheobronchial fistula or stenosis. All patients with esophago-tracheal fistula complained of stubborn cough when feeding, which was aggravated when the patients were lying down. Conservative treatments, such as anti-inflammatory treatment, gastrointestinal decompression and enteral nutrition by jejunal feeding tube, were used for these patients before stenting.

Preoperative Preparation

All patients with esophago-tracheal fistula had varying levels of malnutrition, and an intestinal feeding tube was inserted first to maintain caloric intake before airway stent was manufactured. A routine examination, such as a blood test, blood coagulation function test, liver and renal function, was performed before stenting. Bronchoscopy and chest SCT were used to confirm the diagnosis and determine the location of the fistulas or stenosis. All the bifurcated covered stent and stent delivery system were designed and manufactured by Micro-Tech Co. Ltd. (Nanjing, China) [17]. The material of stent was made of temperature-memory nickel–titanium alloy wire, and the type of stent is self-expanding, fully covered. The airway stents were customized for each patient according to the inner diameter of the trachea and bronchi measured by chest SCT (Fig. 1A). The anteroposterior diameters and transverse diameters were measured on the cross section, and the mean values were taken as the diameters of the cross section. Diameter of the stent oversized 10–20% in relation to the diameter on the SCT images [18].

Stenting Procedure

The bifurcated covered stents were implanted under fluoroscopic guidance as previously reported [17]. The patient was sedated and placed in a supine position, with administered oxygen administration via nasal catheter and electrocardiographic monitoring. A vacuum extractor was used at any time for cleaning excreta. A 10 mg of anisodamine (trade name 654-2) and 10 mg of diazepam were injected to reduce airway secretions and to calm patients before the procedure. In order to relieve dyspnea and to improve the tolerability of stent placement, 10 mg of dexamethasone was injected if necessary. A vertebral artery catheter (Cook Corporation, Bloomington, Ind, USA) was introduced over a hydrophilic guide wire (Cook Corporation) into the diseased bronchus. About 5 mL of 2% lidocaine was sprayed via catheter for topical anesthesia of trachea. The location and size of the fistula or stenosis was shown after injection of 5 mL of iodine contrast agent (Iohexol, Guerbet, France; Fig. 1B). The catheter was introduced into the distal end of lobar bronchi of the diseased main stem bronchus. Two stiff guide wires (Cook Corporation) were inserted into the distal end of lobar bronchus and fixed tightly in place. The small bifurcated covered stent delivery system (8 mm in diameter) was introduced over the guide wires into the corresponding lobar bronchi. The branches of the small bifurcated covered stent were deployed first by retracting the retaining threads, and the main body was deployed by withdrawing the covering sheath at the site of the diseased main bronchus (Figs. 1C, 2A, B). Similarly, a large bifurcated covered stent was implanted in the carinal region to overlap with the main body of the small bifurcated covered stent (Figs. 1D, E, 2C, D). Radiography was performed to confirm the seal of fistula or relief of stenosis immediately after stenting.

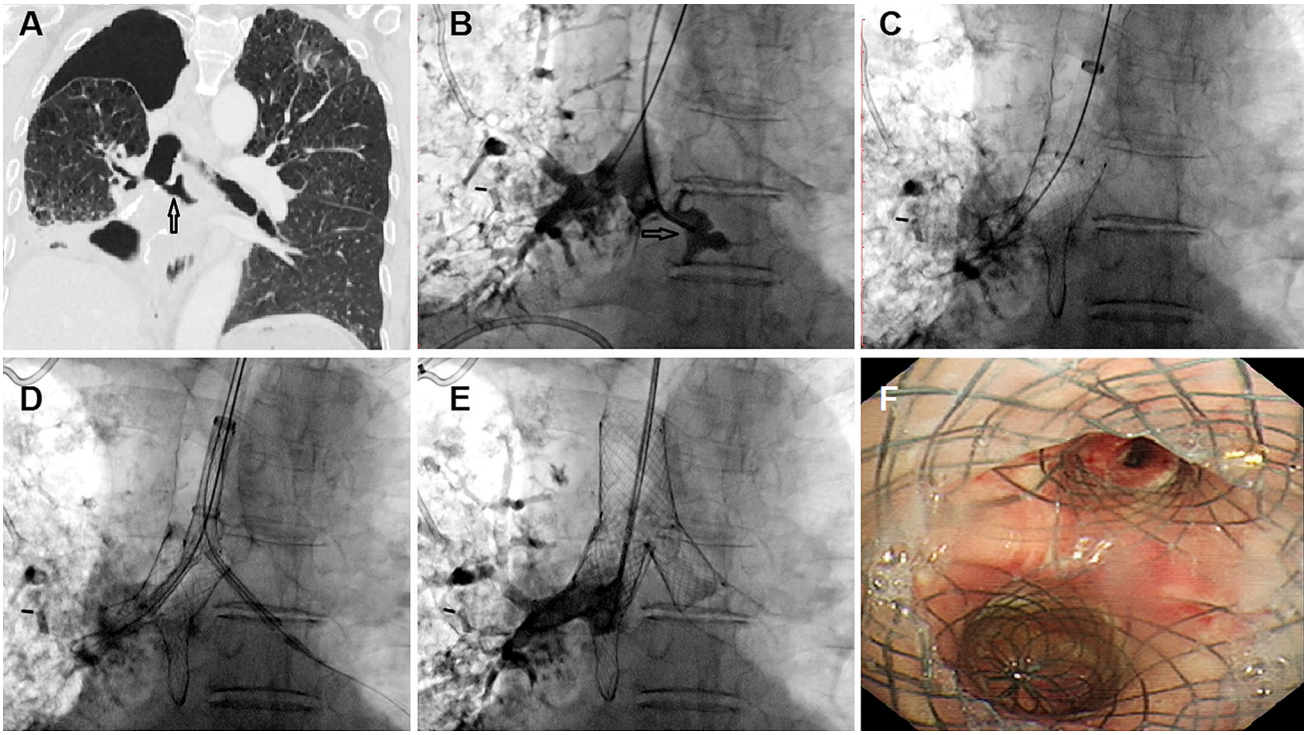

Fig. 1 Treatment of a 74-year-old man with gastrobronchial fistula. **A** A thoracic stomach-right bronchus fistula (arrow) is shown by chest SCT before stenting. **B** This fistula (arrow) is confirmed by radiography, which is in accordance with the SCT findings. **C** A small bifurcated single-plugged stent is inserted in the diseased lobar bronchi. **D** A large bifurcated covered stent is inserted in the carinal region. **E** Repeat radiography confirms that the fistula is completely sealed. **F** Bronchoscopy shows the sealing of tracheobronchial fistula and stent patency

Follow-Up

Bronchoscopy was used to confirm the sealing of tracheobronchial fistula and stent patency with or without sputum suction during follow-up (Fig. 1F). Bronchoscopic cryotherapy was conducted if restenosis due to granulation tissue hyperplasia was present. Symptoms such as coughing when feeding were monitored, and radiography was performed by a swallow of iodine contrast medium during follow-up to determine if a fistula or stenosis was present. Chest SCT, upper gastrointestinal radiography and bronchoscopy were performed once coughing when feeding or dyspnea recurred. Reintervention was conducted once a fistula or severe stenosis was found. Clinical success is defined as successful stent placement, including secondary placement due to stent migration, successful closure of fistula or effective relief of stenosis, without obvious stent intolerance or death within 1 month after stent placement.

Results

Patient Characteristics

Nineteen patients had esophageal cancer and 7 patients showed lung cancer (5 lung squamous cell carcinoma, 1 neuroendocrine carcinoma and 1 adenocarcinoma), the remained 2 patients showed a previous disease of lung inflammatory (tuberculosis/pulmonary abscess). Twenty-four patients had undergone surgical resection of esophageal cancer or lung cancer, and mechanical anastomosis was used for all patients without manual anastomosis. Gastrobronchial fistula and gastrotracheal fistula were found in 3 patients and 15 patients after radical esophagectomy due to esophageal cancer, respectively. Bronchopleural fistula was found in 6 patients after lobectomy (Table 1). Four patients with severe tracheobronchial stenosis were included. One showed stenosis in left main bronchus, and 3 patients showed stenosis in bilateral main bronchi due to lung cancer (n = 3) and tuberculosis (n = 1). No cases showed tracheobronchial stenosis combined with fistula.

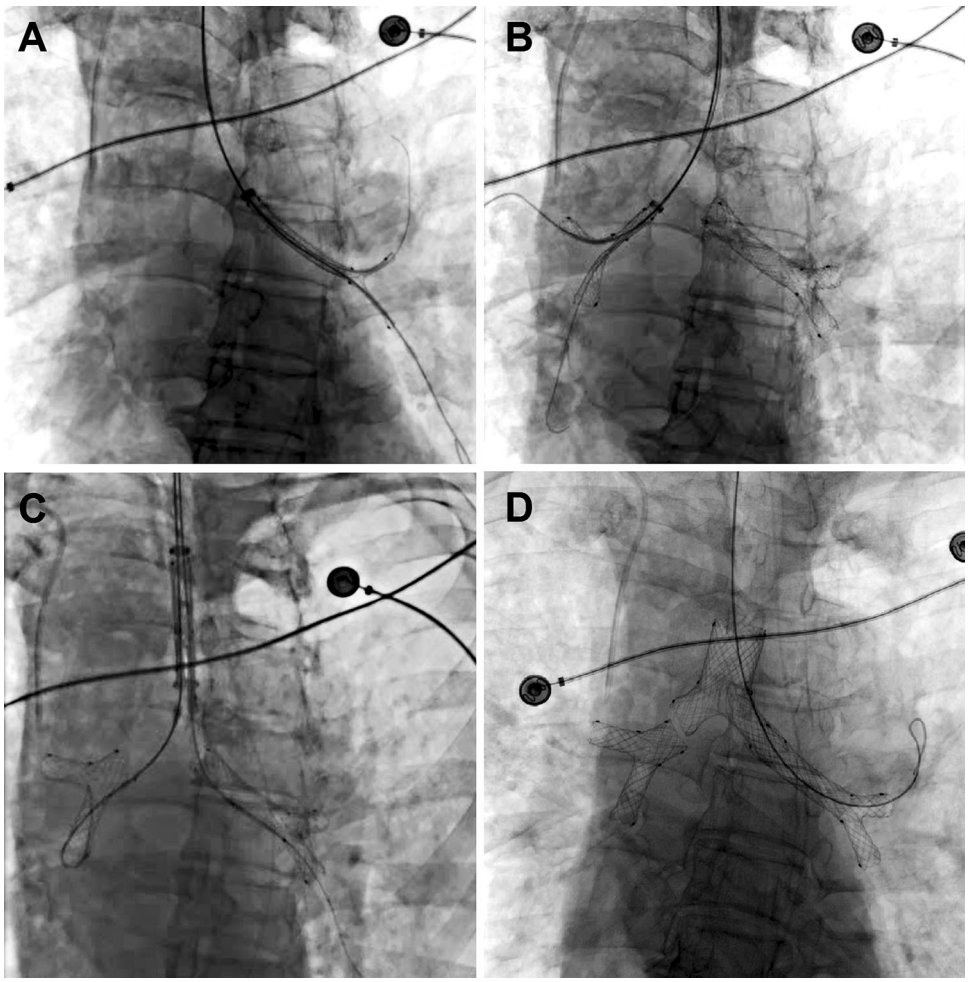

Fig. 2 Treatment of a 74-year-old man with multiple bifurcated covered tracheobronchial stent. **A** A small bifurcated covered stent is inserted in the left diseased lobar bronchi. **B** Similarly, another small bifurcated covered stent is inserted in the right diseased lobar bronchi. **C**, **D** A large bifurcated covered stent is inserted in the carinal region. There is no overlapping of the stents in the right main stem bronchus because the main body of small stent is not long enough

Stenting Procedure

Multiple bifurcated covered stents were successfully inserted in 27 patients at the first attempt. One patient underwent for second attempt for one small bifurcated covered stent due to migration after 11 days. In total, 29 large bifurcated covered stents, 27 small bifurcated covered stents and 5 small bifurcated covered single-plugged stents were inserted (Table 2). One case showed no overlapping of the stents in the right main stem bronchus because the main body of small bifurcated stent was not long enough. Fortunately, there was no stent migration in the patient. Both esophagography and airway radiography performed immediately after the procedure revealed that the fistula was fully sealed. Coughing during eating resolved after stenting, and patients were able to have a liquid or semiliquid diet. Additionally, 8 patients underwent stent removal due to complications, including 2 cases of migration, 4 cases of restenosis and 2 cases of intolerance of stenting. All stents were removed successfully at the first attempt.

Complication and Stent Removal

No perioperative death or severe complications such as massive hemorrhage or tracheal rupture occurred during the procedure. A total of 19 complications were found in 12 patients (43%), 8 patients needed stent removal or replacement, and the major complication rate was 29% (8/28). Four patients underwent stent removal, and 2 received endoscopy treatment due to stent restenosis. Endoscopic sputum aspiration was performed for patients with sputum obstruction. One patient showed stent migration 10 days later due to enlarged fistula. Another patient developed stent migration 11 days later, which may have been caused by a severe cough. A second stenting procedure was performed for these two patients after the stent removal, and larger stents with a larger diameter were used. Stent intolerance which required stent removal was found in 2 patients, which may be due to the oversensitivity of the airway to stimuli of the stent. The rest of patients tolerated the stent well and had good palliation of airway symptoms, for a clinical success rate of 93% (26/28) (Table 3). During procedure, 2 small bifurcated covered stents did not fully

Table 1 Patients' characteristics

Characteristics	Median (IQR) or No. (%)
Patients, no.	28
Age, years	62.5 (28–78)
Male/female gender	25/3
Duration of clinical symptom, months	0.9 (0.3–4)
Interval between surgery and clinical symptom, months	0.85 (0.2–7)
Previous underlying disease and etiology	
Esophageal cancer	19 (68%)
Lung cancer	7 (25%)
Tuberculosis/pulmonary abscess	2 (7%)
Indications for airway stent placement	
Gastrotracheal or gastrobronchial fistula	18 (64%)
Bronchopleural fistula	6 (21%)
Tracheobronchial stenosis	4 (14%)
Location of fistula or stenosis	
Main bronchus	21 (75%)
Right middle lobe bronchus	3 (11%)
Lower lobe bronchus	2 (7%)
Tracheal carina	2 (7%)
Previous treatments before stenting	
Surgical resection	24 (86%)
Chemotherapy or radiotherapy	9 (32%)
None of the above	2 (7%)

Table 2 Types and measurement of individual airway stents

Types of individual airway stents	No.	Median diameter (IQR)	Median length (IQR)
Large bifurcated covered stent, mm	29	MB 22 (20, 24)	MB 37.5 (30, 40)
		RMB 14 (12, 15)	RMB 15 (10, 20)
		LMB 14 (12, 15)	LMB 20 (15, 30)
Small bifurcated covered stent, mm	27	MB 15 (12, 16)	MB 20 (15, 35)
		BL 10 (10, 12)	BL 10 (10, 20)
Small bifurcated single-plugged stent, mm	5	MB 15.5 (13, 18)	MB 20 (12.5, 20)
		BL 11 (9, 12)	BL 10 (10, 14)
		PL 12 (10, 15)	PL 12 (11, 18)

MB main body, *PL* plugged bullet limbs, *BL* bronchial limbs, *LMB* left main bronchus, *RMB* right main bronchus

Table 3 Total complications of stenting

Complication	N (%)	Days after stenting	Treatments
Stent restenosis	6 (21%)	85.5 (71, 129)	Stent removal/Endoscopy
Stent migration	2 (7%)	10, 11	Second stenting after removal
Intolerance of stenting	2 (7%)	4, 17	Stent removal
Dyspnea requires intubation	1 (4%)	During procedure	Tracheal incubation
Inadequate expansion of stent	2 (7%)	During procedure	Balloon dilation
Retention of purulent sputum	6 (21%)	11 (3, 202)	Endoscopic sputum suction

expand after placement; successful dilation was performed with a balloon catheter of 10 mm in diameter and 40 mm in length.

Follow-Up

All but 2 patients have been followed up for a median time of 19 months (range 1–145 months), with a median survival of 33 months. Fifteen patients died of tumor recurrence, but none of them had experienced any coughing during eating. One patient died of intractable lung infection. The 1-, 3- and 5-year survival rate is 64%, 42% and 35%, respectively (Fig. 3). One patient with a gastrobronchial fistula showed the recurrence of gastrobronchial fistula in left main bronchus after 5 months. A small bifurcated covered stent was inserted again in the left main bronchus. The 4 patients who underwent stent removal due to stent restenosis did not receive a new stent afterward. During follow-up, 2 patients lost follow-up, 9 patients are alive without symptom, and one patient is alive, but the fistula is not healed, and refuses further treatment due to financial burden.

Discussion

Tracheobronchial stent has been widely used clinically for the treatment of tracheobronchial stenosis or tracheal fistula [4–12, 15, 17]. Currently, bifurcated covered silicone airway stents [19–21] and metallic stents [6, 17] have been widely used to treat carinal stenosis or tracheobronchial fistulas. The silicone stents often show advantages of durability, easy removability and low cost when compared with metallic stents [22–25]. The metallic stents show good support and flexibility and may be less traumatizing the

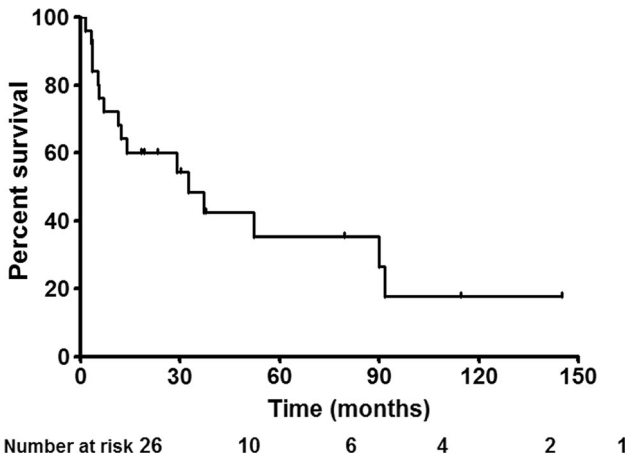

Fig. 3 Long-term survival rate follow-up. The median survival was 33 months, and the 1-, 3- and 5-year survival rate is 64%, 42% and 35%, respectively

placement in patients with an airway fistula [26]. Silicone stents placement is usually performed under general anesthesia by flexible bronchoscopy, and metallic stents placement can be performed under fluoroscopy guidance. Currently, few studies have described the treatment of complex tracheobronchial fistula or stenosis, such as gastrotracheal fistula and gastrobronchial fistula caused by tumor recurrence and radiation necrosis [14–16]. In the case of complex tracheobronchial fistulas or stenosis that involves the carina and/or the right or left main bronchus, and for large fistulas involving the carinal region, a single tubular airway stent might not completely seal fistulas or dilate stenosis. In this study, we chose multiple bifurcated covered metallic stents to treat complex tracheobronchial fistulas or stenosis. Stents were successfully inserted in 27 patients at the first attempt. All patients with fistula could resume eating without coughing after the procedure.

The metallic stents showed similar complications of silicone stents, such as stent migration, granulation tissue proliferation and sputum retention [27, 28]. No perioperative death or severe complications occurred in this study. Nineteen complications were found in 12 patients (43%), and 8 patients underwent successful stent removal due to complications. Sputum retention was one of the most common complications due to the cilia function disability after covered metallic stents are in place. Adequate expectorants and antiasthma agents were administered intravenously after stenting, and bronchoscopic sputum suction was performed if necessary to treat this complication. Stent restenosis is another most common complication, considering that stents showed no effectivity against neoplasm and proliferating granulation tissue. Thus, bronchoscopic surveillance with or without debridement of granulation tissue was necessary to treat this complication during follow-up. For patients with severe dyspnea or repeated stenosis, stents should be removed. In this study, 8 patients underwent successful stent removal due to complications, in which half of the removal procedures were performed due to stent restenosis.

There are several limitations in our study. This is a retrospective study and performed in a single central without control group. Patients with complex diseases are rare; sample size is relatively small and a study with larger sample sizes is needed. Besides, the covered esophageal stent can be used for the esophago-tracheal or esophago-bronchial fistula. However, stent migration may be more likely to occur if covered esophageal stents were inserted in the residual gastric cavity for gastrobronchial fistula and gastrotracheal fistula.

In conclusion, multiple bifurcated covered metallic stenting is effective and safe for complex tracheobronchial fistulas or stenosis, with good symptom palliation.

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Compliance with Ethical Standards

Conflict of interest The authors declared that they have no conflicts of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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