

# Long-term outcomes of palliative colonic stenting versus emergency surgery for acute proximal malignant colonic obstruction: a multicenter trial



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## Bibliography

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## ABSTRACT

**Background and study aims** Long-term data are limited regarding clinical outcomes of self-expanding metal stents as an alternative for surgery in the treatment of acute proximal MBO. The aim of this study was to compare the long-term outcomes of stenting to surgery for palliation in patients with incurable obstructive CRC for lesions proximal to the splenic flexure.

**Patients and methods** Retrospective multicenter cohort study of obstructing proximal CRC patients with who underwent insertion of a SEMS (n=69) or surgery (n=36) from 1999 to 2014. The primary endpoint was relief of obstruction. Secondary endpoints included technical success, duration of hospital stay, early and late adverse events (AEs) and survival.

**Results** Technical success was achieved in 62/69 (89.8%) patients in the SEMS group and in 36/36 (100%) patients who underwent surgery (P=0.09). In the SEMS group, 10 patients underwent stenting as a bridge to surgery and 59 underwent stent placement for palliation. Clinical relief was achieved in 78% of patients with stenting and in 100% of patients who underwent surgery (P<0.001). Patients with SEMS had significantly less acute AEs compared to the surgery group (7.2% vs. 30.5%, P=0.003). Hospital mortality for the SEMS group was 0% compared to 5.6% in the surgery group (P=0.11). Patients in the SEMS group had a significantly shorter median hospital stay (4 days) as compared to the surgery group (8 days) (P<0.01). Maintenance of decompression without the recurrence of bowel obstruction until death or last follow-up was lower in the SEMS group (73.9%) than the surgery group (97.3%; P=0.003). SEMS placement was associated with higher long-term complication rates compared to surgery (21% and 11% P=0.27). Late SEMS AEs included occlusion (10%), migration (5%), and colonic ulcer (6%). At 120 weeks, survival in the SEMS group was 5.6% vs. 0% in the surgery group (P=0.8).

**Conclusions** Technical and clinical success associated with proximal colonic obstruction are higher with surgery when compared to SEMS, but surgery is associated with longer hospital stays and more early AEs. SEMS should be considered the initial mode of therapy in patients with acute proximal MBO and surgery should be reserved for SEMS failure, as surgery involves a high morbidity and mortality.

## Introduction

Acute malignant large bowel obstruction (MLBO) represents an urgent or emergent condition and occurs in up to 20% of patients with colon cancer [1]. In patients with incurable obstructive colorectal carcinoma (CRC), a palliative diverting colostomy has been considered the treatment of choice. Many patients with MLBO are poor operative candidates and have a high incidence of post-surgical adverse events (AEs) including prolonged hospitalization, abscess formation, anastomotic

leakage and sepsis [2]. Emergent surgery for colonic obstruction has historically had a high mortality rate of 10% to 30% [3]. Furthermore, patients with a permanent colostomy have been found to have lower health-related quality of life and increased costs related to a variety of factors, many of which relate to colostomy care [4].

The role of colonic self-expanding metal stents (SEMS) in patients with MLBO is well established as a therapeutic option in patients with locally unresectable distal (descending colon, sigmoid colon, rectosigmoid, and rectum) colorectal carcinomas

and is first line therapy at many centers [1, 5, 6]. SEMs allow relief of colonic obstruction and allow for medical resuscitation, optimization of comorbid disorders, bowel preparation, and staging [5]. Emergent surgery and a surgical stoma can thus often be avoided in these patients [4]. Colonic SEMs can also decrease hospital stay and reduce hospital costs compared to emergency surgery [7, 8].

In patients with acute proximal CRC obstruction (defined as caused by lesions proximal to the splenic flexure), the current standard of care at many centers is still surgical resection and primary anastomosis, with older literature suggesting that outcomes in patients undergoing emergent surgery are comparable to those undergoing elective surgery. However, recent data suggest that emergent right-sided colonic resections may have a significantly higher mortality and morbidity when compared to elective procedures [9].

There is a paucity of data on the role of colonic SEMs for therapy of acute obstruction from proximal colonic lesions. Campbell et al. have reported successful placement of SEMs to relieve a proximal transverse colon obstruction [10]. Repici and Dronamraju et al. have both performed small retrospective, single-arm analysis demonstrating that SEMs appear to be safe and effective in the treatment of malignant obstruction of the proximal colon [11, 12]. However, there continues to be significant concern about the safety of SEMs in the proximal colon, in particular about their long-term patency rates and AEs [13, 14].

We conducted a retrospective multicenter trial to compare long-term outcomes of endoscopic stenting and surgery for in patients with unresectable obstructing colorectal cancer (CRC) and lesions proximal to the splenic flexure.

## Patients and methods

### Patients

We performed a retrospective cohort study of patients with acute proximal malignant colon obstruction from unresectable colon cancer at 5 institutions (Molinette Hospital in Turin, Italy, University of Texas–Houston Medical School, Istituto Clinico Humanitas, Milan, Italy, Thomas Jefferson University Hospital and Mayo Clinic in Rochester, MN) who underwent either placement of a colonic SEM or surgery for palliation between February 1999 and October 2015.

Patients who were eligible for the study had clinical and radiological findings of acute colonic obstruction. The medical records of patients identified were then reviewed by physicians who used a structured data form to collect the following data: demographic information (age, race, and gender), presentation, tumor histological diagnosis, and location of the colonic stricture. All patients underwent contrast-enhanced computed tomography scanning or a gastrograffin enema study to determine the site of the lesion and the presence of distant metastases. Patients were excluded from the study if they had clinical and/or radiological evidence of bowel perforation, peritonitis or significant gastrointestinal bleeding.

### Endoscopic placement of colonic SEMs

All patients underwent enema preparation prior to the endoscopy. Patients were sedated with intravenous midazolam and meperidine or general endotracheal anesthesia (GETA). The endoscope was passed to the site of the obstructive tumor and a guide wire was passed across the stricture under endoscopic and fluoroscopic guidance. Water-soluble contrast was injected to determine the length of the lesion. Based upon the length of stenosis, a 6-, 9- or 12-cm uncovered Wallstent™ or WallFlex™ Colonic Stent (Boston Scientific, Natick, USA) was used to traverse the stenosis. The stent was placed so as to extend at least 2 cm on each end beyond the tumor margin using both endoscopic and fluoroscopic visualization.

### Emergent surgery for therapy of colonic obstruction

In patients who underwent surgery, the type of operation was decided on by the attending surgeon. Palliative resection with primary anastomosis was attempted if possible. If a primary colostomy was performed, then restoration of bowel continuity by surgical anastomosis was considered in 4 to 6 months. In patients in whom stents were placed as a bridge to surgery, elective surgery was performed within 1 to 4 weeks after stent placement.

### Definitions

In the SEMs group, technical success was defined as successful deployment of the colonic stent across the stricture. Immediate clinical success was defined as colonic decompression and relief of obstructive symptoms within 24 hours after stent placement. In the surgery group, clinical success was defined as colonic decompression and relief of obstructive symptoms within 24 hours after surgery [15, 16]. In both groups, late success was defined as maintaining colonic decompression without the recurrence of intestinal obstruction until death or last follow-up [16].

### Patient adverse events

AEs were defined as those leading to new symptoms, reobstruction, or alteration of management [17]. Early AEs were defined as those that presented within 30 days of stent placement or surgery; late adverse events were those that occurred after 30 days of the time of procedure [12, 17].

### Patient outcomes and statistical analysis

All values are presented as mean, median (range), or percentage. The primary outcomes of this study were to evaluate the success and complication rates between the SEMs group and the surgery group. Secondary outcomes were patient AEs, duration of hospital stay and overall survival rates in the 2 groups.

Data were analyzed using cross tabulation. Categorical variables were evaluated using Chi-Square or Fisher's Exact Test, where appropriate. Continuous data were compared using the unpaired *t*-test or Mann-Whitney tests. Survival analysis was performed using the Kaplan-Meier actuarial method, and survival curves were compared using the log-rank method. All val-

► **Table 1** Patient demographics.

	Surgery	SEMS	P value
Number of patients	36	69	
Age (mean, years)	58	63	0.04
Sex ratio M:F	18:18	40:29	0.536
Site of colon obstruction (%)			
▪ Cecum/ascending colon	44.4	42	0.83
▪ Transverse colon	8.4	37.7	0.001
▪ Hepatic flexure	47.2	20.3	0.006
Median follow-up, weeks	29.3 (range, 1–121 weeks)	26.3 (range, 2–80 weeks)	0.7

SEMS, self-expanding metal stent

ues were presented as means. Statistical significance was determined a priori at  $P \leq 0.05$ .

## Results

### Baseline patient characteristics (► Table 1)

During the study period, a total of 105 patients presented with acute colonic obstruction from a tumor that was located proximal to the splenic flexure. Sixty-nine patients were treated endoscopically by placement of a colonic SEMS while 36 patients underwent surgery. Twenty-four patients underwent a right colectomy and primary anastomosis and 12 had a right colectomy and an ostomy. In the SEMS group, stenting was attempted as a bridge for surgery in 10 patients and a palliative treatment in 59 patients. The choice of therapy was decided per local practice and the physician's discretion. Patient characteristics are summarized in ► **Table 1**. There were no statistically significant differences in the sex or ethnicity between the 2 groups. The mean age of patients who underwent SEMS was statistically greater as compared to patients that underwent surgery (63 vs. 58 years respectively;  $P = 0.04$ ). All stents placed were 22 mm in diameter.

The site of colonic obstruction in the SEMS group was as follows: cecum/ascending colon = 31 (44.4%), hepatic flexure = 6 (8.4%), transverse colon = 32 (47.2%). The site of colonic obstruction in the surgery group was as follows: cecum/ascending colon = 15 (42%), hepatic flexure = 7 (20.3%), transverse colon = 14 (37.7%). A greater number of patients with a hepatic flexure obstruction underwent surgery compared to undergoing a colonic SEMS ( $P = 0.006$ ). Conversely, in patients with a transverse colon obstruction, there were a greater number of patients in the SEMS group as compared to those who underwent surgery ( $P = 0.001$ ).

### Early patient outcomes and adverse events (Within 30 days of initial SEMS placement)

Procedural technical success was achieved in 62/69 (89.9%) patients in the SEMS group and in 36/36 (100%) patients who underwent surgery ( $P = 0.09$ ). In the 62 patients in which the technical success with the SEMS was achieved, clinical relief of the

colonic obstruction was achieved in 54 (78%) patients in the SEMS group and in all 36 (100%) patients who underwent surgery ( $P < 0.01$ ).

There were no technical failures in the surgery group. In the SEMS group, technical failure occurred in 7 patients (10.1%) because of inability to pass a guidewire across the lesion ( $n = 2$ ), failure of stent expansion ( $n = 2$ ), stent malposition ( $n = 2$ ), and colonic perforation during the procedure ( $n = 1$ ). In the patients with the failure of stent expansion, one occurred in the ascending colon and the other in the hepatic flexure; both these patients did not improve their obstructive symptoms within 24 hours and were referred for surgery. The one case of bowel perforation was caused by the passage of the Wallflex™ stent through the wall of the ascending colon during insertion. Stent malposition occurred in 1 patient with a lesion at the hepatic flexure and 1 patient where the lesion was in the proximal transverse colon. This was felt to be a result of an acute angulation at the site of obstruction.

After the procedure, the SEMS group had a significantly lower rate of early AEs compared to the surgery group (7.2% vs. 30.5%;  $P = 0.003$ ). In the SEMS group, delayed colonic perforation developed in 1 patient at day 15 after stenting; this patient underwent emergent right hemicolectomy with colostomy. Stent reobstruction occurred in 1 patient due to tumor overgrowth and in 1 patient who developed a stool impaction; the stent reobstruction occurred on day 19 and day 28 after initial placement respectively. Both these patients underwent a successful second stenting with relief of their bowel obstruction. There were no stent related deaths during within 30 days of stent placement.

In the surgery group, 4 patients developed a wound infection requiring intravenous antibiotics, 1 patient had an anastomotic leak requiring surgical revision, 2 patients developed respiratory failure that warranted an intensive care unit admission, 1 patient had a iatrogenic ruptured spleen that did not require surgery, 1 patient had urinary dysfunction and 2 patients died in the early (<30 days) postoperative period.

Patients in the SEMS group had a significantly shorter median hospital stay (4 days) as compared to the surgery group (8 days) ( $P < 0.01$ ).

## Late patient outcomes and adverse events (30 days after initial SEMS placement)

Among patients who underwent colonic stenting as a palliative procedure, the mean duration of follow-up in the SEMS group was 26.3 weeks (range, 2–80 weeks). The mean duration of follow-up in the surgery group was 29.3 weeks (range, 1–121 weeks). Maintenance of colonic decompression without the recurrence of bowel obstruction until patient death or last follow-up was lower in the SEMS group (73.9%) than in the surgery group (94.4%;  $P=0.02$ ).

The median duration of first stent patency was 19 weeks (range 12–44 weeks). Seven of 10 patients in whom stent failure developed were able to be managed by placement of a second stent while the other 3 required a surgical ostomy based on the discretion of the primary surgical team although gastroenterology was not consulted prior to this decision. The cause of recurrence of bowel obstruction in the SEMS group was tumor overgrowth leading to stent occlusion ( $n=7$ ) or stent migration ( $n=4$ ), while bowel obstruction recurrence in the surgery group ( $n=1$ ) occurred as a result of small bowel obstruction from adhesions.

Although the overall late AE rate was higher in the SEMS group ( $n=14$ ; 21%) as compared to the surgery group ( $n=4$ ; 11%), this did not reach statistical significance ( $P=0.29$ ). Late AEs in the SEMS group included stent occlusion due to tumor ingrowth ( $n=8$ ), stent migration ( $n=4$ ), delayed perforation ( $n=1$ ), and colonic ulcer leading to hematochezia ( $n=1$ ) (► **Table 2**). Late AEs of surgery occurred including formation of an enterocutaneous fistula ( $n=1$ ), small bowel obstruction from adhesions ( $n=1$ ), anorectal abscess ( $n=1$ ), and ventral hernia formation ( $n=1$ ). Only the presence of a transverse colon obstruction independently predicted late adverse events in the SEMS group ( $P<0.001$ ). Age, sex, race, and type of stent were all not found to be risk factors for late adverse events in the SEMS group. The outcomes and AEs of both groups are summarized in ► **Table 3**.

At gastrografin 120 weeks, patient survival in the SEMS group was 5.6% compared to 0% in the surgery group ( $P=0.8$ ) (► **Fig. 1**)

## Discussion

This multicenter study demonstrated that in patients with primary proximal CRC and obstructive symptoms both SEMS and surgery are both viable clinical options. The technical success and maintenance of colonic decompression without recurrence of bowel obstruction until patient death or last follow-up was higher with surgery as compared to the SEMS group in patients with unresectable disease. However, patients who underwent surgery had a significantly longer hospital stay and a higher rate of early AEs compared to the SEMS group, highlighting the risks and the more invasive nature of emergent surgical hemicolectomy when compared to colon stents. Long-term AEs and survival were similar in both groups.

The current literature supports the non-surgical approach of placing colonic SEMS to relieve distal colonic obstruction (le-

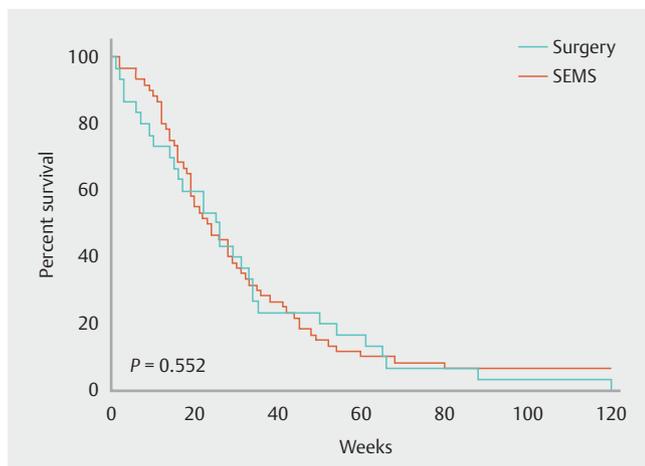
► **Table 2** Early and late adverse events of colon surgery and SEMS.

Adverse events	Surgery (n = 36)	SEMS (n = 69)
Overall		
▪ Early	11 (30.5%)	5 (7.2%)
▪ Late	4 (11%)	14 (21%)
Perforation		
▪ Early	0	2 (2.8%)
▪ Late	0	1 (1.4%)
Hematochezia		
▪ Early	0	1 (1.4%)
▪ Late	0	1 (1.4%)
Tumor outgrowth		
▪ Early	0	1 (1.4%)
▪ Late	0	0 (0%)
Tumor ingrowth		
▪ Early	0	0 (0%)
▪ Late	0	8 (11.6%)
Stool impaction		
▪ Early	0	1 (1.4%)
▪ Late	0	0 (0%)
Stent migration		
▪ Early	–	0 (0%)
▪ Late	–	4 (5.8%)
Enterocutaneous fistula		
▪ Early	0	0 (0%)
▪ Late	1 (2.8%)	0 (0%)
Small bowel obstruction		
▪ Early	0	0 (0%)
▪ Late	1 (2.8%)	0 (0%)
Other		
▪ Early	0	0 (0%)
▪ Late	2 (5.6%)	0 (0%)
SEMS, self-expanding metal stent		

sions distal to the splenic flexure). Colonic stents in this subset of patients have been shown to a highly effective and safe therapy to relieve colonic obstruction. In addition, patients who receive SEMS have less acute mortality and morbidity compared to patients who undergo emergent surgical decompression for distal malignant colonic obstruction [4, 5, 17–19]. Two large studies comparing SEMS to surgical intervention for predominantly distal colonic obstruction have supported the above mentioned findings [16, 20].

**Table 3** Comparison of patients having insertion of a SEMS or emergency surgery.

	Surgery (n=36)	SEMS (n=69)	P value
Early success, no. (%)			
▪ Technical Success	36 (100%)	62 (89.9%)	0.09
▪ Clinical success after procedure	36 (100%)	54 (78%)	<0.001
Maintenance of colonic decompression until patient death or last follow-up, no. (%)	34 (94.4%)	51 (73.9%)	0.02
Adverse events, no. (%)			
▪ Early	11 (30.5%)	5 (7.2%)	0.003
▪ Late	4 (11%)	14 (21%)	0.29
Acute mortality (within 30 days of procedure)	2 (5.5%)	0 (0%)	0.12
Mean hospital stay (days)	8	3.5	<0.001
SEMS, self-expanding metal stent			

**Fig. 1** Patient survival in the SEMS and Surgery group at 120 weeks. SEMS, self-expanding metal stent

There continues to be much debate about the role of colonic SEMS for proximal colonic obstruction in patients with unresectable disease [13,21]. As opposed to distal colonic obstructions, proximal lesions can sometimes be managed with a much simpler 1-stage laparoscopic surgical operation with resection and ileocolonic anastomosis without the need for a formal bowel preparation. Repici et al. reported their experience with 13 patients who underwent palliative colonic stent placement for “right-sided malignant colonic obstruction” (proximal to the mid transverse colon) [12]. In this series, they reported that SEMS were a safe and effective treatment for malignant obstruction of the proximal colon, with technical and clinical success rates comparable to those seen with distal colonic stenting. Similar findings were also reported in a small cases series of 16 patients with proximal colonic obstruction by Dronamraju et al. [11]. Conversely, Jung et al. reported that proximal location of the colon obstruction was a significant factor associated with poorer outcome for colonic stenting. Patients with a distal colorectal obstruction that were stented had significantly bet-

ter outcomes than those with a proximal colorectal obstruction ( $P=0.015$ ) [22]. The authors hypothesized that proximal colonic lesions may be difficult to reach due to the unprepped colon as well as curvatures of the colon. Lastly, Cho *et al* showed that technical success and clinical improvement with SEMS used to treat proximal colon obstruction was lower than patients with distal colon obstruction [23].

In our study, the procedural success rate for placement of the colonic SEMS was 89% compared to 100% technical success achieved by surgery. Similarly, relief of colonic obstruction initially achieved by surgery was significantly greater when compared to the SEMS group (100% vs. 87% respectively;  $P=0.02$ ). The lower rate of clinical improvement in the SEMS was mostly due to technical failure of stent insertion which included inability to pass the guidewire across the lesion, failure of stent expansion, and stent malposition as a result of an excessively angulated site through a fixated stricture [24]. Excessive angulation, especially at the hepatic flexure or proximal transverse colon can lead to stent malposition and failure for the stent to expand adequately as we seen in our cohort. We hypothesize that other causes of technical failures leading to difficulties in correct colonic stent deployment included the long distance from the anus, the bowel being tortuous, and poor endoscopic view due to incomplete bowel preparation [23,25].

Early complication rates (<30 days after the initial procedure) were statistically significantly lower in patients who underwent successful colonic SEMS placement compared to the surgery group (7.2% vs. 30.5%;  $P=0.003$ ). No deaths were seen in the SEMS group. There was 1 anastomotic leak requiring surgical revision and 2 deaths in the surgery group during the early post-operative period. The 2 patients died to anastomotic dehiscence that led to sepsis. All these factors contributed to a longer median hospital stay in the surgery group compared to the SEMS group.

One of the findings in our study was that colonic decompression without the recurrence of bowel obstruction until patient death or last follow-up was lower in the SEMS group (73.9%) than in the surgery group (97.3%;  $P=0.003$ ). The mean dura-

tion of SEMS patency in our study was 19 weeks. However, it should be noted that 7/10 patients with stent malfunction were able to be managed by placement of a second stent and only 3 required a surgical ostomy. It is unclear if these 3 patients could have been managed endoscopically as they were treated with a primary surgical intervention.

In our study, the presence of a transverse colon obstruction was the only independent factor that predicted late adverse events in the SEMS group. While we cannot definitively determine the cause of this, stents in transverse colon may have a higher rate of occlusion because the stools become more solid in this region of the colon as compared to the cecum/ascending colon/hepatic flexure, and therefore make them more prone to occlusion as the tumor in grows with the stent lumen. As expected, there was no survival difference between the 2 groups as all these patients had unresectable advanced CRC.

There are several limitations of the current study because it is a retrospective rather than a randomized study comparing 2 different therapeutic modalities. There will inevitably be an element of selection bias in choosing patients for different treatment options. It may be the case that the healthier patients with colonic obstruction underwent surgery while patients considered to be at high surgical risk were declined for surgical intervention and then referred to gastroenterology for endoscopic stent placement. Evidence for this is suggested by the fact that the SEMS patients were significantly older than the surgery patients i.e. surgeons more commonly selected surgery in younger patients and may have been shunting older patients to endoscopy. Furthermore, patients presenting with acute colonic obstruction are typically seen by surgery first, giving them a “right of first refusal” i.e. surgeons may have chosen to operate on patients they felt were better surgical candidates and may have been more likely to refer sicker patients with more comorbidities to endoscopy. While this was not true at all institutions, in at least 1 institution (UTH) all of the SEMS patients had been declined for surgery prior to referral for SEMS placement. This bias could certainly alter the overall outcomes among the two groups in favor of the patients that underwent surgery. In addition, there are variations in expertise for both techniques. A randomized study to reinforce our conclusions is recommended.

## Conclusions

In conclusion, our current trial suggests that both SEMS and surgery are viable options in patients with acute proximal colonic obstruction, although both approaches have drawbacks. Technical success with proximal colonic obstruction is higher with surgery when compared to SEMS, although inpatient hospitalizations are longer with surgery. We recommend consideration of SEMS as the initial mode of therapy for patients with acute proximal colonic obstruction and surgery as consideration only for SEMS failure, as surgery is associated with high rates of morbidity. While SEMS have a lower acute complication and acute mortality rate, surgery was associated with some better long-term outcomes and lower rates of AEs.

## Competing interests

Drs. Siddiqui and Adler are consultants for Boston Scientific.

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