



## Colonic acute malignant obstructions: effectiveness of self-expanding metallic stent as bridge to surgery

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### ABSTRACT

**Background/Aims:** Bowel obstruction is a frequent event in patients with adenocarcinoma, affecting, in some series, almost one-third of the patients. In the last decades, in addition to surgery, self-expanding metallic stents (SEMSs) are available both as a bridge to surgery (BTS) or palliation. The aim of our study was to demonstrate the safety and efficacy of the use of SEMSs as BTS in selected patients with acute colonic malignant obstructions.

**Materials and Methods:** In total, 125 patients with malignant colonic obstruction who underwent emergency surgery or stent insertion were retrospectively enrolled in our study; 62 patients underwent surgery initially, whereas 62 were subjected to stenting as BTS. The 6-month and 1-year survival rates after the procedure (stenting or surgery) and short-term and long-term complication rates were considered as primary endpoints; the recanalization rate after Hartmann's procedure and the length of hospitalization were considered as secondary endpoints.

**Results:** On comparing the surgery group (SG) and the BTS group (BG), we observed a lower short-term complication rate ( $p < 0.05$ ) and a reduction in the mean hospital stay ( $16.1 \pm 7.7$  vs.  $13.5 \pm 3.0$ ,  $p < 0.05$ ) in the latter. No differences in long-term complications were found. The recanalization rate after Hartmann's procedure was higher in BG than in SG, although this was not statistically significant.

**Conclusion:** Our experience shows that SEMS insertion is a safe and effective technique in selected patients with colonic malignant obstruction; the reduction in hospital stay and short-term complications in BG is an important cost-saving aim.

**Keywords:** Colorectal cancer, self-expanding metallic stent, colonic stent, bridge to surgery, Hartmann's procedure, cost-saving

### INTRODUCTION

Colorectal cancer (CRC) is one of the most problematic challenges for the National Health Services in the western world because of its high incidence and mortality (1-3).

In a percentage that varies from 7% to 30% of the cases, according to different data, CRC presents as an obstructive form (4-6), which is often suggestive of an advanced stage and is frequently burdened by a higher surgical complication rate. Furthermore, these patients are generally elderly people with a poor performance status and many comorbidities (7).

The aim of our study was to confirm, according to recent literature, that the placement of a self-expanding metallic stent (SEMS) as a bridge to surgery (BTS) rep-

resents a valid and safe first step in a large number of patients after correct multidisciplinary evaluation in a university hospital with broad experience.

### Surgical Treatment

Surgical therapeutic options for obstructive CRC include curative and palliative surgery; curative surgery can be performed as a single-step procedure that consists of a resection of the lesion and a primary anastomosis or as a double-step procedure (Hartmann's procedure): in the latter case, the surgeon resects the lesion and makes a stoma, which is subsequently potentially removable with the possibility of recanalization. To date, a three-step procedure is scarcely ever used (2). The choice of the type of procedure to use depends on the experience and the knowledge of the surgeon and the timing of the surgery, regardless of whether it is an emergency one (8).

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**Received:** May 6, 2016

**Accepted:** October 17, 2016

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Higher complication rates have been demonstrated in patients who underwent the single-step procedure in case of an emergency; nevertheless, randomized controlled trials are not available (9). Several recent trials have indeed shown that the single-step procedure is safe, with a lower complication rate and reduced time of hospitalization (10).

In most cases, palliative surgery for obstructive CRC consists of a stoma, upstream with respect to the stricture, but this technique is not routinely used because of its high complication rate and the many nursing issues involved (2).

### SEMS Insertion

Since the first half of the 90s, SEMS was available for use in malignant colonic obstruction as BTS or as palliative treatment, mostly for left-sided obstructive CRC; stentings in right-sided obstructions are technically more difficult and involve a higher risk of complications. The rational use of SEMS as BTS is to decompress the colon, and to improve the patient's global condition, deferring surgery, with the possibility of a well-prepared colon and, for those patients that take anticoagulant drugs, to switch to low-molecular-weight heparin (LMWH). Furthermore, in several trials, BTS stenting seems to reduce hospitalization, intraoperative morbidity, and mortality (11), whereas, so far, no study has demonstrated any advantage in terms of long-term survival in comparison to urgent surgery; furthermore, the European guidelines do not recommend it as BTS in potentially resectable patients.

Several types of stent are available; steel metallic stents were used initially; later, they were made from Elgiloy (a mixture of chromium, cobalt, and nickel), and the most recent material used is nitinol, a mixture of nickel and titanium.

There are basically two positioning techniques: in the "through-the-scope" technique, the guide wire is passed through the operative channel of the scope; the latter is used for anatomically difficult colonic strictures and for those sited proximally. The "over-the-wire" technique is instead used to stent left-sided lesions and is used especially for those located less than 30 cm from the anal margin. It is necessary to use fluoroscopic guidance to evaluate the extension and the morphology of the stenosis, for a better choice of the right type of stent to insert (12). Stents can also be covered or uncovered, the former having the advantage of being less subject to neoplastic invasion of the metallic web, but having the disadvantage of a higher incidence of dislocation of the stent. SEMS are also used in the treatment of benign obstructions, but this is not the aim of our study.

## MATERIALS AND METHODS

### Patients

A retrospective single-center comparison study was designed; 125 symptomatic patients, with malignant colonic obstruction due to adenocarcinoma, were urgently admitted to the Emergency Department of our hospital from January 2009 to June 2015 and subsequently underwent urgent surgical procedures

or successful stent positioning. Symptoms included vomiting, abdominal pain, rectal bleeding, fever, constipation, and overflow diarrhea. All the patients selected for the study were previously evaluated by means of colonoscopy, computed tomography (CT), magnetic resonance imaging (MRI), or colonic barium enema. Data were obtained, dividing patients in a surgery group (SG) and a BTS group (BG).

Inclusion criteria were the emergency presentation of occlusion symptoms (less than 72 hours), an American Society of Anesthesiologists (ASA) Physical Status of  $\geq 3$ , and age of  $>50$  years. Exclusion criteria were palliative stent positioning, the presence of an extrinsic obstruction, previous colonic surgery, benign nature of the stricture, and the presence of sepsis at the beginning of the evaluation. Thirty-four patients were excluded from the analysis because of palliative stenting.

Demographic data were collected, including age, sex, comorbidity (among these, we considered diabetes, cardiovascular disease, chronic kidney failure, and pulmonary disease), site of the obstruction, and oncological stage, according to 7<sup>th</sup> ed. TNM staging. Our study was approved by a local ethics committee as retrospective observational analysis.

### Stent Positioning and Surgery

The decision to refer a patient for stent positioning or for urgent surgery was taken by a multidisciplinary team consisting of an endoscopist, a radiologist, a surgeon and an anesthetist, according to the age of the patient, the comorbidities, the staging of the tumor, and the site of the obstruction.

Four types of SEMSs, covered and uncovered, were used for stenting: Hanarostent Colorectal (MI Tech, Korea), Evolution Colonic Stent (Cook, USA), Ultraflex Precision Colonic (Boston Scientific, Japan), in nitinol, and Wallstent Enteral (Boston Scientific, Japan), in Elgiloy. We used a colonoscope CF H180AI (Olympus medical system, Japan), for all the cases of SEMS placement (Figures 1, 2a, and 2b).

Two types of surgical interventions were performed for curative intent by a one-step surgery, with primary anastomosis, or a Hartmann's procedure, namely, a two-step procedure with the creation of a stoma and a subsequent recanalization.

Both endoscopists and surgeons who performed the procedures had more than five years of experience in the management of colonic obstruction.

### Clinical Outcomes

Six-months and one-year survival after the procedure (stenting or surgery), was considered as a primary end-point, as well as short-term (7 days) and long-term (after the seventh day, within 3 months) complication rates. As complications for stent insertion, we considered stent stenosis, stent migration, rectal bleeding, and perforation; as complications for surgery, we considered anastomosis dehiscence, rectal bleeding, occlusions, and sepsis. For rec-

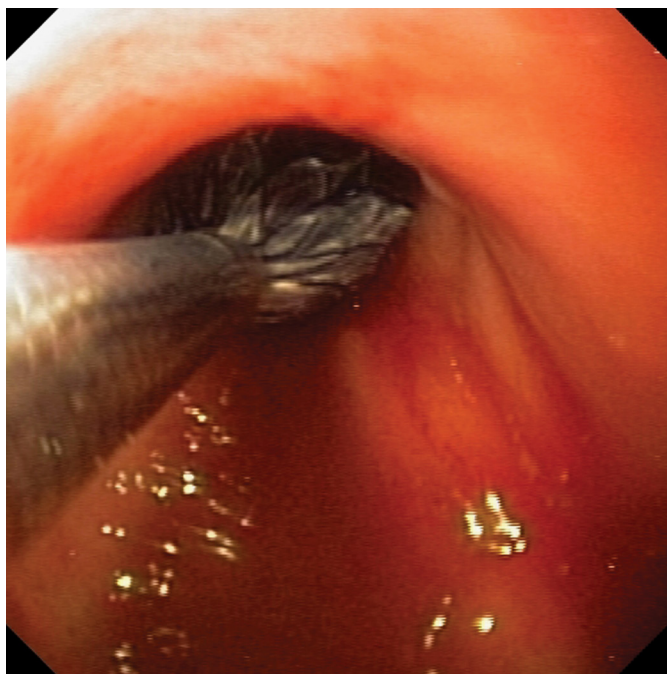


Figure 1. A colonic stent at the moment of release

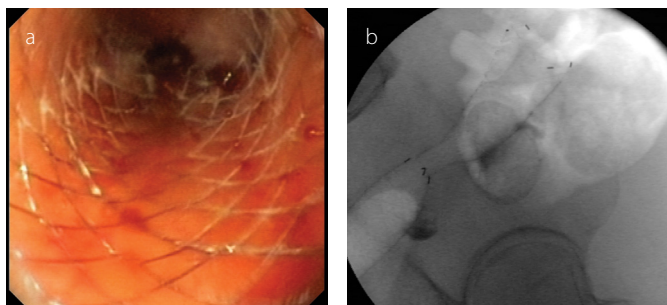


Figure 2. a, b. A fully deployed colonic stent: (a) observed from the inside; (b) observed at fluoroscopy

tal bleeding, we considered only the clear presence of red blood in the feces with a drop of hemoglobin >2 g/dL in the first twelve hours after bleeding; conversely, we did not consider as bleeding the presence of a few traces of red blood or clotted blood in the feces. The diagnosis of bowel perforation, dehiscence, occlusion, and sepsis was clinical, and always confirmed by imaging. A comparison between the surgical complication rates in the two groups was also made; only the early post-operative complications (within first seven days) for BG were considered separately to be better compared to SG complications.

Secondary end-points were considered as the recanalization rate after Hartmann's procedure and the overall number of days of hospitalization.

**Statistical Analysis**

Continuous data are expressed as mean and standard deviation; categorical data are presented as numbers and percentages. Comparisons of the qualitative data were estimated using the Mann-Whitney U test; the Spearman correlation test was used to analyze the interdependence between continuous variables. The results were considered significant at  $p < 0.05$ .

**RESULTS**

**Overall**

In total, 125 patients were included in our study (mean age 72.1 years  $\pm$  9.9 Standard Deviation (SD), male/female 56/69); all patients (Table 1) had a diagnosis of CRC, mostly localized at the left side of the colon (about 90% of patients). In our cohort, cardiovascular disease and diabetes had a high prevalence of 37.6% and 30.4%, respectively, whereas the most frequent symptoms were constipation and abdominal pain in 75.2% and 53.6% of cases, respectively; vomiting was less common, occurring only in about one fifth of the patients. About 18% of the patients took anticoagulant drugs at the moment of the occlusion, in detail, 7 patients (11.1%) in SG and 16 patients (25.8%) in BG. The mean tumor extension was 5.1  $\pm$  1.6 cm.

At the statistical analysis, no differences (Table 2) concerning sex, comorbidities, symptoms, and tumor extension were found between SG and BG; only for the mean age at the moment of the procedure, was there a statistically significant difference, 70.0  $\pm$  8.2 and 74.2  $\pm$  10.6 years in SG and in BG, respectively. All the patients were submitted to colonoscopy to assess the diagnosis before the surgery; in BG, two thirds of the patients had a colonoscopy, while the remaining patients underwent a CT scan or MRI (22 patients). Only one patient was submitted to colonic barium enema.

**Procedures**

In SG (63 patients), the types of surgery performed were substantially two (Table 3): 39 patients (62%) underwent a one-step procedure with a primary anastomosis, while 24 patients (38%) were submitted to a Hartmann's procedure.

In BG (62 patients), an endoscopic stent insertion was performed in all cases (Table 4); covered stents were placed in 4 (6.4%) cases, and the most commonly used was the nitinol type. All patients in BG taking anticoagulant drugs shifted to LMWH.

**Clinical Outcomes**

Twelve patients (19%) from SG had complications within the 7<sup>th</sup> day after the procedure, i.e., six had rectal bleeding (in none of these cases was there life-threatening bleeding, and in all cases an endoscopy was performed to achieve hemostasis), three had dehiscence of the anastomosis, (two treated with conservative therapy, and one with second-look surgery), and three patients had sepsis (in all cases treated by antibiotic therapy; in one case it was also necessary to transfer the patient to an Intensive Care Unit). Only four complications (6.4%) were observed in BG after seven days (two cases of sepsis and two cases of perforations treated by antibiotic therapy and conservative therapy, respectively) and this difference was statistically significant ( $p = 0.03$ ). No differences between SG and BG were found regarding the complication rate in the 3<sup>rd</sup> month after the procedure, there being 14 cases in SG (four cases of occlusions, eight cases of sepsis, and two cases of rectal bleedings) and 16 cases (nine cases of occlusions and seven cases of sepsis) in BG. The survival rate was similar for both groups: 80.9% and 79.0% at 6 months and 62% and 72% at 1 year, respectively (Table 5).

**Table 1.** Overall demographic features

Variables	Number (%)
Age (years), mean±SD	72.1±9.9
Sex (F/M)	69/56
<b>Comorbidities</b>	
Cardiovascular disease	47 (37.6)
Diabetes	38 (30.4)
Anticoagulant drug use	23 (18.4)
Pulmonary disease	18 (14.4)
Chronic kidney disease	10 (8.0)
<b>Symptoms</b>	
Constipation	94 (75.2)
Abdominal pain	67 (53.6)
Vomiting	27 (21.6)
Overflow diarrhea	21 (16.8)
Rectal bleeding	15 (12.0)
<b>Previous evaluation</b>	
Colonoscopy	102 (81.6)
CT/MRI	22 (17.6)
Colonic barium enema	1 (0.8)
<b>Tumor staging (TNM)</b>	
1	58 (46.4)
2	50 (40.0)
3	16 (12.8)
4	1 (0.8)
<b>Site of obstruction</b>	
Sigmoid colon	66 (52.8)
Rectum	29 (23.2)
Descending colon	18 (14.4)
Transverse colon	7 (5.6)
Ascending colon	5 (4.0)
<b>Tumor extension (cm), mean±SD</b>	5.1±1.6

CT: computed tomography; MRI: magnetic resonance imaging; SD: standard deviation

In SG, only 15 patients (15/24, 62.5%) were submitted to recanalization; the remaining 9 patients failed the second surgical procedure due to their poor patient clinical condition or personal choice, in six and three cases, respectively. In BG, 53 (85.4%) patients underwent a single-step procedure and 9 (14.5%) were scheduled for a Hartmann's procedure. Five patients (8%) in BG had post-surgical complications within the 7<sup>th</sup> day after intervention: three cases had bleeding (in all cases, an endoscopic examination was required and, in two cases, hemostasis was also necessary) and two cases had anastomotic dehiscence (in one case conservative therapy was sufficient, and in the other a second intervention was necessary). Seventeen patients (27%) had a complication in the first three months after surgery: nine pa-

**Table 2.** Comparison between SG and BG demographic characteristics

Variables	SG (n=63) Number (%)	BG (n=62) Number (%)	p
Age (years), mean±SD	70.0±8.2	74.2±10.6	0.06
Sex (F/M)	35/27	34/29	NS
<b>Comorbidities</b>			
Cardiovascular disease	20 (31.7)	26 (41.9)	NS
Diabetes	17 (26.9)	20 (32.2)	NS
Anticoagulant drug use	7 (11.1)	16 (25.8)	NS
Pulmonary disease	8 (12.6)	10 (16.1)	NS
Chronic kidney disease	4 (6.3)	6 (9.6)	NS
<b>Symptoms</b>			
Constipation	49 (77.7)	45 (72.5)	
Abdominal pain	32 (50.7)	35 (56.4)	NS
Vomiting	12 (19.0)	15 (24.1)	NS
Overflow diarrhea	12 (19.0)	9 (14.5)	NS
Rectal bleeding	9 (14.2)	6 (9.6)	NS
<b>Previous evaluation</b>			
Colonoscopy	63 (100)	39 (62.9)	<0.001
CT/MRI	0 (0)	22 (35.4)	<0.001
Colonic barium enema	0 (0)	1 (1.6)	NS
<b>Tumor staging (TNM)</b>			
1	30 (47.6)	28 (43.5)	NS
2	26 (41.2)	24 (38.7)	NS
3	6 (9.5)	10 (16.1)	NS
4	1 (1.5)	0 (0)	NS
<b>Site of bowel obstruction</b>			
Sigmoid colon	30 (47.6)	36 (58.0)	
Rectum	15 (23.8)	14 (22.5)	NS
Descending colon	10 (15.8)	8 (12.9)	NS
Transverse colon	4 (6.3)	3 (4.8)	NS
Ascending colon	4 (6.3)	1 (1.6)	NS
<b>Time to the surgery after stenting (days), mean±SD</b>	-	5.1±1.8	-
<b>Tumor extension (cm), mean±SD</b>	5.4±1.6	4.9±2.4	NS

SG: surgery group; BG: BTS group; NS: not significant; CT: computed tomography; MRI: magnetic resonance imaging; SD: standard deviation

**Table 3.** SG and BG features: type of surgical procedure

Type of surgery	SG (n=63)	BG (n=62) (after stenting)	p
One-step	39 (61.9)	53 (85.4)	0.002
Two-step (scheduled)	24 (38.1)	9 (14.6)	0.002

SG: surgery group; BG: BTS group

**Table 4.** BG features: type of stenting

Variables Type of stent	BG (n=62)	Covered stents (n=4, 6.4%)
Ultraflex	30 (48.3)	0
WallFlex	15 (24.1)	0
Hanarostent	12 (19.3)	4
Evolution	5 (8.0)	0

BG: BTS group

**Table 5.** Primary and secondary outcomes: comparison between SG and BG

Outcomes	SG (n=63)	BG (n = 62)	p
Complication rate within the 7 <sup>th</sup> day after the procedure	12 (19.0)	4 (6.4)	<0.05
Complication rate on the 3 <sup>rd</sup> month after the procedure	14 (22.2)	16 (25.8)	NS
Six-month survival rate	51 (80.9)	49 (79.0)	NS
One-year survival rate	39 (61.9)	37 (59.6)	NS
Hospitalization duration (days), mean±SD	16.1±7.7	13.5±3.0	<0.05
<b>Recanalization after Hartmann's procedure</b>	15/24 (62.5)	8/9 (88.8)	NS

SG: surgery group; BG: BTS group; NS: not significant; SD: standard deviation

tients had occlusions, seven patients had sepsis, and one patient had rectal bleeding (in this case, due to the onset of hypovolemic shock, it was necessary to perform urgent endoscopic hemostasis and rapid blood volume restoration with plasma expanders and blood transfusion).

Also, comparing complication rates between the two post-surgical periods, the results in the bridge to surgery group (BG) were lower than in SG, respectively, in 8% and in 19 of patients; the early complications (within the 7<sup>th</sup> post-operative day) were not considered among the other complications and were counted separately.

The average time of surgery after SEMS insertion was 5.1±1.8 days. The recanalization rate in BG patients scheduled for a two-step procedure was higher compared to SG patients who underwent surgery initially, 88.8% (8/9 patients) and 62.5% (15/24), respectively, although not statistically significant. Only in one patient in BG, recanalization was not feasible due to poor patient clinical conditions. One step-surgery was more frequently feasible in the BG group, compared to the SG group, respectively, in 85% and 62% of cases (Table 3), probably due to: (1) better overall status of the patients; (2) better surgical procedure preparation; (3) antibiotic prophylaxis; (4) a lower degree of bowel distension and inflammation.

Finally, the average hospitalization time was significantly higher for those patients belonging to SG (16.1 days) compared to the patients in BG (13.5 days), and this result was statistically significant (p<0.05).

**DISCUSSION**

Bowel obstruction in patients with CRC is not an infrequent event, affecting almost one-third of the patients (4-6). Therapeutic strategies include surgery and stent insertion, both with a curative or palliative scope. Urgent surgery seems to have higher complication and mortality rates than elective surgery, as reported in a large Norwegian study: 24% vs. 38% and 3.5% vs. 10%, respectively (10). Use of the stent improved the management of the obstructed patients in emergencies, allowing surgery to be delayed and enabling better therapeutic strategies to be chosen.

Despite several studies demonstrating the safety and efficacy of stent insertion, no randomized controlled trials are available, and a recent survey, in which 148 surgeons in Australia and New Zealand were interviewed, confirmed the lack of agreement in this field. In fact, more than 70% of the surgeons preferred the use of stents only for palliation, while they referred patients with curable disease for surgical treatment. In addition, American and European guidelines agree that SEMS insertion as BTS is not recommended as a standard treatment in potentially curable patients. SEMS insertion can however be considered in elderly patients, with many comorbidities and with a high ASA score (13). Conversely, all authors agree on the use of SEMS in palliative treatment, except in patients treated with antiangiogenic drugs.

Despite these warnings, SEMS insertion is a safe procedure; in fact, a prospective study by Repici et al. (14), that evaluated the use of WallFlex colonic stents on 42 patients with malignant colonic obstruction, showed low complication rates in the first 30 days after the procedure, which included only one perforation, one stent migration, and one stent occlusion. Also Meisner et al. (15) reported a similar complication rate within the first 30 days (7%), whereas Gajendran et al. (16) described, on 16 patients who underwent SEMS insertion, no immediate complications (<24 hours), two stent stenosis, due to stent kinking, in the first 7 days, and two stent migrations, which occurred after 34 and 91 days. No perforation or rectal bleeding occurred. In our series, according to the literature data, we observed a lower short-term complication rate in BG in comparison to SG, 6.4% vs. 19.0%, respectively. In our study, the recanalization rate, although with a small sample size and with no statistical significance, was higher in BG compared to SG, probably due to resolution of occlusions and an improvement in global clinical and nutritional assessment. SEMS insertion and a delay in surgical intervention appears to reduce the mean time of hospital stay, to 13.5±3 days, compared to 16.1±7.7 days in SG, as described in the literature (17-20), and this leads to significant cost-saving. We explain the reduction in the length of hospital stay by a lower rate of early complications between the two procedures (stenting and surgery) (Table 5) and by a lower rate of early complication between urgent surgery and delayed surgery (Table 6), although this latter data was not statistically significant.

Two recent meta-analyses, although performed very cautiously, confirmed these data and concluded that the insertion of SEMS as BTS appears to be a safe practice, with a low rate of complications and a higher rate of primary anastomosis (21,22).

**Table 6.** Post-surgical complications: comparison between SG and BG

Outcomes	SG (n=63)	BG (n=62) (after stenting)	p
Complication surgery (7 <sup>th</sup> day)	12 (19.0)	5 (8.0)	0.07
Complication surgery (3 <sup>rd</sup> month)	14 (22.2)	17 (27.4)	NS
<b>Overall</b>	26 (41.2)	22 (35.4)	NS

BG: BTS group; NS: not significant

The main drawback of our study is its retrospective nature and the fact that it was not based on intention-to-treat analysis. Several sources of bias could affect our results: first of all, the use of different types of SEMs (WallFlex, Ultraflex, Hanarostent, and Evolution), due to the features of the various materials, their different conformations and their different radial and axial strengths; also, the main parts of the SEMs used were not covered. Other important sources of bias are the statuses of the heterogeneous cancers among the patients examined and the different locations of the obstructions, although most of the patients included had a distal obstruction.

Our study, although limited by its retrospective design, highlights the safety and the effectiveness of SEMs insertion as BTS; reduction of the short-term complications and shortening of the hospital stays are important goals to achieve, from the perspective of sparing economic resources and for the sustainable management of a growing issue. The choice to refer patients for surgery or for stenting must be made on a case-by-case basis, according to the patient's general condition and after a multidisciplinary evaluation; in any case, randomized controlled trials on a larger number of patients will be necessary to confirm the superiority of stenting as BTS over urgent surgery in colonic malignant obstructions.

**Ethics Committee Approval:** Ethics committee approval was received for this study from the ethics committee of University Hospital of Messina.

**Informed Consent:** Not required for retrospective study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – S.P., M.G.F.; Design – M.C., F.F., S.P., M.G.F.; Supervision – P.C., S.P.; Resources – P.C., G.G., A.T.; Materials – P.C., G.G., A.T.; Data Collection and/or Processing – P.C., M.C., S.P.; Analysis and/or Interpretation – P.C., M.C., A.T., F.F., S.P.; Literature Search – G.G., M.C., F.F., S.P.; Writing Manuscript – G.G., M.C., F.F., S.P.; Critical Review – P.C., G.G., M.C., A.T., F.F., S.P., M.G.F.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study has received no financial support.

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