Factors leading to tracheobronchial self-expandable metallic stent fracture

Fu-Tsai Chung, MD,* Shu-Min Lin, MD,* Hao-Cheng Chen, MD, Chun-Liang Chou, MD, Chih-Teng Yu, MD, Chien-Ying Liu, MD, Chun-Hua Wang, MD, Horng-Chyuan Lin, MD, Chien-Da Huang, MD, and Han-Pin Kuo, MD, PhD

Objective: This retrospective study was to determine factors that contribute to self-expandable metallic stent fracture in patients with tracheobronchial disease.

Methods: From 2001 to 2006, 139 patients (age, 62.1 ± 15.4 years; range, 23–87 years) with benign (n = 62) and malignant (n = 77) tracheobronchial disease received 192 Ultraflex (Boston Scientific, Natick, Mass) self-expandable metallic stents (98 in patients with benign disease and 94 in patients with malignant disease).

Results: Seventeen fractured self-expandable metallic stents were found; the incidence was 12.2% (17/139 patients) among patients with tracheobronchial disease. Tortuous airway (odds ratio, 4.06; 95% confidence interval, 1.04–18.34; $P = .04$) independently predicted self-expandable metallic stent fracture. Most self-expandable metallic stent fractures (64.7%, 11/17) were detected 500 to 1000 days after self-expandable metallic stent implantation. Clinical presentations for patients with fractured self-expandable metallic stents included dyspnea exacerbation (70.6%, 12/17) and cough (23.5%, 4/17).

Conclusions: Self-expandable metallic stent fracture is not uncommon in patients with tracheobronchial disease. Tortuous airway is an independent predictor for it. Although management of the fractured self-expandable metallic stent in our study was feasible and safe, self-expandable metallic stents should be restricted to a more select population.

Endoscopic airway stent implementation for airway stenosis has been an increasingly popular treatment over the last decade. Silicone stents are widely used in the maintenance of airway patency because they are easily removed and repositioned.[1,2] However, their complications include migration, granulation tissue formation, and airway obstruction. Metallic stent management of tracheobronchial obstruction was introduced 10 years ago.[3] Since then, self-expandable metallic stents (SEMSs) have become widely used for management of benign and malignant airway disease. They can be successfully implanted with a flexible bronchoscope during conscious sedation and local anesthesia.[4-6]

Although the US Food and Drug Administration announced a warning for the use of SEMSs in benign conditions, many patients received this therapeutic modality before the warning. In addition, among patients who refused surgical intervention or were not suitable for surgical intervention because of medical comorbidity or poor pulmonary function, metallic stents were reported to be safe and effective in patients with benign and malignant airways obstruction.[7,8] Unlike silicone stents, SEMSs have decreased migration rates, greater cross-sectional airway diameters (because of thinner wall construction), better conformation with irregular airways, epithelialization within the stent that maintains mucociliary clearance, and easier placement.[4,9]

Although SEMSs adequately manage the narrow airway lumen caused by tracheobronchial diseases, complications include stent fracture, migration, granulation tissue formation, impaired mucociliary clearance, recurrent stent obstruction by the lumen, and increased bacterial infection.[3,10,11] Therefore because of these complications, the US Food and Drug Administration warned that SEMS implantation should be considered only if the patients are not eligible for surgical intervention, rigid bronchoscopy, or silicone stent implantation. However, previous studies reported that SEMSs offer benefits in long-term treatment for benign central tracheal stenosis in a certain group of patients,[12,13] but the characteristics of the patients who would benefit from SEMS implantation were not well defined.

Among the potential complications of SEMSs, fracture is of major concern because it can cause potential obstruction and wall perforation.[14] Proposed causes of such fractures include repetitive coughing, esophageal compression during swallowing,[10] metal fatigue,[4] granulation, and shearing forces.[15] However, contributory factors to fracture have not been well documented.[10,15] This study explores these factors in patients with tracheobronchial disease.

MATERIALS AND METHODS

Patients

From August 2001 to September 2006, 139 patients (age 62.1 ± 15.4 years) underwent 192 endoscopic airway stent placements at Chang Gung Memorial Hospital, a university-affiliated hospital in Northern Taiwan.

From the Department of Thoracic Medicine, Chang Gung Memorial Hospital, Chang Gung University, College of Medicine, Taipei, Taiwan.

* FTC and SML contributed equally to the work on this project as first authors, and none of the authors have any conflicts of interest to disclose.

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Address for reprints: Han-Pin Kuo, MD, PhD, Department of Thoracic Medicine, Chang Gung Memorial Hospital, 199 Tun Hwa N Rd, Taipei, Taiwan (E-mail: q8828@ms11.hinet.net).

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Abbreviations and Acronyms
CI = confidence interval
IQR = interquartile range
IRB = institutional review board
SEMS = self-expandable metallic stent

Ninety-eight stents were used in 62 patients with benign tracheobronchial disease, whereas 94 stents were used in 77 patients with malignancy. Silicon or other metallic stents were used by thoracic surgeons in our institution. However, most of them require rigid bronchoscopic intervention. Thoracic surgeons were routinely consulted for feasibility of surgical intervention for all the benign diseases before SEMS implantation. Of 62 patients with benign disease, 37 patients with poor pulmonary function and 19 patients with severe comorbid conditions were precluded from surgical intervention. The other 6 patients refused surgical intervention. Informed consent was obtained from all patients or their surrogates before the procedure of bronchoscopic SEMS implantation and follow-up. Methodology and patient confidentiality were approved by our institutional review board (IRB). The IRB was also asked to review the design of the project in December 2006 and approved this retrospective study in March 2007. The IRB confirmed that this study constituted an audit, which did not require patient consent to this retrospective study.

Stent Implantation

SEMSs were implanted by means of flexible bronchoscopy during conscious sedation and local anesthesia. The choice of stent length and type (with or without cover) was determined by means of previous endoscopic examination and chest computed tomographic scanning. SEMSs were implanted at the choke point, as determined by using flow–volume curve, endobronchial ultrasonography, bronchoscopy, or 3-dimensional computed tomography before and after stenting.[16] Ultraflex (Boston Scientific, Natick, Mass), a tightly weaved SEMS composed entirely of a single strand of nickel–titanium alloy, was the stent of choice for this study.

Assessment of Stent Condition

After implantation of the stent, a second bronchoscopic study was performed in 48 hours. The presence of incomplete stent expansion and incomplete stent lumen expansion was recorded and evaluated in the follow-up bronchoscopic studies. In addition, each patient underwent bronchoscopic examination 1 week after implantation and then every 3 to 6 months thereafter to evaluate stent position and degradation, granulation tissue formation, and airway alignment. If dyspnea, severe coughing, increased mucus production, or other fracture symptoms occurred, additional bronchoscopic analysis was performed.

Definition of Airway and SEMS Conditions

SEMS fracture was defined as the physical breaking of the stent (Figure 1). A tortuous airway was defined as a failure to visualize either the main carina from the trachea or the second carina from either the main bronchus during bronchoscopy (Figure 2) or torsion of the airways on radiographic imaging study (Figure 3). The airway disease was defined as patients with asthma or chronic obstructive pulmonary disease. Incomplete stent lumen expansion was defined because the lumen does not complete expansion after stent implantation for more than 72 hours. Narrow stent opening was defined because the shape of the stent was not round or ovoid after implantation.

Treatment for SEMS Fracture

The treatment strategies for stent fracture include stent removal,[17] another stent implantation, or observation because of no symptoms. Patients who underwent SEMS implantation or removal were consciously sedated with midazolam during flexible bronchoscopy. Electrocautery and forceps were applied alternatively to remove the fractured stent piece by piece because SEMSs were usually tightly embedded into the epithelium of the airway mucosa. SEMS removal usually costs several days' hospitalization because it is difficult to completely remove a stent at once. Although we might spend hours removing the stent each time, neither mortality nor severe morbidity occurred. The whole hospitalization course for each stent removal was usually less than 1 week. The choice of treatment was judged individually by bronchoscopists according to the patients' clinical

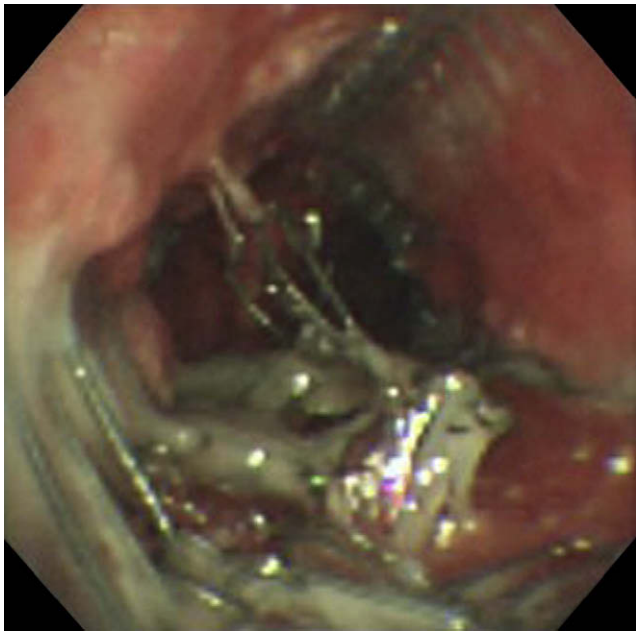

FIGURE 1. A patient with self-expandable metallic stent fracture expressed as the physical breaking of the stent.

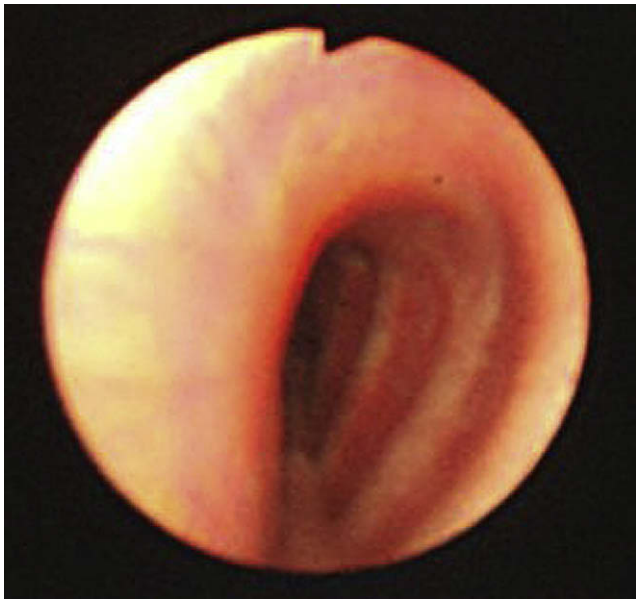

FIGURE 2. Tortuous airway expressed as failure to visualize either of the main carina from the trachea during bronchoscopic analysis.

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