Timing of silicone stent removal in patients with post-tuberculosis bronchial stenosis

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Abstract:

CONTEXT: In patients with post-tuberculosis bronchial stenosis (PTBS), the severity of bronchial stenosis affects the restenosis rate after the silicone stent is removed. In PTBS patients with incomplete bronchial obstruction, who had a favorable prognosis, the timing of stent removal to ensure airway patency is not clear.

AIMS: We evaluated the time for silicone stent removal in patients with incomplete PTBS.

SETTINGS AND DESIGN: A retrospective study examined PTBS patients who underwent stenting and removal of a silicone stent.

METHODS: Incomplete bronchial stenosis was defined as PTBS other than total bronchial obstruction, which had a luminal opening at the stenotic segment on bronchoscopic intervention. The duration of stenting was defined as the interval from stent insertion to removal. The study included 44 PTBS patients and the patients were grouped at intervals of 6 months according to the duration of stenting.

RESULTS: Patients stented for more than 12 months had a significantly lower restenosis rate than those stented for less than 12 months (4% vs. 35%, \( P = 0.009 \)). Multiple logistic regression revealed an association between stenting for more than 12 months and a low restenosis rate (odds ratio 12.095; 95% confidence interval 1.097-133.377). Moreover, no restenosis was observed in PTBS patients when the stent was placed more than 14 months previously.

CONCLUSIONS: In patients with incomplete PTBS, stent placement for longer than 12 months reduced restenosis after stent removal.

Key words: Airway obstruction, bronchoscopy, device removal, stents, tuberculosis

Silicone airway stents are an effective treatment option for benign airway stenosis;\(^1\)\(^-\)\(^4\) however, long-term stent placement has various complications, such as sputum retention, stent migration and granulation tissue formation.\(^5\) Therefore, after the bronchial strictures have healed, it is important to remove silicone airway stents.

Traditionally, elective stent removal is performed 6-18 months after stent insertion in patients with benign airway stenosis, regardless of etiology, based on expert opinion.\(^6\)\(^-\)\(^7\) Research on the timing of stent removal in each etiology is needed and some studies using distinct protocols for the timing of stent removal have reported varying outcomes in patients with benign airway stenosis.\(^6\)\(^,\)\(^8\) Brichet et al. removed silicone airway stents 6 months after stenting in patients with post-intubation tracheal stenosis and reported 70% restenosis after stent removal.\(^9\) Martinez-Ballarin et al. performed stent removal after 18 months and restenosis occurred in 19% of patients with benign airway stenosis other than post-tuberculosis strictures.\(^9\) These results suggest that the long-term placement of silicone stents in patients with benign airway stenosis other than post-tuberculosis stenosis reduces the restenosis rate after stent removal. However, no report has examined the timing of silicone airway stent removal in patients with post-tuberculosis bronchial stenosis (PTBS).

Recently, data on the factors allowing successful stent removal in PTBS patients were published.\(^9\) Patients without complete lobar atelectasis on computed tomography (CT) scan at initial presentation had a better prognosis than those with complete atelectasis. Therefore, the completeness of stenosis affects the outcome of bronchoscopic intervention; patients with stenosis severe enough to cause complete atelectasis had a higher restenosis rate (72%) than patients with incomplete stenosis who had no atelectasis (restenosis rate 31%). Although patients with incomplete PTBS had a favorable clinical outcome, the optimal timing of elective stent removal is still unclear. Therefore, this study evaluated the optimal timing of bronchial stent removal in patients with incomplete PTBS.
Methods

Study subjects
This retrospective study enrolled 76 consecutive PTBS patients who underwent bronchoscopic interventions between January 2004 and December 2009 at Samsung Medical Center, the Teaching Hospital of Sungkyunkwan University, Seoul, Korea. The completeness of bronchial stenosis was assessed using bronchoscopy; complete bronchial stenosis was defined as total obstruction of the bronchial lumen due to fibrotic stenosis at bronchoscopy and incomplete bronchial stenosis was defined as PTBS other than complete bronchial stenosis, with a luminal opening at the stenotic segment. Of the 76 PTBS subjects, 57 patients underwent silicone stenting in the main bronchi or bronchus intermedius and the stents were removed in 54 patients [Figure 1]. In the 54 patients who underwent elective stent removal, incomplete and complete bronchial stenosis was found in 44 and 10 patients, respectively. This study considered the 44 patients with incomplete bronchial stenosis. Some of the clinical data on the patients enrolled between 2004 and 2008 were included in articles published in 2011 and 2012.\[9,10\]

The institutional review board of Samsung Medical Center approved the analyses of the clinical and radiological data. Informed consent was waived because of the retrospective nature of the study.

Therapeutic bronchoscopy
Rigid bronchoscopy was performed using standard techniques as described previously.\[7,11,12\] A representative case of PTBS is shown in Figure 2. Briefly, the patients were intubated with a rigid Hopkins bronchoscope (Karl-Storz, Tuttlingen, Germany) under general anesthesia. Then airway stenosis was identified based on a detailed examination of the bronchial tree using a flexible bronchoscope (EVIS BF 1T240, Olympus, Tokyo, Japan) introduced through the rigid bronchoscope. After identifying bronchial stenosis, all patients underwent mechanical dilatation using a rigid tube, ballooning (Boston Scientific, Natick, MA) or neodymium: Yttrium-aluminium-garnet laser cauterization (Lasersonics, Milpitas, CA).

After mechanical dilation, a silicone bronchial stent (N-stent; TNO, Seoul, South Korea) was inserted for the following indications: (1) Symptomatic restenosis, including dyspnea, occurred after the first intervention without stenting; (2) bronchomalcia was observed over more than 180° of the dilated lumen, which led to severe dyspnea without stenting (bronchomalcia was assessed visually during rigid bronchoscopy by an interventional pulmonologist) or (3) the longitudinal stenotic segment was longer than 2 cm. The diameters of all implanted stents were 9 mm (inner) and 10 mm (outer). The length of the stent was selected by the interventional pulmonologist.

Elective removal of a bronchial silicone stent
Silicone stent removal was considered once the patients had been stable for more than 6 months and was typically 6-12 months from the initial stenting. The patients were usually discharged from the hospital the day following stent removal.

Definitions and patients grouping
Restenosis after stent removal, i.e., stent removal “failure,” was defined as the occurrence of bronchial obstruction after stent removal that needed bronchoscopic intervention. The duration of stenting was defined as the interval from stent insertion to removal. Using the duration of stenting, the study population was grouped at 6-month intervals.

Statistical analysis
All results are presented as numbers (percentage) for categorical variables and medians (interquartile range [IQR]) for continuous variables. Because the data were not distributed normally, non-parametric analyses, such as the Mann-Whitney U-test, were used for continuous variables. Proportions were compared using the Pearson Chi-square test or Fisher’s exact test. Following univariate analyses, a logistic regression model was constructed using the variables with \( P < 0.1 \) in

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Figure 1: Selection of the study subjects from 76 post-tuberculosis bronchial stenosis patients. *Due to dense fibrosis, mechanical dilatation failed in one patient. †One patient underwent a right upper lobectomy and resection of the right main bronchus with distal carina-bronchus intermedius anastomosis when restenosis developed. ‡Three patients refused stent removal due to concerns regarding restenosis. ¶Forty-four patients with incomplete bronchial stenosis who underwent elective stent removal were selected for this study and the restenosis rate after stent removal was 16%. §Patients with complete bronchial stenosis suffered 70% restenosis after stent removal, which was significantly higher than those with incomplete stenosis (\( P = 0.002 \)). PTBS = Post-tuberculosis bronchial stenosis, BD = Bronchial dilatation.
Timing of bronchial stent removal

The baseline characteristics of the 44 study subjects with incomplete bronchial stenosis are presented in Table 1. A total of 35 patients (80%) presented with dyspnea and all achieved symptomatic improvement immediately following the procedure: Dyspnea disappeared in 27 patients (77%) and improved in 8 (23%). The most common abnormal finding on chest CT was atelectasis: 1 patient (4%) had two-lobe atelectasis and 15 (31%) had one-lobe atelectasis. The median follow-up period after stent removal was 9 (IQR 5-27) months. After the first rigid bronchoscopy, there were 45 additional interventions in 27 patients (61%) and the median intervention interval was 2 (IQR 1-4) months. Of the 44 patients, the duration of stenting was <12, 12-18, and >18 months in 17, 12, and 15 patients, respectively. The overall changes in the pulmonary function tests are presented in Table 2.

Restenosis after stent removal

Of the 44 subjects, 7 (16%) had restenosis after stent removal and the median duration of stenting of all patients was 14 (IQR 10-22) months. The median interval from stent removal to restenosis was 1 (IQR 0-2) month and all restenosis developed within 3 months of stent removal. The restenosis rate after stent removal was 35%, 8% and 0% in patients with duration of stenting <12, 12-18, and >18 months, respectively [Figure 3]. There was a significant difference in the restenosis rate between patients with durations of stenting <12 months and ≥12 months (P = 0.009), but no significant difference between patients with duration of stenting <12 and 12-18 months (P = 0.019) or 12-18 and >18 months (P = 0.444).

Table 1: Baseline characteristics of the 44 study subjects

| Characteristics                                      | No. (%) or median (IQR) |
|------------------------------------------------------|-------------------------|
| Age, years                                           | 35 (31-45)              |
| Female gender                                        | 36 (82)                 |
| Active TB                                            | 1 (2)                   |
| TB medication at first intervention                  | 9 (21)                  |
| Duration of TB treatment, months                     | 6 (6-12)                |
| Initial CT findings, overlapped                      |                         |
| No parenchymal lesion                                | 7 (16)                  |
| Atelectasis involving more than one lobe             | 16 (36)                 |
| Consolidation                                        | 7 (16)                  |
| Nodular lesion                                       | 14 (32)                 |
| Fibrocalcific lesion                                 | 10 (23)                 |
| Stenting site                                        |                         |
| Left main bronchus                                   | 36 (82)                 |
| Right main bronchus                                  | 3 (7)                   |
| Right bronchus intermedius                           | 5 (11)                  |
| Modalities for airway dilatation, overlapped         |                         |
| Ballooning                                           | 44 (100)                |
| Laser therapy                                        | 3 (7)                   |
| Bougienation                                         | 1 (2)                   |
| Stent length, mm                                     | 43 (40-50)              |
| Duration of stenting, months                         | 14 (10-22)              |
| Restenosis after elective stent removal              | 7 (16)                  |
| FEV1 = Forced expiratory volume in 1 s, FVC = Forced vital capacity
| Timing of pulmonary function tests                   |                         |
| Before stenting*                                     | 67 (62-71)              |
| After stenting                                       | 77 (70-90)              |
| After stent removal†                                  | 86 (76-94)              |
| | FEV1/FVC                                             |                         |
| Before stenting*                                     | 65 (54-76)              |
| After stenting                                       | 70 (62-79)              |
| After stent removal†                                  | 67 (59-78)              |

Figure 2: Representative case of post-tuberculosis bronchial stenosis. (a) On chest computed tomography scan, the left main bronchus was narrowed to approximately 2 mm in diameter (black arrow), whereas the right main bronchus showed normal airway patency (white arrow). (b) On bronchoscopy, the left main bronchus was partially obstructed by fibrotic stenosis. (c) After mechanical dilatation, a silicone bronchial stent was inserted into the left main bronchus (inner diameter 9 mm, outer diameter 10 mm, stent length 40 mm). (d) Twenty months after silicone stenting, elective stent removal was performed

Figure 3: Restenosis rate according to the duration of stenting in post-tuberculosis bronchial stenosis patients with incomplete stenosis. There was an apparent difference in restenosis rate between patients with duration of stenting <12 months and ≥12 months (P = 0.009)
Of patients with duration of stenting ≥12 months, only one
developed restenosis after stent removal and there was a
significant difference in the restenosis rate between patients
with durations of stenting <12 and ≥12 months (35% vs. 4%,
P = 0.009). Moreover, after 14 months from stenting, there was
no restenosis after stent removal [Figure 4].

Factors associated with restenosis after stent removal other
than stenting duration
To identify the factors contributing to restenosis other than
stenting duration, univariate analysis was conducted [Table 3].

Patients with restenosis after stent removal were much younger
than those without restenosis (P = 0.027) and the interval from
tuberculosis medication to first intervention was much shorter
in patients with restenosis than in those without restenosis,
with borderline statistical significance (P = 0.057).

Multiple logistic regression analysis of restenosis after stent
removal
Multiple logistic regression analysis was performed to
determine whether stenting duration >12 months was
independently associated with the outcome after stent
removal. This revealed an association between the stent
placement >12 months and a lower restenosis rate after stent
removal (P = 0.042; odds ratio 12.095; 95% confidence interval
1.097-133.377) [Table 4].

Discussion
There are no objective criteria for when to remove silicone
airway stents in benign airway stenosis. To the best of our
knowledge, this is the first descriptive study of the timing of
stent removal in PTBS. We analyzed 44 PTBS patients with
incomplete bronchial stenosis, who underwent elective stent
removal. All patients achieved substantial improvement in
dyspnea and pulmonary function tests after stenting. Our
data suggest that the restenosis rate is reduced significantly
after stenting for at least 12 months in PTBS patients with
incomplete stenosis.

Unlike PTBS patients with complete stenosis, patients
with incomplete stenosis had a relatively favorable clinical
course after stent removal.34 We considered two probable

Table 3: Factors contributing to restenosis after stent removal

| Variables                                | No restenosis (n=37) | Restenosis (n=7) | P value |
|------------------------------------------|----------------------|-----------------|---------|
| Age, years                               | 36 (32-46)           | 27 (24-39)      | 0.027   |
| Female gender                            | 29 (78)              | 7 (100)         | 0.318   |
| Baseline pulmonary function tests        |                      |                 |         |
| FEV1, % predicted                        | 67 (63-71)           | 67 (58-76)      | 0.947   |
| FVC, % predicted                         | 81 (70-92)           | 85 (59-102)     | 0.841   |
| FEV1/FVC, %                              | 66 (54-76)           | 63 (56-83)      | 0.911   |
| Active TB                                | 1 (3)                | 9 (0)           | 1.000   |
| TB medication at first intervention      | 8 (22)               | 1 (14)          | 1.000   |
| Duration of TB treatment, months         | 6 (6-11)             | 6 (6-12)        | 0.725   |
| Interval from TB medication to intervention, months | 48 (10-86) | 7 (3-33) | 0.057   |
| Interval from symptom onset to intervention, months | 4 (1-18) | 5 (1-7)  | 0.975   |
| Stenting site                            |                      |                 |         |
| Left main bronchus                       | 31 (84)              | 5 (71)          |         |
| Right main bronchus                      | 3 (8)                | 0 (0)           | 0.241   |
| Right bronchus intermedius               | 3 (8)                | 2 (29)          |         |
| Stent length, mm                         | 45 (38-50)           | 40 (40-45)      | 0.469   |
| Shortest diameter of stenosis, mm        | 1 (1-3)              | 1 (1-3)         | 0.925   |
| Patients with additional interventions   | 22 (59)              | 4 (57)          | 1.000   |
| Stent-related complication               |                      |                 |         |
| Mucostasis                               | 5 (14)               | 2 (29)          | 0.318   |
| Stent migration                          | 15 (41)              | 3 (43)          | 1.000   |
| Granulation tissue overgrowth            | 15 (41)              | 2 (29)          | 0.689   |
| Duration of stenting >12 months          | 26 (70)              | 1 (14)          | 0.009   |

Values are expressed as numbers (percentage) or median (interquartile range). FEV1 = Forced expiratory volume in 1 s, FVC = Forced vital capacity, TB = Tuberculosis.
Mechanical airway dilatation with ballooning, laser therapy or bougienage causes considerable mucosal trauma, followed by unpredictable healing and restenosis. Therefore, the decision on stent removal should be based on whether the mucosal trauma to the stenotic segment, induced by mechanical dilatation, has fully recovered. In PTBS patients with incomplete bronchial obstruction, a great reduction was seen in the restenosis rate after stenting for 12 months; therefore, recovery of the mechanically dilated bronchus might take at least 12 months. As a result, we suggest that the elective removal of a bronchial silicone stent in PTBS patients with incomplete stenosis should be considered 12 months after stent placement.

There are clear limitations to this study. First, it had a retrospective design. The treatment plan was devised by an interventional pulmonologist on a case-by-case basis. However, all procedures were performed by an interventional pulmonologist with 20 years of experience who consistently used standard methods. Further randomized prospective studies with different interventional bronchoscopists are required to establish objective criteria for elective stent removal in PTBS patients. Second, our results cannot be generalized to other interventional bronchoscopists are required to establish objective criteria for elective stent removal in PTBS patients. Second, our results cannot be generalized to other airway stenoses besides PTBS. Finally, the current study was conducted with relatively small study population, which was due to the rarity of PTBS.

In conclusion, stent placement for longer than 12 months can reduce restenosis after stent removal in patients with incomplete PTBS.

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