Placement of Metallic Stents for Critical Airway Stenosis Due to Malignant Diseases

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ABSTRACT — Background. Placement of a silicon tracheobronchial prosthesis in emergency situations has become an established therapeutic option to relieve airway stenosis due to malignant diseases. However, the alternative use of a metallic stent has never been fully evaluated. Purpose. To elucidate the clinical relevance of placing metallic stents in patients with critical airway stenosis due to malignant diseases. Patients and Methods. Thirteen patients with critical airway stenosis treated by placing metallic stents and meeting some defined conditions were retrospectively reviewed in terms of usefulness and adverse events. The stents were placed by flexible bronchoscopes under topical anesthesia in all cases. Results. Metallic stent placement was easy, quick and successful in every patient, and airway stenosis was quickly relieved after the procedure in all patients. Accordingly, dyspnea as assessed by a scoring system was improved from 1 day to 1 month after the placement. Performance status was not improved significantly by the procedure. Adverse events of serious nature were observed in 6 of the 13 patients. Conclusion. Metallic tracheobronchial stents for patients with airway stenosis and critical conditions seemed to have advantages in relieving dyspnea. Considering the adverse events, however, the choice of this option should be restricted to patients with limited expected survival. (JJSB. 2003;25:421-426

KEY WORDS — Metallic stent, Prosthesis, Airway stenosis, Malignancy, Lung cancer

INTRODUCTION

Placement of tracheobronchial prostheses or stents is sometimes a powerful tool to improve a critical condition with malignant airway stenosis, especially in an emergency, and radiotherapy and chemotherapy are not suitable because of time limitations. Thanks to the efforts of dedicated pioneers since the 1990s, several types of stents are currently available, either silicon and metallic.1–5 Among them, silicon stents such as the Dumon and Dynamic stents are placed with the aid of a rigid bronchoscope under general anesthesia. Thus, although they are complex and time-consuming procedures, the usage of rigid bronchoscopes and general anesthesia may ensure measurably safe outcomes. However, an easier, faster and more convenient procedure in patients with malignant airway stenosis even in emergency situations is the placement of metallic stents such as Ultraflex and Spiral Z,6–8 because a flexible bronchoscope with topical anesthesia with or without mild sedation can generally be used. Placement of metallic stents, however, has never been completely investigated in terms of safety.

To evaluate the clinical relevance of metallic stent placement for patients with malignant airway stenosis, a retrospective analysis of 13 patients was carried out.

PATIENTS AND METHODS

Patients

Among patients receiving metallic stents in our institute during the period from 1998 to 2002, those meeting all of the following conditions were enrolled for this analysis: 1) complete clinical record, 2) airway stenosis or obstruction caused by some type of malignant disease, 3) dyspnea because of the airway stenosis, 4) written informed

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consent for placement of metallic stents, and 5) critical condition requiring immediate release of airway stenosis. Here, the critical condition includes any of the following: 1) severe dyspnea, i.e., grade 3 or 4 of the dyspnea score as shown below, 2) deterioration of consciousness because of hypoxia and/or hypercapnea, 3) imminent obstruction at the trachea, bilateral major bronchi, or unilateral major bronchi when contralateral to the affected lung by any condition of the malignancy. The dyspnea scoring system consisted of 5 grades: grade 0, asymptomatic while climbing stairs; grade 1, symptomatic while climbing stairs; grade 2, symptomatic after walking 100 meters on flat ground; grade 3, symptomatic with the least effort (talking, getting dressed); and grade 4, symptomatic in bed, at rest. Finally, 13 patients were enrolled for this study.

**Metallic Stents and Their Placement**

A metallic Gianturco-Rosch Z stent (Cook, Bloomington, IN, USA) was placed in the first patient (n = 1). Ultraflex metallic stents (Boston Scientific Japan, Tokyo, Japan) were chosen for other earlier patients (n = 4) and when Spiral Z stents (Medico’s Hirata, Osaka, Japan) became commercially available, they were chosen for the rest of the patients (n = 8). Bronchoscopic examinations were carried out under mild sedation and regional anesthesia according to the standard operational procedures of our department, except for additional tracheal intubations for insertion of the bronchoscopes. These additional intubations enabled us to insert and remove the bronchoscopes, guide wires and introducers together with stent delivery devices very easily. A single channel fiber optic bronchoscope, BF type 30, or video bronchoscope, EVIS BF type 200 or P 240 (Olympus, Tokyo, Japan), was used for each patient. The stents were placed with the aid of guide wires and other delivery devices according to the manufacturers’ instructions, and all processes were monitored by fluoroscopy.

**Clinical Parameters Evaluated**

The severity of airway obstruction, performance status (PS, ECOG) and the dyspnea score at 1 day, 1 week, 1, 2 and 3 months after the stent placement were compared with the values immediately preceding procedure. Methods of oxygen supply were also documented. The severity of airway obstruction was evaluated by visual inspection of thoracic computed tomography with aid of chest radiographic tomography in some cases, and then the percentage of obstruction was documented. Adverse events were also documented.

**Statistical Analysis**

All the parameters evaluated at any time point after stent placement were compared to their counterparts prior to the placement using Student’s paired t test for the severity of airway obstruction and Wilcoxon T test for the dyspnea score and PS. Differences with p values of less than 0.05 were judged as statistically significant. Survival time starting from the date of stent placement to death was shown by Kaplan-Meier’s method.

**RESULTS**

**Stent Placements and Their Locations**

The patient characteristics are shown in Table 1. Briefly, the 13 patients consisted of 11 with lung cancer and 2 with esophageal cancer. Twenty-four stents were placed at 26 locations in the 13 patients. Stent placement was successful in every case, except for one patient in whom the first stent at the upper trachea dropped off soon, and a second one was put in place with the first remaining one. Airway reopening was immediate with each placement. In one patient with a Spiral Z stent, the placement for complete obstruction of the left main bronchus successfully ameliorated airway stenosis immediately without any accompanying treatment such as laser irradiation or ethanol injection, and the airway was almost completely opened within one week following necrotization of the polyp (Figure 1). In another case, it was also possible to ameliorate severe airway stenosis extending to a wide region by placing multiple stents (Figure 2).

**Altered Clinical Parameters Before and After Stent Placement**

The severity of airway stenosis was improved during the period from 1 day to 2 months after stent placement when compared to the condition prior to the placement (Figure 3A). In parallel, the dyspnea score was also improved between 1 day and 1 month after stent placement when compared to that before placement (Figure 3B). PS, however, was not significantly improved by stent placement (Figure 3C).

As for the method of oxygen supply, before stent...
Table 1. Patient characteristics

<table>
<thead>
<tr>
<th>Age (mean, range)</th>
<th>67 years, from 37 to 76 years</th>
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</thead>
<tbody>
<tr>
<td>Sex (M : F)</td>
<td>12 : 1</td>
</tr>
<tr>
<td>Prior treatments (no. of case)</td>
<td>CT (5), CT and RT (3), no TX * (5)</td>
</tr>
<tr>
<td>Post treatments (no. of case)</td>
<td>CT (1), RT (3), no TX (9)</td>
</tr>
<tr>
<td>Disease (no. of case)</td>
<td>Lung cancer (11)</td>
</tr>
<tr>
<td></td>
<td>Adenocarcinoma (4)</td>
</tr>
<tr>
<td></td>
<td>Squamous cell carcinoma (2)</td>
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<tr>
<td></td>
<td>Small cell carcinoma (4)</td>
</tr>
<tr>
<td></td>
<td>Non-small cell carcinoma † (1)</td>
</tr>
<tr>
<td></td>
<td>Esophageal cancer (2)</td>
</tr>
<tr>
<td>Stent (used no. in total /no. of case)</td>
<td>Ultraflex (10/4)</td>
</tr>
<tr>
<td></td>
<td>Spiral Z (13/8)</td>
</tr>
<tr>
<td></td>
<td>Z (1/1)</td>
</tr>
<tr>
<td></td>
<td>Total (24/13)</td>
</tr>
<tr>
<td>Locations of stenting (no. of location)</td>
<td>Trachea (5)</td>
</tr>
<tr>
<td></td>
<td>Right main bronchus (7)</td>
</tr>
<tr>
<td></td>
<td>Right intermediate trunk (6)</td>
</tr>
<tr>
<td></td>
<td>Left main bronchus (7)</td>
</tr>
<tr>
<td></td>
<td>Left upper lobe bronchus (1)</td>
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</table>

* CT, chemotherapy; RT, radiotherapy; TX, treatment.
† Diagnosed not further specifically.

Figure 1. The left main bronchus was completely obstructed by a polypoid growth of recurrent lung adenocarcinoma in a 75-year-old man (left). For this patient, metallic Spiral Z stent (tapered 14 mm at the proximal site, 12 mm at the distal site in diameter, and 40 mm in length) was placed under the guidance of a guide wire without any pretreatment. In this patient, an additional Spiral Z stent was also placed for stenosis at the right intermediate trunk (data not shown). The left main bronchus became patent 7 days after the metallic stent placement (right). Note that the metallic stent relieved airway obstruction by making the polyp necrotic with its expansion force. Metallic stents have strong expansion force even for such severe stenosis.

placement 7 of the 13 patients were with tracheal intubation (n = 1), Venturi mask (n = 1) and nasal cannula (n = 5). In contrast, after stent placement (between 1 day and 1 week after the procedure) only 4 of the 13 patients were with Venturi mask (n = 1) and nasal cannula (n = 3). Twelve of the 13 patients were discharged from the hos-
Figure 2. An example demonstrating that metallic stents can be placed even for stenosis in a wide area. Three Spiral Z stents were placed for severe tracheobronchial stenosis in a 37-year-old man with chemotherapy- and radiotherapy-resistant lung adenocarcinoma. Because a giant tumor was located at the right upper lobe, jeopardizing the right main bronchus and intermediate trunk, the first stent (15 mm in diameter and 40 mm in length) was placed there. Then, two stents at the upper trachea (20 mm in diameter and 80 mm in length) and at the lower trachea to the left main bronchus (tapered 20 mm at the proximal site, 14 mm at the distal site in diameter, and 80 mm in length) were placed to relieve the tracheal stenosis (A). Three-dimensional reconstruction images of CT and virtual bronchoscopes clearly demonstrated the tracheal stenosis before the stent placement (B) and its elimination after the stent placement (C).

Adverse Events
Six of the 13 patients experienced adverse events. Two patients died from hemoptysis at days 46 and 102, respectively, possibly in relation to stent placement. Tumor ingrowth, pneumothorax probably because of mistaken use of a guide wire, chest discomfort, and stent migration were encountered in one patient, respectively. Stent migration occurred in a patient with severe upper tracheal stenosis immediately after the placement, causing much more severe airflow limitation until the next urgent stent placement.

Survival
Survival of the 13 patients from stent placement ranged from 26 to 189 days, with a median survival time of 80 days (Figure 4).

DISCUSSION
For airway stenosis due to malignant diseases, radiation therapy and/or chemotherapy is usually indicated to ameliorate the patient’s symptoms. In critical and emer-
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Figure 3. Alterations in airway stenosis, dyspnea score and PS after metallic stent placement in the 13 patients. The extent of airway stenosis was decreased with statistical significance from 1 day to 2 months after the stent placement compared to before the placement (A). With the decrease in airway stenosis, the dyspnea score also improved, with statistical significance from 1 day to 1 month after stent placement, compared to the score before placement (B). PS, however, did not show any statistically significant difference after placement (C). Asterisks indicate the points that showed statistically significant differences from the values before stent placement (Student paired t test for the severity of airway stenosis and Wilcoxon T test for the dyspnea score and PS).

Figure 4. The survival curve of the 13 patients starting from the day of metallic stent placement. Survival ranged from 26 to 189 days, with a median of 80 days. There were no censored cases.

gency situations, however, neither radiotherapy nor chemotherapy has enough instant power to quickly relieve airflow limitation. The present data were based on the clinical relevance of metallic stent placement for patients with airway stenosis due to malignant diseases that actually caused dyspnea and critical conditions. All 13 patients fulfilled all of the selection criteria stated in the “Patients and Methods” section, and such patients would have had a critically deteriorated clinical course because of airflow limitation and/or obstructive pneumonia without immediate relief of the severe airway stenosis.

Metallic stent placements were successful in all of the 13 patients, giving immediate airflow limitation relief to every patient. This was clearly demonstrated by the improved airway obstruction and dyspnea score. Accordingly, the oxygen supply methods could be changed to less aggressive ones. On the other hand, PS was not improved by the stent placement. Although the precise mechanisms for these failures remain unclear, other concomitant complex conditions such as compression atelectasis caused by cancer or pleural effusion, pulmonary infection, pain, malnutrition and a deteriorated general condition rather than airway stenosis might have been involved to some degree. In our study, adverse events included some major complications, such as death from hemoptysis in 2 patients, and tumor ingrowth, pneumothorax, chest discomfort and stent migration, in one patient each. The use of metallic stents even in such patients, however, was considered to be useful because they would have died from airway obstruction much ear-
lier without the procedure, as they had all been in critical condition.

For tracheobronchial stenosis, silicon stents have been primarily chosen because some of them were less expensive than metallic stents and were also able to be removed when they become unnecessary. On the other hand, metallic stents are unable to be removed and have the potential risk of breakage and penetration in surrounding tissues, sometimes causing fatal hemoptysis. Nonetheless, they have distinctive advantages over silicon stents in that they can be placed with a flexible bronchoscope with regional anesthesia and the placement procedure itself is very easy and quick. In addition, recent upgrading of metallic stents has improved their safety. Therefore, metallic stents rather than silicon stents are considered suitable especially when airway stenosis is severe enough that silicon stents would never expand completely, is located at inflected portions where silicon stents would never fit in, is accompanied by bleeding, as metallic stents have the potential to arrest hemorrhage by asirction, and extends to a wide region where silicon stent placements would hamper sputum excretion. We have found other advantages of metallic stents over silicon stents. One is their suitability for patients with airway stenosis and critical condition due to malignant diseases, because they can be placed without general anesthesia which is to be avoided for such patients with poor prognosis. In addition, metallic Spiral Z stents can be placed without obstructing branching bronchus, as shown in Figure 2. As also shown in Figure 2, the recent development of imaging technologies, including three-dimensional reconstruction of the CT images and virtual endoscopies, has enabled us to perform non-invasive follow-up after stent placement. The choice of metallic stent placement by flexible bronchoscope together with such new technologies would benefit patients with critical airway stenosis whose survival is limited.

In conclusion, metallic stents were useful in saving the lives and improving the quality of life of patients with severe tracheobronchial stenosis due to malignant diseases and critical conditions. Careful patient selection, however, is imperative because adverse events must be considered.

**REFERENCES**