CLINICAL STUDY

Self-Expandable Metal Stent Use to Palliate Malignant Esophagorespiratory Fistulas in 88 Patients

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ABSTRACT

Purpose: To identify predictors associated with clinical outcomes (initial clinical failure, stent patency, and survival) after self-expandable metal stent (SEMS) placement for malignant esophagorespiratory fistulas (ERFs).

Materials and Methods: Using logistic and Cox regression analyses, this study reviewed 88 patients (mean age 59.4 y ± 8.4; 84 men [95.5%] and 4 women [4.5%]) who underwent fluoroscopic SEMS placement for palliating malignant ERF from January 2000 to December 2016.

Results: Technical success was achieved in all patients. Initial clinical success was achieved in 78.4% (69/88; 95% confidence interval [CI], 68.7%–85.7%). Among the 69 patients in whom initial clinical success was achieved, aspiration symptoms recurred in 37.7% (26/69; 95% CI, 27.2%–49.5%). Overall major complication rate was 25.0% (22/88; 95% CI, 17.1%–35.0%). Cumulative stent patency and cumulative survival rates at 1, 3, 6, and 12 months were 72.8%, 38.9%, 32.4%, and 21.6% and 81.4%, 51.9%, 30.5%, and 13.3%, respectively. Stricture of the upper esophagus was an independent predictor of initial clinical failure (odds ratio, 3.760; 95% CI, 1.207–11.811) and shorter stent patency (hazard ratio [HR], 2.036; 95% CI, 1.170–3.544). Initial clinical failure was an independent predictor of shorter survival (HR, 2.902; 95% CI, 1.587–5.305).

Conclusions: SEMS placement offers sufficient short-term relief despite considerable major complications. Stricture of the upper esophagus is an independent predictor of initial clinical failure and shorter stent patency. Initial clinical failure is an independent predictor of shorter survival.

ABBREVIATIONS

CI = confidence interval, ERF = esophagorespiratory fistula, HR = hazard ratio, IQR = interquartile range, OR = odds ratio, SEMS = self-expandable metal stent

An esophagorespiratory fistula (ERF) is a devastating complication of malignancy because it causes chronic contamination of the pulmonary system, resulting in malnutrition and respiratory failure. Without treatment, the reported median survival after ERF diagnosis is 1–2.8 months (1–4). ERFs develop in 5%–15% of patients with esophageal cancer and in < 1% of patients with bronchogenic carcinoma (5); however, it can also occur because of surgery, radiotherapy, chemotherapy, laser therapy, or stent placement (6,7). Self-expandable metal stent (SEMS) placement has recently been widely used for treating malignant ERFs because of its convenience, safety, and effectiveness (8), with successful closure achieved in 67%–100% of patients (1,5,9–12). In addition, several retrospective studies have demonstrated the superiority of SEMS placement for improving overall survival time (1,4) and quality of life (3) compared with supportive therapies, such as feeding gastrostomy or percutaneous jejunostomy.

Despite the benefits of SEMS, the associated predictors of clinical failure and patient survival have been poorly described. Shin et al (5) showed that survival was significantly short in patients with an initial clinical failure;

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however, they did not investigate the factors affecting the failure. Therefore, this study aimed to identify predictors associated with clinical outcomes (i.e., initial clinical failure, stent patency, and survival) after fluoroscopic SEMS placement for malignant ERFs in 88 consecutive patients.

MATERIALS AND METHODS

This single-center, retrospective case series study was approved by the institutional review board. Informed consent was waived by the board because of the retrospective nature of the analysis.

Study Population

From January 2000 to December 2016, all consecutive patients who underwent fluoroscopic esophageal SEMS placement for treating ERF secondary to an inoperable cancer were included. Patients who were lost to follow-up within a month and who underwent double stenting (stent placement both in the esophagus and in the airway) were excluded.

From the database search, 93 patients were identified. Five patients were excluded because they were lost to follow-up within a month (n = 2) or they underwent double stenting (n = 3). Consequently, 88 (mean age 59.4 y ± 8.4, 84 men [95.5%] and 4 women [4.5%]) patients were included in this study. All patients had fistulas with concomitant strictures, which were identified with either esophagography or endoscopy. The most common malignancy was esophagus cancer (77.3%; 68 of 88), followed by carcinomas of the lung (20.5%; 18 of 88), breast (1.1%; 1 of 88), and hypopharynx (1.1%; 1 of 88). The most common stricture location was the middle esophagus (63.6%; 56 of 88), followed by the upper (23.9%; 21 of 88) and lower (12.5%; 11 of 88) esophagus, and mean stricture length was 6.4 cm ± 2.5. The median interval from cancer diagnosis to fistula diagnosis was 189 days (interquartile range [IQR], 107–385 d). The most frequent opening site was the trachea (31.8%; 28 of 88), followed by the right bronchus (26.1%; 23 of 88), left bronchus (19.3%; 17 of 88), lung parenchyma (19.3%; 17 of 88), and pleura (3.4%; 3 of 88). Prior radiation and/or chemotherapy (concurrent chemoradiotherapy [81.8%; 72 of 88], radiotherapy [3.4%; 3 of 88], and chemotherapy [2.3%; 2 of 88]) was performed in 87.5% (77 of 88) of patients.

Stent Placement and Follow-up

Two types of fully covered esophageal SEMSs were used: Niti-S (Taewoong Medical Co, Ltd, Gimpo-Si, Korea) stent and EGIS (S&G Biotech Inc., Seongnam-Si, Korea) stent (Fig 1). The Niti-S stent consists of 3 parts: the upper head, the body, and the lower head. Both head parts are 24 mm in diameter and 20 mm long when fully expanded and are connected at right angles to the body part, which is 16 mm or 18 mm in diameter. Total stent length is 100–160 mm when fully expanded. The EGIS stent also consists of 3 parts, but both head parts have a double-stepped design. Outer larger rims are 24–28 mm in diameter and 13 mm long, and inner smaller rims are 20–24 mm in diameter and 7 mm long and are connected to the body part, which is 16–20 mm in diameter. Total stent length is 90–170 mm when fully expanded. The EGIS stent has a knitted design to improve conformability.

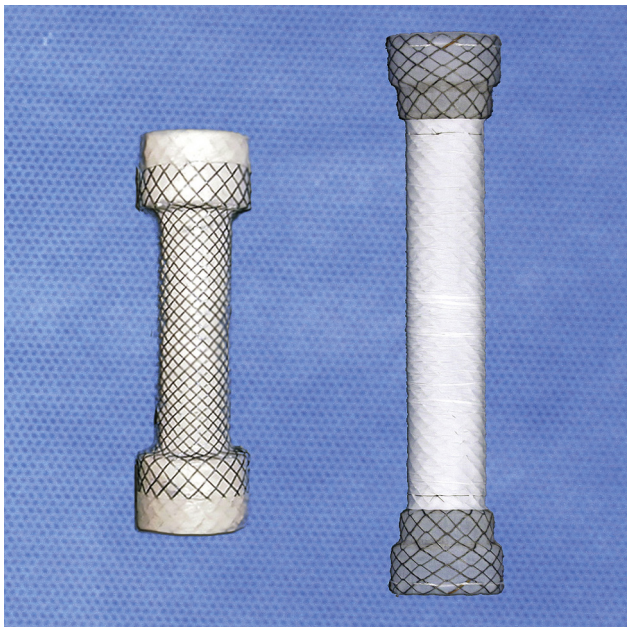

Figure 1. Two types of fully covered esophageal SEMSs used in this study: Niti-S (left) and EGIS (right).

The techniques used for esophageal stent placement have been previously described (5). A topical lidocaine spray (Dai Han Pharmaceutical Co, Ltd, Seoul, Korea) was applied to the pharynx or larynx before the procedure. Then a 0.035-inch exchange stiff guide wire (Radifocus M; Terumo Corp, Tokyo, Japan) was inserted through the mouth across the stricture under fluoroscopic guidance, and the stent was placed using a 6-mm introducer system. To verify closure of the ERF, esophagography was performed immediately after stent placement (Fig 2a–c). If complete sealing was achieved, the patient was encouraged to resume a soft diet 2 hours after the procedure and then to resume a solid diet as soon as possible. Routine follow-up esophagography was performed 4–7 days after stent placement to evaluate reopening of the fistula and stent patency. If complete sealing was not achieved, the patient was restricted from resuming a soft diet and esophagography was repeated 1–3 days after stent placement to verify stent expansion. A routine follow-up esophagogram was obtained 4–7 days after stent placement. If contrast leakage was persistent on that esophagogram, the procedure was considered as an initial clinical failure, and further treatments were performed depending on the clinical setting.

Patients with uneventful procedures had follow-up examinations every 1 or 2 months thereafter on outpatient basis. If possible, follow-up esophagography was performed concomitantly. If this was not practical, the patient was contacted