



Temporary self-expandable metallic stent placement in post-gastrectomy complications

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Abstract

Background Self-expandable metallic stents in the upper gastrointestinal tract are used for treating malignant esophageal or gastroduodenal outlet obstructions and fistulas. Recently, self-expandable metallic stent use has been expanded to benign esophageal or gastroduodenal strictures and post-operative complications. However, there is scarce data available regarding efficacy, long-term complications, and outcomes with the use of self-expandable metallic stent in benign disease, especially post-gastrectomy complications.

Methods Data of 57 patients who underwent upper gastrointestinal tract self-expandable metallic stent insertion for post-operative complications between March 2009 and June 2017 were analyzed. All patients underwent a curative gastrectomy for gastric cancer. Data collected included patient demographics, indication for procedure, type of stent used, complications, and patient outcomes.

Results Self-expandable metallic stent placement was technically successful in all patients. Of the 57 patients, 33 had self-expandable metallic stent placement for anastomosis site leakage, 12 for anastomosis site refractory stricture, and 12 for obstruction due to angulation. After self-expandable metallic stent placement, symptomatic improvement was achieved in 56 patients (98.2%), among which, three patients (5.4%) had recurrent symptoms, two underwent repeated stent insertion, and one underwent balloon dilatation. After self-expandable metallic stent placement, median time to initiating dietary intake was 6 days (range 1–30 days), and median duration of hospitalization was 13 days (range 3–135 days). At the follow-up (mean 24.6 months), migration was the most commonly reported complication, which developed in 15 (26.3%) patients.

Conclusions Self-expandable metallic stent placement is an effective and safe treatment for post-gastrectomy anastomosis site leakage, stricture, and obstruction, which can decrease the risk of reoperation related mortality and modalities.

Keywords Stent · Post-gastrectomy complications · Gastrointestinal tract

Introduction

Self-expandable metallic stent (SEMS) insertion into the upper gastrointestinal (GI) tract has been used for the palliative treatment of malignant esophageal or gastroduodenal outlet obstructions and fistulas [1–3]. Recently, the use of

SEMS has expanded to benign esophageal or gastroduodenal strictures, which are resistant to balloon dilation or bougienation. Its use in patients with complications after upper GI surgery, such as anastomosis site leakage or stricture, has also been reported [4].

Gastric cancer is the fourth most common type of cancer worldwide and large numbers of patients undergo gastrectomy [5]. Post-gastrectomy complications, such as anastomotic stricture, leakage, and obstruction, are rare but important, and conventionally require reoperation to resolve the condition. Reoperation increases the risk of condition deterioration and puts a psychological and social economic burden on patients. Recently, the temporary use of SEMS in post-gastrectomy complications has been reported [4, 6]. However, there is scarce data available regarding efficacy,

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complications, and outcomes with use of SEMS in benign disease, especially for post-operative complications. Therefore, its use in patients with post-operative benign disease is not well established. The concerns for the associated complications and difficulty in stent removal still also remain.

In the present study, we evaluated the efficacy and safety of temporary SEMS placement in post-gastrectomy patients including complications and stent removal.

Patients and methods

From March 2009 to June 2017, a total of 2680 curative gastrectomies were performed at our hospital, and 591 patients developed post-operative complications. During the study period, 57 patients who underwent SEMS insertion into the upper GI tract for post-gastrectomy complications at Seoul St. Mary's Hospital, Seoul, Korea, were retrospectively enrolled. All enrolled patients met the following inclusion criteria: (1) underwent curative gastrectomy, which was defined as macroscopically no residual tumor and margin negative surgical resection, and (2) diagnosed as having post-gastrectomy mechanical complications including obstruction, stricture, or leakage by endoscopy, computed tomography (CT), and/or upper GI tract (UGI) series imaging (Fig. 1). In cases with obstruction after gastrectomy, A loop or E loop syndrome, which was caused by loop kinking, volvulus or acute angulation. A loop or E loop syndrome with other etiologies, including such as malignant reasons or post-operative adhesion, were excluded. For cases with anastomotic stricture, patients with persistent or recurrent anastomotic stricture after at least two balloon or bougie dilatation procedures were included. The indications of patients with leakage included benign post-operative fistulae, anastomotic leakage and iatrogenic perforations with or without septic condition.

Patients who were followed up for less than 6 weeks and had SEMS insertion due to disease progression or recurrence after a gastrectomy were excluded.

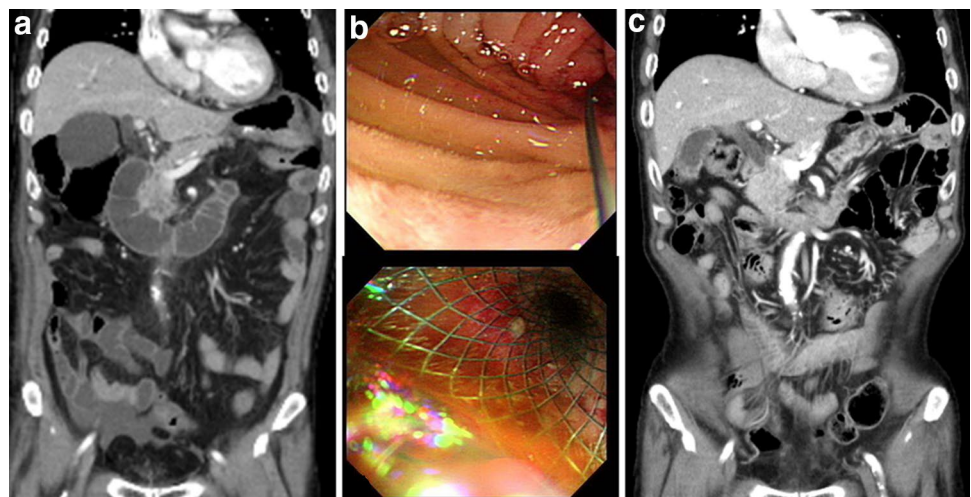
Data collected included patient demographics, indications for the procedure, type and characteristic of SEMS, patient outcomes, and complications.

SEMSs were placed via endoscopy and fluoroscopy with a guide wire. Endoscopy was performed to confirm the correct positioning and expansion of the stent within the stricture. All procedures were performed by three expert gastroenterologists. Type, length and diameter of SEMSs were determined by patients' clinical condition based on endoscopic and fluoroscopic images that were performed by gastroenterologists. Additional therapy, such as percutaneous drainage by radiological intervention, was performed in cases of persistent leakage with abscess.

Patients were asked to progressively increase from the ingestion of liquids up to a normal diet without restriction, according to their condition. In addition, patients underwent endoscopy, UGI, or abdominal CT to confirm the resolution (Fig. 1). Persistent improvement was defined as no recurrence of dysphagia and no recurrence of the stricture at least after the 1-month follow-up.

Primary endpoints were the technically and clinically successful treatment of post-gastrectomy complications. Technical success was defined as the successful insertion of the SEMS device across the target lesion. Clinical success was defined as the ingestion of a normal diet without any other symptoms after SEMS placement. Hospitalization was another measure of clinical outcome, defined as the number of days that patient stayed in hospital from the day when SEMS insertion took place to the discharge. In addition, we investigated the success of SEMS removal and complications. All patients were followed up at our institution. The Institutional Review Board of our institution approved this study (KC17RESI0485).

Fig. 1 Use of SEMS in A loop syndrome after subtotal gastrectomy with Billroth II reconstruction. **a** Fluid distended afferent loop on the 13th post-operative day. **b** An SEMS was inserted at the gastrojejunostomy anastomosis site with a guide wire. **c** Regression of A loop syndrome after stent insertion



Results were expressed as mean ± standard deviation (SD), and medians with range, as appropriate. The Mann–Whitney *U* test and Pearson’s χ^2 test for categorical variables were used as appropriate. Statistical analyses were performed using SAS software package (ver. 8.02, SAS Institute, Cary, NC, USA).

Results

Baseline characteristics of patients and SEMSs

Our study involved 57 patients; 39 were male with a mean age of 64.8 (± 10.5). The most common type of surgery and

anastomosis method were the total gastrectomy and Roux-en-Y methods, respectively. Among 41 patients who underwent total gastrectomy, anastomosis site leakage (29/41, 70.7%) was the most common indication for SEMS insertion. Of the 26 patients who underwent subtotal gastrectomy, obstruction due to A loop or E loop syndrome (8/16, 50.0%) was the most common indication for SEMS insertion. The mean follow-up period was 24.6 months (Table 1).

Table 2 summarizes the characteristics of the SEMSs. In total, 59 SEMSs were placed in 57 patients (median 1, range 1–2); 57 SEMSs were placed initially and two additional SEMSs were placed due to symptom recurrence. Among the two patients with additional SEMSs, the first patient had initial SEMS placement due to E loop syndrome and the secondary SEMS was placed because of migrated index SEMS without symptom improvement. The second patient with anastomotic stricture had secondary SEMS placement overlying the index SEMS.

A fully covered SEMS was the most commonly used. SEMSs with the diameter ranging 18–22 mm and length ranging 60–160 mm were used. The median time interval between SEMS insertion and gastrectomy was 16 days (range 3–645). The median stenting duration was 31 days (range 2–1165).

Clinical outcomes and complications

All SEMSs were successfully placed. Among the 57 patients, 56 achieved a clinical improvement. The remaining one patient underwent SEMS insertion due to E loop syndrome, and underwent reoperation to resolve the obstruction. Of the 56 patients, 53 achieved long-term clinical success. Meanwhile, three patients with anastomotic stricture, leakage, and E loop syndrome had symptom recurrence; the two patients with anastomotic stricture and E loop syndrome underwent

Table 1 Demographic and clinical characteristics of patients

Age, year (mean ± SD)	64.8 ± 10.5
Sex, % (no./total no.)	
Male	68.4 (39/57)
Female	31.6 (18/57)
Indication, % (no./total no.)	
Anastomotic leakage	57.9 (33/57)
Anastomotic stricture	21.1 (12/57)
A loop or E loop syndrome	21.1 (12/57)
Type of surgery, % (no./total no.)	
Subtotal gastrectomy	28.1 (16/57)
Total gastrectomy	71.9 (41/57)
Reconstruction methods, % (no./total no.)	
Billroth I	12.3 (7/57)
Billroth II	14.0 (8/57)
R en Y	73.7 (42/57)
Follow-up duration, month, (mean ± SD)	24.6 ± 18.6

Data are expressed as number (%) or mean ± SD as appropriate

Table 2 SEMS characteristics according to the indications

	Total (N=57)	Anastomotic leakage (N=33)	Anastomotic stricture (N=12)	A loop or E loop syndrome (N=12)
Type of SEMSs				
Full covered	51 (89.5%)	32 (97.0%)	10 (83.3%)	9 (75.0%)
Partial covered	3 (5.3%)	1 (3.0%)	1 (8.3%)	1 (8.3%)
Uncovered	3 (5.3%)	0 (0.0%)	1 (8.3%)	2 (16.7%)
Stent diameter (mm)				
18	21 (36.8%)	17 (51.5%)	0 (0.0%)	4 (33.3%)
20	22 (38.6%)	5 (15.2%)	9 (75.0%)	8 (66.7%)
22	14 (24.6%)	11 (33.3%)	3 (25.0%)	0 (0.0%)
Stent length (cm)				
6–8	27 (47.4%)	13 (39.4%)	5 (41.7%)	9 (75.0%)
9–11	22 (38.6%)	14 (42.4%)	5 (41.7%)	3 (25.0%)
12–16	8 (14.0%)	6 (18.2%)	2 (16.7%)	0

Data are expressed as number (%)

an additional SEMS placement. The one patient with anastomotic leakage had anastomosis site stricture after removal of the index SEMS and underwent balloon dilatation.

Initiation of a regular diet was available after a median of 6 days (range 1–30 days) after the index SEMS insertion, and the median hospitalization duration was 13 days (range 3–135 days). According to the indications, patients with anastomotic leakage had a longer time interval from index SEMS placement and normal dietary intake, as well as a longer hospital stay (Table 3).

At 3 months after SEMSs insertion, a total of 56 patients were followed up, and one patient was followed up loss at 53 days after SEMS insertion. All the followed up patients achieved the long-term clinical improvement. However, seven patients had prolonged hospital stay (range 33–135 days) due to other clinical reasons, such as aspiration pneumonia. Moreover, six patients (6/56, 10.7%) had retained stents at 3 month after SEMS insertion.

Complications after SEMS placement were observed during the follow-up. Migration of the SEMS occurred in 15 patients. All migrated SEMSs were distal; six migrated to the large bowel and were expelled spontaneously, and nine migrated to the small bowel, which were 5–20 cm distally from the index site. Among nine patients of migrated to small bowel, six patients had no other complications. Two patients had small bowel perforation and one patient had obstruction due to the migrated stent and subsequently underwent surgery. No other severe adverse events, such as a death, were reported (Table 3). Among the patients with migrated stents, 12 (80.0%) were asymptomatic and were

found incidentally at the regular every 1-month follow-up after SEMS insertion. Only three patients (20.0%) had symptoms; the two with perforation complained of abdominal pain and fever, and the one with obstruction had abdominal pain and vomiting.

Stent removal

In a total of 57 patients, 44 underwent attempted SEMS removal endoscopically; 43 (97.7%) patients achieved successful endoscopic SEMS removal. The remaining one patient had a non-covered SEMS, which resulted in failure of endoscopic removal because of tissue hyperplasia. Endoscopic SEMS removal was performed by pulling back with rat-tooth forceps without any complications. Of the remaining 13 patients, three patients underwent SEMS removal during surgery, of which two underwent emergency surgery due to stent-related perforation, and one underwent surgery due to adhesive ileus. Three patients decided to retain the SEMS at end of the study and one patient was lost to follow-up (Table 3).

Discussion

We investigated the temporary use of SEMSs for the treatment of post-gastrectomy complications, including leakage, stricture, and obstruction. Leakage and obstruction were the representative life-threatening post-gastrectomy complications that required prompt treatment. Conventional treatment

Table 3 Clinical outcomes and complications according to the indications

	Total (N=57)	Anastomotic leakage (N=33)	Anastomotic stricture (N=12)	A loop or E loop syndrome (N=12)
Technical success	57 (100%)	33 (100%)	12 (100%)	12 (100%)
Clinical success	56 (98.2%)	33 (100.0%)	12 (100.0%)	11 (91.7%)
Recurrence of symptom, no./total no	3/56 (5.4%)	1/33 (3.1%)	1/12 (8.3%)	1/11 (9.1%)
Methods of SEMSs removal				
Endoscopic removal	43 (75.4%)	32 (97.0%)	5 (41.7%)	6 (50.0%)
Surgery	3 (5.3%)	0 (0.0%)	1 (8.3%)	2 (16.7%)
Spontaneous expulsion	6 (10.5%)	1 (3.0%)	3 (25.0%)	2 (16.7%)
Time interval between gastrectomy and stent placement, days (range)	15.0 (3–645)	11.0 (3–71)	84.5 (14–455)	16.5 (10–645)
Stenting duration, days (range)	31 (2–1165)	31 (11–113)	37 (12–718)	29 (2–1165)
Time interval between stent placement and diet, days (range)	6 (1–30)	7 (2–30)	3 (1–8)	2.5 (1–14)
Duration of hospitalization, days, median (range)	13 (3–135)	15 (7–135)	8 (3–28)	10 (6–29)
Patient no. with additional procedures	3 (5.3%)	1 (3.1%)	2 (16.7%)	2 (16.7%)
Complication				
Migration	15 (26.3%)	6 (18.2%)	5 (41.7%)	4 (33.3%)
Perforation	2 (3.5%)	0	2 (16.7%)	0

Data are expressed as number (%) or median (range) as appropriate

of leakage is conservative care with or without drainage, but it frequently leads to reoperation. In addition, the treatment principal of post-gastrectomy obstruction is operation. And reoperation increases the morbidity and mortality rates. In our study, post-operative SEMS insertion was safe and achieved a high technical and clinical success rate. Although it is difficult to compare hospital stay or dietary goal with other studies, through these successful cases of SEMS insertion, the duration of hospitalization might be significantly reduced compared with prolonged conservative care and/or reoperation.

In our study, temporary placement of SEMS for anastomosis site leakage was safe and effective. Swinen et al. and Bege et al. investigated temporary SEMS insertion due to leakage after bariatric surgery [7, 8]. Although these studies included the sleeve gastrectomy or gastric bypass surgery, which were different from our study, the result of a favorable success rate was consistent. Other studies assessed both early (< 30 days) and late (> 30 days) referral after detection of post-operative leakage or fistula; early intervention was reported to have a higher success rate [8, 9]. In our series, all selected patients with post-operative leakage underwent immediate endoscopic SEMS placement, which was indicated to lead to a high success rate.

Guidelines recommend SEMS insertion for benign upper GI disorders in limited cases [3, 10, 11]. Refractory stricture is one of the indications. There are varying results from studies regarding the use of SEMS or self-expandable plastic stent (SEPS) placement for benign esophageal stricture, including post-operative anastomotic strictures, which are controversial [9]. According to various studies, SEPS are easier to remove and have a lower late complication rate than SEMS; however, the long-term clinical improvement rate is lower [12–14]. Fully covered SEMSs are thought to have a low late complication rate and can be easily removed like plastic stents. We investigated the refractory post-operative anastomotic stricture with fully covered SEMS placement, and all patients had symptom improvement without long-term recurrence or complications. We found that the temporary SEMS placement for refractory stricture was effective.

A loop and E loop syndrome are relatively rare complications after gastrectomy, as reported in 0.3–1.0% of cases [15, 16]. We experienced 12 patients with A loop or E loop syndrome treated with temporary SEMS insertion. We achieved a 100% technical success rate and 91.7% (11/12) clinical success rate. In addition, these patients took a median of 2.5 days to achieve a normal diet after SEMS placement, which was an encouraging result. Despite these encouraging initial outcomes, we experienced four migration cases with fully covered SEMSs, one of which was subjected to emergency surgery due to perforation. Emergency surgery was also required in case with an uncovered SEMS, which had adhesive ileus. Furthermore, there are no study reports,

only a case report, regarding the temporary placement of an uncovered SEMS in post-gastrectomy A loop or E loop syndrome [15]. Therefore, more case-controlled studies are required to confirm and standardize a safer and more effective SEMS protocol in post-gastrectomy obstruction.

In our study, the most common complication was migration, which was consistently reported by other studies [9, 17, 18]. As we expected, most of the migratory cases were with fully covered SEMSs in our study (13/15, 86.7%), which was a slightly lower migration rate than in the previously mentioned studies. We placed the SEMS with clips on the proximal part of the stent to prevent stent migration, as described in various studies [7, 19]. We also observed one migration patient with a partially covered SEMS, as was shown in Deviere's team series [20]. In addition, three of the migration cases (3/15, 20.0%) resulted in perforation and obstruction due to the stent, which led to emergency surgery. Therefore, careful observation is required. In our study, we had too small number of patients with small bowel perforation to investigate risk stratification. In other studies, avoiding fully covered SEMSs as well as use of long stent, clipping on proximal part of stents, and anchoring of proximal ends into the mid esophagus reduced the migration of SEMSs [7, 9, 19]. Although there was no definite guideline for duration of temporary SEMSs insertion, our study presented median 31 days, which was determined by patients' clinical condition. Many studies recommended the removal of SEMSs within 6 weeks [8, 21, 22], and this is consistent with our study. Further studies are needed to find better patient, SEMS selection and better procedures including duration of temporary SEMSs insertion.

Our study has some limitations. This study was a single-center retrospective study. The minor complications including symptoms of post-SEMS insertion were not investigated precisely. In addition, we could not access the outcome of conventional therapy for post-gastrectomy complications as control group. Further head to head comparison studies of SEMSs insertion versus conventional treatment for post-gastrectomy complications would be needed to confirm and extend the findings of our study. However, a strength of our study is the tightly controlled follow-up of the patient cohort after gastrectomy for early gastric cancer, with uniformly performed endoscopic procedures by expert gastroenterologists. Our experience suggests the endoscopic procedures could be one choice to treat post-gastrectomy complications. It also could be considered as an alternative to surgical management, especially in high-risk reoperation patients.

In conclusion, the use of temporary SEMSs for the treatment of post-gastrectomy complications, such as stricture, leakage, and obstruction, is feasible, safe, and effective. Our results suggest that endoscopic temporary SEMS placement could reduce the risk of reoperation. However, improvements to the SEMS are still required, as well as the

standardization of the procedure according to the indication of post-gastrectomy complications.

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Compliance with ethical standards

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions.

Conflict of interest The authors declared that they have no conflict of interest.

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