The role of self-expandable metallic stents as "bridge to surgery" for the treatment of acute malignant colorectal obstruction.



Ann. Ital. Chir., 2017 88, 5: 418-424 pii: S0003469X17026860

Our experience

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The role of self-expandable metallic stents as "bridge to surgery" for the treatment of acute malignant colorectal obstruction. Our experience.

INTRODUCTION: Despite the widespread use of screening programs, the colorectal cancer occurs in 7-29% of cases with a bowel obstruction, needing an immediate decompression treatment by emergency surgery; unfortunately, the emergency surgery is characterized by high morbidity and mortality rates. The endoscopic placement of self-expandable metallic stents can be a useful alternative, allowing to decompress the acute obstruction in a short time, in order to correct dehydration, electrolytic imbalance and to improve the overall clinical conditions prior to adequately plan the intervention of elective surgery.

AIM: The objective of our study was to evaluate the clinical success and potential complications related to the stent placement as "bridge to surgery".

ment as bridge to surgery.

MATERIALS AND METHODS: Twenty-four patients with acute intestinal obstruction due to colorectal cancer were retrospectively observed in our Surgery Unit. They were selected only patients in whom technical success, defined as the correct placement of the stent, was recorded. All patients underwent a preoperative abdominal X-rays and whole body contrast-enhanced Computed Tomography (ceCT). Furthermore, an intraoperative fluoroscopy was also performed to obtain a better anatomical depiction of the lesions. The sites of obstruction were in the left colon (n=13) and in the proximal rectal tract (n=11). Covered and uncovered stents were placed respectively in 12 and 12 patients. The Over The Wire (OTW) technique has been used in 11 patients while the Through The Scope (TTS) technique in 13 subjects. All patients were brought to elective surgery in 5-10 days. The clinical success was defined as the resumption of normal bowel function within 48-72 hours and the absence of complications.

RESULTS: Technical success was documented in 24 patients (100%). Clinical success was recorded in 17 patients (70.8%) while, in 7 patients, as treatment complications were recorded: 2 stent migrations (8.3%), 2 cases with tenesmus (8.3%), 2 bleeding (8.3%), 2 cases of abdominal pain (8.3%) and 1 case of perforation (4.2%), were recorded.

CONCLUSION: In our series we found that placing self-expandable metallic stents, considered as "bridge to surgery", was a useful technique in the resolution of acute malignant colorectal obstructions, with high success rate and low rate of complications.

KEY WORDS: Colorectal cancer, Clinical success, Large bowel obstruction, Radiology, Self-expanding metallic stent, Stenting, Surgery

Pervenuto in Redazione Dicembre 2016. Accettato per la pubblicazione Marzo 2017

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Introduction

The colorectal cancer is the second most common kind of cancer in women and the third in men ¹.

Complication of colorectal cancer is the colic acute malignant obstruction, occurring in 7-29% of patients ² . The

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colon obstruction causescolonic dilatation, bacterial translocation, electrolyte and fluid imbalanceand, finally, necrosis and perforation. This emergency condition needs a prompt evaluation and treatment ³. Therefore, the emergency surgery represents the main treatment of colonic malignant obstruction; this kind of treatment is associated with a high physiological insult on patients already nutritionally replete, determining high rates of mortality (15%-34%) and morbidity (32%-64%) ⁴.

In the last two decades, the colonic stenting represents a treatment for this emergency condition, alternative to surgical intervention. Since 1991, Dohmoto *et al.* ⁵ used the first stent for palliative treatment of a malignant colonic obstruction. The use of colonic stents as a "*bridge to surgery*" was described by Tejero *et al.* in 1994 ⁶: in fact, they proposed this treatment in those patients too unstable or weak for surgery, which a potential benefit from definitive surgery.

The role of self-expandable metallic stent (SEMS) as a "bridge to elective surgery" has been the subject of many reviews, which highlight its efficacy, particularly emphasizing its capability in reducing ostomy rates, allowing faster return to oral diet, minimizing extended post-operative convalescences and higher quality of life (7). Also in Italy, the experience with SEMS has been documented in several original articles, especially as alternative to colostomy in unresectable patients with colorectal cancer in emergency ^{8,9}.

To date, the palliative treatment of malignant obstructions with pre-operative decompression is the most important indication of SEMS for colonic ¹⁰.

The aim of our study was to investigate the role of SEMS, considered as "bridge to surgery", in the treatment of colorectal malignant obstructions we documented in our practice, by examining the clinical procedural success and complications.

Materials and Methods

Twentyfour patients with acute malignant colonic obstruction, 19 men (79%) and 5 women (21%), (age 65-86 years-old), underwent endoscopic stenting, in our Department, during the 2010-2015.

Exclusion criteria for this article were:

- asymptomatic patients with a malignant colorectal obstructions;
- benign stenosis;
- patients undergoing colonic stents for palliative intent;
- patients with clinical evidence of perforation and/or peritonitis;
- patients with rectal stenosis closer lower than 5 cm to the anal sphincter.

All patients undergone preoperative abdominal X-rays and whole body contrast enhanced CT. In all cases, preoperative imaging showed the malignant causes of the

obstruction, the specific location and the technical and clinical potential feasibility. Therefore, the obstruction were in left colon in 13 patients (54%) and proximal rectum in 11 patients (46%) (Table I).

All stenting procedures were preceded by rectal enema and placement of nasogastric tube.

Covered and uncovered stents were used in 12 and 12 patients respectively. *Through The Scope* (TTS) technique was used in 13 patients while in 11 patients we used *Over The Wire* (OTW) technique Table II).

The patients were randomized for the use of covered and uncovered stents.

We used the OTW technique in patients with stenosis of the proximal rectum, until 30 cm from anus orifice. We used the TTS technique in patients with left side malignant obstruction and patients with stenosis of distal rectum above 30 cm from the anal orifice.

The used SEMS were: S-Enteral Colonic Stent (Taewoong Medical), covered and uncovered; Ultraflex Precision (Boston Scientific), uncovered; Wallstent Endoprothesis (Boston Scientific), uncovered; D-Enteral Colonic Stent (Taewoong Medical), uncovered. Table III synthetizesthe technical characteristics of used 'technical detail.

The used colonic endoscopeswere: Olympus CF-Q160 Land Pentax EC38-i10F.

The positioning of SEMS with colic TTS technique was performed under general anesthesia or conscious sedation, standing to the patients compliance, with all patients in left lateral decubitus or gynecological position.

The stenting procedure was carried out as follows:

- Introduction of the colonic endoscope near the lower margin of the tumor;
- Intraoperative evaluation of stenosis morphology using contrast-enhanced fluoroscopy, in order to choose the correct device;

Table I - Side and gender distribution of malignant obstruction.

	Men	Women	
Left-side colon	10	3	13
Proximalrectum	9	2	11
	19	5	24

TABLE II - Distribution of OTW and TTS technique.

YANLE II	Left-side colon	Proximalrectum	
OTW	0	11	
TTS	13	0	
	13	11	24

TABLE III - Types used stent and number of patients.

Manufacteur Model	Delivery System	Diameter (mm)	Flares/Flanges	Length (mm)	Covered/Uncovered	Number of patients
	Otw	22	Present	100	Covered	2
	Otw	26	Present	100	Covered	3
S-Enteralcolonicstent	Otw	28	Present	100	Covered	2
(Taewoongmedical)	Otw	28	Present	80	Covered	1
Ü	Tts	26	Present	80	Covered	1
	Tts	28	Present	80	Covered	1
	Tts	28	Present	100	Covered	2
Ultraflex Precision	Otw	25/30	Present	87	Uncovered	2
(Boston Scientific)	Otw	25/30	Present	117	Uncovered	1
Wallstentendoprothesis	Tts	22	Absent	60	Uncovered	
(Boston Scientific)	Tts	22	Absent	90	Uncovered	4
D-Enteralcolonicstent	Tts	26	Absent	80	Uncovered	1
(Taewoongmedical)	Tts	26	Absent	100	Uncovered	3 24

- Placing of the guide wire through the operator channel, beyond the stenosis, under endoscopic andradiological control;
- Introduction and release of the SEMS under endoscopic and radiological control, 2 cm above and 2 cm below of the stenosis;
- Removal of the guide wire.

OTW technique was performed with the same operator time of TTS technique, with the only difference that the guide wire and prosthesis have been passed externally of the endoscope.

The stent placement was performed in all patients within 14 hours after onset the acute obstruction presentation. The correct stent placementwas verified intraoperatively using contrast-enhanced fluoroscopy. After the correct stent placement, the resolution of the occlusive status was determined, in all patients, by the evidence of the passage through the stent of fecal material. After 48 hours aX-rays of the abdomen confirmed all these data. In fact, the complete expansion of the stentoccurs within 48-72 hours.

23/24 patients, after the resolution of occlusive framework, underwent bowel preparation with Macrogol 70 mg and undergone CT colonographyin the before to be submitted to surgical intervention in election the 5th and the 10th day after the admittance.

In a patient, because of the perforation occurred three days following the stenting, it was not possible to perform the bowel preparation, and was subjected to surgery, in the fourth day.

The technical success was defined as the correct placement of the stent within the stenosis, as intraoperatively assessed by using contrast-enhanced fluoroscopy and subsequently with X-rays of the abdomen.

The clinical success was defined as resumption of canalization between 48-72 hours after the placement of the

prosthesis in absence of clinical complications. Clinical complications were considered as the appearance of tenesmus, bleeding, perforation, abdominal pain and stent migration after a technical success of stent's positioning.

Results

The technical success was recorded in all patients (24/24; 100%).

The clinical success was achieved in 70.8% of cases (n = 17/24). In this group were included 14 men and 3 women. Seven patients presented complications: registered complications were: 2 stent migrations (8.3%), 2 cases of tenesmus (8.3%), 2 cases of bleeding (8.3%), 2 cases of abdominal pain (8.3%) and 1 case of colic perforation (4.2%). In particular, one patient presented both abdominal pain and tenesmus and another one presented abdominal pain and perforation.

The surgery treatment was performed in all cases (n = 24/24) 5-10 days after the stent placement.

In 23/24 patients (95.8%)we opted for a complete surgical resection in election followed by anastomosis and recanalization in the same surgical intervention. In 1 patient (4.2%) emergency surgery was performed, due to perforation and the strong perilesional tissue suffering. Therefore, considering the rate of clinical success as the technical ability to bring the patient in elective surgery, this would be 95.8%.

Since the stent placement was performed in all patients within 14 hours after the clinical presentation of acute colorectal obstruction, therestoration of the functional intestinal activity was observed immediately after the stent placement even if the complete rescue of the peristalsis requires 12-24 hours from the procedure to be definitive.

Any patient had complications during the procedure. All patients were kept under observation after the procedure

for 4 days. After the stenting procedure, all patients had a significant improvement in water and electrolyte balance. The liquid oral therapy started after 24 hours from the procedure. There are no recorded cases of death related to the stenting technique.

Table IV shows the clinical complications, technical and clinical success rates after the SEMS in all patients.

Discussion

Colorectal cancer is the most common cause of large bowel obstruction, and still represents a condition of surgical emergency with high degree of mortality and morbidity because of the generally poor conditions of the patients (electrolyte imbalance, dehydration, and underlying disease) at the diagnosis ^{11,12}. Griffith RS ¹² and Scott NA *et al.* ¹³ showed thatmortality and morbidity rates for emergency surgical decompression are 15-20% and 50%, respectively, as opposed to a mortality rate of 0.9-6% when patients undergo elective surgery.

However, in a recent meta-analysis by Xuan Huang et al. 14 there was no statistically significant difference in the postoperative mortality comparing SEMS as bridge to surgery (10.7%) and emergency surgery (12.4%). On the other hand, a recent original article by Formisano et al. in a large population showed the limits of surgical intervention in emergency without colonic stenting as "bridge to surgery". In fact, the Authors examined 238 patients affected by colorectal cancer and they found that operative mortality occurred in 11% of cases, an high rate due to general complications and anastomotic failure, while the elective surgery was related to a lower mortality (7%). Also for this reason, we can state that the "bridge to surgery" stenting positioning can play a feasible role in determining the survival of patients with an acute colic malignant obstruction ¹⁵.

In our study covered and uncovered stents were used. Kee Myung Lee *et al.* ¹⁶ in their study, based on 80 patients (where uncovered stents were attempted in 39 patients, and covered stents were used in 41), showed that technical and clinical success rates of uncovered and covered stents were not different (100%; 95.1%, P > .05, 100%; 97.4%, P > .05).

A Prospective Multicenter Study 17 based on 68 patients (covered n = 31; uncovered n = 37), showed that there were no significant differences between both stents in terms of technical and clinical success rates.

In a recent meta-analysis by Y. Zhang *et al.* ¹⁸ no significant difference was foundin technical success, clinical success, tumor overgrowth, early migration, perforation or overall complications between the covered and uncovered group.

From the analysis of these data ^{16,18}, it is clear that there are no significant differences between covered and uncovered stents, and for this reason, we have used indiscriminately the two types of stents.

The technical success of a stenting procedure in an enteric stenosis is usually defined as the appropriate stent placement across the entire length of the stenosis; the clinical success is defined as the resolution of the colonic obstruction in the early days following the stent placement ¹⁹. In our study, we considered the technical success as expressed above while we considered the clinical success as usually considered, also emphasizing the absence of post-procedural complications. In particular, we considered as features of clinical success not only the resolution of the colonic stenosis but also the absence of complications.

Therefore, the clinical success rate in our series was 70.8%, a value lower than reported in literature where, considering the classical definition of clinical success, are reported significantly higher values in a range of 46-100% 18,19.

In a systematic review focusing on 88 studies published in 2007 by Watt *et al.* ²⁰ the median rate of technical success was 96.2%, in a range of 66.6%-100%, and clinical success was achieved in 92% of the cases, in a range of 46%-100%.

In a recent meta-analysis that included seven randomized clinical trials, pooled data showed a mean success rate of 76.9% ranging from 46.7%-100% ²¹.

Complications we have seen are summarized in Table IV: 2 stent migrations (8.3%), 2 cases with tenesmus (8.3%), 2 bleeding (8.3%), 2 cases of abdominal pain (8.3%) and 1 case of perforation (4.2%), were recorded.

In a recent randomized controlled trial, performed on 26 patients, Young *et al.* ⁷ reported that in a popula-

Table III - Complications, technical and clinical success rates after endoscopic colonic stent placement. Seven patients showed an overall amount of 9 complications.

Total case (n) (%)	Technical success (n) (%)	Complication	(n)	(%)	Management	Clinical Success (n) (%)
24 (100)	24 (100)	Tenesmus	2	8.3	Follow-up	17 (70.8)
, ,	, ,	Bleeding	2	8.3	Follow-up	, ,
		Perforation	1	4.2	Stomy creation	
		Abdominal Pain	2	8.3	Pharmacologicaltherapy	
		Stent Migration	2	8.3	Stent removal	

tion of patients with incurable large bowel obstruction with distant metastases, the stent placing was associated with fast return to diet, decreased stoma rates, reduced post-procedure permanence and some benefitsmisured with EuroQOL EQ-5D quality of life questionnaire.

For other Authors, controversial is its usefulness in case of disease potentially treatable with surgery, considering the risk of converting a potentially curable disease to incurable ^{22,23}.

In his meta-analyses, Sagar J ²⁴ showed no significant difference for mortality (OR 0.9) and morbity (OR 2.05) rates, between the two strategies while the permanent stoma creation rate was higher in the surgical group as compared to the stent group (OR 3.12).By comparing surgery and colonic stenting in studies which analyzed the use of stenting as a "bridge to surgery," the pooled analysis showed that primary anastomosis was more frequent in the stent group as compared to the surgical group (OR 0.42), and the stoma creation was more frequent in the surgical group as compared to the stent group (OR 2.36).

In a systematic reviews and meta-analyses by Tan CJ *et al.* ²⁵ that included four RCTs with 234 patients, was compared the use of SEMS like "bridge to surgery" versus emergency surgery. It showed that the use of SEMS is associated with a high incidence of clinical (6.9%) and silent (14%) perforation. However, as a bridge to surgery, SEMS has higher successful primary anastomosis and lower overall stoma rates, with no significant difference in complications or mortality.

Zhang Y et al. ²⁶ in his meta-analyses based on 8 studies and 601 patients, showed that the use of a stent as a bridge to surgery for obstructive left-sided colorectal cancer could increase the chance of primary anastomosis (risk

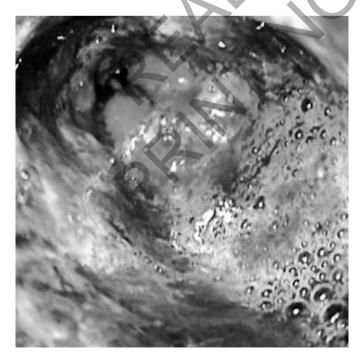


Fig. 1



Fig. 2

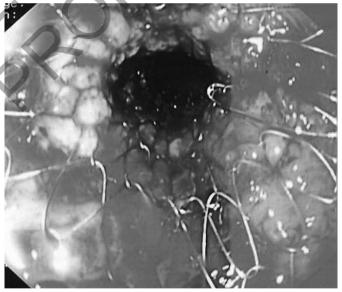


Fig. 3

ratio RR, 1.62; 95% confidential interval CI, 1.21–2.16; p = 0.001) and reduce the need for stoma creation (RR, 0.70; 95% CI, 0.50-0.99; p = 0.04) and post-procedural complications(RR, 0.42; 95% CI, 0.24–0.71; p = 0.001). Stent insertion before subsequent surgery has no effect on perioperative mortality and long-term survival. Therefore, three meta-analyses $^{24-26}$, did not show any advantage in terms of post-operative mortality between the emergency surgery and stenting groups after surgery treatment.

On the other hand, Young *et al.* ⁷ already showed a similar mortality in both groups.

A mortality rate of 12.9% in patients undergoing traditional surgical intervention for left-sided acute colonic obstruction was recordedin a review of the United Kingdom National ²⁷, while a mortality rate significantly lower (1%) was obtained by the use of stents in similar population, supporting the evidence that usingstents is a safe method to decompress a patient as a bridge to surgery ¹⁷.

I our study, we reported a lower clinical success rate than reported in literature by different meta-analysis that we considered (70.8% vs a calculated mean of 93.9%) ^{20,21}. If we consider the clinical success as it is usually considered and above explain ¹⁹, this rate would increase to 95.8%.

Our data are lower than other studies: van Hooft *et al.* reported 6 stent-related perforations in 47 patients (12.76%) in the SEMS group ²⁹ and Pirlet *et al.* reported 2 stent perforations (6.66%) and eight silent perforations (26.66%) in 30 patients randomized to colonic stenting as a bridge to surgery ³⁰.

Moreover, van Hooft JE *et al.* (10) showed how adverse events related to colonic stent placement are usually divided into early (≤30 days) and late (>30 days). The main early complications are perforation (range 0%-12.8%), stent failure after technically successful stent deployment (range 0%-11.7%), stent migration (range 0%-4.9%), re-obstruction (range 0%-4.9%), pain (range 0%-7.4%), and bleeding (range 0%-3.7%). Late adverse events related to SEMS mainly include re-obstruction (range 4.0%-22.9%) and stent migration (range 1.0%-12.5%), and more rarely perforation (range 0%-4.0%). Other SEMS complications reported less frequently in the literature are tenesmus (up to 22%, related to rectal SEMS), incontinence, and fistula.

Our data about bleeding (8.3% vs 0-3.7%), abdominal pain (8.3% vs 0-7.4%) and stent migration (8.3% vs 0-4.9%) seem to be higher than the data reported in the previous analysis while the data about colonic perforation (4.2% vs 0-12.8%) and tenesmus (8.3% vs more than 22%) are lower than the average reported.

However, we have reason to believe that this is due to the small sample size we analyzed.

Xuan Huanget al. ¹⁴ in their meta-analyses selected 7 RCTs and included 382 patients: 195 who were given a colonic stent and 187 controls who received emergency surgery. This work showed that SEMS serve as a safe and effective bridge to subsequent surgery in patients with obstructing left-sided colon cancer. The procedure significantly improves one-stage surgery rates (OR 2.01; 95 % CI:1.21–3.31, P =0.007), and decreases the rates of permanent stoma (OR 0.28; 95 % CI: 0.12-0.62, P = 0.002) and wound infection (OR 0.31; 95 % CI: 0.14-0.68, P =0.004). Anastomotic leakage, mortality (OR 0.88; 95 % CI: 0.40-1.96, P =0.76), intra-abdominal infection and overall morbidity were not better in

the colonic stent group compared with the emergency surgery group.

Clinical success, defined as we considered, if in one side is a limit to the studies, excluding all patients who have benefited of the stent as a bridge to surgery, but experienced complications, on the other hand allowed us to see how the stenting technique, however, is a viable alternative to emergency surgery, where mortality rates are still very high. Study's limits are: have considered only patients in which we use SEMS, without having an earnings comparison with any surgery group; small simple size; we didn't considered the long-term outcome and result, and the oncological safety of the procedure; the study population was not heterogeneous, but included only patients older than 65 years; we don't analyzed our data about covered and uncovered stents but we believe that the type of stent does not influence results in any way, when the stents is used as bridge to surgery. With our study, we only focused on short-term results.

A limit of our study is the complete absence of treated right colonic obstructions, probably due the lower probability of such lesions, as already reported by Formisano *et al.* in their population ³⁰. In fact, on 238 examined patients in the study, only 23 had right-sided lesion in comparison with 92 left-sided lesions. However, this limit it is also common to other interesting studies focused on our topic ³¹. In 2007 first described their experience in the colorectal bridge to surgery stenting in 3 patients with left-sided colic malignant obstruction. Subsequently, on a significantly larger population of 114 patients, Salamone *et al.* ³² examined only patients with left-sided colic malignant obstruction.

A further limit of our study is the poor examined population, not meaningful for an useful statistical analysis. However, future studies planned in our Department will deep our expertise and will enlarge our population.

Conclusion

In conclusion, we can state that colonic stenting used as a "bridge to surgery" is an excellent technique especially in clinically unstable patients, where the mortality rates for emergency surgery would stand at very high rates, allowing to stabilize patients and carrying on elective surgery, with an acceptable rate of complications. Unclear is the oncological safety of the procedure.

Further prospective studies on larger population, planned in our Department, will deep the knowledge on the role of SEMS in patients with acute malignant colorectal obstruction as *bridge to surgery*, in order to better plan the elective surgical intervention. However, our preliminary data seem to suggest that the stent placement can play a feasible role in the management of cases with an acute bowel obstruction, which occurs in a significant minority of colon cancer patients.

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