

Clinical outcomes and patency of self-expanding metal stents in patients with malignant colorectal obstruction: a prospective single center study

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Abstract

Backgrounds and aims Self-expanding metal stents (SEMS) have been used as a palliative treatment for malignant colorectal obstruction. However, the reports about primary stent patency rate and associated factors have been limited. This study was performed to evaluate clinical outcomes and factors associated with long-term complications and patency of SEMS in patients with malignant colorectal obstruction.

Materials and methods Patients who underwent palliative endoscopic placement with uncovered SEMS for a malignant colorectal obstruction were prospectively enrolled at Seoul National University Hospital between April 2005 and August 2007.

Results Forty-nine patients underwent 51 SEMS placements. Obstruction sites were rectum in 15 patients (30.6%), descending or sigmoid colon in 25 (51.0%), and transverse colon in nine (18.4%), respectively. The causes of obstruction were colorectal cancer in 36 patients (73.5%), direct invasion of gastric cancer in seven (14.3%) and others in six (12.2%). Technical success was achieved in 100% and clinical success in 86%, and there was one procedure-related perforation. Re-obstruction and migration occurred in 16% and 6%, respectively, during mean follow-up period of 331 days. Median stent patency duration was 204 days, and patency rates at 30, 90, and 180 days were 91.2%, 81.0%, and 53.3%, respectively, which was not associated with patient demographics, site of obstruction, or palliative chemotherapy.

Conclusion Endoscopic SEMS placement is a safe and effective palliative treatment for malignant colorectal obstruction, and overall long-term complication and patency were favorable irrespective of the palliative chemotherapy.

Keywords Colorectal cancer · Malignant obstruction · Self-expanding metal stents · Patency

Introduction

Malignant obstruction is the most common cause of emergent colorectal surgery, and up to 30% of patients with primary colorectal cancer present with obstructive symptoms. However, emergent surgical decompression is associated with high morbidity and mortality, and curative resection is not feasible in up to 30% of patients with obstruction because of extensive tumor infiltration, distant metastasis, or severe co-morbidity [1, 2]. In addition, surgical decompression often results in a temporary or permanent colostomy, which has a negative impact on quality of life [3].

Self-expanding metal stents (SEMS), which expand radially upon deployment, are currently used to treat variable sites of the gastrointestinal tract and biliary obstruction [4]. The placement of SEMS to relieve malignant colorectal obstruction was first described by Dohmoto [5], and since then, they have been widely used as a bridge to surgery allowing single-stage operation or as a definitive palliative procedure with the availability of more dedicated stents and delivery systems [6–8]. A pooled analysis found that colonic stenting has technical and clinical success rates of 94% and 91%, respectively, and concluded that it is a safe definitive procedure for the palliation of malignant colorectal obstruction [9, 10]. Despite recent advances, stent re-obstruction by

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progressive tumor ingrowth or overgrowth and stent migration still pose problems that necessitate additional intervention. In addition, the majority of studies conducted to date has been retrospective and involved small groups of patients that were treated with stents either as a palliative measure or as a bridge to surgical intervention and not addressed long-term stent patency and related factors [10, 11].

The purposes of this prospective study were to evaluate clinical outcomes, including technical and clinical success rates, and to identify factors associated with long-term patency of SEMS in palliation for advanced malignant colorectal obstruction.

Materials and methods

Patients

Patients who underwent palliative endoscopic SEMS (M.I. Tech, Seoul, Korea) placement for a malignant colorectal obstruction were prospectively enrolled at Seoul National University Hospital between April 2005 and August 2007. Due to the presence of advanced or metastatic disease or a high surgical risk, none of these patients was suitable for curative surgical treatment. Patients were excluded if they had already undergone palliative surgery or fluoroscopy-guided stent placement or had experienced recurrence at an anastomotic site after curative surgery. Information concerning the following was collected: age, sex, site of obstruction, diagnosis, stent types, procedure outcomes (technical success and procedure-related complications), clinical outcomes, palliative chemotherapy after stent placement, complications including tumor overgrowth, ingrowth, and stent migration, and time to complication or death. Informed consent was obtained from all patients before SEMS placement, and the study was approved by the ethics committee of the Seoul National University Hospital (IRB No. H-0610-006-185) and performed in accordance with the Declaration of Helsinki.

Endoscopic SEMS placement

Before stent placement, site, degree, and length of obstruction were assessed by computerized tomography (CT), conventional colonoscopy, and/or water-soluble contrast enema. Stent size and length were chosen according to the measured lengths of obstructions, and uncovered stents (diameter, 18, 20, 22, or 24 mm) were used. The length of stent was chosen to be at least an additional 3 cm on each side of the obstruction to allow adequate margins. Generally, patients underwent cleansing enemas for bowel preparation and were maintained under conscious sedation with intravenous 0.05 mg/kg midazolam [12]. All procedures were per-

formed under endoscopic guidance using a conventional endoscope (CF-H260, Olympus, Tokyo, Japan) by one expert endoscopist (Fig. 1). When the endoscope passed through the obstructive lesion, a flexible biliary guide-wire (Terumo, Tokyo, Japan) was inserted through the endoscope channel without fluoroscopic guidance [12]. If the endoscope could not pass the obstructive lesion, the length of obstruction was measured by CT finding or water-soluble contrast enema, and the flexible guide-wire passed easily through the

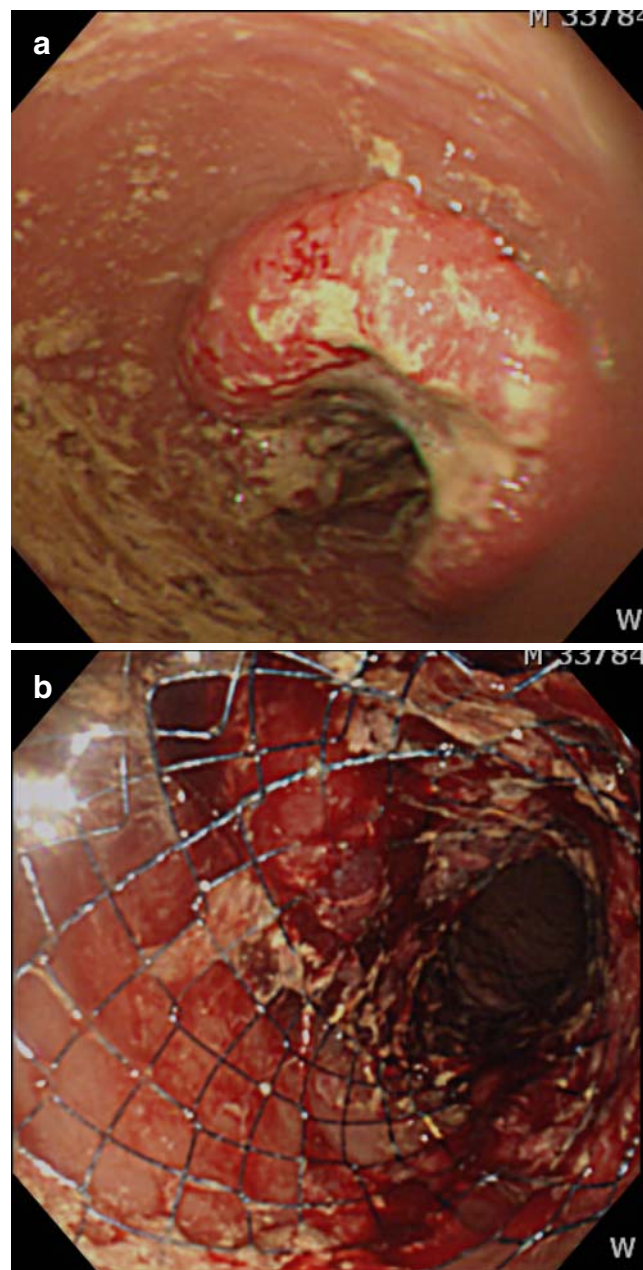


Fig. 1 Self-expanding metal stents (SEMS) placement to palliate malignant obstruction in a 69-year-old patient with sigmoid colon cancer. Endoscopic view of rectosigmoido-junctional obstruction caused by sigmoid colon cancer (a), and SEMS (M.I. Tech) immediately after successful deployment (b)

obstructive lesion under endoscopic guidance without fluoroscopy. Once stent was passed along the guide-wire across the obstruction through the endoscope channel, stent was deployed under direct endoscopic guidance. After placement, adequate positioning and expansion of stent was confirmed by simple abdomen radiography.

Clinical outcomes and stent patency

Technical success was defined as successful deployment across an obstructing lesion and clinical success as an acceptable colonic decompression, i.e., enough to relieve the obstructive symptoms and signs [7]. Patients that achieved technical and clinical success were followed at intervals of 1 to 3 months to observe complications and document survival. Stent patency duration was defined as the time between stent placement and recurrence of obstructive symptoms caused by tumor overgrowth, ingrowth, or stent migration, which were confirmed either endoscopically or radiologically. When no stent-related complication occurred, patency duration was considered to equal survival time, but such cases were censored from patency duration analysis. Relations between patient demographics, obstruction site, diameter of stent, diagnosis or palliative therapy, and long-term complication and stent patency were investigated.

Statistical analysis

Results were expressed as mean±standard deviation (SD) or as percentages (number, percent). Statistical analysis was performed using the chi-squared test, Student's *t* test, or Fisher's exact test. Stent patency and the patient survival were calculated using Kaplan–Meier method, and findings were compared using log rank test. Putative predictors of patency duration were identified using the chi-squared test or Fisher's exact test: patient age at time of stent placement, sex, diagnosis, diameter of stent, chemotherapy after stent placement, and patient survival. Factors associated with patency duration were assessed using Cox multivariable regression analysis for patients who achieved technical and clinical success. *P* values of less than 0.05 were considered statistically significant. All statistical analyses were conducted using SPSS software (version 12.0, SPSS, USA).

Results

Patients' characteristics

A total of 49 patients (36 men; mean age, 63.6 years; range, 22–86 years) with a malignant colorectal obstruction underwent 51 SEMS placements (Table 1). Two stents were used

Table 1 Patients' characteristics

Characteristics	
Age (years, mean±SD)	63.6±12.8
Male, <i>n</i> (%)	36 (73.5)
Site of obstruction, <i>n</i> (%)	
Rectum	15 (30.6)
Sigmoid or descending colon	25 (51.0)
Proximal to splenic flexure	9 (18.4)
Diagnosis, <i>n</i> (%)	
Colorectal cancer	36 (73.5)
Gastric cancer	7 (14.3)
Others	6 (12.2)
Stage, <i>n</i> (%)	
II or III	4 (8.2)
IV	45 (91.8)

SD Standard deviation

in two patients with peritoneal seeding from gastric and prostatic cancer to cover different sites of obstruction and a long segment obstruction, respectively. Sites of obstruction were rectum in 15 patients (30.6%), descending or sigmoid colon in 25 (51%) and transverse colon in nine (18.4%). The causes of obstruction were colorectal cancer in 36 patients (73.5%), metastasis from gastric cancer in seven (14.3%), and others in six (12.2%). Four patients (8.2%) with locally advanced colon cancer did not undergo curative resection due to a poor general condition. Twenty-three patients (46.9%) received palliative chemotherapy after stent placement.

Technical and clinical outcomes

Successful deployments of SEMS were achieved in 51 placements (100%), and clinical success was achieved in 86% (43 cases) of the 50 placements without complication. In two patients who received two stents with a week interval, their obstructive symptoms were not alleviated due to multiple intestinal obstructions caused by peritoneal seeding. Three mortalities occurred due to disease progression or a complication associated with colonic obstruction within a week of SEMS placement.

Complications and subsequent interventions

In one male patient with a sigmoid colonic obstruction, perforation occurred immediately after stent deployment, and the patient received emergent palliative left hemicolectomy. Although minor complication, such as abdominal pain and tenesmus, was improved with conservative management, there was no significant stent-related bleeding. Twelve long-term complications (24%) occurred among 50 SEMS placements in 43 patients who achieved

clinical success during a mean follow-up period of 331 days (range, 23–655; Table 2). The most common complication was re-obstruction caused by tumor ingrowth and overgrowth, which occurred in six (12%) and three cases (6%), respectively, followed by stent migration (three cases; 6%). There was one case of perforation in a patient with rectal cancer 87 days after SEMS placement proximal to the stent placement site and required a Hartmann operation. Additional SEMSs were placed in six cases that developed re-obstruction. Three patients who developed re-obstruction due to tumor overgrowth or ingrowth underwent palliative surgery and achieved a satisfactory clinical outcome. Of the three patients in whom stent migration occurred, obstructive symptoms were not evident in two who had good response to chemotherapy, and no further intervention was necessary in these two cases. The remaining patient was treated with a second SEMS placement after stent removal because of recurrent obstruction and achieved clinical success. A total of three SEMSs were placed due to migration and re-obstruction by tumor ingrowth in one patient with a sigmoid colonic obstruction.

Survival and stent patency

A total of 17 patients (39.5%) died with a median survival of 327 days (Fig. 2a). Stent patency rates at 30, 90, and 180 days were 91.2%, 81.0%, and 53.3%, respectively, and median stent patency duration was 204 days. Predictors of stent patency identified by univariate analysis were entered into a Cox multivariate regression model (Table 3). Stent patency was not found to be associated with site of obstruction, underlying malignancy, diameter of stent, or palliative chemotherapy (Fig. 2b) after controlling for patient age and survival.

Discussion

Acute colorectal obstruction is usually caused by malignancy and poses a potentially life-threatening emergency with a poor prognosis. It has been estimated that 7–29% of

Table 2 Long-term complications of self-expanding metal stents (SEMS) in relation to obstruction site

Complications	Rectum, 12 [n (%)]	Left colon, 28 [n (%)]	T-colon, 10 [n (%)]	50 [n (%)]
Overall	1 (8.3)	8 (28.6)	3 ^a (30)	12 (24)
Tumor ingrowth	0 (0)	4 (14.3)	2 (20)	6 (12)
Tumor overgrowth	0 (0)	2 (7.1)	1 (10)	3 (6)
Stent migration	0 (0)	2 (7.1)	1 (10)	3 (6)
Perforation	1 (8.3)	0 (0)	0 (0)	1 (2)

^a Ingrowth and overgrowth in one patient

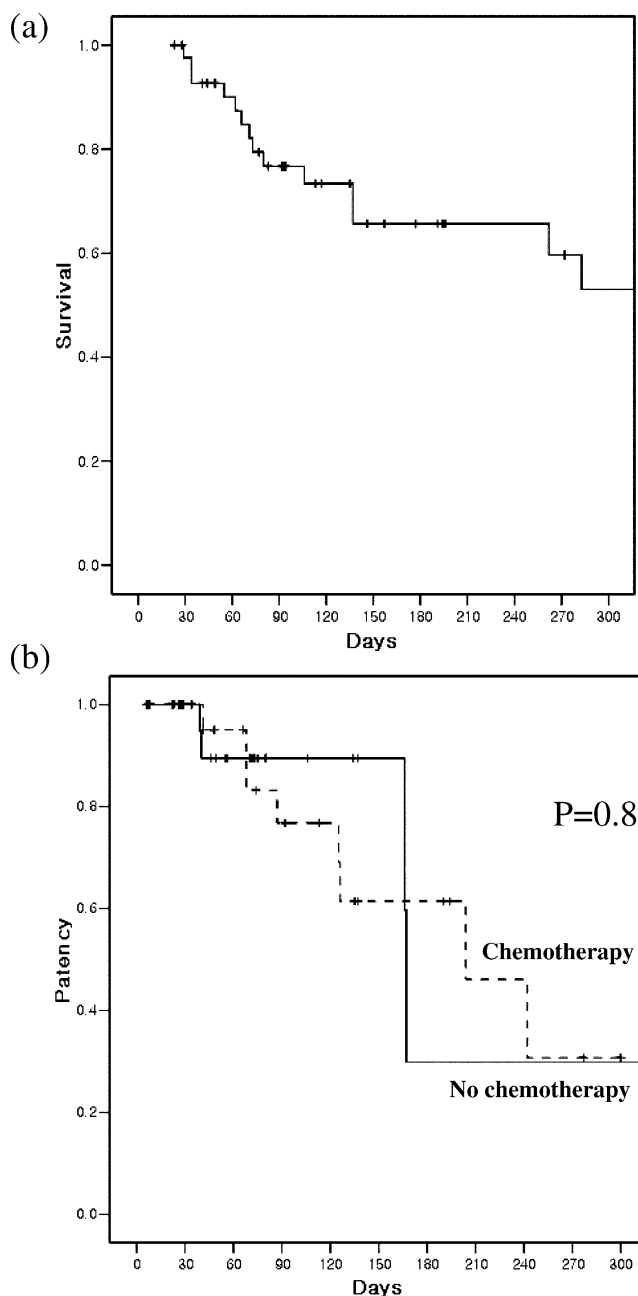


Fig. 2 Kaplan–Meier curve of patient survival (a) and stent patency according to palliative chemotherapy (b). Median survival was 327 days, and stent patency duration was not significantly different according to chemotherapy

patients with primary colorectal cancer presents with colorectal obstruction, and patients that present in this manner tend to have more advanced disease [13]. Moreover, emergent colonic resection of an unprepared bowel is associated with higher morbidity and mortality, and therefore, staged procedure creating colostomy is usually advocated [14, 15]. However, the colostomy is likely to be permanent in patients that undergo a palliative operation, which has a negative impact on quality of life. Patients with a large bowel obstruction due to extensive local or

Table 3 Univariate analysis of long-term complication

Variables	Complication, <i>n</i> (%)		<i>P</i> value
	Yes	No	
Age			
<65 years	4 (18.2)	18 (81.8)	0.39
≥65 years	8 (28.6)	20 (71.4)	
Sex			
Male	10 (26.3)	28 (73.7)	0.71
Female	2 (16.7)	10 (83.3)	
Diagnosis			
Colorectal cancer	12 (31.6)	25 (68.4)	0.08
Gastric cancer	0 (0)	7 (100)	
Others	0 (0)	4 (100)	
Site of obstruction			
Rectum	1 (8.3)	11 (91.7)	0.34
Left sided colon	8 (28.6)	20 (71.4)	
Transverse colon	3 (30)	7 (70)	
Diameter of stent			
22 mm or less	10 (27.0)	27 (73.0)	0.48
24 mm	2 (15.4)	11 (84.6)	
Palliative chemotherapy			
Yes	8 (33.3)	16 (66.7)	0.13
No	4 (15.4)	22 (84.6)	
Median survival			
<100 days	1 (4.3)	22 (95.7)	0.003
≥100 days	11 (40.7)	16 (59.3)	

metastatic colorectal disease are also poor operative candidates for surgical resection because many are elderly, dehydrated, in a state of electrolyte imbalance, or are unstable due to concomitant diseases [16].

Since Dohmoto reported the first case of colonic stenting, SEMs has been shown to provide rapid and effective relief of colorectal obstruction without the need for surgery. SEMs can be used as a palliative treatment in patients with an unresectable malignant colorectal obstruction or as a bridge for temporary colonic decompression in those with acute, potentially respectable colorectal cancer [6, 17, 18]. In the palliative setting, SEMs placement in colonic obstructed patients is associated with significant reductions in length of hospital stay and in rates of stoma formation, mortality rate, and medical complications compared with palliative surgery [10, 19, 20].

According to a recent pooled analysis, the technical success rate for SEMs placement by an expert is over 95%, and the clinical success rate exceeds 90% in a palliative setting [9, 10]. In the present study, comparable results were achieved with a technical success rate of 100% and a clinical success rate of 86.8%. Colonic perforation after stent placement is a well-recognized complication and is more common after balloon predilatation [1]. In the present study, one patient who did not receive predilatation developed a colonic perforation proximal the SEMs and

underwent Hartmann's operation. However, no procedure-related mortality occurred, which concurs with previous reports.

Different types of SEMs are used to provide palliative treatment for malignant colorectal obstruction according to obstruction site and length. Although covered and uncovered SEMs have similar technical and clinical success rates, they have their own advantages and disadvantages [10, 21]. Covered stents can prevent tumor ingrowth through the metal mesh, but stent migration remained as a problem that necessitates additional interventions. Conversely, uncovered stents are subject to tumor ingrowth and the resultant re-obstruction, but they present a low migration risk and have lower delayed complication rates than covered stents and thus are recommended for the palliative treatment of malignant colorectal obstructions [21, 22]. All patients were initially treated with uncovered stents in the present study, and rates of re-obstruction by tumor ingrowth and overgrowth were 12% and 6%, respectively, which are slightly higher than published rates for covered stents [9, 10]. Given the use of palliative chemotherapy, especially of therapies based on recently developed agents in advanced disease, a decrease in tumor size is not uncommon. Chemotherapy after stent placement in patients with a malignant gastric outlet obstruction was found to be independently associated with prolonged oral intake duration [23]. However, complication and long-term patency were not found to be significantly different in relation to patient demographics, diameter of stent, or palliative chemotherapy in the present study, though median survival was marginally longer in patients that received palliative chemotherapy than those who did not. Moreover, stent migration occurred in only three patients and two of whom had partial response to palliative chemotherapy without recurrent obstructive symptom. This finding supports the tumor shrinking effect of chemotherapy and suggests that it has an impact on stent patency. However, further prospective randomized trials are needed to identify other possible factors associated with complication and stent patency.

The median mean patency duration of 14 studies conducted on palliative populations was 106 days and ranged between 68 and 288 days [10, 24, 25]. These variations in stent patency duration may have been due to different demographic factors, underlying malignancies, or stent types [9, 10]. The median stent patency duration of 204 days in the present study is comparable to or longer than those of reported studies, which implies that uncovered SEMs can be used effectively in patients with colorectal obstruction in a palliative setting. A recently introduced dual-design stent has produced promising results, but further studies are needed to compare the efficacy and safety between this new stent and uncovered stent [26].

In conclusion, uncovered SEMSs were found to be effective and safe for the palliative management of patients with malignant colorectal obstruction. Overall long-term complications and patency were found to be favorable irrespective of the underlying disease, site of obstruction, diameter of stent, or palliative chemotherapy. Further prospective randomized trials are needed to identify the factors associated with stent patency to target appropriate patients, especially for newly developed SEMSs.

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