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ORIGINAL ARTICLE

Endoscopic stenting as bridge-to-surgery (BTS) in left-sided obstructing colorectal cancer: Experience with conformable stents

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Summary

Background: Compared to emergency surgery, self-expandable metallic stents are effective and safe when used as bridge-to-surgery (BTS) in operable patients with acute colorectal cancer obstruction. In this study, we report data on the new conformable colonic stents.

Objectives: To evaluate clinical effectiveness of conformable stents as BTS in patients with acute colorectal cancer obstruction.

Design: This was a retrospective study.

Settings: The study was conducted at six Italian Endoscopic Units.

Patients: Data about patients with acute malignant colorectal obstruction were collected between 2007 and 2012.

Main outcome measures: All patients were treated with conformable stents as BTS. Technical success, clinical success, rate of primary anastomosis and colostomy, early and late complications were evaluated.

Results: Data about 88 patients (62 males) were reviewed in this study. Conformable SEMS were correctly deployed in 86 out of 88 patients, with resolution of obstruction in all treated patients. Tumor resection with primary anastomosis was possible in all patients. A temporary colostomy was performed in 40. Early complications did not occur. Late complications occurred in 11 patients. Stent migration was significantly higher in patients treated with partially-covered stents compared to the uncovered group (35% vs. 0%, $P < 0.001$). Endoscopical re-intervention

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was required in 12% of patients. One patient with rectal cancer had an anastomotic dehiscence after surgery and he was successfully treated with endoscopic clipping. One year after surgery, all patients were alive and local recurrence have not been documented.
Limitations: This was a retrospective and uncontrolled study.
Conclusions: Preliminary data from this large case series are encouraging, with a high rate of technical and clinical success and low rate of clinically relevant complications. Partially-covered SEMS should be avoided in order to reduce the risk of endoscopic re-intervention.

Abbreviations

CRC	colorectal cancer
SEMS	self-expandable metallic stents
BTS	bridge-to-surgery
RCTs	randomized controlled trials
ESGE	European Society of Gastrointestinal Endoscopy
PTFE	polytetrafluoroethylene
TTS	through-the-scope
TS	technical success
CS	clinical success
CT	computed tomography
PC covered	partially-covered stents
OTW	over-the-wire

Introduction

Colorectal cancer (CRC) is a global public health problem, being the third most commonly diagnosed cancer in males and the second in females [1]. In 8—29% of CRC patients, obstruction is the predominant symptom at the time of diagnosis, particularly in left-sided colon cancers [2]. Emergency surgery is the traditional treatment, to obtain immediate decompression, but is associated with a high rate of complications [2]. Up to 40% of patients require a permanent colostomy after emergency surgery and have low health-related quality of life [3,4]. The increasing use of self-expandable metallic stents (SEMS) has allowed a more conservative approach to these cases. The acute obstruction can be solved with the endoscopic placement of SEMS, which can be employed for palliation of colonic obstruction in inoperable patients or as a bridge-to-surgery (BTS) in those patients who are deemed fit for intervention after staging examinations. Several meta-analyses of randomized controlled trials (RCTs) have demonstrated that the placement of SEMS as a BTS allows a higher successful primary anastomosis and lower overall stoma rates, with no significant difference in complications or mortality, when compared with emergency surgery [5—13].

However, SEMS can be technically demanding to position, especially in the presence of narrow, angulated bowel loops. In such conditions, SEMS cannot fully expand, resulting in migration or perforation due to excessive forces applied to the colon wall. These are determined by the stiffness of the device, whose radial forces oppose the narrowing of the stricture. A recent study showed that in patients aged 75 years or less, stenting and delayed surgery were associated with a higher local recurrence rate compared with emergency surgery. This may be due to stent-related complications, such as ''silent'' perforation [14]. In light of these data, recent ESGE guidelines have limited the use of the BTS strategy to patients at high surgical risk [15].

A new uncovered colonic stent (Niti-S D-Weave™, Taewoong Medical, Seoul, South Korea) has characteristics that may reduce the risk of complications. It is a self-expanding nitinol (an alloy of nickel and titanium) stent, whose composition and its D-shaped mesh confer interesting properties, such as compliant flexibility and conformability, reducing the risk of migration, perforation and inadequate expansion.

The same characteristics are present in the double-layered combination, partially-covered stent (Niti-S™ enteral colonic stent Comvi type, Taewoong Medical, Seoul, South Korea) that has a biocompatible polytetrafluoroethylene (PTFE) membrane tube fixed between the inside and outside of the D-weave uncovered stent body.

This paper reports our experience with conformable SEMS as a BTS in patients with acute, malignant, left-sided large bowel obstruction.

Methods

Between January 2007 and June 2012, data about patients with clinical and radiological evidence of acute colonic obstruction due to CRC were retrospectively collected from six endoscopy units in Italy. Insertion of SEMS was performed as an urgent procedure. Data about patients who received conformable Niti-S colonic stents as a BTS were reviewed in this study; patients with metastatic disease were not included.

Before colonic stenting was performed, the distal colon was prepared with a sodium phosphate enema (133 mL volume). Colonic stenting was performed by a senior endoscopist with more than 10 years' experience of operative endoscopy. Procedures were performed under moderate intravenous sedation employing only midazolam 0.05 mg/kg and meperidine 0.4 mg/kg.

Colonoscopies were performed with Olympus CF-H185L/I, CF-Q180A or CF-Q165I/L colonoscopes (Olympus Corporation, Tokyo, Japan). A guide wire (Tracer Metro™, Cook, Inc., Winson-Salem, North Carolina, USA, 0.035 inch × 480 cm or a Hydra Jagwire™, Boston Scientific,

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Table 1 Outcomes in uncovered and partially-covered conformable SEMS.

	Uncovered SEMS 68	Covered SEMS 20	Total 88
Technical success	66/68 (97%)	20/20 (100%)	86/88 (98%)
Clinical success	66/66 (100%)	20/20 (100%)	86/86 (100%)
Early complication	0	0	0
Late complication	3/66 (4.5%)	8/20 (40%)	11/86 (12.8%)
Bleeding	0	0	0
Occlusion	2/66 (3%)	1/20 (5%)	3/86 (3.5%)
Migration	0	7/20 (35%)	7/86 (8.1%)
Perforation	0	0	0
Silent perforation	1/66 (1.5%)	0	1/86 (1.2%)

Marlborough, USA, 0.035 inch × 450 cm) was placed across the stricture under endoscopic and fluoroscopic control. The guide wire was positioned using a standard ERCP catheter or, in the case of angulated stenosis, by means of a papillotome. Water-soluble contrast was injected via catheter to confirm the intraluminal placement of the guide wire, as well as to assess the length of the stenosis. SEMS were available in different lengths (60, 80 100 and 120 mm) and diameters (20, 22, 24, 26 and 28 mm), partially-covered or uncovered. Length and diameter of SEMS were chosen on the basis of the characteristics of stenosis; larger SEMS were placed in the rectum (28 × 60 mm; 28 × 80 mm). d SEMS were used in patients with active bleeding neoplasia.

The stenosis was not dilated before or directly after stent placement, because this has been reported to be associated with a higher incidence of perforation [16]. Only through-the-scope (TTS) SEMS were used to better control their release. Technical success (TS) was defined as successful stent placement across the stricture and its deployment. Clinical success (CS) was defined as adequate bowel decompression within 24 hours of stent insertion without need for re-intervention.

Plain abdominal radiography was performed 24 hours after stent insertion to confirm its position and expansion. The colon proximal to the obstruction was examined using colonoscopy three days after successful decompression and after bowel preparation with polyethylene glycol solution. Abdominal CT scans provided preoperative staging criteria to select cases suitable for elective surgical resection.

Patients who had successful stenting and decompression had elective surgery. BTS time was reported for each patient and median BTS time was calculated.

The number of primary anastomosis, stoma and SEMS-related complications and symptoms up to 12 months after surgery were reported for each case. Stent-related complications were divided into early (< 24 hours) and late (> 24 hours).

The data were analyzed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were analyzed by the Chi^2 test or Fisher's exact test. $P < 0.05$ was considered as statistically significant.

The study was approved by the Institutional Review Boards of the hospitals involved in the study.

Written informed consent was obtained from all participants.

Results

The study data are displayed in Table 1. Data about 88 patients (62 males, median age 73 years, range: 36—91 years) were reviewed in this study. Histological analysis of biopsies showed a diagnosis of adenocarcinoma in all lesions. A total of 86 conformable SEMS were correctly deployed in 86/88 (98%) patients.

The malignant stenosis was localized in the left colon or in the proximal rectum (distal margin at least 10 cm from the anal verge) in all patients. Uncovered SEMS were used in 66 patients, and partially-covered (PC) SEMS in 20 patients. In two cases, the stenosis was too tight and angulated to allow proper passage of the guide wire and the SEMS could not be placed, so the TS was 98%.

Resolution of obstruction occurred within 12—24 hours in the 86 patients treated with SEMS (CS 100%). Median BTS time was 19 days (range, 10—38). Tumor resection with primary anastomosis was possible in all patients. A temporary colostomy to protect the anastomosis was undertaken in 40 (45.4%) cases, according to preference of surgeon. In the 2 patients in whom stent placement failed, a decompressive colostomy was performed and the formal resection carried out at a later time.

Early complications did not occur. Late complications occurred in 11 (12.5%) patients (stent obstruction in 3 patients, silent perforation in one and stent migration in 7). Late complications in uncovered and partially-covered SEMS are shown in Fig. 1.

Stent migration occurred only in patients treated with partially-covered (PC stents), with a statistically significant difference compared to uncovered stent group (35% vs. 0%, $P < 0.001$). All 7 patients with stent migration were still hospitalized and were successfully treated with an uncovered stent placement, without modifying the treatment plan of elective surgery.

Obstruction was observed in 3 patients 7—18 days from stent placement (2 uncovered and 1 PC stents): stents were clogged with fecal material and colonoscopy failed to restore the patency in one case. A second stent (Niti-S, 22 × 80 mm) was then successfully placed through the first one and this patient was re-admitted to undergo SEMS placement. The other two patients underwent outpatient colonoscopy. A silent perforation was detected during surgery in a patient with an uncovered stent (22 × 60 mm)

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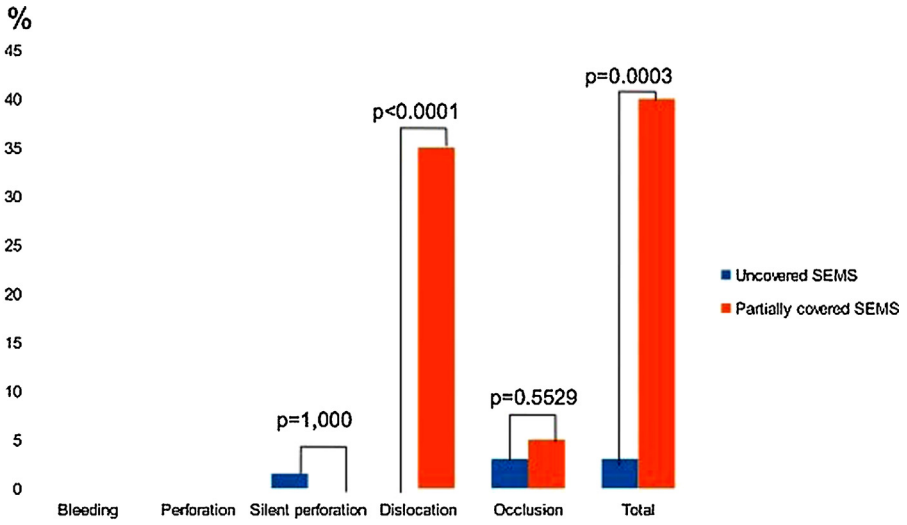

Figure 1 Late complications in uncovered and partially-covered SEMS.

placed in the sigmoid colon (TNM: T3, N2, M0). The pathology report described the perforation at the proximal end of the stent. Morbidity and mortality of surgery were respectively 3.4% and 0%. One patient with rectal cancer had an anastomotic dehiscence 5 days after surgery, which was successfully treated conservatively by endoscopic clipping. After surgery, 2 patients had a mild rectal bleeding which was self-limited, requiring blood transfusion in one case. Temporary colostomy was successfully closed in all patients with a second operation after about 6 months.

All patients underwent follow-up colonoscopy and CT scan; no local recurrences were diagnosed in the first year after surgery. All patients were alive after 12 months.

Discussion

In this study, we retrospectively analyzed a large cohort of patients with malignant colonic obstruction, treated by conformable SEMS as BTS. Our results confirm that SEMS are effective in resolving acute malignant colonic obstruction. Endoluminal stents have proved effective in resolving left-sided colonic obstructions in most instances, although data from randomized and non-RCTs are not consistent. When RCTs only are analyzed, the technical and clinical success rates ranged from 71% to 76%, and from 69 to 73%, respectively [5—7].

The percentages increased from 100% to 94%, respectively, when uncontrolled studies are also considered [7,8]. A systematic review reported only minor differences between technical and clinical success rates when comparing covered and uncovered stents [17].

The placement of a SEMS in patients with acute malignant colorectal obstruction is challenging, but in this study, the technical and clinical success rates were high (98% and 100%, respectively).

These favorable results can be explained if we consider both the high experience of endoscopists, and the choice of a innovative of stent.

The high TS can be explained considering that the hospitals involved were referral centers for endotherapy and the wide experience of endoscopists in the placement of colonic SEMS. In fact, in all but 2 patients was possible to overcome the stenosis with the guideword, without excessive manipulation of it, and avoiding excessive air insufflation and balloon dilation before and after stent release. These measures are recommended to minimize the risk of perforation [18,19].

Even the estimation of stenosis length and the consequent choice of a suitable stent depended on the experience of endoscopists.

Similar favorable results have been reported in previous studies using the same type of stents [20,21].

In our study, the cases of technical failure were due to the impossibility of crossing the stenosis with the guide wire rather than a SEMS failure. The good expansion of SEMS allowed to solve bowel obstruction within 24 hours in all treated patients, avoiding emergency surgery. In all studies, the comparison of outcomes in stent as BTS and emergency surgery groups showed an advantage of stent placement in terms of reduction of stoma creation and increase in primary anastomosis [5—13].

All meta-analyses did not find a statistically significant difference in perioperative mortality between stent as BTS and emergency surgery groups [5—12].

In our study, the rate of stoma creation was rather high (45,4%), since the surgeon was free to choose whether to perform a temporary colostomy to protect the anastomosis. However, a decompressive colostomy was needed only in the two patients in whom SEMS was not placed. In all patients, it was possible to achieve a primary anastomosis and all protective colostomies were closed 3—6 months after surgery.

Discrepancies among different meta-analyses are evident when considering adverse events, in particular perforation and silent perforation. The meta-analysis by De Ceglie et al., including 14 randomized and non-controlled studies for SEMS as a BTS, reported a low percentage of stent-related adverse events: by pooled analysis, the migration rate was 0%, and

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the perforation and silent perforation rates were 0.1% [7]. Considering four RCTs, Tan et al. reported a 7% rate of clinically evident perforations and 14% rate of silent perforations, while another study, including 353 patients from 8 RCTs, detected 8% of silent perforations [5,6].

Perforation is the most feared complication: it may be caused by attempts to overcome the stenosis or it can occur after SEMS placement. In the case of overt perforation, surgical intervention is mandatory. On the contrary, silent perforation means a small wall defect that gives no clinical signs and which is found on the surgical specimen after resection surgery. However, as the silent perforation may seem of little relevance in the clinical setting, recent data have shown that it can negatively change the natural history of disease [22—25]. Microperforations can promote the peritoneal dissemination of cancer cells, even in the earlier stage of disease, when the tunica serosa has not yet been affected by the tumor. In clinical practice, a colon cancer that occurs with acute obstruction is often locally advanced [25]. A low rate of complications, such as perforation, has been observed when TTS SEMS have been used because of better release control, in comparison with over-the-wire (OTW) implantation [26]. We did not observe perforations, probably due to stent characteristics, as compliant flexibility and conformability, and to endoscopist experience. A silent perforation at the proximal end of an uncovered stent was detected during surgery. In this patient, the stricture resulted to be long about 6 cm and angled, although at first endoscopic and fluoroscopic evaluation was estimated to be 4 cm long. The stent used in this case (22 × 60 mm) was probably too short to optimally fit to the narrow bowel loop. However, no local recurrence has been reported until the latest follow-up. Since surgery in this patient occurred 25 days after SEMS placement, it is likely to think that minimizing bridge-to-surgery time could reduce the risk of such a complication, as suggested by ESGE guidelines [15]. Another possible cause of open or silent perforation may be the choice of the stent with a diameter too large for the colonic segment in which it is placed. The choice of the size and length of stent should always take into account the characteristics and location of the stenosis in order to reduce the risk of perforation. In a previous study, van Hooft et al. pointed out that the large diameter (30 mm) of the stent used (Wallflex stent) to palliate left-sided colon cancers as a possible risk factor for perforation [27], but other studies did not support this hypothesis [28—30]. When SEMS are used as BTS, there is concern about the oncologic outcome of those patients whose disease is potentially curable; theoretically, SEMS placement could induce tumor seeding, adversely affecting the long-term outcome. Data from retrospective studies and RCTs are discordant, ranging from similar long-term survival between patients with stent as a BTS and emergency surgery groups [31—34] to an adverse effect on the 5-year overall and disease-free survival rates when stent as BTS was compared with elective non-obstructing surgery (38.4% vs. 65.6% and 48.3% vs. 75.5%, respectively) [35]. These results have not been confirmed in a retrospective study in which the 5-year survival rate was 60% and 58%, respectively, in stent as BTS patients and elective surgery patients [36]. Sabbagh et al. showed that the overall survival and the 5-year survival were significantly lower in the patients with SEMS than in the emergency surgery group (25% vs. 62), also when considering patients with no perforation and no metastasis at the time of diagnosis (30% vs. 67%) [22]. Comparing pathological data, the same authors found that ulceration at/or near the tumor, perineural invasion and lymph node invasion were significantly more frequent in the stent as BTS group, and locally advanced tumors (T4) and tumor size in these patients were risk factors [23]. Sloothaak et al. showed a slight but significant increase in disease recurrence in patients in whom there was a perforation due to the colonic stent [24]. A Danish nationwide cohort study reported that the use of SEMS might be associated with an increased CRC recurrence. The overall 5-year survival after CRC resection was higher in patients in the BTS group than those in the emergency surgery group (48.7% vs. 40.3%), but it was lower if compared to those patients undergoing elective surgery (65%). These findings were expected, being preoperative stenting and urgent resection related with an acute condition, such as CRC obstruction, whereas elective surgery is used for non-obstructive cancer [25]. As we mentioned earlier, in our study, conformable stents had no problems of release and expansion and have been shown to have excellent adhesion and adaptation to the colonic walls. These characteristics have also significantly reduced the risk of SEMS-related complications in our study (12.5%). In other studies, inoperable CRC patients experienced early and late complications in up to 38% of cases, with different types of SEMS used for palliation of acute obstruction: this is probably due to the long duration of stenting in this setting, but it may also depend on different stents characteristics, and different adaptation to the stenosis [37].

In this study, stent migration occurred only in patients treated with the double-layered combination, partially-covered stents, with a statistically significant difference compared to the uncovered stent group (35% vs. 0%, $P < 0.001$). This complication can be easily managed by endoscopy: in these patients, it was possible to replace uncovered stents. Our experience suggests that the uncovered stents should be preferred in these patients. Few studies have compared the clinical efficacy of uncovered stents with covered stents. Moon et al. have compared the Niti-S enteral colonic stent, Comvi type, with the uncovered stent D type, reporting a higher rate of late stent migration in the first type (22.2% vs. 0%), in spite the presence of the outer uncovered layer. The rate of late stent occlusion by tumor ingrowth was lower in Comvi type stent group, but not statistically significant when compared to uncovered stent [20]. Therefore, this advantage does not seem to balance the risk of migration of covered SEMS. Similar results have been reported in other studies [38,39]. In a randomized prospective single center study comparing the clinical efficacy of uncovered WallFlex stents (Boston Scientific Co.) and covered Comvi stents (Tae-Woong Medical Co.), complications, mainly cancer ingrowth, were more frequently observed in the WallFlex group (14.5% vs. 3.8%). The rate of stent migration was higher in the Comvi group (21.1% vs. 1.8%) [38]. In a retrospective study comparing four types of uncovered [Wallstent (Boston Scientific, Natick, MA), Niti-S (Tae-Woong Inc., Gimpo, South Korea), Bonastent (Standard Sci-Tech Inc., Seoul, South Korea), and Hanarostent (M.I. Tech, Pyeongtaek, South Korea)], and two types of covered [Niti-S (Taewoon Inc.) and Bonastent (Standard

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Sci-Tech Inc.)] stents used for malignant colonic obstruction, no statistically significant difference was observed in outcomes, except for migration (3.3% vs. 16.7% in uncovered and covered stent, respectively) [39]. ESGE guidelines suggest a BTS time of 5 days [15], in order to reduce the risk of SEMS-related complication. Our study was carried out before the publication of these guidelines and BTS time of 19 days was probably too long. In fact, we reported 3 cases in which the stent was clogged with fecal material; no case of ingrowth or overgrowth obstruction was observed. In two cases, colonic lumen was restored during colonoscopy by washing, while in the third patient, a second stent was successfully released through the first one. Effective outcomes in patients with malignant colorectal obstruction have been reported using this technique [40]. However, in our study, either covered stent migration or stent obstruction have occurred belatedly, after proper resolution of intestinal obstruction was obtained: therefore, also in this case, shortening bridge-to-surgery time could reduce the risk of this type of complications and the need for endoscopic re-intervention.

This study is limited by the absence of a control group. However, preliminary data on this large case series are encouraging given the high rate of technical and clinical success, with low rate of clinical relevant complications. Covered SEMS should be avoided in order to reduce the risk of migration. It is also necessary to optimize bridge-to-surgery time to reduce the overall risk of SEMS-related complications. Conformable stents seem promising as a BTS in patients with stenosing CRC. Randomized controlled trials versus other types of SEMS are needed to confirm these data.

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Authors contributions

Massino Conio: substantial contributions to conception and design of the study, critical revision of the article for important intellectual content, and final approval of the version to be published.

Andrea Parodi: supplying patients, maintaining a database, obtaining follow-up data, analysis and interpretation of data; drafting the article.

Antonella De Ceglie: analysis and interpretation of data; drafting the article.

Luca De Luca, Rita Conigliaro, Riccardo Naspetti, Paola Arpe, Gianni Coccia: supplying patients, critical revision of the article for important intellectualcontent.

Disclosure of interest

The authors declare that they have no competing interest.

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