Use of a Retrievable Metallic Stent Internally Coated with Silicone to Treat Airway Obstruction

Jin Hyoung Kim, MD, Ji Hoon Shin, MD, Ho-Young Song, MD, Se Chul Lee, MS, Kyung Rae Kim, MD, and Jung-Hoon Park, RT

PURPOSE: The authors hypothesized that internally covered stents can reduce the rates of stent migration or mucous retention. The authors performed this study to report their experience with use of a retrievable metallic stent internally coated with silicone in patients with benign or malignant central airway obstructions.

MATERIALS AND METHODS: From 2004 to 2007, the authors performed fluoroscopically guided placement of a retievable metallic stent internally coated with silicone in 26 consecutive patients with benign (n = 5) and malignant (n = 21) central airway obstructions. Stents were woven from a single thread of a 0.2-mm-diameter nitinol wire in a tubular configuration and internally covered with silicone membrane.

RESULTS: Stent placement was technically and clinically successful in 93% (25/26) and 85% (22/26) of the patients, respectively. There were eight complications (31%) after stent placement, including tumor overgrowth (n = 2), stent migration (n = 1), symptomatic granulation tissue formation (n = 1), severe pain (n = 1), improper stent location (n = 1), symptomatic sputum retention (n = 1) and esophagobronchial fistula (n = 1). Because of complications, five stents were removed with a retrieval hook under fluoroscopic guidance without difficulty. The median survival period and stent patency were 150.0 days ± 91.4 and 143.0 days ± 26.7, respectively.

CONCLUSIONS: The use of a retrievable metallic stent internally coated with silicone is a safe and effective method for relieving dyspnea, with adequate stent patency in patients with benign or malignant central airway obstructions. This stent design seems to be less prone to migration or mucous retention.

J Vasc Interv Radiol 2008; 19:1208–1214

Abbreviation: PTFE = polytetrafluoroethylene

CENTRAL airway obstruction caused by either a benign or malignant process can lead to dyspnea, respiratory distress, obstructive pneumonia, and even early death by suffocation (1–4). Surgical intervention may provide the most successful treatment option; however, the extent of the disease or comorbidities often prevents curative surgery (5). Nonsurgical, minimally invasive therapies may be crucial for patients with inoperable disease or limited pulmonary function (6,7).

Metallic airway stents are being placed with increasing frequency in patients with benign or malignant airway obstruction (2–5,8–10). The factors favoring the use of a metallic stent for treating central airway obstructions may include dramatic relief of dyspnea, improved performance, and better quality of life. Furthermore, airway stent placement may positively affect the survival rate of patients with advanced malignant airway obstruction (11).

Covered metallic stents have the advantages of minimal tissue ingrowth and easy retrievability. However, unlike uncovered stents, covered metallic stents do not incorporate into tissue and may thus have high migration rates. These airway stent migration rates has been reported to be as high as 18%–22% (2,9,12).

Because of the aforementioned reasons, we designed retrievable metallic stents internally covered with silicone. Compared with an externally covered stent, an internally covered stent may lead to decreased rates of stent migration due to improved friction between the bare metal on the outside of the

From the Department of Radiology, Asan Medical Center, University of Ulsan College of Medicine, 388-1, Poongnap-2dong, Songpa-gu, Seoul 138-736, Republic of Korea (J.H.K., J.H.S., H.Y.S., K.R.K., J.H.P.), and the Department of Radiology, Seoul National University College of Medicine, Seoul National University Hospital, Seoul, Republic of Korea (S.C.L.). Received December 2, 2007; final revision received April 24, 2008; accepted May 2, 2008. **Address correspondence to** J.H.S.; E-mail: jhshin@amc.seoul.kr

From the SIR 2008 annual meeting.

None of the authors have identified a conflict of interest.

DOI: 10.1016/j.jvir.2008.05.004

stent and the tracheobronchial wall. Herein, we report our experience with these internally covered retrievable metallic stents in patients with benign or malignant central airway obstruction.

MATERIALS AND METHODS

Patient Population

Informed consent was obtained from each patient, and our institutional review board approved this prospective study. From November 2004 to July 2007, we prospectively performed fluoroscopically guided placement of a retrievable metallic stent internally coated with silicone in 26 consecutive patients. The inclusion criteria for stent placement were as follows: (*a*) documented and inoperable disease; (*b*) extrinsic compression of the trachea or bronchus, with or without an intraluminal lesion, by a malignant or benign cause; (*c*) esophagobronchial fistula; and (*d*) benign obstruction refractory to balloon dilation. Patients were excluded if they were mildly symptomatic and if an adult endoscope could be passed through the stricture. The characteristics of the patient population in this study are summarized in the **Table**.

Stent Design

Stents were woven from a single thread of 0.2-mm-diameter nitinol wire in a tubular configuration and were internally covered with silicone membrane (NuSil, Carpinteria, California). The stent and introducer set were constructed by a local manufacturer (S & G Biotec, Seongnam, Korea).

The tracheal stent was 16 or 20 mm in diameter when fully expanded and 40–80 mm long, and the bronchial stent was 10 or 12 mm in diameter and 30–50 mm long (**Fig 1**). To make the stent removable, a 2-mm-diameter nylon loop was hooked inside each bend of the upper end of the stent and two nylon threads were passed through each of these nylon loops to form a larger loop (drawstring) to fill the inside circumference of the proximal end of the stent (**Fig 1**).

Stent Placement and Removal Technique

Before stent placement, the severity and length of the strictures were evaluated with chest radiography, computed tomography (CT)—including three-dimensional reconstructions—and bronchoscopy. Whenever possible, stents at least 10 mm longer than the stricture were selected for placement so that the proximal and distal regions would rest on the upper and lower margins of the stricture, respectively.

The details of stent placement are provided elsewhere (13) and are only summarized here. Before the procedure, topical anesthesia of the pharynx and larynx was routinely achieved with an aerosol spray. Sedation drugs were routinely used. Under bronchscopic guidance, a 0.035-inch exchange guide wire (Terumo, Tokyo, Japan) was inserted through the patient's mouth, across the stricture, and into the distal portion of the trachea or bronchus. A straight, 5-F, graduated-sized catheter (Cook, Bloomington, Indiana) was passed over the guide wire to the distal part of the stricture to measure the length of the stricture. The 0.035-inch exchange guide wire was then changed to a super-stiff J-tip guide wire (Medi-tech/Boston Scientific, Watertown, Massachusetts). Stent placement was performed over the stiff wire under fluoroscopic guidance.

The indications for stent removal included stent-related complications (eg, stent migration) or marked granulation tissue formation or tumor growth above or below the stent. The stents were removed under fluoroscopic guidance by using a retrieval hook (9). When the hook grasped and pulled the drawstring of the proximal end of the stent into a sheath, the proximal end collapsed and the stent could be removed (**Fig 2**).

Follow-up

Bronchoscopy was performed immediately after stent placement in all patients to evaluate the position and expansion status of the stent. All patients underwent chest radiography and clinical examination 1–3 days, 1 month, and then every 3 months after stent placement to evaluate the status of the stent and the patient's respiratory function. Examinations were also performed immediately, 1 month, and then every 3 months after stent removal. When there were complications or symptom recurrence, chest radiography, clinical examination, and bronchoscopy were performed. When it was not possible to perform a clinical examination, the patient or his or her family was contacted by telephone every 3 months for as long as the patient remained alive to obtain information concerning his or her respiratory status. All data were obtained prospectively with completion of clinical surveys.

Data Definition and Analysis

We analyzed the data on an intent-to-treat basis. Technical success was defined by successful insertion of a stent in the proper position and without any major complications. The Hugh-Jones classification was used in all patients to evaluate improvement in respiratory function before and 1–7 days after stent placement. This classification is a five-grade system used to assess breathlessness on the basis of daily activities, with grade 5 indicating the most severe form of dyspnea, as detailed elsewhere (2). Clinical success was defined as an improvement of more than one grade on the Hugh-Jones classification scale 1–7 days after stent placement. Complications and related interventions were evaluated. Removed stents were examined grossly to evaluate membrane degradation. In terms of complications, sputum retention was assessed when it was symptomatic and increased after stent placement, and tumor overgrowth, tumor in-growth, or granulation tissue was confirmed by using bronchoscopy and biopsy. Membrane degradation was defined as a membrane tear or opening in the silicone covering.

Stent patency was defined as the interval between stent placement and loss of stent function due to clinical failure, stent migration, or stent occlusion. If no loss of stent function occurred, data about stent patency was censored at the date of the patient's death or at the study endpoint. Overall patient survival and the stent patency were calculated by using the Kaplan-Meier method. All statistical analysis was performed with software (SPSS version 12.0; SPSS, Chicago, Illinois).