An Assessment of the Optimal Time for Removal of Esophageal Stents Used in the Treatment of an Esophageal Anastomotic Leak or Perforation

Richard K. Freeman, MD, MBA, Anthony J. Ascioti, MD, Megan Dake, PA-C, and Raja S. Mahidhara, MD

Department of Thoracic and Cardiovascular Surgery, St. Vincent Hospital, Indianapolis, Indiana

Background. **Esophageal stent for the treatment of a perforation or anastomotic leak has been shown to be effective and safe. However, the optimal timing for stent removal is in question. This purpose of this investigation was to identify a time for stent removal in patients treated for an acute perforation or anastomotic leak that resulted in sealing of the leak while minimizing the incidence of stent-related complications.**

Methods. **Patients undergoing esophageal stent placement for the treatment of an acute perforation or intrathoracic anastomotic leak were identified from a single institution's prospectively collected database. Patient outcomes were recorded and analyzed. Complications were segregated by stent dwell time.**

Results. **During the study period, 162 patients underwent esophageal stent placement for an acute perforation (n = 117) or anastomotic leak (n = 45). Patients whose stent was removed in less than 28 days after placement for an acute perforation realized a stent complication rate that was independently reduced by 39% (odds ratio, 0.61; 95% confidence interval, 0.54 to 0.78; $p < 0.01$), whereas patients whose stent was removed in less than 14 days after placement for an acute perforation realized a stent complication rate that was independently reduced by 56% (odds ratio, 0.44; 95% confidence interval, 0.38 to 0.69; $p < 0.001$).**

Conclusions. **Endoluminal esophageal stent placement is a safe and effective treatment for patients with an acute esophageal perforation or intrathoracic anastomotic leak after esophagectomy. Removal of stents at 2 weeks for anastomotic leak or 4 weeks for perforation has the potential to significantly decrease the incidence of complications associated with stent use.**

(Ann Thorac Surg 2015;100:422–8)

Esophageal stent placement for the treatment of an acute perforation or an intrathoracic anastomotic leak after esophagectomy has become a recognized treatment option for selected patients. These patients include patients with an intrathoracic leak without esophageal necrosis or a mucosal injury greater than 6 cm in length. Stent placement for an acute perforation offers the potential advantages of earlier oral nutrition, a reduced hospital stay, and avoidance of the morbidity and recuperation associated with an operative repair while achieving success rates that compare favorably with traditional primary closure [1]. Esophageal stent placement for an anastomotic leak offers the same advantages and appears to significantly reduce the rate of anastomotic stricture requiring treatment compared with reoperative repair or expectant management [2].

However, untoward events have been reported after esophageal stent placement for the treatment of an anastomotic leak or acute esophageal perforation. These include fistulization with vascular structures, migration with distal bowel obstruction, airway fistulization or compression, esophageal necrosis, and stent fracture or degradation. The purpose of this investigation was to identify an optimal stent dwell time that produced a high rate of sealing the perforation or leak while minimizing stent-related complications.

Patients and Methods

Patients undergoing esophageal stent placement for the treatment of an intrathoracic leak resulting from an acute esophageal perforation or at the site of an intrathoracic anastomosis after esophagectomy were identified from a comprehensive general thoracic surgery database at a single institution cared for by three thoracic surgeons. The institutional review board approved this retrospective review of the off-label use of an esophageal stent for the treatment of an esophageal perforation or anastomotic leak after esophagectomy and waived individual patient consent for this investigation. Patients with a cervical or intraabdominal esophageal perforation or anastomosis after esophagectomy were excluded. Also excluded were patients with an acute perforation associated with a malignancy. Eligible for inclusion were patients

Accepted for publication March 25, 2015.

Presented at the Sixty-first Annual Meeting of the Southern Thoracic Surgical Association, Tucson, AZ, Nov 5–8, 2014.

Address correspondence to Dr Freeman, 8433 Harcourt Rd, Indianapolis, IN 46260; e-mail: richard.freeman@stvincent.org.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2015.03.085

transferred from other facilities, patients who underwent chemotherapy and/or radiation therapy before esophagectomy, and patients who had undergone an attempt at operative repair of a leak or perforation with subsequent persistent leak requiring stent placement.

A retrospective analysis from a prospectively collected database was performed after eligible patients were identified. Patient demographics, time to oral intake, length of hospital stay, morbidity, mortality, and patient condition 1 month from discharge were all recorded. Any complication related to use of the stent was reviewed. Stent migration within 72 hours of placement was not considered a complication for the purposes of this analysis, but was included in the overall stent migration rates for this study. Stent dwell time for each patient was assessed. In instances when a patient required the replacement of a stent for malposition or migration, the total time a stent was in place was recorded. Complications identified where segregated by esophageal perforation or anastomotic leak and then by stent dwell time for analysis.

Patient Evaluation and Stent Placement

The presence of an intrathoracic esophageal leak from either an acute perforation or at the site of an anastomosis after esophagectomy was documented and localized by diatrizoic acid (Gastrografin; Bracco Diagnostics, Inc, Monroe Township, NJ) or barium esophagram before any treatment. To be considered a significant leak eligible for treatment other than observation, contrast had to be seen leaving the lumen of the esophagus with extravasation into the mediastinum or pleural space (Fig 1). Additionally, all patients being considered for stent placement after an acute esophageal perforation underwent computer-aided tomographic imaging of the neck, chest, and abdomen.

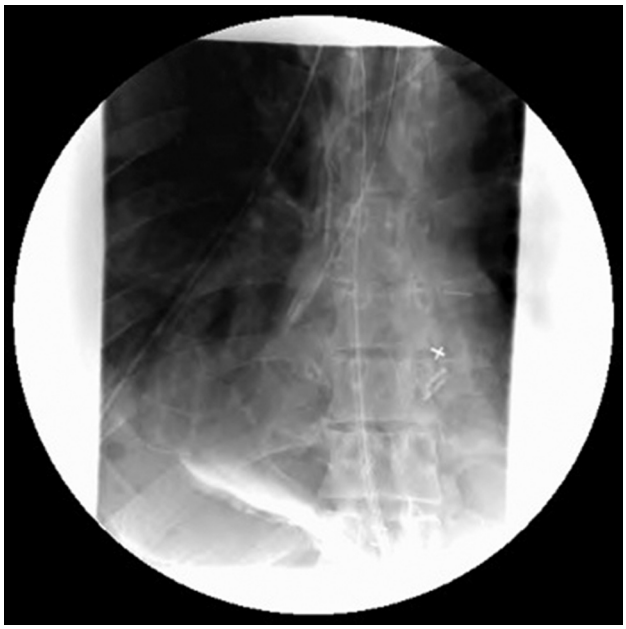

Fig 1. Esophagram displaying a leak at the site of an intrathoracic esophagogastrostomy after esophagectomy with contrast drained by a tube thoracostomy.

All esophageal stents were placed in the operating room using general anesthesia and fluoroscopy by a thoracic surgeon after flexible esophagoscopy. It is our practice to routinely oversize esophageal stents in length and diameter to minimize stent migration and achieve a seal of the leak site. Adequate drainage of infected areas was also achieved either by video-assisted thoracoscopic surgery or image-guided percutaneous drainage. Leak occlusion was confirmed by contrast esophagram a minimum of 24 hours after stent placement or when the patient was able to participate in the examination. In the absence of a continued leak, a diet was initiated.

It was the intention to remove all patients' esophageal stents after a sufficient amount of time to allow the leak to seal. This was based on the lack of a leak on esophagram and normalization of clinical, laboratory, and imaging data such as the character and amount of chest tube drainage, resolution of ileus, lack of fever and leukocytosis, and absence of a ipsilateral pleural effusion. Stent removal was carried out in the operating room under general anesthesia. Flexible esophagoscopy was performed before and after stent removal. An esophagram was performed after stent removal before discharge.

Statistical Analysis

Analysis of data was carried out using GraphPad Prism software 4.02 (San Diego, CA) for Windows (Microsoft Corp, Redmond, WA). Continuous data are expressed as the mean ± standard deviation except as otherwise indicated. Differences between categorical variables were evaluated by Fisher's exact test. Differences between continuous variables were measured by two-tailed Student's t test or the Mann-Whitney U test for nonnormally distributed data. A probability value of less than 0.05 was considered significant. Multiple logistic regression analysis was used to study relationships between patient variables and the identified outcome measures. The Poisson distribution, a discrete probability distribution that expresses the probability of a given number of events occurring in a fixed interval of time, was also used to predict the effect of stent dwell times for complications related to the treatment of esophageal perforation or anastomotic leak [3].

Results

During the 7-year study period, 162 patients with an acute esophageal perforation (n = 117) or an anastomotic leak (n = 45) after esophagectomy were identified as meeting the inclusion criteria for this investigation (Table 1). Each of these patients had either a silicon-coated plastic stent (Polyflex; Boston Scientific, Natick, MA) or a covered nitinol stent (Alveolus Inc, Charlotte, NC) placed at the study institution. All of these stents were fully covered and occlusive. Stent choice was at the discretion of the surgeon.

Thirty-four of these patients had undergone their esophagectomy elsewhere before being transferred to our