



Use of silicone stents for the management of post-tuberculosis tracheobronchial stenosis

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ABSTRACT: The role of bronchoscopic management in post-tuberculosis tracheobronchial stenosis is not well defined. To investigate the role of bronchoscopic intervention, including silicone stenting, in the management of post-tuberculosis tracheobronchial stenosis, the current retrospective study was conducted at a tertiary referral hospital.

Under rigid bronchoscopy, 80 patients underwent ballooning, neodymium-yttrium aluminium garnet laser resection and/or bougienation as first-line methods of airway dilatation between January 2000 and December 2003 inclusive, and were followed for a median of 41 months.

Silicone stents were required in 75 out of 80 (94%) patients to maintain airway patency. Bronchoscopic intervention provided immediate symptomatic relief and improved lung function in 88% of the patients. After airway stabilisation, stents were removed successfully in 49 out of 75 (65%) patients at a median of 14 months post-insertion. Three patients out of 75 (4%) eventually underwent surgical management. Acute complications included: excessive bleeding (n=1); pneumothorax (n=5); and pneumomediastinum without mortality (n=2). Stent-related late complications, such as migration (51%), granuloma formation (49%), mucostasis (19%) and re-stenosis (40%), were controllable during a median follow-up of 41 months.

In conclusion, bronchoscopic intervention, including silicone stenting, could be a useful and safe method for treating post-tuberculosis tracheobronchial stenosis.

KEYWORDS: Airway stenoses, bronchoscopy, intervention, tuberculosis

Post-tuberculosis tracheobronchial stenosis (PTTS) is the most common cause of benign tracheobronchial stenosis in tuberculosis (TB) endemic areas, such as South Korea, where the prevalence of pulmonary TB is 1.0% [1, 2]. Even when taking effective anti-TB medication, some cases of PTTS may progress to obstruction of major airways [1, 2]. Surgical resection and reconstruction after the eradication of *Mycobacterium tuberculosis* has been the preferred treatment for most patients with PTTS [1, 2].

Stenting has been developed to deal with airway stenosis and avoid the potential morbidities of open surgery. However, the use of metallic stents has resulted in some irreversible complications, such as stent fracture and impaction into the mediastinum [3, 4]. Interventional bronchology and silicone airway stenting has opened up a new way to treat patients with benign airway stenosis [3, 4]. Until recently, only a few studies have reported the result of bronchoscopic intervention in patients with PTTS [5–8]. However, the number of patients was <40 in some of these.

The current authors have experienced 80 cases of PTTS requiring bronchoscopic intervention, including ballooning, laser resection and/or silicone stenting. The purpose of the present study was to investigate the clinical efficacy of bronchoscopic intervention with the role of silicone stenting in the management of PTTS patients.

PATIENTS AND METHODS

Inclusion criteria

In total, 80 patients who underwent bronchoscopic intervention for the treatment of PTTS at the Samsung Medical Center (Seoul, South Korea) were included between January 2000 and December 2003. To describe clinical characteristics, the methods of management used and the clinical outcomes achieved, medical records were retrospectively reviewed.

Bronchoscopic intervention in patients with PTTS diagnosed by three-dimensional computed tomography scans and/or bronchoscopy were indicated by the following conditions: 1) a

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progressive deterioration of respiratory symptoms, such as progressive dyspnoea; or 2) recurrent (>2 yrs) post-obstructive pneumonia; or 3) an abrupt complete collapse of one lung with reduced lung function.

For patients with active TB, adequate medications were administered according to American Thoracic Society guidelines [9, 10]. In most patients with active TB, bronchoscopic intervention was postponed until negative conversion. However, when complete lung collapse occurred or life-threatening dyspnoea developed, intervention was performed regardless of activity.

Definitions and parameters

Active TB was defined as the documentation of acid-fast bacilli by staining or culture for *M. tuberculosis* from sputum or bronchial aspirate and/or bronchial biopsy. Previous TB was defined as a definite history of *M. tuberculosis* infection proven by microbiology or pathology.

Forced expiratory volume in one second (FEV₁) was used as an objective parameter of ventilation. FEV₁ could be obtained in 76 patients before the intervention and in 73 patients just after intervention.

Stents

In 2002, a newly designed silicone stent known as the Natural stent was developed at the Samsung Medical Center (fig. 1) [11]. This stent is composed of moulded silicone and is straight in shape. It features regularly placed "C" circular studs on its outer surface by interposing a flexible posterior wall, which mimics the posterior membrane of the trachea for the tracheal stenosis, or external round studs without an interposing smooth wall for bronchial stenosis. These stent designs increase stent-to-wall contact and maintain physiological airway constriction and dilation. Previous studies in a canine model of tracheal stenosis and clinical experience in patients with benign tracheobronchial stenosis have shown that the Natural stent is as effective and safe as the Dumon stent [11, 12].

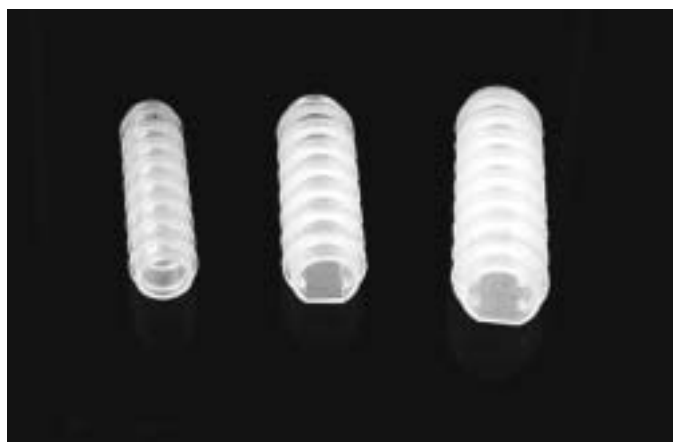


FIGURE 1. Three Natural silicone stents. On the left is a 10-mm stent for the bronchus. In the middle is a 12-mm stent for a female trachea, and on the right a 14-mm stent for a male trachea.

A Dumon stent (BryanCorp, Woburn, MA, USA) or a Natural stent (TNO Co., Seoul, South Korea) of 12–14-mm outer diameter was used for tracheal stenosis, and a 10-mm stent for bronchial stenosis. Adequate size and type of stent was selected and used according to the interventionist's decision. The use of the Natural silicone stents in the current study was approved by the Institutional Review Board at the Samsung Medical Center and written informed consent was obtained from all participants.

Airway intervention techniques

Airway intervention was performed following the standard techniques of COLT and DUMON [3] and KIM [4]. After the induction of general anaesthesia, patients were intubated with a rigid bronchoscope tube (Hopkins, Karl-Storz, Tuttlingen, Germany). A flexible bronchoscope (EVIS BF 1T240; Olympus, Tokyo, Japan) was then introduced through the rigid bronchoscope, and airway narrowing was evaluated. For ballooning, a 10 mm-sized controlled radial-expansion balloon (Boston Scientific, Boston, MA, USA) was inflated two or three times to 303.9 kPa for 20 s. When localised dense fibrosis was observed, a neodymium-yttrium aluminium garnet laser (LaserSonics, Milpitas, CA, USA) was used to cut fibrotic bands, using a G56D noncontact fibre (LaserSonics). Fibrotic stenoses were also gently dilated mechanically using a rigid bronchoscope. Mechanical dilatation was immediately followed by stent insertion. A stent of an appropriate size was folded longitudinally, introduced into a stent pusher (BryanCorp), and properly re-positioned using alligator forceps. Airway stents were implanted using the standard technique described by DUMON [13]. Silicone stenting was indicated when: 1) malacia of >180° of the angle of the dilated lumen was observed; 2) the longitudinal stenotic segment was longer than 2 cm; or 3) a third recurrence of airway narrowing after the intervention occurred.

After airway intervention, patients were usually discharged from hospital 24 h after the procedure and followed up with chest radiography and spirometry 1, 3, 6, 9 and 12 months after intervention, and every 6 months thereafter. All patients were followed for at least 24 months.

Statistical analysis

A p-value <0.05 was considered significant. Group comparisons of categorical variables were made using the Pearson Chi-squared test or Fisher's exact test. To assess relationships between the groups' continuous variables, the Mann-Whitney U-test was used for nonnormally distributed data or the Wilcoxon signed-ranks test for paired FEV₁ data. Values are expressed as median (range) values for continuous variables, or as numbers (percentages).

RESULTS

The characteristics of study participants are summarised in table 1. There was a predominance of females, with a median (range) age of 33 (14–73) yrs. The most common location of stenosis was the left main bronchus (65%).

Bronchoscopic findings and interventions

The bronchoscopic findings and interventions are summarised in table 2. A representative case is presented in figure 2.

TABLE 1 Baseline characteristics of the study population

Characteristics	
Subjects	80
Sex male/female	9/71
Age yrs	33 (14–73)
Disease activity on first intervention[#]	
Active tuberculosis	33 (41)
Past tuberculosis	47 (59)
Chest radiography	
No abnormal parenchymal lesion	9 (11)
Atelectasis or collapse	40 (50)
Consolidation with volume loss	14 (18)
Fibrous lesion ± calcified granuloma	17 (21)
Baseline pulmonary function test	
FEV ₁ % pred	63 (15–100)
FVC % pred	73 (40–102)
FEV ₁ /FVC ratio	69 (17–97)
Sites of stenosis[†]	86
Trachea	12 (14)
Left main bronchus	56 (65)
Right main bronchus	11 (13)
Bronchus intermedius	6 (7)
Left lower lobar bronchus	1 (1)

Data are presented as n, median (range) or n (%). FEV₁: forced expiratory volume in one second; % pred: percentage predicted; FVC: forced vital capacity. [#]: either bacteriological or pathological; [†]: overlapped.

The median (range) luminal diameter was 9.5 (8–11) mm in the trachea and 5 (4–6) mm in the bronchus when the lumen was measured by bronchoscopy.

The most common method of airway dilation was ballooning in 77 out of 109 patients. However, airway dilatation was usually performed in combined modalities. After airway dilation, stenting was needed in 75 out of 80 (93.7%) patients.

Outcomes and complications

Overall clinical outcomes are summarised in table 3 and figure 3. Immediate subjective relief of dyspnoea was achieved in 70 out of 80 (88%) patients. After the intervention, the median luminal diameter was increased from 9.5 to 10 mm in the trachea and from 5 to 7 mm in the bronchus.

Spirometry was repeated 1 month after the intervention. The FEV₁ % predicted significantly improved by a median (range) of 21.8 (–9–258) % in each patient. After the stent was removed, improved FEV₁ % pred was maintained (fig. 4).

The median (range) duration of overall stent placement in all 75 patients was 24 (1–50) months. Stents could be removed in 54 out of 75 (72%) patients after a median of 14 months. In 54 patients in whom a stent was removed, 49 patients had a successful stable clinical course during a follow-up period of 36 months. However, five patients showed recurrence and needed re-stenting. Finally, 23 (18 plus five recurred) out of 75 patients (31%) experienced prolonged stent placement of a median (range) 32 (1–55) months as shown in figure 3. Three patients showed no response after intervention and underwent

TABLE 2 Bronchoscopic findings and parameters of intervention

Stenosis type[#]	
Fibrous stricture	55 (69)
Malacia	8 (10)
Fibrous stricture and malacia	17 (21)
Luminal diameter	
Trachea mm [†]	9.5 (8–11)
Main bronchus mm ⁺	5 (4–6)
Time of intervention	
Active TB after starting anti-TB therapy months [§]	6 (1–11)
Past TB after starting anti-TB therapy yrs [‡]	5 (1–40)
Method of airway dilatation overlapped^{##}	
Ballooning	77
Nd-YAG laser	13
Bougienation	19
Number of used stent per patient	2 (1–12)
Duration of overall stent placement months^{†*}	24 (3–50)
Duration of follow-up months⁺⁺	41 (24–53)

Data are presented as n, n (%) or median (range). TB: tuberculosis; Nd-YAG: neodymium-yttrium aluminium garnet. [#]: n=80; [†]: n=12; ⁺: n=73; [§]: n=33; [‡]: n=47; ^{##}: n=109; ^{†*}: n=75; ⁺⁺: n=80.

surgical resection involving end-to-end anastomosis. During a median (range) follow-up period of 41 (24–53) months, clinical outcome was unchanged in all patients.

The majority of patients experienced minor complications, which included cough, mucus plugging and blood-tinged sputum; however, stents were tolerable. Eight out of 80 (10%) patients experienced major complications. Massive bleeding developed in one patient, and the patient was treated by mechanical ventilation and blood transfusions without mortality. Pneumothorax occurred in five patients and pneumomediastinum in two patients. These air leakage complications were treated by oxygen supplement and/or chest tube insertion in three patients.

TABLE 3 Outcome of bronchoscopic intervention in patients with post-tuberculosis tracheobronchial stenosis

Immediate symptomatic relief[#]	
Improved	70 (88)
Unchanged	10 (12)
Rate of successful stent removal	65 (49/75)
Duration of stent placement months	14 (1–47)
Follow-up after removal months	36 (3–50)
Rate of persistent stent placement	31 (23/75)
Duration of stent placement months	32 (1–55)
Rate of surgical management[†]	4 (3/75)
Follow-up after surgery months	30 (21–38)

Data are presented as n (%), % (n/N) or median (range). [#]: n=80; [†]: these patients underwent surgical resection with end-to-end anastomosis.

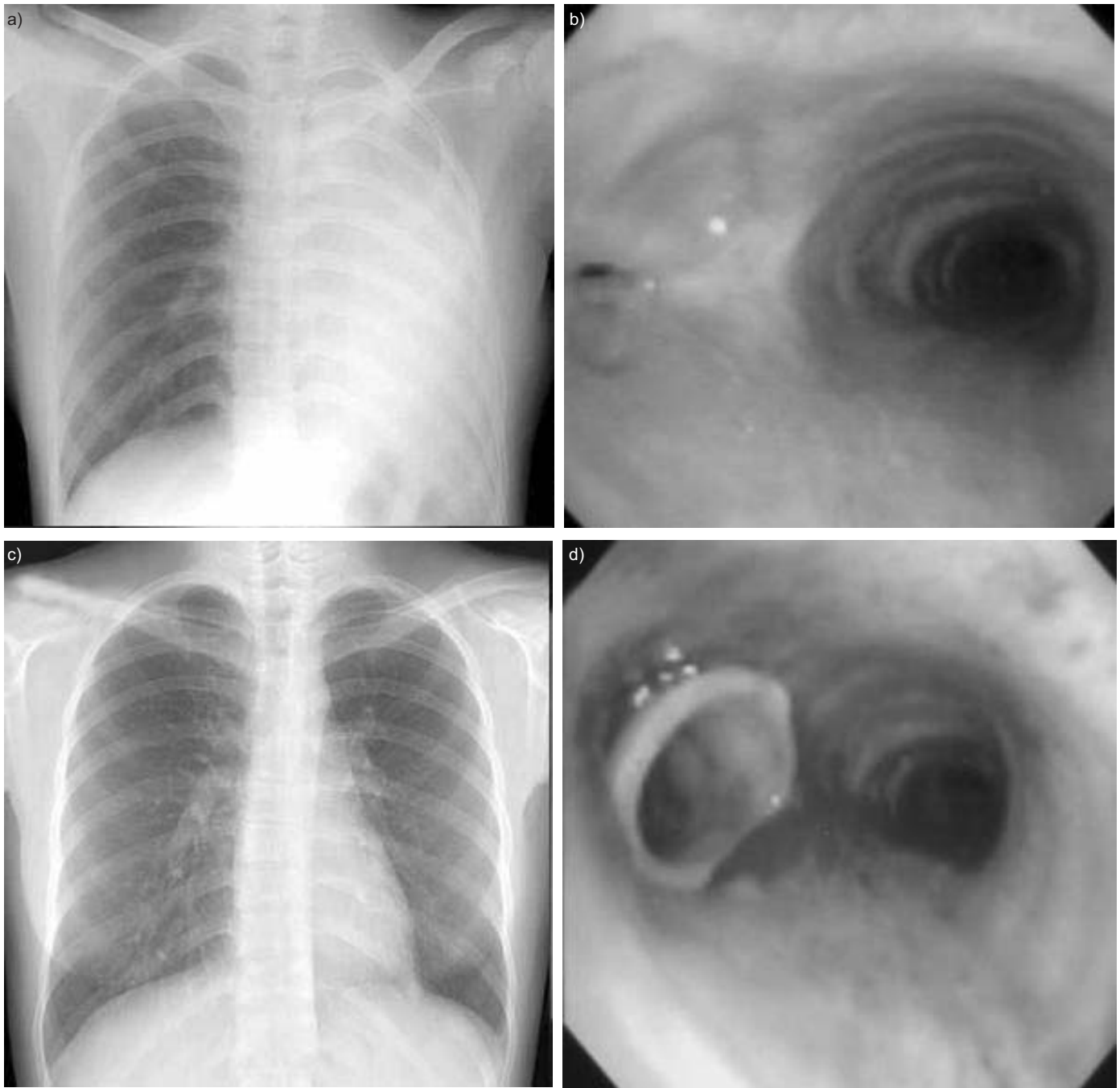


FIGURE 2. A representative case of bronchial intervention. Marked narrowing of the left main bronchus was noted in a 32-yr-old female patient (a, b). After the 10-mm silicone stent was inserted, the left main bronchus was widened to normal calibre (c, d).

Stent-related late complications were common. Stent migration developed in 38 out of 75 (51%) patients, in growth of granulation tissue at the end of the stent or through stent interstices occurred in 37 of the 75 (49%) patients, and restenosis in 30 (40%) patients. Repeated bronchoscopic interventions were needed to treat complications. The median (range) number of bronchoscopic interventions was 4 (1–16) and the median (range) number of stents used was 2 (1–12) per patient during a median follow-up of 41 months.

Subgroup analysis

Patients were subgrouped into those who had the stent successfully removed (stent removed, table 4) and those who could not have it removed (stent remaining, table 4). Patients in whom the stent could not be removed or re-inserted (stent remaining) were found to have a lower baseline FEV1 and needed bougienation more frequently for pre-stenting dilatation. Restenosis and granulation tissue formation were also more frequently observed in patients in whom the stent was remaining.

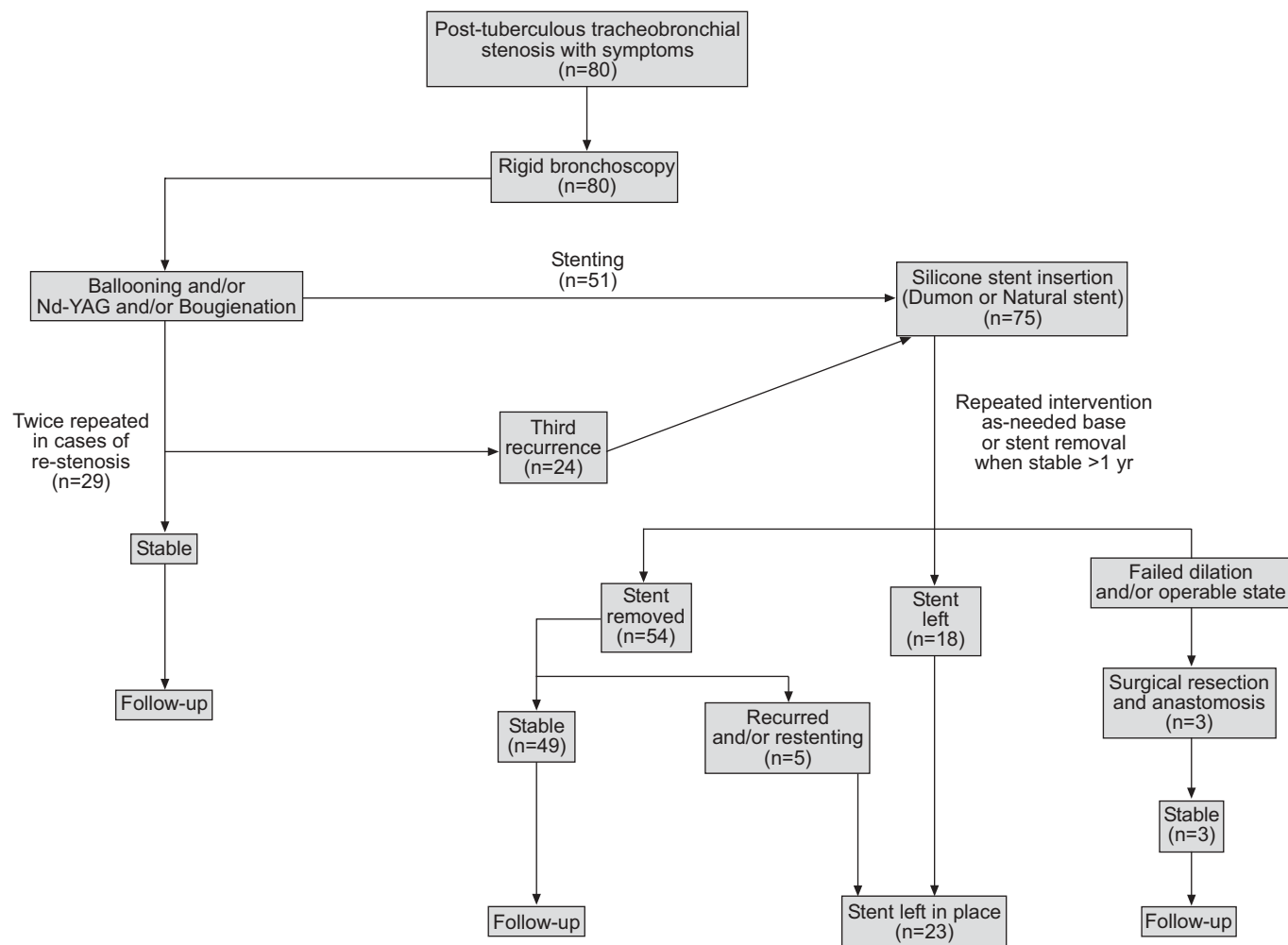


FIGURE 3. Therapeutic diagram of bronchoscopic interventions in 80 post-tuberculosis tracheobronchial stenosis patients. Nd-YAG: neodymium-yttrium aluminium garnet.

Subgroup analysis was also performed according to the type of stent. No significant difference was found with respect to sex ratio, median age, TB activity, or sites of tracheobronchial stenosis between those that received a Dumon or a Natural stent (data not shown). Moreover, no significant difference was found in clinical outcomes and complications between the types of stent.

When clinical outcomes were compared for patients with active and past TB, re-stenosis was more frequently developed in patients with active TB (63 *versus* 37%, $p=0.005$), but no significant difference was found for the other clinical parameters.

DISCUSSION

The present study demonstrates that bronchoscopic intervention, including silicone stenting, could be a useful method for treating patients with PTTS. To the current authors' knowledge, the present study is the largest series of PTTS managed by bronchoscopic intervention with silicone stenting.

Airway involvement by respiratory tract TB was reported to occur in 11–15% of routine bronchoscopies in a TB sanatorium [14]. After effective anti-TB chemotherapy, endotracheal or

endobronchial TB usually responds well and, in particular, generally little subclinical airway narrowing remains. However, in patients with symptomatic airway stenosis, bronchoscopic intervention is essential for improving lung function and controlling TB.

Studies have been conducted on bronchoscopic intervention using ballooning and stenting [5–8, 12, 15]. However, recurrence is common in patients who have undergone balloon dilatation. In the present study, ballooning was successful in only five out of 80 (6.3%) PTTS patients, and airway stenting was required in the majority of patients (75 out of 80, 93.7%). As granulomatous inflammation and fibrosis are natural consequences of the TB healing process, mechanical dilation alone might be ineffective to maintain airway patency.

Metallic stents have been used in PTTS patients, but critical complications have been reported [5–8, 12, 15]. Therefore, removable silicone stents, such as Dumon stents, are preferred for benign airway stenoses, especially in PTTS patients [5–8, 12, 15]. Silicone stents have the advantage that they can be re-positioned and removed as many times as needed. In PTTS patients, airway remodelling usually follows bronchoscopic intervention. Therefore, stent re-position, and even stent

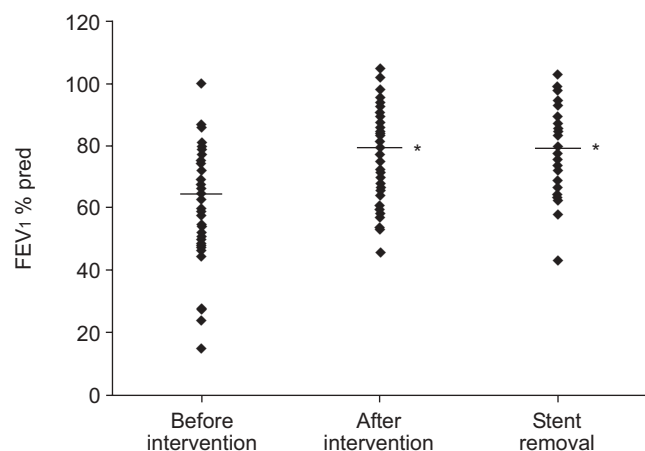


FIGURE 4. Forced expiratory volume in one second (FEV1) before (n=76) and after intervention (n=73), and after stent removal (n=34). % pred: per cent predicted. Horizontal bars represent the median value. *: $p < 0.05$ compared with FEV1 before intervention.

changes, are necessary to manage frequent stent migration and airway re-stenosis. In the present study, stent migration was observed in 38 out of 75 (51%) patients and re-stenosis in 30 (40%) patients. These complication rates are higher than previous studies, in which most of the included patients were non-PTTS [16–20].

Although no definite guidelines have been issued concerning the timing of stent removal, previous studies have recommended that in cases of benign airway stenosis stents should be placed for 6–18 months [13, 16]. In the present study, stents could be successfully removed a median of 14 months after insertion in 49 out of the 75 (65%) patients. These patients then showed a stable clinical course for a median of 36 months. Considering the natural fibrotic process that occurs after endobronchial TB by *M. tuberculosis* infection [2, 21], stents should be replaced at least once a year.

In 23 out of the 75 (31%) patients, stents could not be removed due to recurrent airway stenosis or malacia. When the group of successful stent removal was compared with those of stent remaining, there was more frequent granulation tissue formation or re-stenosis by fibrotic stricture. Extensive fibrosis could provide an explanation for these patients because they showed reduced baseline pulmonary function and needed bougienation more frequently due to tight stricture.

Fibrotic stricture of the airway in PTTS is usually eccentric. As the fibrotic lesion is composed of dense fibrosis tissue, it would be more resistant to the stretching tension. When balloon or bougie is blindly used, the fibrotic stricture would not be widened and only the cartilage of normal airway would be injured resulting in the aggravation of airway malacia. Therefore, the use of a laser or mechanical dilatation on the direct vision of the stricture should be encouraged rather than blind ballooning in patients with PTTS.

Re-stenosis was more frequent in patients with active TB than in those with past TB. Granulation tissue formation and fibrosis are natural host defence mechanisms against TB by anatomical isolation of infection. As these defence mechanisms

TABLE 4 Subgroup analysis between patients in whom stent was removed or remaining

Variables	Stent removed	Stent remaining	p-value
Subjects	49	23	
Sex male/female	8/41	1/22	0.255
Age yrs	34 (17–73)	29 (14–50)	0.060
Active/past TB	18/31	13/10	0.114
FEV1 % pred			
Before stenting	65 (24–100)	55 (15–78)	0.013
After stenting	79 (46–117)	73 (34–105)	0.184
Change after stenting [#] %	19 (–9–258)	28 (–1–159)	0.159
Tracheal involvement	5 (10)	5 (22)	0.273
Stenosis type			0.555
Fibrous stricture	32 (65)	17 (74)	
Malacia	6 (12)	1 (4)	
Fibrous stricture and malacia	11 (22)	5 (22)	
Method of airway dilatation			
Ballooning	47 (96)	22 (96)	1.000
Nd-YAG laser	7 (14)	4 (17)	0.736
Bougienation	8 (16)	9 (39)	0.034
Type of stent used			0.258
Dumon	24 (49)	8 (35)	
Natural	25 (51)	15 (65)	
Late complications			
Stent migration	23 (47)	13 (56)	0.251
Granulation tissue formation	20 (41)	14 (61)	0.047
Re-stenosis	13 (27)	15 (65)	<0.0001

Data are presented as n, median (range) or n (%). TB: tuberculosis; FEV1: forced expiratory volume in one second; % pred: percentage predicted; Nd-YAG: neodymium-yttrium aluminium garnet. [#]: (FEV1 % before stenting–after stenting)/FEV1 % before stenting × 100%.

are ongoing, re-stenosis would be more frequent in patients with active TB. In addition, a paradoxical aggravation of airway TB may occur, especially in patients with endotracheal TB. Although adequate anti-TB medications have been given, the current authors experienced that active endotracheal TB spread longitudinally over the stented trachea. These patients required a longer stent or another stenting. However, almost all of these patients could be treated by prolonged anti-TB medications and repeated intervention.

No difference was found according to the type of stent, *i.e.* Dumon or Natural stents. The present study suggests that Natural stents could be an alternative to Dumon stents in patients with PTTS, but, to confirm this, a prospective randomised study is required.

In conclusion, it was found that bronchoscopic intervention with silicone stenting could provide an effective means of managing post-tuberculosis tracheobronchial stenosis patients.

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