ORIGINAL ARTICLE

Endoscopic Palliation in Patients With Incurable Malignant Colorectal Obstruction by Means of Self-expanding Metal Stent

Analysis of Results and Predictors of Outcomes in a Large Multicenter Series

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Objectives: To evaluate the short- and long-term efficacy of self-expanding metal stents (SEMSs) in patients with colorectal obstruction and incurable cancer and the related factors that affect outcomes.

Design: Retrospective analysis of SEMS placement for incurable colorectal obstruction in a 3-year period.

Setting: Five tertiary care endoscopic centers.

Patients and Intervention: Consecutive patients (N = 201) undergoing stenting for incurable malignant obstruction.

Main Outcome Measurements: Clinical and technical success of stenting, complications rate, and factors affecting outcomes.

Results: Technical success was achieved in 184 of 201 patients (91.5%) and clinical success occurred in 165 of 184 patients (89.7%; 82.1% of 201 patients). Technical and clinical failures were more frequent in extrinsic and long colorectal stenoses. Overall, 165 patients had normal bowel movements during follow-up (mean [SD], 115.5 [100.3] days; range, 1-500 days), 15 developed complications, 127 had a functioning SEMS at the time of death, and 23 were alive at completion of the study. Twenty-four (11.9%) major complications occurred: 11 migrations, 12 perforations, and 1 reobstruction. Migration of SEMSs was associated with stent diameter less than 25 mm. Bevacizumab therapy increased the risk of perforation by 19.6-fold. Karnofsky performance status of 50 or less was associated with shorter survival and a 3.7-fold higher risk of death within 6 months after the stent was placed.

Conclusions: The use of SEMSs is safe and effective for palliation of incurable malignant colonic obstruction; approximately 75% of patients with SEMSs are able to avoid colostomy.

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ONE-QUARTER OF PATIENTS with colorectal cancer (CRC) develop bowel obstruction.[1] In approximately 30% of these individuals, curative resection is not feasible because of advanced disease and comorbidities. Surgical intervention in these patients usually results in later creation of colostomy, which cannot be reversed in up to 50% of the cases.[2] Self-expandable metal stents (SEMSs) represent a valid alternative to operations, either as a bridge to surgical intervention or for palliation.

See Invited Critique at end of article

Use of SEMSs has a 90% success rate, acceptable complication rate, and negligible incidence of mortality.[3-7] Once placed, a SEMS relieves obstruction, avoiding colostomy, with improved quality of life until death in approximately 85% of patients.[3,7-10] However, approximately 25% of patients with this stent develop complications, such as perforation, occlusion, and migration, which are usually early events.[3,4,6] The endoscopist's experience, tumor location, stricture predilation, and stent characteristics are closely related to the development of early complications.[3,4,6] Late complications are likely the result of several factors involving the interaction between the SEMS and host, such as stent characteristics, tumor location, tumor progression, different treatments, and length of patient survival.[3,4,6] Reduction in the early complication rate can be achieved by improving the insertion technique and the selection of appropriate patients and lesions. Development

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of late complications is often unpredictable. Treatment with bevacizumab has been related to an increased risk of perforation in patients with SEMSs.[6,11,12] Theoretically, the longer the stent remains in the colon, the higher the likelihood that a complication will develop. A SEMS theoretically should be placed in patients with either high surgical risk or short life expectancy. Therefore, while managing care for a patient with incurable CRC who develops an obstruction, we need to carefully consider all factors that are likely to influence both survival and possible stent-related complications.

The objective of this study was to evaluate the short- and long-term efficacy of SEMSs in a large series of patients with colorectal obstruction and incurable cancer. Different factors affecting the immediate success of SEMSs, as well as early and late complications, were analyzed to identify useful criteria in choosing between an operation and use of a SEMS for the care of patients with incurable cancer who develop an obstruction.

METHODS

STUDY DESIGN

We retrospectively evaluated all patients with incurable cancer and colonic obstruction consecutively undergoing SEMS placement in 5 Italian endoscopic centers from January 11, 2007, to December 20, 2009. All patients were diagnosed as having colorectal obstruction due to incurable CRC or extracolonic cancer, confirmed by computed tomography and/or colonoscopy. Obstruction was considered to be complete if the patients were unable to pass stool and gas. Obstruction was considered to be partial if patients were symptomatic but able to pass gas or had paradoxical diarrhea.

Patients were identified retrospectively by using a dedicated database in each center. After approval by the ethics committee of each institution, the data were retrieved, pooled, and reviewed by one of the authors (G.M., M.dB., L.F., A.R., and E.M.), with all patient data remaining confidential.

STENTING TECHNIQUE

The SEMSs were inserted in the conventional manner by 1 of 2 endoscopists in each center.[13] All the endoscopists were experts in therapeutic endoscopy. To minimize the risk of perforation, dilation of the stricture was avoided.

DEFINITIONS

The patient was considered to have incurable cancer when curative resection of metastatic disease was impossible because of extended liver metastases (bilobar multiple lesions, involvement of the hilum or 3 major hepatic veins, or remnant liver volume <30% after hepatectomy) or extrahepatic disease.

Technical success was defined as successful placement of the SEMS, with correct deployment and positioning at the level of the stenosis, determined with radiologic procedures. Clinical success was defined as complete colonic decompression within 72 hours after SEMS insertion, clinically and radiologically assessed. Death was considered to be related to SEMS complications if it occurred within 7 days after insertion.

Major complications were events leading to surgical or endoscopic reintervention or requiring admission to the intensive care unit. Perforation, stent obstruction, and migration were considered to be major complications. Mild complications were events leading to rehospitalization or prolonged hospital stay without fulfilling the major complications criteria.

PATIENT ASSESSMENT AND FOLLOW-UP

Before SEMS placement, a routine workup, including computed tomography of the abdomen and chest, as well as calculation of Karnofsky performance status (KPS), was conducted.[14] After successful placement of the stent, patients were monitored in the outpatient clinic until death occurred, an operation was performed, or a complication developed. No patient was lost to follow-up. For patients who missed periodic clinic visits, data were obtained by means of telephone calls to the patient or the closest relative and by reviewing medical records. Technical and clinical success of the SEMSs, occurrence and timing of complications, and need for surgical intervention were analyzed.

Early outcomes were assessed 72 hours after insertion of the SEMS; these included (1) successful placement, both technical and clinical; (2) unsuccessful placement due to technical or clinical failure; and (3) development of a major complication during SEMS placement (immediate complication) or during the first 24 to 72 hours after its placement (early complication). Late outcomes were assessed at the end of follow-up and were identified by development of a major complication, surgical or endoscopic reintervention, or death of the patient.

STATISTICAL ANALYSIS

Variables analyzed included patient characteristics, tumor characteristics, technical details, and chemotherapy performed. Univariate descriptive statistics at baseline were computed for the entire patient group. Association between baseline characteristics and technical and clinical success, as well as early and late complications, was analyzed by means of the χ^2 test; the odds ratio (OR) and 95% confidence interval (CI) were calculated. Time to considered end points (occurrence of complications, surgical intervention, or death) was measured. Kaplan-Meier survival analysis was performed to calculate the cumulative rate of clinical success, such as sustained relief of obstruction and lack of complications. Statistical significance was defined as $P < .05$. Analyses were performed using commercial software (SPSS package, version 13; SPSS Inc, Chicago, Illinois).

RESULTS

The study flowchart is depicted in **Figure 1**. During a 3-year period, 242 patients with colorectal obstruction underwent SEMS placement. One hundred five patients had complete bowel obstruction and underwent urgent stenting. Forty-one SEMSs were used as a bridge to an operation and were clinically successful in 36 patients who underwent an elective operation 9.4 (5.01) days (range, 4-21 days) later. In this subset of 36 patients, colostomy was required for only 14. The remaining 64 patients were considered to be unfit for surgical procedures at the subsequent workup, and a SEMS was the final palliation. One hundred thirty-seven patients with partial bowel obstruction and advanced metastatic disease underwent SEMS placement for palliation. The latter was the indication for use of the stent in 201 patients.

Demographic and clinical characteristics of the patients are reported in **Table 1**. One hundred fifty-three

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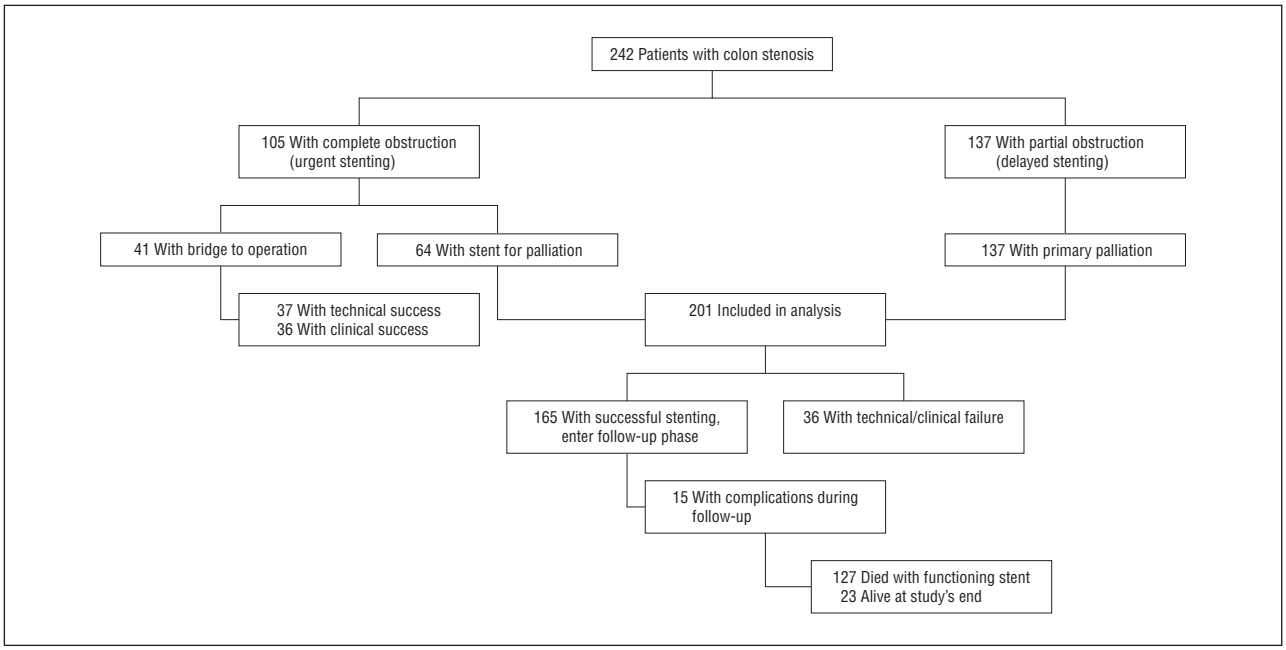

Figure 1. Study flowchart.

patients were affected by primary CRC, 20 had developed anastomotic recurrence of CRC, and 28 had an extrinsic compression due to extracolonic cancer. The majority of SEMSs were placed in the rectosigmoid colon (Table 1). Overall, 204 stents were inserted in 191 patients. Insertion of a SEMS failed in 10 patients because of the inability to place the guide wire across the stenosis. In 5 patients, 2 consecutive stents were placed in a long stricture. A second stent was inserted in 8 patients after migration of the first one. Characteristics of the SEMSs are described in **Table 2**. One hundred eighty-four patients (90.2%) were treated with uncovered stents, which were placed through the endoscope in 169 patients (82.8%).

EARLY OUTCOME AND RELATED FACTORS

In the palliation group, technical success was achieved in 184 of 201 patients (91.5%) at the first SEMS placement. Reasons for technical failure were inability to place a guide wire across the stenosis in 10 patients, stent malposition in 4, immediate perforation in 1, and failed stent deployment in 2. All patients with stent failure underwent an immediate operation for bowel decompression, and 1 patient died. Clinical success with colonic decompression was achieved in 165 of 184 patients (89.7%; 82.1% of the whole series). Causes of clinical failure included early stent migration in 6 patients and stent malposition in 13. Migration of the SEMS was treated by placing a new stent in 4 cases; 1 patient underwent an operation. The sixth patient was treated conservatively and died 5 days after SEMS migration. Eleven of 13 cases of stent malposition were decompressed surgically. The clinical course of 2 other patients was complicated by cecum blowout and colonic perforation. The first complication occurred 3 days after a failed attempt to place a SEMS, and the patient died without further endoscopic or surgical therapy. The second complication was diagnosed 4 days after stent placement, and the patient underwent an operation. **Table 3** reports factors correlated with technical and clinical failure of the stents according to univariate analysis. Strictures due to extrinsic compression and stenoses longer than 4 cm were significantly correlated with a higher failure rate.

LATE OUTCOME, COMPLICATIONS, AND RELATED FACTORS

One hundred sixty-five patients who underwent successful placement and functioning of a SEMS were followed up for a mean of 115.5 (100.3) days (range, 1-500 days) until death or development of complications. Sustained relief of obstruction was achieved in 127 patients (77.0%) until death. Twenty-three patients were alive, with a functioning stent, at the end of the study period. Overall, 90.9% of patients with successfully placed stents in our series did not develop complications during follow-up. According to the Kaplan-Meier survival curves, the stent patency rate was 82.1% at 6 months and 65.7% at 12 months (**Figure 2**).

Late major complications caused SEMS failure in 15 patients: 7 perforations, 1 reobstruction, 1 abscess, 1 rectovaginal fistula, and 5 stent migrations. Ten patients were treated surgically: 9 received a permanent colostomy and 1 died. The remaining 5 patients (4 cases of stent migration and 1 of stent obstruction) were treated conservatively by endoscopic placement of a new SEMS. Another patient died 24 hours after stenting; however, his death was not considered to be stent related because of prompt colonic decompression and no early complications.

Overall, 24 major complications (11.9%) were observed in the study group. These included stent migration (11 [5.5%]); colonic perforation including an abscess, a fistula, and a colonic blowout (12 [6.0%]); and

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Table 1. Demographic and Clinical Characteristics of the Study Group

Characteristic	No. (%)
Age, mean (SD) [range], y	68.86 (14.15) [21-100]
Sex	
Male	110 (54.7)
Female	91 (45.3)
Karnofsky performance status, mean (SD) [range]	55 (16.2) [20-80]
Occlusive symptoms	
Total obstruction	64 (31.8)
Subtotal obstruction	137 (68.2)
Stenosis site	
Rectosigmoid colon	134 (66.7)
Descending colon	14 (7.0)
Splenic flexure colon	15 (7.5)
Tranverse colon	9 (4.5)
Hepatic flexure	6 (3.0)
Ascending colon	3 (1.5)
Colorectal or colocolic anastomosis	20 (10.0)
Source of obstruction	
Colorectal cancer	153 (76.1)
Recurrent colorectal cancer	20 (10.0)
Extrinsic compression due to extracolonic cancer	28 (13.9)
Stenosis length, mean (SD) [range], cm	4.47 (1.9) [1-15]
Chemotherapy. No.[a]	
Yes	74 (44.8)
No	91 (55.2)
Follow-up time until death or complication, mean (SD) [range], d	115.5 (100.3) [1-500]
Patients who developed complications during follow-up, No.	15
Patients who died during follow-up, No.	127
Patients without complications alive at the end of the study, No.	23

[a] Data total 165 because only patients who were successfully stented were included.

Table 2. SEMS Characteristics

Characteristic	No. (%)
Stent model, manufacturer	
Bonastent, Alpharetta, Georgia	20 (9.8)
Hanaro, MiTech, Seoul, Korea	25 (12.3)
Evolution, Evolution Cook, Limerick, Ireland	33 (16.2)
Ultraflex Precision, Boston Scientific, Natick, Massachusetts	27 (13.2)
Wallflex, Boston Scientific	82 (40.2)
Wallstent, Boston Scientific	17 (8.3)
Stent length, mm	
≤60	30 (14.7)
≤90	102 (50.0)
≤120	45 (22.1)
>120	27 (13.2)
Stent diameter, mm	
<25	65 (31.9)
≥25	139 (68.1)
Insertion technique	
Through the endoscope	169 (82.8)
Not through the endoscope	35 (17.2)
Uncovered/covered stent	
Uncovered	184 (90.2)
Covered	20 (9.8)

Abbreviation: SEMS, self-expanding metal stent.

Table 3. Univariate Analysis of Factors Related to Technical and Clinical Failure

Variable	OR (95% CI)	*P* Value
	Technical Failure	
Male sex	1.57 (0.50-4.40)	.45
Complete occlusion	0.49 (0.18-1.30)	.17
Extrinsic tumor	3.60 (1.60-10.70)	.02
Rectosigmoid location	0.68 (0.18-2.40)	.76
Length >4 cm	5.33 (1.40-20.10)	.008
	Clinical Failure	
Male sex	1.80 (0.80-3.90)	.10
Complete occlusion	0.68 (0.30-1.40)	.30
Extrinsic tumor	4.35 (1.80-10.20)	.001
Rectosigmoid location	0.77 (0.30-1.90)	.60
Length >4 cm	2.40 (1.00-5.50)	.03

Abbreviations: CI, confidence interval; OR, odds ratio.

reobstruction (1 [0.5%]). Nine complications were correlated with the procedure, and 15 occurred after successful colonic decompression during follow-up. Thirteen of these late complications (86.7%) developed within 3 months, and 2 developed 6 months after stenting.

Development of complications did not correlate with any of the analyzed variables (sex, symptoms, tumor type, tumor location, length of the stenosis, and chemotherapy). Only small-caliber SEMSs (<25 mm) were associated with stent migration ($P=.002$; OR, 7.0; 95% CI, 1.9-24.6). Overall, chemotherapy did not increase the risk of complications; however, 50.0% (4 of 8) of patients treated with bevacizumab experienced perforation. In comparison, untreated patients, or those who received standard chemotherapy, had a complication rate of 2.5% ($P<.001$; OR, 19.6; 95% CI, 5.9-64.5).

PATIENT SURVIVAL

The KPS significantly correlated with the survival of patients after placement of the SEMS. A KPS value of 50 or less determined a significantly shorter mean survival time (110.3 [140.1] vs 159.6 [98.7] days, $P>.03$) and was associated with a 3.7-times (95% CI, 1.1- 9.7; $P=.02$) higher risk of death within 6 months after placement of the SEMS.

COMMENT

Colostomy provides relief of colonic obstruction sustained until death in most patients with incurable neoplasia.[3-7] However, surgical intervention is expensive and may be associated with serious complications, even death. A SEMS is likely to represent a valid alternative to surgery in achieving effective colonic decompression.[9,10] In our series, immediate technical and clinical success rates were 91.5% and 82.1%, respectively. These results are similar to those reported in 2 systematic reviews[3,4] and correlate the results of single-center studies.[5,6] These data support the concept that colonic recanalization by means

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of SEMSs is effective, easy, and safe when performed by experienced endoscopists.[6] Accurate selection of patients for placement of a SEMS is crucial to maximize immediate success and minimize the risk of complications. According to our data, strictures due to extrinsic compression and long stenoses are usually associated with increased failure rates. Some authors[3,4,6] have also demonstrated that predilation of the stenosis and the inexperience of the endoscopist may contribute to clinical failure and development of complications. All these factors must be considered when deciding between placement of a SEMS or an operation in the management of malignant colonic obstruction.

Although short-term efficacy of SEMSs has been demonstrated, the long-term results are still debated.[12,15] Patients with incurable CRC have a median survival time ranging from 4 to 17 months.[16] Those who receive stents have a longer life expectancy and are likely to develop late complications. Therefore, efforts should be made to identify patients who receive better palliation with use of SEMSs and those who may benefit from surgical intervention. To our knowledge, there has been only 1 prospective, randomized controlled study[12] that compared the results of SEMSs and operations for palliation of incurable malignant colonic obstruction. This trial was closed prematurely because of the high number of serious adverse events in the SEMS arm (6 perforations in 11 patients). However, noncontrolled studies[6,17-19] reported that use of SEMSs provided sustained relief of obstruction until death in approximately 85% of patients with incurable obstructive CRC. Small et al[6] reported that 108 of 122 patients with stents were free of obstruction until death. Karoui et al[18] observed a mean survival time of approximately 14 months after SEMS placement, which was similar to that reported in a group of patients treated with surgical procedures. In our study, 90.9% of successfully stented patients died with a functioning SEMS, and approximately 75.0% of all obstructed patients did not require colostomy, which likely resulted in better quality of life, shorter hospitalizations, and overall cost savings.[9,10]

Fifteen of the 165 patients in whom stenting was successful developed late complications. An analysis of the factors related to late complications shows a significant association between SEMS migration and small-caliber stents and between colonic perforation and bevacizumab therapy. It has been suggested[6] that male patients and those with left-sided stenosis or complete obstruction develop more complications. Technical issues, such as stent manufacturer and characteristics (covered or uncovered, different shapes and materials) have been advocated[3,6,12,20] as possible explanations for different outcomes. In our study, different SEMS models were used, and no significant difference among SEMSs was observed in both early and late outcomes.

After palliative stenting, many patients undergo chemotherapy. This treatment determines tumor shrinkage and can weaken the colonic wall. Both colon perforation and stent migration have been described[6,12,15,18] in patients treated with chemotherapy. In the study of van Hooft et al,[12] 7 patients with stents were treated with chemotherapy; 4 of them developed colonic perforation. Karoui et al[18] observed a 6% perforation rate in patients undergoing chemotherapy after SEMS placement. In our study, chemotherapy did not increase the complication rate. Conversely, 4 of 8 patients who received bevacizumab developed a perforation, which suggests an increased risk for perforation in this subset of patients. Few patients in our series were treated with bevacizumab; therefore, our results may not be statistically valid, representing a possible error. However, these data are in accordance with the results of some recent reports[6,11,21,22] and should be taken into account because the new bevacizumab-based schedules of chemotherapy are increasingly prescribed in patients with CRC.

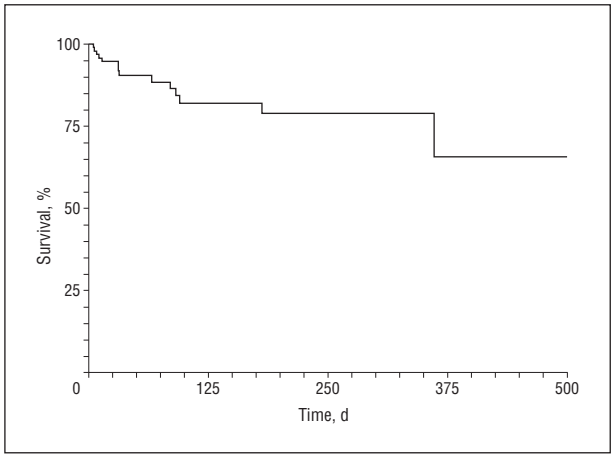

Figure 2. Kaplan-Meier curve for clinical success of self-expanding medical stents. Clinical success was 82.1% (95% CI, 0.73-0.91) at 180 days and 65.7% (95% CI, 0.40-0.91) at 1 year. CI indicates confidence interval.

Our hypothesis was that the longer patients survive after stenting, the higher the likelihood of SEMS-related major complications. Accordingly, patients selected for palliative use of SEMSs should have a life expectancy shorter than the expected stent patency time. In our series, patients with a KPS of 50 or less had a 3.7-times higher chance of surviving less than 180 days and therefore were the best candidates for SEMSs. A higher KPS should be an indication for palliative surgery. However, we observed that the majority of complications developed within the first few days after SEMS insertion, with only 2 complications occurring after 6 months. According to the Kaplan-Meier curve, 82.1% of stents maintained their patency at 6 months and 65.7% of them were still functioning 1 year after placement. The fact that complications do not occur in patients with long-term survival suggests that palliative use of SEMSs may be a good option for patients who are not seriously ill and have a good life expectancy. Accurate patient selection and use of SEMSs with proper characteristics are crucial for obtaining long-term efficacy of colorectal stents. If the SEMS is not appropriate for the patient or the tumor, it could be associated with the development of complications within a few days after placement.

Our study design deserves some considerations. Its retrospective fashion could represent a bias that should be considered when interpreting the results. The multicenter design carries both advantages and limitations. The main limitation is the heterogeneity of the data, which originate from 5 different centers and may differ in terms of pa-

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tient selection, endoscopic technique, SEMSs used, and modality of follow-up. However, the fact that demographic and clinical characteristics as well as outcomes did not differ significantly among the participating centers seems to minimize the problem. The multicenter design of the study could be an advantage because the results are likely applicable to the clinical routine of every tertiary endoscopic center. Patients were enrolled for 3 years, which is shorter than in other studies.[6] The participating physicians were expert endoscopists who had already placed numerous SEMSs. Therefore, poor results, usually related to the learning curve, are not part of the study; this fact makes our data homogeneous over time.

In conclusion, our study further suggests that SEMSs are an alternative to operations for patients with incurable malignant colorectal obstruction because approximately 75.0% of patients who receive the stents do not require colostomy. In our clinical practice, we consider SEMSs the first therapeutic option for these patients, especially if their KPS is 50 or less. We have identified some factors associated with poor SEMS outcomes, such as extrinsic and long stenoses, small-diameter stents, and bevacizumab treatment. All these factors have to be considered when choosing between SEMS and operation. The long patency rate of most colorectal SEMSs suggests that selection of the appropriate patient and stent is crucial for achieving the best results in the management of colorectal obstruction due to incurable cancer.

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Author Contributions: Dr Manes had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Manes, Repici, Masci, and Ardizzone. *Acquisition of data:* Manes, de Bellis, Fuccio, Repici, Ardizzone, Mangiavillano, Carlino, Rossi, Occhipinti, and Cennamo. *Analysis and interpretation of data:* Manes, Repici, and Ardizzone. *Drafting of the manuscript:* Manes, Mangiavillano, and Carlino. *Critical revision of the manuscript for important intellectual content:* Manes, de Bellis, Fuccio, Repici, Masci, Ardizzone, Rossi, Occhipinti, and Cennamo. *Administrative, technical, and material support:* Manes, Repici, Ardizzone, Mangiavillano, Carlino, Rossi, and Occhipinti. *Study supervision:* Manes, de Bellis, Fuccio, Masci, and Cennamo.
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Additional Contributions: Maura C. Tracey, BSN, RN, provided editorial assistance.

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