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Enteral stents for the management of malignant colorectal obstruction

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Abstract

Colorectal cancer (CRC) is the 3rd most common cancer in the United States with more than 10000 new cases diagnosed annually. Approximately 20% of patients with CRC will have distant metastasis at time of diagnosis, making them poor candidates for primary surgical resection. Similarly, 8%-25% of patients with CRC will present with bowel obstruction and will require palliative therapy. Emergent surgical decompression has a high mortality and morbidity, and often leads to a colostomy which impairs the patient's quality of life. In the last decade, there has been an increasing use of colonic stents for palliative therapy to relieve malignant colonic obstruction. Colonic stents have been shown to be effective and safe to treat obstruction from CRC, and are now the therapy of choice in this scenario. In the setting of an acute bowel obstruction in patients with potentially resectable colon cancer, stents may be

used to delay surgery and thus allow for decompression, adequate bowel preparation, and optimization of the patient's condition for curative surgical intervention. An overall complication rate (major and minor) of up to 25% has been associated with the procedure. Long term failure of stents may result from stent migration and tumor ingrowth. In the majority of cases, repeat stenting or surgical intervention can successfully overcome these adverse effects.

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Key words: Colorectal cancer; Colonic obstruction; Self expanding metal stents; Intestinal obstruction/etiology; Intestinal obstruction/mortality; Intestinal obstruction/surgery; Survival rate

Core tip: Colonic stents are of benefit both as a bridge to surgery and as definitive therapy for colorectal obstruction in a large group of patients. Careful patient selection is required. Patients should be carefully managed in conjunction with the oncologist and surgeon. Endoscopists should also be vigilant for acute and delayed complications associated with colonic stent deployment.

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INTRODUCTION

A common complication of colorectal neoplasms is malignant large bowel obstruction. In the past, this complication was primarily managed with surgical resection; however, over the past 20 years endoscopic stenting has become an alternative, non-surgical approach. The first

Table 1 Commercially available self-expandable metal stent for malignant colonic obstruction

Manufacturer model	Delivery system	Diameter (mm)	Flares/flanges	Length (mm)	Covered/uncovered
WallFlex ¹ (Boston Scientific)	TTS	22/27	Present	60, 90, 120	Uncovered
Ultraflex Precision ¹ (Boston Scientific)	OTW	25/30	Present	57, 87, 117	Uncovered
Wallstent endoprosthesis ¹ (Boston Scientific)	TTS	20, 22; no flare	Absent	60, 90	Uncovered
D-Enteral Colonic Stent (Taewoong Medical)	TTS/OTW	18, 20, 22, 24, 26	Absent	60, 80, 100, 120, 140, 150	Uncovered
Comvi Colonic Stent (Taewoong Medical)	TTS/OTW	18, 20, 22, 24, 26, 28	Absent	60, 80, 100, 120	Partially Covered
S-Enteral Colonic Stent (Taewoong Medical)	TTS/OTW	18, 20, 22, 24, 26, 28	Present	60, 80, 100, 120, 140, 150, 230	Fully and Partially Covered
Evolution Colonic Stent (Cook Endoscopy)	TTS	25	Present	60, 80, 100	Uncovered
Colonic Z-Stent ¹ (Cook Endoscopy)	TTS	25	Present	40, 60, 80, 100, 120	Uncovered
Hanarostent (M.I.Tech)	TTS/OTW	20, 22, 24	Present	60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180	Uncovered, Fully Covered
Enterella (ELLA-CS)	OTW	22, 25, 30	Absent	75, 82, 88, 90, 112, 113, 123, 135, 136	Uncovered, Covered
Bonastent (EndoChoice)	TTS	22, 24, 26	Absent	60, 80, 100	Uncovered, Partially Covered
Aixstent (Leufen Medical)	TTS/OTW	25, 30	Present	80, 100	Uncovered, Partially Covered
Micro-Tech (MICRO-TECH Europe)	TTS/OTW	20, 25, 30	Present	60, 80, 100, 120	Uncovered, Partially Covered, Fully Covered

¹Colonic stents available in the United States. TTS: Through-the-scope; OTW: Over-the wire.

studies demonstrating successful stenting of the colon to relieve malignancy-related obstruction were done in the early 1990s^[1,2]. Since that time, the use of self-expanding metal stents (SEMS) has been implemented more frequently both as a bridge to surgical resection, as well as for palliation in advanced colorectal cancer and in patients who are poor surgical candidates. This review will discuss the types of stents currently available on the market, techniques for placement, indications, and adverse effects of colonic stenting in colorectal cancer.

TYPES OF SEMS

Currently, there are over a dozen different types of colonic SEMS available commercially worldwide (Table 1). These stents can be covered, partially covered, or uncovered and range from 20-30 mm in diameter with lengths of 6-18 cm. In the United States, only uncovered stents are approved for use in the large bowel, primarily because they have been shown to have a lower rate of migration when compared to covered stents. Studies have shown a migration rate among patients who received uncovered stent was 0%-2% as compared to 20%-40% among those with covered stents^[1-4]. Uncovered stents may have a lower risk of other complications, such as stent fracture, failure of expansion, and loss of stent function^[4,5]. Additionally, using uncovered stents improves the success rate of post-stent colonoscopies, which can be performed to evaluate for synchronous tumors following the diagnosis of colorectal cancer^[6]. Finally, uncovered stents may be technically easier to deploy into more distal areas of

obstruction, because they tend to use a smaller delivery systems and are less rigid.

The one major disadvantage of uncovered stents is the higher frequency of tumor ingrowth, which can precipitate stent occlusion^[1,2,4]. Recent research has focused on developing colonic stents that would maintain their position, but also have the ability to prevent significant tumor in-growth. Moon *et al*^[7] looked at outcomes of using a novel double-layered combination covered stent, with an internal membrane to prevent tumor in-growth and an external uncovered wire that should embed itself into the surrounding tumor. However, this stent, still showed an increased rate of migration when compared to uncovered stent, although not as high as documented in prior studies. Therefore, further innovation is necessary to design a stent that is a combination of covered and uncovered components to optimize its efficacy.

INDICATIONS FOR SEMS PLACEMENT

The high frequency with which colorectal cancer presents with malignant obstruction has created a growing use for self-expanding metal stents as palliation for malignant colonic obstruction as well as a bridge to surgery. Palliative stents offer the advantage of sparing patients surgical intervention which frequently results in colostomy. In patients for whom emergent surgical resection is planned, SEMS have been utilized as an efficacious method of delaying surgery and therefore reducing operative risk. Endoscopic stenting allows bowel decompression and sparing the patient emergent surgical decompression

which carries a mortality rate as high as 30%^[8]. The low rate of morbidity and mortality associated with endoscopic colonic decompression when compared to surgery is therefore an attractive option.

Following the initial determination of the location and nature of the obstruction, a colonoscopy should be performed. Visualization of the site of obstruction provides the opportunity for a tissue biopsy as well as assessment of the potential for stent placement. Other considerations include the length of the stricture as well as the presence of an extrinsic versus intrinsic mass. If the colonoscope is easily passed through the site of obstruction, there is an increased risk for stent migration^[9]. Stent placement is contraindicated in patients with perforation, intra-abdominal abscess, intestinal ischemia, or uncorrectable coagulopathy^[10]. Placement of stents within 3–4 cm of the anal sphincter is not contraindicated but may be associated with increased incontinence and pain after placement, although in some patients a low lying stent in the rectum is their only clinical alternative to colostomy^[11].

Palliative stents in patients with unresectable colorectal obstruction

Multiple comorbidities and metastatic disease are frequent contra-indications for surgical intervention to relieve malignant small bowel obstruction. In such situations, colonic stenting has been shown to be a safe and effective alternative approach for palliation^[12]. In a retrospective, five-center study, Manes *et al.*^[13] looked at 201 patients with malignant large bowel obstruction who underwent palliative stenting and documented a 91.5% technical success rate and an 89.7% clinical success rate, defined as colonic decompression after 72 h. Another prospective study found a technical success rate of 95% and clinical success rate of 81%, which was defined as continued stent patency 6 mo after initial placement^[14].

Although outcomes with SEMS appear to be quite good, there are few studies that directly compare colonic stenting with surgical resection. The data that is available indicates that utilizing SEMS confers certain benefits over surgical intervention, although the data pertaining to long term morbidity and mortality remains equivocal. Law *et al.*^[15] found that patients who underwent palliative colonic stenting had fewer admissions to the ICU and a lower likelihood of ultimately requiring resection with stoma creation as compared to the group that underwent surgery initially. Several other studies also showed statistically significant reduction in length of hospitalization, fewer short term complications, and decreased frequency of the need for stoma formation^[15–17]. However, none of these studies showed any difference in overall survival between the two groups.

Colonic stents as a bridge to surgery

In the setting of an acute bowel obstruction in patients with potentially resectable colon cancer, stents may be used to delay surgery and thus allow for decompression, adequate bowel preparation, and optimization of the

patient's condition for curative surgical intervention. Systematic reviews of stent placement as bridge to surgery have shown a technical success rate of 85%–92%^[18]. Watt *et al.*^[19] performed a meta-analysis that included 88 studies and 1785 patients with 1845 stents placed. A total of 782 (43%) had stent placement as a bridge to surgery. Technical success and clinical success were reported to be 96.2% and 92% respectively. Data also suggested that placing colonic stents as a bridge to surgery increased the likelihood that the resection and re-anastomosis could be done as a one-stage procedure without the need for stoma formation when compared to an emergent operation. These studies documented that the one-step surgery was successful in 65%–73% of patients^[20,21].

Few studies have compared colonic stenting as a bridge to surgery with emergent surgical decompression. Ng *et al.*^[21] performed a case-matched study of 20 patients who underwent SEMS as a bridge to surgery compared to 40 patients who had emergent surgical decompression. Patients in the stent group had statistically higher rates of primary anastomosis and shorter hospital and ICU stays. No difference was seen in mortality rates between the two groups.

In patients undergoing stent placement as a bridge to surgery in which it is later determined that surgery will not take place, the colonic stent may stay in place as a palliative measure. The benefits afforded by delaying surgery must be weighed against potential complications of stent placement which include such risks as perforation, bleeding, and stent migration. A study by Pirlet *et al.*^[22] comparing the stenting to surgery was stopped prematurely due to high rates of perforations in the stent group. A further source of uncertainty is whether stenting confers a survival benefit and decreased rate of stoma placement at 30 d. Further randomized control studies will be needed to determine the comparative clinical success of emergent surgery versus stenting as a bridge to surgery.

Techniques for stent placement

Colonic stent placement is a safe technique for the relief of large bowel obstruction secondary to malignancy. Recent studies have shown technical success rates that were close to 100% and clinical success rates, determined by the effective and persistent relief of the obstruction, of 85%–91%^[23–25]. However, the complexity of the procedure can be significantly increased if the colon cannot be prepped before the intervention, if the obstruction is complete, and if the culprit lesion is located within a flexure or area of angulation. Additionally, the complexity of colonic stenting frequently requires the use of ERCP equipment and studies have shown that advanced endoscopists with pancreatobiliary experience tend to have fewer complications and better outcomes^[26]. Colonic stent placement can be performed by endoscopic guidance either using through-the-scope (TTS) or over-the-wire (OTW) delivery systems. The former is ideal when using smaller diameter stents and for proximal lesions that cannot be accessed without an endoscope. The latter allows the delivery of larger stents and is most applicable

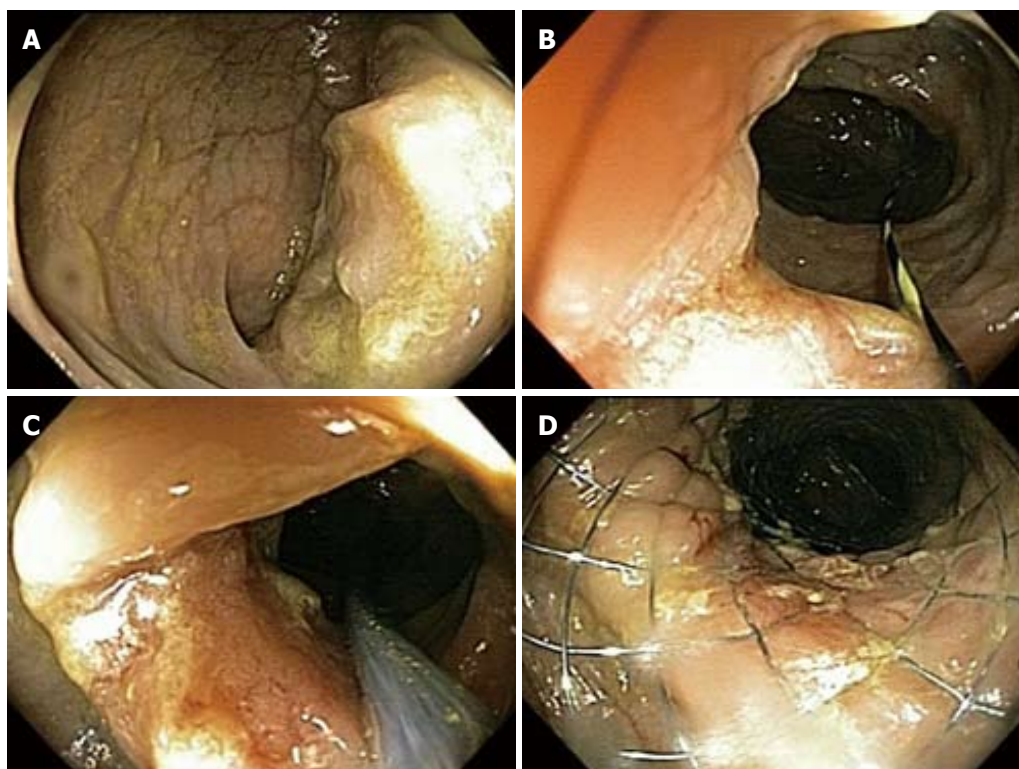


Figure 1 Through-the-scope approach has been shown to be safe and effective both in right-sided and left-sided colonic lesions. A: The patient presented with an obstructing colon cancer who was evaluated for an endoscopic colonic stent; B: The endoscope was passed to the site of the obstructive tumor and a 0.035 inch teflonated guide wire was passed across the stricture under endoscopic and fluoroscopic guidance; C: A catheter was subsequently passed over the guidewire; D: A colonic self-expanding metal stent (SEMS) was used to decompress the colon. The stent was placed so as to extend at least 2 cm on each end beyond the tumor margin. After the stent was deployed, the position was assessed by endoscopic and fluoroscopic visualization.

in cases of rectosigmoid obstruction.

The TTS approach has been shown to be safe and effective both in right-sided and left-sided colonic lesions (Figure 1)^[27,28]. Almost all colonic stent deployed today use the TTS approach. Initially, an attempt should be made to pass the endoscope through the obstructing lesion, as this can facilitate the positioning of the guidewire and determination of the stricture length. The SEMS delivery system can then be passed over the guidewire and the stent deployed under direct endoscopic visualization. If the endoscope cannot be advanced beyond the obstruction, a hydrophilic biliary guidewire can be advanced through a biliary catheter to cannulate the lesion. Once fluoroscopy confirms that the guidewire has passed through the entirety of the obstruction and emerged on the proximal side, the stent is deployed^[28]. The biliary catheters can also be used to aid in measurement of stricture length. One approach is to inflate the catheter balloon and position it at the distal end of the stricture. Subsequently, contrast is injected through the catheter and fluoroscopy is used to visualize the length of the stricture. Alternatively, the biliary catheter can be advanced all the way through the lesion and the balloon inflated. The catheter is then pulled back until resistance is met, indicating that it is now abutting the proximal end of the lesion. The endoscopist marked this point on the catheter by grasping it at the biopsy port exit point with his fingers. Then, the balloon is deflated and the catheter

continues to be withdrawn until the balloon is visualized emerging at the distal end of the lesion. The distance between this point and the point marked by the endoscopist's fingers represents the length of the stricture^[28]. Once the length of the stricture is determined, an appropriate SEMS needs to be selected. The ideal stent needs to extend at least 1-2 cm beyond the edge of the lesion on both proximal and distal ends to ensure that it will properly deploy and stay in place. When positioning the stent, the endoscopist needs to take into account shortening that occurs during deployment, as well as the rebound effect that occurs when the sheath is removed from the stent. After deployment, proper positioning is confirmed radiographically by an "hourglass" shape of the stent, with the ends beyond the obstruction fully expanded and the middle cinched by pressure from the lesion. Contrast can also be injected through the stent to confirm patency.

If the target lesion is in a difficult to reach location, such as a flexure or within an angulation of the colon, the endoscope may not be able to be positioned in a way that would allow successful passage of the guidewire. In such a situation a biliary sphincterotome can aid in the cannulation of the obstructing lesion^[29-31]. The guidewire is loaded through the sphincterotome, which can then be rotated and bent in different directions until it positions the guidewire at an angle that would allow it to effectively traverse the extent of the obstructing lesion.

If the colonic obstruction is located in the descend-

ing colon, the non through-the-scope (OTW) approach can be used. This approach can be executed either under endoscopic guidance or with the aid of fluoroscopy. If the former method is used, rather than passing the SEMS through the working channel of the endoscope, the stent delivery system is advanced over a stiff guidewire, while the endoscope is passed next to it. This allows for direct visualization in order to make sure that the stent is properly deployed in the correct location. When this technique is employed, a colonoscope, which has a smaller diameter and is more flexible as compared to an upper endoscope, should be used. If the endoscopist chooses to use fluoroscopy, he or she first needs to mark the distal and proximal ends of the strictures with something that would be radiographically visible. Once this is done, the SEMS delivery system can be advanced over the guidewire to the site predetermined by the markers and deployed under fluoroscopic guidance.

Complications of SEMS

While self-expanding metal stents have been successfully used as a bridge to surgery in malignant obstruction of the colon as well as palliation, an overall complication rate (major and minor) of up to 25% has been associated with the procedure^[18].

Vemulapalli *et al*^[17] found more late-term complications in the stent group as compared to the surgical group, although this difference did not reach statistical significance. This finding was supported by data from several other studies that found that the late term complications in patients who received palliative SEMS was 24%-51%^[17,26,32,33]. Factors that increased the risk of complications included operator experience, stent type, type of stricture, and tumor location as well as patient-related factors which include concomitant use of chemotherapy (specifically Avastin) and radiation. Complications may be grouped into minor and major categories

Minor complications of self-expanding metal stent placement

Bleeding, tenesmus, and pain are commonly reported following stent placement. Pain categorized as severe is seen in 5% of patients following stent placement. Pain and alterations in bowel habits is most often seen when stents are placed within 5 cm of the anal verge. Similarly, late-onset of tenesmus, pain, incontinence, and foreign body sensation may be seen with stent migration into the anorectal area^[11,34]. However, Song *et al*^[11] demonstrated that these symptoms typically resolve within 1 week or were responsive to analgesia.

Clinically mild bleeding is the most commonly-seen complication following SEMS placement with a reported incidence of 8%-12%. Bleeding can be attributed to friable mucosa associated with intrinsic masses as well as ulcerations and erosion and almost always resolves with conservative management^[29]. Later bleeding can usually be attributed to ulcerations/erosions in the colonic mucosa.

Major complications

Stent migration: The incidence of covered stent migration

significantly exceeds that of uncovered stents (50% *vs* 36%). Park *et al*^[4] demonstrated that the lower rate of uncovered stent migration can be attributed to an increased rate of tumor ingrowth/infiltration. While frequently an adverse incidence, stent migration may herald improvement in a colonic stricture secondary to a response to therapy. Endoscopic removal of a covered stent may be performed in cases in which stent migration to the anorectal area results in pain or irritation. In the case of uncovered stent migration, argon plasma coagulation combined with rat-tooth forceps has been used^[35]. Avoidance of stent migration is frequently achieved by placing the stent in the center of the stricture (or slightly above) and ensuring that it projects 2 to 4 cm proximally and distally into normal colon^[18].

Perforation: The most serious complication of colonic SEMS placement is perforation, which has a reported mortality rate of 0.8% per stented patient^[30]. Higher rates of complications have been reported in certain types of patients including those undergoing chemotherapy^[36-38]. Faragher *et al*^[16] reported an increased complication rate of 34.8% in patients receiving bevacizumab following stenting as compared to a 22.8% in untreated patients. This association may have also contributed to the high perforation rate in the stented group that lead to the premature termination of the only randomized controlled trial that attempted to compare outcomes between surgical intervention and SEMS in stage IV colon cancer patients on chemotherapy^[35]. Chemotherapeutic agents, in particular bevacizumab, have been linked to an increased risk of colonic perforation^[35].

Tumor overgrowth and ingrowth

Delayed stent obstruction due to tumor ingrowth or overgrowth is the most common complication following stent placement, with a reported incidence of up to 10%^[10,37]. As the described above, the rate of tumor ingrowth is reduced with the use of covered stents. However, these SEMS have not been approved for use in the United States due to a higher risk of stent migration. Management options for stent re-obstruction include ablation, argon plasma coagulation, surgery and stenting. Repeat stenting with a stent-within-stent approach is the most common treatment approach and is almost always successful^[39-42]. Far less common is stent failure secondary to stent collapse or stent fracture. van Hooft *et al*^[38] demonstrated an increased incidence of stent fracture when used to treat benign obstructions.

Operator factors: As is seen with a multitude of different medical procedures, operator experience is inversely related to rates of complications in the placement of SEMS^[34]. Colonic stenting is frequently performed on patients with extensive co-morbidities in acute settings. Consequently, the insufflation of air and manipulation of the different apparatuses will often result in higher rates of colonic perforation, the most serious complication associated with stent placement^[9,10,37,43]. Some authors have

advocated use of carbon dioxide during colonic stenting as a preventive measure to reduce the risk of perforation.

Patient-related factors

Higher rates of complication including treatment failure have been observed in patients with extrinsic lesions^[36]. Similarly, patients with longer segments of obstruction requiring stents longer than 10 cm had shorter event-free survival^[44]. This can be attributed to the increased difficulty of placing these SEMS. Nonetheless, dilation of the bowel prior to stent deployment is not advisable given the risk of tumor fracture. Data regarding complication rates related to tumor location have been conflicting with no strong indication that SEMS placement in the right colon is unsafe.

CONCLUSION

Self-expanding metal stents are increasingly being used as palliation and as bridge to surgery in patients with malignant obstruction of the colon. With high technical and clinical success rates, endoscopic stenting provides a viable alternative to surgery. When used for these purposes colonic stents have the potential to decrease morbidity and cost as well as increase patient quality of life. Further randomized control studies will be needed to compare the efficacy of SEMS placement to traditional surgical approaches in the treatment of malignant obstructions.

Numerous studies have demonstrated a low incidence of complications associated with SEMS placement. The majority of reported adverse events are minor and self-limiting including pain and bleeding. Colonic perforation remains the most serious complication. Long term failure of stents may result from stent migration and tumor ingrowth. In the majority of cases, repeat stenting or surgical intervention can successfully overcome these adverse effects.

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