

Full covered self-expandable metal stents for the treatment of anastomotic leak using a silk thread

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Abstract

To evaluate the safety and effectiveness of fixation of the fully covered self-expandable metal stent (SEMS) placement using a silk thread for complete closure of an anastomotic leak. An anastomotic leak is a life-threatening complication after gastrectomy. Although the traditional treatment of choice was surgical re-intervention, an endoscopic SEMS can be used alternatively.

During the study period, we retrospectively reviewed consecutive patients who received a modified covered SEMS capable of being fixed using a silk thread (Shim technique) due to an anastomotic leak after gastrectomy to prevent stent migration. Demographic data, stent placement and removal, clinical success, time to resolution, and complications were evaluated.

A total of 7 patients underwent fully covered SEMS with a silk thread placement for an anastomotic leak after gastrectomy to treat gastric cancer. The patients' mean age was 71.3 ± 8.0 years. Male sex was predominant (85.7%). All patients' American Society of Anesthesiologists (ASA) scores were between I and III. Total gastrectomy was performed in 5 patients (71.4%) and proximal gastrectomy was performed in 2 patients (28.6%). The time between gastrectomy and stent insertion was 22.3 ± 11.1 days. The size of the leaks was 27.1 ± 11.1 mm. Technical success and complete leak closure were achieved in all patients. Stent migration was absent. All stents were removed between 4 and 6 weeks. Delayed esophageal stricture was found in 1 patient (14.2%) and successfully resolved after endoscopic balloon dilation.

For an anastomotic leak after gastrectomy, fully covered SEMS placement with a silk thread is an effective and safe treatment option without stent migration. The stent extraction time between 4 and 6 weeks was optimal without severe complications.

Abbreviations: ASA = American Society of Anesthesiologists, BMI = body mass index, CRP = C-reactive protein, F = female, Hb = hemoglobin, M = male, SD = standard deviation, SEMS = self-expandable metal stent.

Keywords: gastrectomy, gastric cancer, leak, self-expandable metal stent

1. Introduction

For adenocarcinoma located in the upper third of the stomach, radical gastrectomy with esophagojejunal anastomosis is the treatment of choice. Anastomotic leak after esophageal anastomosis is fairly common; the reported incidence is 7.9% to 10%.^[1,2] The mortality rate after anastomotic leak was reported to be 9% to 18%.^[2,3] The traditional standard approach to treat an anastomotic leak consists of conservative treatment with nil per mouth, abscess drainage, and surgical re-exploration with

repair of the anastomosis. However, the high risk of operative morbidity and mortality is a major concern. Early recognition and management of the leak is crucial. Anastomotic leaks may be associated with a variety of factors such as systemic disease (such as hypertension, diabetes mellitus, preoperative chemoradiation, cardiovascular disease, respiratory disease, and advanced age), technical factors (such as misfire of stapler, inadequate staple size, tissue trauma, ischemia of the anastomosis due to tension, excessive bleeding, and the experience of the surgeon) and postoperative factors (such as infection, re-exploration for bleeding, and continued hypoxemia).^[4,5] Although several treatment methods have been used, no standard treatment guideline has been clarified. In recent years, instead of surgical re-exploration, stents have been used for the treatment of benign esophageal perforation or leaks.^[6–8]

The self-expandable metal stent (SEMS) was introduced for the palliative treatment of malignant obstruction. In recent years, the fully covered SEMS has been used for the treatment of benign conditions such as perforation, leaks, and strictures.^[3,9] Other than the fully covered SEMS, the self-expandable plastic stent and partially covered SEMS can also be used. The efficacy of different stent types is not significantly different.^[10] The advantages of the SEMS are decreased morbidity and mortality associated with intervention, minimal invasion, faster procedure time, earlier oral intake after stent placement, and shorter hospitalization compared with reoperation.^[11] However, the use of fully covered SEMS for the treatment of benign disease poses several problems, including a higher migration rate compared with that in malignant stricture; additionally, hyperplasia in the uncovered parts of the stents can make stent removal difficult.^[3] To prevent stent migration, various methods have been used, such as

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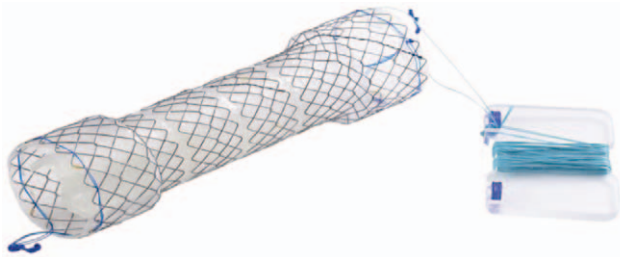


Figure 1. Full covered self-expandable metal stent used in the present study (Hanarostent; M.I. Tech Co, Seoul, Korea). The stent consists of a modified covered metallic stent designed with a silk thread attached at the edge of the proximal end of the stent and retrieval lasso at the distal end of the stent. After stent deployment, the silk thread can be fixed to the patient's nose or ear lobe using tape.

endoscopic clips,^[12] an endoscopic suturing device,^[13] and Shim technique.^[14] Shim technique consists of a modified covered metallic stent designed with a silk thread attached at the edge of the proximal end of the stent. After stent deployment, the silk thread is fixed to the patient's nose or ear lobe with tape to prevent stent migration.^[14]

In the present study, we used a fully covered SEMS with a silk thread (Shim technique) for the treatment of esophagojejunal anastomotic leaks after gastrectomy to treat gastric cancer. The clinical outcomes of SEMS placement, especially stent migration and complete closure of leak rate, were evaluated.

2. Patients and methods

2.1. Patients

From January 2009 to December 2016, we retrospectively reviewed the medical records of patients who underwent fully

covered SEMS placement for the anastomotic leaks at Pusan National University Yangsan Hospital in South Korea. A total of 7 patients were enrolled. Written informed consent was obtained from all patients before the procedures. The study was approved by the Ethics Committee of the Institutional Review Board.

2.2. Endoscopic procedures and patient management

The diagnosis of leak was made by performing a gastrograffin swallow or endoscopy. Abdominal and chest computed tomography were performed to evaluate the presence of abnormal fluid collection or abscess in the abdominal or thoracic cavity. Stent placement was performed under endoscopic and fluoroscopic control. We used Shim technique and fully covered SEMS (Hanarostent; M.I. Tech Co, Seoul, Korea) with a silk thread attached at the edge of the proximal end of the stent and retrieval lasso at the distal end of the stent (Fig. 1). Patients were consciously sedated with intravenous midazolam (2.5–5 mg) during the procedure. Under fluoroscopic and endoscopic visualization, the length of the leak was measured. A stent 4 cm longer than the length of the leak was chosen. After the guidewire was inserted through the stricture, the delivery system of the stent was gently introduced. After stent placement, the positioning of the stent was assessed both radiographically and endoscopically. After stent deployment, the silk thread was removed through the nose and fixed to the patient's ear lobe using tape (Shim technique, Fig. 2).^[14] Just after stent placement, esophagography with gastrograffin was performed to evaluate fluid passage and evaluate the proper position of the SEMS. On the day after the procedure, if the stent was maintained in place on chest radiography, per oral intake was started with a small amount of liquid. Chest radiography was evaluated at intervals of 1 to 2 weeks to evaluate the stent position until SEMS removal. If an abscess was found on abdominal or chest computed

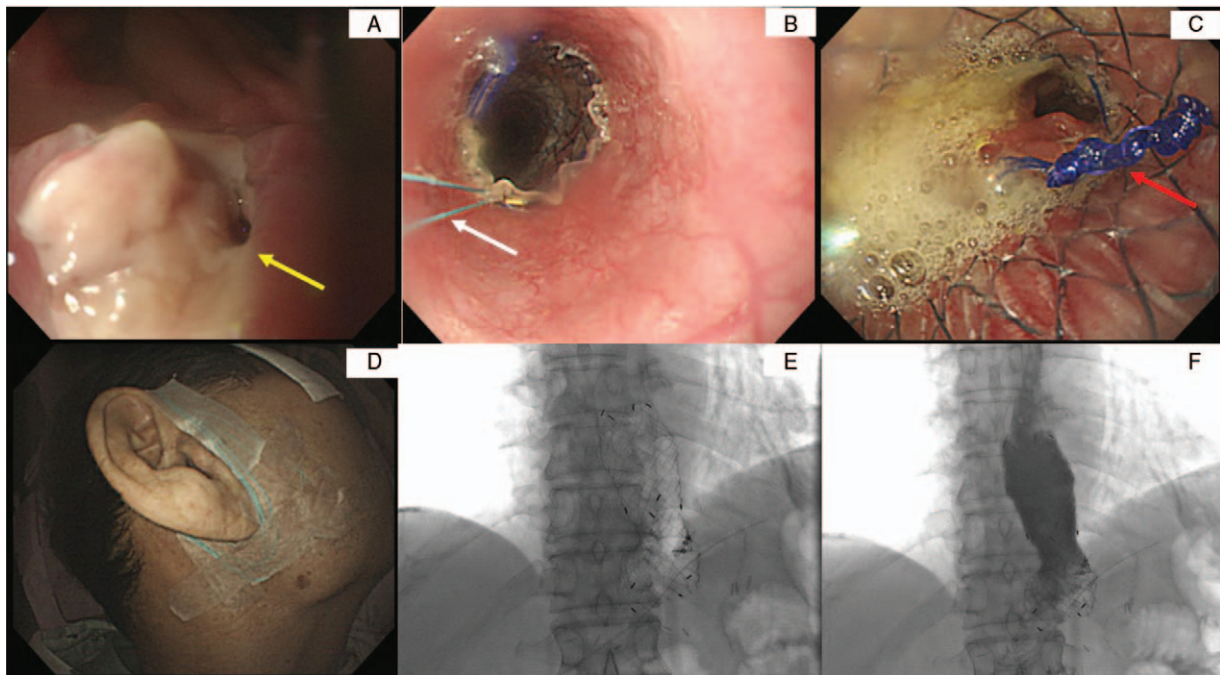


Figure 2. Placement of a full covered SEMS with Shim technique. A. Anastomotic leak after total gastrectomy (yellow arrow). B–C. A fully covered SEMS was placed. A silk thread attached at the edge of the proximal end of the stent (white arrow) and retrieval lasso at the distal end of the stent (red arrow). D. The thread is fixed to the patient's ear lobe using tape. E. Fluoroscopic finding after stent placement. F. A control esophagogram confirms the absence of the leak after placement. SEMS = self-expandable metal stent.

tomography, abscess drainage was performed along with intravenous administration of broad spectrum antibiotics.

All stent extraction was performed between 4 to 6 weeks after SEMS placement. First, we cut the silk thread attached to the ear. Second, after insertion of the endoscope, the retrieval lasso on the distal end of the stent was retrieved using endoscopic rat-tooth forceps and attached to the tip of endoscope. The endoscope and SEMS were removed at the same time through the mouth. If significant bleeding was suspected during stent extraction, a second-look endoscopy was performed the next day. After stent removal, regular follow-up endoscopic examination was recommended 6 months later. If the patients complained of dysphagia, endoscopic examination was performed to evaluate the presence of stricture.

2.3. Definitions

The primary outcomes were the technical success rates and complete healing (clinical success) rates. The technical success of stent placement was defined as the adequate positioning and stent deployment with complete bridging of the leak. Complete healing (clinical success) was defined as no evidence of persistent leak while the stent was in place and after stent extraction. Leak size was determined according to the endoscopic reports and photographs. Stent malfunction was defined as stent migration, food impaction, or other complications such as aspiration pneumonia and perforation. To evaluate the patients' physical status and nutrition state, we calculated the American Society of Anesthesiologists (ASA) physical status score,^[15] body mass index (body weight [kg] divided by the square of the body height [meter]), serum hemoglobin, albumin, and C-reactive protein.

2.4. Data management

Continuous variables were expressed as mean (standard deviation, SD), and categorical variables were expressed as a percentage (%). Data were analyzed using SPSS version 21.0 (SPSS Inc., Chicago, IL).

3. Results

A total of 7 patients underwent fully covered SEMS placement for an anastomotic leak after gastrectomy to treat gastric cancer

(Table 1). The patients' mean age was 71.3 ± 8.0 years. The male sex was predominant (85.7%, 6/7). The mean body mass index was $20.8 \pm 8.9 \text{ kg/m}^2$. The mean serum albumin level was $4.1 \pm 2.7 \text{ g/dL}$. Serum C-reactive protein level was $4.8 \pm 5.4 \text{ mg/dL}$. Serum hemoglobin was $10.4 \pm 1.4 \text{ g/dL}$. All patients' ASA physical status scores were between I and III. Total gastrectomy was performed in 5 patients (71.4%) and proximal gastrectomy was performed in 2 patients (28.6%).

Clinical outcomes and associated variables were shown in Table 2. The time between gastrectomy and stent insertion was 22.3 ± 11.1 days. The size of the leaks was $27.1 \pm 11.1 \text{ mm}$. Technical success was achieved in all patients. The complications associated with SEMS, including stent migration, were absent. The time between stent insertion and stent extraction was 34.3 ± 5.9 days. All stents were removed between 4 and 6 weeks after placement (Table 3). After removal of the stent, all leaks were closed successfully. Minor bleeding during stent extraction was stopped spontaneously without endoscopic intervention. Delayed esophageal stricture was found in 1 patient (14.2) and successfully resolved after repeated endoscopic balloon dilation (6 times) (Table 3). In all patients, only 1 stent and 1 SEMS placement were needed.

4. Discussion

The postoperative anastomotic leak is a dreaded complication, with a 3-fold higher mortality rate seen in patients with leaks than in patients without leaks.^[2] In addition, reoperation for anastomotic leaks is associated with a high mortality rate.^[3] In recent years, endoscopic placement of stents was used instead of surgical intervention. The reported complete closure rate was 77% to 97%^[7,16] and the procedure-associated complications such as perforation (approximately 2%) and stent-related bleeding (approximately 0.8%) were low.^[3] In the present study, the study population was restricted to anastomotic leaks occurring after gastrectomy to treat gastric cancer. The complete closure rate was 100% and the procedure-related complications such as severe bleeding requiring endoscopic intervention or

Table 1

Baseline characteristics of enrolled patients.

Demographics	Total (n=7)
Age, years, mean (SD)	71.3 (8.0)
Male sex, n (%)	6 (85.7)
Body mass index, kg/m^2 , mean (SD)	20.8 (8.9)
Albumin, g/dL, mean (SD)	4.1 (2.7)
C-reactive protein, mg/dL, mean (SD)	4.8 (5.4)
Hemoglobin, g/dL, mean (SD)	10.4 (1.4)
ASA physical status score, n (%)	
I	3 (42.9)
II	3 (42.9)
III	1 (14.2)
History of radiation therapy, n (%)	0 (0)
Diabetes mellitus, n (%)	1 (14.2)
Hypertension, n (%)	4 (57.1)
Coronary artery disease, n (%)	1 (14.2)
Types of operation, n (%)	
Total gastrectomy	5 (71.4)
Proximal gastrectomy	2 (28.6)

ASA=American Society of Anesthesiologists, SD=standard deviation.

Table 2

Clinical outcomes associated with fully covered self-expandable metal stents.

Variables	Total (n=7)
Time between gastrectomy and stent insertion, days, mean (SD)	22.3 (11.1)
Size of leak, mm (SD)	27.1 (11.1)
Technical success, n (%)	7 (100)
Time between stent insertion and stent extraction, days, mean (SD)	34.3 (5.9)
Clinical outcomes, n (%)	
Complete resolution of leak	7 (100)
Stent related perforation	0 (0)
Stent migration	0 (0)
Complications during stenting	0 (0)
Complications after stent extraction, n (%)	
Bleeding needing endoscopic intervention or transfusion	0 (0)
Stricture needing endoscopic balloon dilations	1 (14.2)
Successful stent extraction	7 (100)
Perforation	0 (0)
More than 2 times stent insertion, n (%)	0 (0)
Required more than 2 stents, n (%)	0 (0)

SD=standard deviation.

Table 3**Summary of clinicopathologic features and treatment outcome in 7 patients.**

Patients (No.)	Sex	Age (y)	Types of operation	Date of stent insertion after operation (d)	ASA score	leak size (mm)	Diabetes mellitus	Hypertension	Coronary artery disease	CRP (mg/dL)	Albumin (g/dL)	Hb (g/dL)	BMI (kg/m ²)	Date of stent removal	Closure of leaks	Complications	Percutaneous drainage
1	M	80	Total gastrectomy	43	I	3	0	0	0	3.5	3.6	8	17.2	28	Yes	No	No
2	M	77	Total gastrectomy	17	II	2	0	1	0	3.99	3.3	9.7	20.2	30	Yes	No	No
3	M	68	Proximal gastrectomy with jejunal transposition	21	II	1	0	1	0	1.32	2.8	10.6	23.7	34	Yes	No	No
4	M	73	Total gastrectomy	16	II	3	0	1	0	3.26	2.9	9.9	20.8	41	Yes	No	No
5	M	65	Total gastrectomy	20	I	2	0	0	0	1.82	3.1	11.4	18.7	37	Yes	Stricture needing dilations	No
6	F	58	Proximal gastrectomy with jejunal transposition	9	III	4	1	1	Dual antiplatelet medication	16.86	2.8	11	29.8	28	Yes	No	Yes
7	M	78	Total gastrectomy	30	I	4	0	0	0	2.9	10.3	12.68	15.2	42	Yes	No	Yes

ASA=American Society of Anesthesiologists; BMI=body mass index, CRP=C-reactive protein, F=female, Hb=hemoglobin, M=male.

perforation were absent. One patient needed 6 endoscopic balloon dilations due to stricture after stent removal. Mortality associated with postoperative leaks and stent was absent. The major concerns regarding the endoscopic SEMS treatment for anastomotic leaks may be stent migration and the optimal time of stent extraction. In the present study, stent migration was absent and successful stent removal without severe complications was achieved between 4 and 6 weeks after the procedure.

Endoscopic SEMS placement was developed in order to achieve faster per oral intake in patients with malignant esophageal or gastric outlet obstruction. The advantages of SEMS compared with surgical intervention are clear. The fully covered SEMS placement for anastomotic leak is minimally invasive and has a faster procedure time. After successful SEMS placement, oral intake can be started within 1 to 3 days and hospitalization may be shorter than surgical operation.^[11] Although the technical success rate of stent placement is nearly 100%, stent migration rate was reported to be higher compared with that of SEMS placement for malignant strictures (20–40%) because of the absence of stenosis maintaining the stent position.^[3,9,17] In the present study, stent migration was absent. To prevent stent migration, we used Shim technique. As mentioned previously, the silk thread attached at the proximal end of the stent was removed through the nose and to the ear lobe with tape.^[14] Despite the small sample size in our study, the Shim technique with fully covered SEMS was a valuable treatment option to prevent stent migration. Several other methods for preventing stent migration have been reported. A simple method to prevent stent migration is the use of endoscopic clips. Fixation of the proximal flare of the stent to the esophageal mucosa with clips may be useful to avoid stent migration. According to a previous report, fixation of the upper flare end of the stent to the esophageal mucosa with clips reduced the migration rates of fully covered stents from 34% to 13%.^[12] Alternatively, an endoscopic suturing device could be used. According to a report, this method successfully prevents stent migration; unfortunately, the endoscopic suturing device is not universally available.^[13]

When using SEMS to treat an anastomotic leak, the optimal time to remove the SEMS is important. The time to heal can be ascertained only after stent extraction. If the stent is removed too late, the complications associated with stent removal may be high. If the stent is removed too early, the closure of the leaks may be incomplete. Animal studies have suggested that 4 weeks may be sufficient for tissue healing.^[10] Previous clinical studies have shown that the optimal time to remove the SEMS was within 6 weeks.^[3,7] The removal of the SEMS within 6 weeks is associated

with higher complications such as bleeding, stent fracture, stent impaction, and aorto-esophageal fistula.^[7,9] A previous animal study using pigs reported on the reaction of the normal esophageal wall to the insertion of self-expanding nitinol stents. An inflammatory reaction with fibrotic activity and degeneration of the muscular layers was demonstrated between 1 and 8 weeks after stent insertion.^[18] Longer duration of treatment with SEMS may be associated with esophageal wall perforation and fistula formation with the aorta or trachea.^[9,19] In the present study, all the SEMS were removed between 4 and 6 weeks; bleeding was seen in 1 case, but it was self-limiting. One patient showed stricture after healing of the mucosa, which was relieved by repeated endoscopic esophageal balloon dilations. A previous study reported that the complete closure rate of the defect was 70% when the stent was removed 6 weeks after stenting.^[7] Another study showed that the complete closure rate was 77.6% when the stent was removed at 2 weeks after stenting.^[16] However, the complete closure of leaks was achieved in all patients in the present study when the stent was removed between 4 and 6 weeks after stenting. The different results might be associated with the enrolled study population. In the present study, we restricted our cases to anastomotic leaks after total gastrectomy. However, other study groups included causes such as iatrogenic perforation, Boerhaave syndrome, and other causes.^[7] In the present study, among anastomotic leak treatment after gastrectomy cases, the stent removal time between 4 and 6 weeks resulted in a higher complete closure rate and low complications associated with stent removal.

If the predicting factors associated with the complete closure of anastomotic leaks by fully covered SEMS placement are known, we can choose an adequate treatment modality more easily. In the present study, we could not analyze the associated factors regarding the clinical success rate because of the small sample size. The reported factors associated with clinical success (complete closure of leaks) were the size of the leaks (<15 mm), earlier diagnosis of the leaks, infectious status, and time of stent place maintenance.^[3,11,12] A longer delay between leak occurrence and treatment is associated with poor prognosis due to septic complications from infected fluid accumulation in the abdominal or pleural cavity.^[10] In the present study, the time between gastrectomy and stent placement was between 9 and 43 days. Infectious status was evaluated by C-reactive protein level, abdominal/chest computed tomography, and leak findings on endoscopy. While the SEMS was in place, contaminated spaces should be drained by wound opening or percutaneous drainage.^[20] In the present study, all patients had abnormal fluid collection in

the abdominal or thoracic cavity. Abscess formations were suspected in 2 patients after abdominal/chest computed tomography and persistent fever despite intravenous antibiotics. Percutaneous drainage was performed in these patients. In the remaining 5 patients, who had no evidence of uncontrolled infection by intravenous antibiotics, abnormal fluid collection was resolved only with the placement of SEMS without drainage. In the present study, the size of the leaks was between 10 and 40 mm in maximal diameter and the stent in place time was 28 to 42 days. Though different leak sizes and stent indwelling time were seen, clinical success was achieved in all patients. An anastomotic stricture 40 mm in length requiring endoscopic balloon dilation was present in 1 patient. The mucosal tissue hyperplasia at the tip of the stent and the embedding stent tip on the esophageal mucosa might be a causative factor for stricture rather than leak size in esophageal stricture. Tissue hyperplasia and an embedded stent tip interfered with gentle extraction of the stent. Removal of the underlying esophageal tissue beneath the stent might cause extensive bleeding and ulcerations.

There are some limitations of this study. First, the present study was retrospective in design using an academic referral center. Second, the small sample size of our study may not allow for generalization of the study results. Third, because of the small sample size, the associated risk factors with incomplete leak closure or complications could not be analyzed. Further prospective studies comparing other types of SEMS or surgical intervention may provide more valuable information.

In summary, in patients with an anastomotic leak after gastrectomy to treat gastric cancer, fully covered SEMS placement is an effective and safe alternative treatment option to surgical reoperation. Stent migration can be prevented by using Shim technique. Complications such as bleeding associated with stent removal and stricture can be managed by performing endoscopic maneuver without other surgical procedures.

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