

A pilot study about the oncologic safety of colonic self-expandable metal stents (SEMS) in obstructive colon cancer: is occlusion always better than “silent” perforation?

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Abstract. – OBJECTIVE: To evaluate the oncologic safety of colonic self-expandable metal stents (SEMS) in obstructive colon cancer.

PATIENTS AND METHODS: We retrospectively reviewed all the patients who were treated with endoscopic placement of a self-expandable metallic stent (SEMS) at our institution.

RESULTS: A total of 26 patients were identified during the study period, of which 24 patients (92.30%) were treated with SEMS as a bridge-to-surgery and 2 (7.69%) as palliation. In 22 cases (80.76%), the stenosis was localized to the left side. Clinical success with resolution of bowel obstructions was achieved in 22 (84.61%) patients within a short period of time. Among patients treated successfully with SEMS insertion as bridge to surgery (n = 22), 20 (90.9%) underwent one-stage surgery with primary anastomosis while 2 patients (9.09%) underwent colostomy due to intraoperative evidence of a covered perforation by cancer tissue in the pelvis. Patients with subclinical perforation developed an early peritoneal carcinomatosis, 10 patients treated with curative intent subsequently developed liver metastasis after 24 months.

CONCLUSIONS: We reported an overall poor outcome among patients treated with the insertion of SEMS. This led us to think that, in some cases, occlusion may be better than a “silent” perforation.

Key Words:

Self-expandable metal stent (SEMS), Tumor bowel obstruction, Bridge to surgery, Silent perforation.

Introduction

With the diffusion of the westernized lifestyle, the incidence of colorectal cancer has increased¹.

Acute colonic obstruction caused by advanced

disease occurs in approximately 8-13% of colonic cancer and its management remains controversial²⁻⁹.

Emergency surgery for large-bowel obstruction is associated with higher postoperative mortality rates (15%-34%) and a probable long-term poor survival¹⁰. Furthermore, these patients usually present with more severe co-morbid conditions resulting in a higher incidence of post-surgical complications. In fact, up to 40% of them require a permanent colostomy, and have low health-related quality of life¹¹.

The use of colonic self-expandable metal stent (SEMS) placement can be used as a bridge to surgery to permit one stage surgery avoiding stoma creation. This procedure allows then the conversion from urgent to elective surgery and consequently, in many cases, from two stage operation with a colostomy to one-stage treatment with primary anastomosis¹².

Although many prospective studies¹³⁻¹⁵ supported the use of SEMS as an adequate therapeutic option for palliation or as a first-line of treatment and a bridge to surgery, their actual indications remain ill defined. In fact, a recent Cochrane systematic review, which included five randomized clinical trials, found that patients receiving emergent surgery for the palliation of malignant colorectal obstruction had better clinical success than those receiving SEMS (98.84% vs. 78.05%, $p = 0.001$)¹⁶. Other meta-analyses evaluating the use of SEMS as a bridge to surgery reported highly successful primary anastomosis and low stoma rates with the use of SEMS, but no significant differences in the rate of complications or mortality^{17,18}. Moreover, the

oncologic and clinical safety of SEMS has also been questioned in a recent experimental murine model. In fact, the results of these studies¹⁹ reported an increased rate of tumor dissemination and liver metastasis.

This study aims to evaluate the oncologic safety of the use of self-expandable metallic stents (SEMS) in the treatment of malignant colonic stenosis, either as a bridge to surgery or as a palliative measure.

Patients and Methods

Patients

Between August 2013 and March 2015, a total of 26 patients, were treated with endoscopic placement of a self-expandable metallic stent (SEMS) at the Department of Surgery of the University Hospital of Catania, Italy.

The patients included in the study belong to one of the following groups:

1. Patients with potentially curable malignant colorectal obstruction diagnosed by clinical symptoms and imaging study (abdominal x-ray and abdominal computerized tomography (CT) scan) without signs of perforation, but with increased risk of postoperative mortality (American Society of Anesthesiologists physical status > III and/or age > 70 years).
2. Patients considered inoperable or incurable due to tumor metastasis (stage IV), except patients candidates for antiangiogenic drugs, such as Bevacizumab.

The patients with the following characteristics were excluded:

1. Clinical evidence of bowel perforation, peritonitis, free intraperitoneal air on abdominal imaging
2. Rectal cancer < 5 cm from the anal verge
3. Severe heart, liver, kidney disease, or lung failure.

Preoperative and Postoperative Data Collection

All the patients underwent colonoscopic biopsy for histological confirmation of the primary tumor. The presence of distant metastasis was ruled out by liver ultrasound, chest and brain CT before the index treatment. Demographic characteristics, including age, sex, primary disease, stage of the tumor, obstruction location, were collected and retrospectively reviewed. Technical

success and complications of the procedures were also recorded. A colonic perforation contained by the stent producing no preoperative clinical signs, but only diagnosed intraoperatively, was defined as “silent”.

Description of the Endoscopic Procedure

All the patients underwent modified bowel preparation as tolerated and antibiotic prophylaxis with cephalosporin and metronidazole. Uncovered Nitinol SEMS were inserted by an expert endoscopist using the through the scope (TTS) technique. The endoscope was advanced up to the stenosis; a guide wire and catheter were passed across the stenosis via the working channel of the endoscope. If the stenosis was difficult to traverse, very long or in the eccentric position, a soft tipped glide wire was carefully utilized, avoiding creating false passages. Once the stenosis was traversed, and the intraluminal position of the wire was confirmed with fluoroscopic guidance, the guide wire was withdrawn within the catheter, and water-soluble contrast medium injected to verify its correct position.

The stent was then deployed under fluoroscopic guidance and assessed for full expansion.

Statistical Analysis

The only descriptive statistical analysis was utilized in this study. Data are presented as the mean \pm standard deviation (SD), or as proportions of the single event (%), which derived from the number of subjects included in the study out of the total number of subjects.

Results

During the enrolled period, a total of 26 patients, 10 women (38.46%) and 16 men (61.54%) with acute tumour bowel obstruction were treated with endoscopic placement of a self-expandable metallic stent (SEMS). The average age of our patients was 78, with a range of 57-92 years.

All patients were admitted for typical symptoms of bowel obstruction (abdominal distension, abdominal pain, and vomiting) without signs and symptoms related to perforation.

The clinical diagnosis was ascertained through abdominal X-ray and consequently through CT scan of the abdomen and pelvis. All 26 patients presented with primary colon cancer (adenocarcinoma) complicated by neoplastic obstruction. Twenty-four patients (92.30%)

were treated with SEMS as a bridge-to-surgery and only two of them (7.69%) with palliative intent. In 22 patients (80.76%), the stenosis was localized on the left-side, in particular 10 (45.45%) in the sigmoid colon, 9 (40.9%) in the superior rectum, 2 (9.09%) in the descending colon, and 1 at the splenic flexure (4.54%). In 4 patients (15.38%) the obstruction was at the level of the right colon, of which 3 (75%) at the level of the right colic flexure-transverse colon, and 1 at the level of the ascending colon (25%). The majority (69.23%) of the patients had stage III disease, while the remainder (30.77%) had stage IV (Table I). The follow-up ranged between 6 and 36 months.

Technical success was achieved in 23 of 26 (88.46%) patients. Two patients experienced technical failure because of inability to advance the guide wire across the stricture. In one patient the SEMS did not satisfactorily expand. The majority of the patients required one SEMS insertion (96.15%), while insertion of a second stent was required in 1 patient to ensure the patency of the intestinal lumen (3.84%). The mean duration from the onset of symptoms to SEMS insertion was 3.9 days. The mean operative time was 30 ± 15 minutes (range 18 to 80 min). Clinical success with resolution of bowel obstructions was achieved in 22 of 26 (84.61%) patients within a short period. The 4 patients who failed SEMS, 3 because of technical reasons and 1 because of lack of clinical obstruction improvement, underwent palliative Hartmann operation. Among patients treated successfully with SEMS insertion as a bridge to surgery (n = 22), 20 (90.9%) underwent one-stage surgery with primary anastomosis (7-15 days after the placement of the endoprosthesis), while 2 (9.09%) underwent colostomy secondary to intra-operative evidence of a colonic perforation in the region of the pelvis covered by cancer tissue. All of the 24 patients who re-

Table I. Study population.

Variables	Value
Age	78 (range 57-92)
Female	10 (38.46%)
Male	16 (61.54%)
CEA	105 (55-150)
Indication	
Palliation	2 (7.69%)
Bridge to surgery	24 (92.30%)
Length of stricture	4.91 cm
Primary disease	
Colonic adenocarcinoma	17 (65.38%)
Rectal adenocarcinoma	9 (34.61%)
Number of SEMS inserted:	
A single SEMS	25 (96.15%)
Two SEMS	1 (3.84%)
Right-side obstruction	4 (15.38%)
Cecum	0 (0%)
Ascending colon	1 (25%)
Transverse	3 (75%)
Left-side obstruction	22 (80.76%)
Splenic flexure	1 (4.54%)
Descending colon	2 (9.09%)
Sigmoid colon	10 (45.45%)
Superior rectum	9 (40.9%)
TNM Stage	
III	18 (69.23%)
IV	8 (30.77%)

ceived SEMS as a bridge to surgery underwent subsequent chemotherapy.

Stent-related complications occurred in 2 patients. One patient developed an early migration of the prosthesis (within 48h after the insertion), which was handled by the insertion of a second endoprosthesis. Another patient suffered a perforation during the procedure, requiring emergent Hartmann operation. In another two patients, there was evidence of intra-operative contained perforation in the pelvis in the context of the friable cancer tissue. The total complications rate was 15.38%, and none of the complications led to patient death (Table II).

Table II. Stent-related complications.

Age/Sex	Obstructed site	Complication	Treatment of complication	Outcome
70 male	Sigmoid colon	Migration 3.84% (1/26)	Insertion of a second endoprosthesis	Early liver metastasis
65 female	Sigmoid colon	Perforation 3.84% (1/26)	Hartmann operation	Early peritoneal carcinomatosis
73 female	Superior rectum	Silent perforation 7.69% (2/26)	Hartmann operation	Early peritoneal carcinomatosis
83 male				

There was a difference in survival between patients receiving SEMS as a palliative therapy (6.5 ± 3 months) and those who had SEMS inserted as a bridge to surgery (12 ± 4.5 months). The two patients with subclinical perforation developed an early peritoneal carcinomatosis, while another four patients developed peritoneal carcinomatosis within 12 months. Ten patients treated with curative intent subsequently developed liver metastasis after 24 months.

Discussion

The first case of placement of a colorectal endoprosthesis for neoplastic stenosis, was described in 1991 by Dohmoto et al¹⁵. During the last decade many other articles on the use of SEMS have been published, including randomized controlled trials (RCTs), meta-analysis and systemic reviews¹²⁻¹⁵. However, the role of SEMS in the treatment of malignant colonic obstruction remains controversial. SEMS may be used for the purpose of palliation or as a bridge to surgery to allow subsequent one stage surgery. Regarding the use of SEMS with a palliative aim, there are many contrasting findings. Initially, two RCTs comparing the clinical efficacies of SEMS and colostomy showed favorable outcomes for SEMS^{21,22}. However, a recent multicenter randomized controlled trial was ended early due to the unexpectedly high rate of perforation in the SEMS group of patients treated with palliative intent. In fact, Van Hooft et al²³ in their trial reported a technical and clinical success rates of 90%, but in the 11 patients of the SEMS group, the authors reported six cases of stent-related perforation: two cases developed at 12 days after stent placement and four cases at 30 days. Also among patients who received chemotherapy after stenting, four experienced stent-related perforations. During follow-up, stent migration and stent obstruction occurred at rate of 10% and 20%, respectively. Furthermore, among the 10 patients in the surgery group, six underwent resection with primary anastomosis. Therefore, the authors suggested that surgery should be considered the first-line treatment for patients who are candidates for chemotherapy, and the use of SEMS should be avoided in patients treated or considered for treatment with antiangiogenic drugs (e.g. bevacizumab)²³.

Also, two multicenter randomized trials using SEMS were terminated prematurely because of safety consideration correlated to colonic perforations and high morbidity^{24,25}.

Similar findings were confirmed by a recent Cochrane systematic review which included five randomized clinical trials, found that patients receiving emergent surgery for the palliation of malignant colorectal obstruction had better clinical success than those receiving SEMS (98.84% vs. 78.05%, $p = 0.001$)¹⁶.

Although several retrospective and prospective studies support the utility of SEMS as a bridge to surgery, many randomized controlled trials (RCTs) lead to inconclusive and often contradictory results²⁶⁻²⁸.

In a large meta-analysis including 14 randomized and non-controlled studies, De Ceglie et al¹⁷ proved that the use of SEMS as a bridge to surgery has a high technical and clinical success rate of 96.9% (range, 46.7%-100%) and of 94.2% (range, 40%-100%) respectively. The rate of complications related to the procedure were lower: 0% (range, 0%-10.5%) for migration, 0.1% (range, 0%-12.8%) and 0.1% (0%-26.6%) for perforation and silent perforation respectively. Also, primary anastomosis was achieved significantly more frequently in the SEMS group (44.7%-100%) than in the surgery group (13.8%-100%; $p < 0.001$)¹⁷. Mortality and length of hospital stay did not differ between the two groups and also other morbidities, including anastomotic leakage and infections, tended to be low in the SEMS group¹⁷.

A recent meta-analysis¹⁸ confirmed the benefits of SEMS over emergent surgery as a bridge tool to elective surgery for left-side malignant colonic obstruction.

Seven randomized clinical trials have been taken into consideration, and a total of 382 patients were analyzed. SEMS insertion was attempted in 195 patients, while 187 underwent emergency surgery¹⁸.

As compared to the group of patients treated in the emergency setting, the group of patients undergoing stenting and elective surgery, showed a higher rate of primary anastomosis and a lower rate of a permanent colostomy, infections and the overall occurrence of complications. However, there was no significant difference between the two groups regarding anastomotic leak, mortality, and intra-abdominal infection¹⁸.

The same results have been suggested by another meta-analysis, in which the authors report-

ed a highly successful primary anastomosis and low ostomy rates, but again no significant differences in complications or mortality²⁹.

The European Society of Gastrointestinal Endoscopy (ESGE) endorsed by the American Society for Gastrointestinal Endoscopy (ASGE) has recently provided practical guidance regarding the use of SEMS in the treatment of malignant colonic obstruction. The new guidelines limit the use of SEMS to a small group of cases³⁰.

After a thorough diagnostic evaluation, which should include a contrast enhanced computed tomography (CT scan), colonic stenting should be reserved for patients with clinical symptoms and imaging evidence of malignant large-bowel obstruction, without signs of perforation. Colonic self-expandable metal stent (SEMS) placement as a bridge to elective surgery is not recommended as a standard treatment of symptomatic left-sided malignant colonic obstruction. Stent placement may be considered only as an alternative to emergency surgery in those who have an increased risk of postoperative mortality, i.e. American Society of Anesthesiologists (ASA) Physical Status > III and/or age > 70 years²⁸.

Well-known limitations of stent insertion include tumor perforation and tumor cell dissemination, and these represent additional reasons the oncologic safety remains in doubt. Furthermore, recent reports³¹⁻³³ have also shown a lower overall and disease-free survival associated with shorter recurrence time in patients who underwent stent placement. Although not entirely clear, it is possible that SEMS might be associated with a high occurrence of clinical and silent perforation (10-20%), which, in terms, are considered a risk factor for the subsequent development of peritoneal carcinomatosis³¹⁻³³.

In a recent experimental murine model¹⁹, the authors proved that SEMS resulted in an increased metastatic process and a shorter survival time.

In our case series, two patients with subclinical perforation developed an early peritoneal carcinomatosis, while another four patients had peritoneal carcinomatosis within 12 months. Ten patients treated with curative intent subsequently developed liver metastasis after 24 months.

Our data/findings should be interpreted with caution, as they only represent a preliminary experience. However, we reported a poor outcome among patients treated with the insertion of SEMS. This led us to believe that in some cases, occlusion may be better than “silent” perforation.

Conclusions

For malignant obstructions palliation surgery, as initial therapeutic intervention, has a better clinical success than SEMS. In a bridge to surgery management, SEMS seems to be a safe and effective therapeutic option providing patients the possibility to receive one-stage surgery without colostomy. However SEMS placement, as a bridge to elective surgery, is not recommended as a standard treatment of all symptomatic malignant colorectal obstructions. SEMS may be considered only as an alternative to emergency surgery in those who have an increased risk of postoperative mortality. SEMS in patients treated or considered for treatment with antiangiogenic drugs (e.g. Bevacizumab) should be avoided. Patients with perforations or silent perforations have a poor long-term outcome. Therefore, colonic stenting should be avoided in cases of occlusive colorectal tumors treated with curative intent as it might increase the risk of tumor dissemination and early liver metastasis.

Informed Consent Statement

All involved people gave their verbal and written informed consent.

Conflict of Interest

All the authors declare that they have no competing interests.

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