Low Lying Rectal Stents: How Low Can You Go?

INTRODUCTION

In patients with low lying rectal obstruction due to malignancy, there is ongoing debate regarding whether self-expanding metallic stent (SEMS) placement within 5 cm of the anal verge is a feasible, efficacious alternative to surgery. Very few randomized control trials have included patients with low lying malignant rectal obstructions. Much hesitation exists in stenting close to the anal verge or the dentate (pectinate) line, which is the anorectal junction and is about 2 cm from the anal verge. Regardless of the etiology of the obstruction, rectal stenting may be indicated for symptomatic relief in non-surgical candidates or high-risk patients, or as a bridge to surgery, allowing for optimization of the patients’ health prior to the surgical intervention.

While SEMS placement within 5 cm of the anal verge has been approached in a guarded manner due to fears of high rates of adverse effects including proctalgia, tenesmus, incontinence, mucosal ulceration, bleeding, stent migration, and perforation, among other complications, there are multiple factors to consider in determining whether this is a safe and feasible option. In addition to a comprehensive risk-benefit analysis, the type of stent, the method of stent placement, the addition of chemotherapy or radiation, the endoscopists’ experience in placing stents, and the patients’ etiology and location of obstruction should be considered.

Since its introduction in the 1990s, SEMS placement for acute malignant colorectal obstruction has become a widely adopted alternative to surgery. SEMS placement is considered a safe and feasible alternative to emergent surgery for decompression of colorectal obstruction, either for palliation in poor surgical candidates or as a bridge to surgery. In poor surgical candidates, SEMS relieves obstructive symptoms, improving patients’ quality of life. In patients with surgically incurable colorectal cancer, patients who received stents had improved morbidity and mortality compared to patients who underwent surgery. As a bridge to surgery, temporary stent placement allows for elective rather than emergent surgery, which is associated with lower short-term morbidity and lower rates of temporary and permanent stomas.
Less data exists regarding the feasibility and efficacy of stent placement in colorectal obstructions that are within 5 cm of the anal verge. Historically, SEMS placement in these low-lying colorectal obstructions has been approached in a guarded manner due to fears of adverse effects including proctalgia, tenesmus, incontinence, mucosal ulceration, bleeding, stent migration, and perforation. In recent years, there has been increasing data to suggest that stent placement within 5 cm of the anal verge is both safe and clinically effective as a treatment modality for low-lying colorectal obstruction, although many practitioners are still hesitant to place a low lying rectal stent. This review will discuss the indications, techniques, and outcomes of colonic stenting in the distal rectum.

Risk Factors Influencing Clinical Failure
Malignant colorectal obstruction may be caused by primary colorectal cancer or an extracolonic malignancy (i.e. urogenital, gynecologic, gastric, or pancreaticobiliary). Clinical outcomes of SEMS placement for colorectal obstruction due to an extracolonic malignancy tend to be less favorable. Extrinsic compression causing colonic obstruction is reported to be a major cause of technical failure in colorectal SEMS placement. However, technical and clinical success rates of SEMS placement in this scenario varies widely across studies. Data also suggests that stent patency is lower when the etiology of the obstruction is due to extracolonic malignancy rather than primary colorectal cancer. Considering the etiology of malignancy is important, specifically in the case of lower rectal obstructions, because data has shown that obstruction attributed to extracolonic malignancy, not rectal obstruction itself, is an independent risk factor for clinical failure and complications (by both univariate and multivariate analysis in a study by Lee et al.).

Carcinomatosis also appears to be a risk factor influencing clinical failure (by univariate analysis in a study by Lee et al.) regardless of if the stent is placed for a lower rectal obstruction. This may be due to the differences in peritoneal infiltration patterns and in the severity of peritoneal carcinomatosis between patients with extracolonic malignancy and primary colorectal cancer. This may have clinical implications for patient selection with regard to stenting for lower rectal obstructions.

Figure 1a. Large subtotally obstructing rectal cancer approximately 4 cm from the anal verge.

Figure 1b. The same lesion following colonic stent placement. The distal end of the stent is very close to the dentate line, but the patient tolerated the stent well.

Risks of Stenting ≤5 cm From Anal Verge: Anal Pain
A phase 2 clinical study was conducted, during which 33 patients with non-resectable obstruction of the rectum or sigmoid colon had an uncovered metal stent placed through the anus in an obstructive portion under x-ray fluoroscopic guidance. While anal pain occurred in 5 patients, only 1 patient required stent removal due to intolerable pain. Song et al. reported that 10 out of 16 (62.5%) patients with stents placed for obstruction within 5 cm (range 25-50mm) of the anal verge complained of anal pain. In 3 of these patients, the pain resolved.
within 7 days or was tolerated without analgesics. The remaining 7 patients tolerated the pain with analgesics. In all cases, the stent was deployed in a manner by which the distal tip of the stent was located at least 5 mm proximal to the dentate line. This was in comparison to 14 patients with stents placed greater than 5 cm from the anal verge, 1 (7.1%) of whom complained of anal pain. In this study, stent migration occurred in 4 patients, all of whom experienced intolerable pain despite analgesics, likely due to irritation and sensory innervation to the anal canal by the unfixed distal end of the migrated stent as it moved beyond the dentate line. This study suggests that stents placed 5 mm proximal to the dentate line, but not within the anal canal, are usually tolerable to patients from a pain perspective. It also highlights the importance of accurately measuring the distance from the distal end of the obstruction to the dentate line.®

Lee et al. described a novel method for SEMS placement with a proximal-release delivery system (PRDS) to allow for precise SEMS placement for malignant rectal obstruction within 5 cm of the anal verge. The stent is released under endoscopic and fluoroscopic guidance. It is released by pushing the cover sheath, and the proximal portion is expanded before the distal, which differs from conventional stents. In this study, 2 out of 6 patients reported anal pain, tolerable with analgesics in both cases and which resolved within days. Additionally, no patients reported defecation difficulty, incontinence, or foreign body sensation.®

In another study by Lee et al., anal pain occurred more often in patients with stents successfully placed for lower rectal obstruction (<5 cm from anal verge) than upper rectal or left colonic obstruction (14.8% vs 6.2% vs 0.3%; p < 0.001), but ultimately, only a small number (4/27, 14.8%) of patients with lower rectal obstruction reported anal pain. Pain was well controlled by analgesics in 1 patient, but intolerable in the other 3. In 1 patient, this was due to stent migration. The remaining 2 patients’ pain was resolved with either surgery or radiotherapy. In this study, stents were successfully placed in patients as close as 10 mm from the anal verge (range of 10-50 mm from the anal verge). The authors concluded that appropriately positioning the distal end of a SEMS via fluoroscopy-assisted endoscopy is crucial in stenting ≤5 cm from the anal verge.®

Other studies also suggest that pain is more common in patients with stent placement in the rectum. In a study with placement of a dual stent using a 4.5-mm stent delivery system, 5 of the 34 patients who received rectal stents experienced severe rectal pain 2–22 hours after stent placement that required analgesics. None of the other 111 patients in the study who had stents placed in other parts of the colon complained of pain.® In another study with dual stent design, Kim et al. aimed to compare the clinical safety and efficacy of dual-design expandable colorectal stents with flared and bent ends in the treatment of patients with malignant colorectal obstruction. Four of the 35 patients (2 in each group) with stents placed in the rectum complained of rectal pain 2–15 hours after stent placement, while none of the 81 patients with stents placed elsewhere in the colon reported pain. The pain was mild and successfully managed with analgesics.®

Tenesmus
Tenesmus is a known complication of rectal stenting.®,15,21 (Figure 3) In a study by Bayraktar et al., authors retrospectively analyzed data from 49 patients with colorectal cancer who had undergone stent placement. Eighteen of these patients had obstruction in the rectum. Overall, tenesmus occurred in 8.1% of patients. This complication
in patients with malignant colorectal obstruction, bleeding occurred in 2 patients in the bridge-to-surgery group (n = 50) and in 6 patients in the palliative group (n = 101). In all cases, bleeding resolved spontaneously. This study included 34 patients with obstruction specific to the rectum, but it is unclear if patients with rectal obstruction experienced more significant bleeding than patients with obstruction in the rectosigmoid junction (n = 35), sigmoid colon (n = 56), descending colon (n = 10), or transverse colon (n = 16).

This study utilized a dual stent design, which was designed to take advantage of the strengths of both bare and covered stents. The inner and outer stents were each loaded via their own delivery systems. The inner stent was 2 cm shorter than the outer stent, which consisted of three parts: a proximal bare nitinol stent, a nylon mesh, and a distal bare nitinol stent. Both ends of the stent were flared up to 38 mm. The dual stent is believed to be superior to conventional stents in the treatment of colorectal obstruction in two ways: lower risk of stent migration and no tumor ingrowth, resulting in less recurrent obstruction. However, the dual design stent in this particular study also had disadvantages including a more complicated delivery system and risk for perforation due to the diameter of the flared ends of the inner bare stent, which authors investigated further in a follow-up study.

In a study that compared the clinical safety and efficacy of dual-design expandable colorectal stents with flared ends with those of stents with bent ends in the treatment of patients with malignant colorectal obstruction, bleeding occurred after stent placement in 1 patient with a flared-end stent and 3 patients with bent-end stents. Bleeding resolved spontaneously in all cases.

In another prospective clinical cohort study, 447 patients with malignant large-bowel obstruction (15.8% of tumors were specific to the rectum) received colorectal through-the-scope SEMS placement. Only 2 (0.5%) cases of bleeding were identified. Bleeding occurred in 0.4% (2/447) of patients within 6 hours of stent placement and in 0.5% (2/382) of patients within 30 days (cumulatively). The bleeding appeared to be a procedural complication due to stent placement rather than rectal in origin. The denominator of 382 patients with a 30-day follow-up visit reflects

**Bleeding**

Bleeding is typically a minor complication of colorectal stent placement; significant hemorrhage following stenting is rare. Bleeding secondary to stent placement generally does not require intervention and can often be managed conservatively. In a study by Lee et al., 136 of 482 successfully stented patients experienced complications. Bleeding was the fourth most common complication (n = 13; 2.7%), after re-obstruction (n = 103; 21.4%), stent migration (n = 22; 4.6%), and perforation (n = 17; 3.5%). It should be noted that the rates of complications in this study, especially the rate of perforation, are exceptionally high when compared to other studies, and the reasons for this remain unclear. In a phase 2 clinical study, bleeding only occurred in 1 of 33 patients with stent placement for unresectable obstruction of the rectum or sigmoid colon.

In a prospective study investigating the technical feasibility, clinical effectiveness, and safety of a dual-design colorectal stent (consisting of an outer stent and an inner bare nitinol stent)
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Fecal incontinence can occur with stents placed distally in the rectum, particularly if the distal end of the stent is within 2 cm proximal to the upper end of the anal canal. Some patients have also described a constant urge to defecate or a foreign body sensation, sometimes referred to as tenesmus. In a study conducted to investigate the clinical outcomes of SEMS in malignant rectal obstruction in comparison with those in left colonic obstruction, Lee et al. found incontinence to be rare. It occurred at a lesser rate (n = 1; 0.2%) than other complications including reobstruction (n = 103; 21.4%), stent migration (n = 22; 4.6%), perforation (n = 17; 3.5%), bleeding (n = 13; 2.7%), and anal pain (n = 11; 2.2%). However, the complication rate was overall higher in patients with rectal obstruction (37.4% vs 25.1%; p = 0.01).

In another study by Lee et al., authors utilized a novel approach – the PRDS, as described previously – to place stents in 6 patients with symptomatic malignant lower rectal obstruction with lesions located within 5 cm of anal verge (5 patients with rectal cancer, 1 with bladder cancer). The palliative PRDS differs from conventional stents in that the proximal portion is expanded before the distal. The authors evaluated fecal incontinence and defecation issues as an outcome measure; no patients in this study experienced any incontinence or defecation issue including foreign body sensation.

Reobstruction/Stent Occlusion

Stent occlusion can occur due to tumor ingrowth or outgrowth or, rarely, by stool impaction. In a retrospective study of 55 patients who underwent placement of an uncovered SEMS for palliative treatment of malignant colorectal obstruction with metastatic or locally advanced, surgically unresectable cancer, stent occlusion caused by tumor ingrowth or overgrowth (n = 8) was the most common complication (15.4%). Stent occlusion occurred at a mean time of 127 days between stent placement and occlusion (range, 31–360 days). The single patient with tumor overgrowth was treated with placement of an additional stent at the proximal end of the stent. Six patients with tumor ingrowth were treated by overlapping the occluded stent with a second stent. Study authors used the Cox proportional hazard model to identify predictive factors associated with stent occlusion and found that insufficient stent expansion (<70%) 48 hours status post stent placement was significantly associated with increased risk of stent occlusion (odds ratio, 12.55; 95% CI, 2.52–62.48; p = 0.002). The likelihood of stent occlusion by tumor growth increases with the time elapsed after stent placement. Of key importance, in this particular study, the site of obstruction was mainly in the sigmoid colon and rectum (69.1%); while stent placement occurred most commonly in the rectum (23 patients, 41.8%), the authors did not delineate complications by site of obstruction.

In a prospective study, stent occlusion occurred in 5 of 151 patients (rectal obstruction = 38) with a dual-design colorectal stent (outer stent and an inner bare nitinol stent) following placement for colorectal cancer (n = 115), gastric cancer (n = 25), cervical cancer (n = 3), pancreatic cancer (n = 2), ovarian cancer (n = 2), gatllbladder cancer (n = 1), cholangiocarcinoma (n = 1), urinary bladder cancer (n = 1), and renal transitional-cell cancer (n = 1). Stent occlusion was caused by tumor overgrowth in all five cases. These patients were successfully treated by placement of a second (coaxial) stent into the first stent with overlap at the ends.

Stent Migration

Stent migration represents one of the most common complications (overall incidence 10–11%, up to 50% of patients in some studies) after SEMS placement for colorectal obstruction. Notably, stent placement in the distal rectum is cited as one of the predisposing factors for stent migration. Stent migration may be asymptomatic or symptomatic, with the latter type generally requiring endoscopic repositioning, removal or replacement. In rare cases, migration may lead to additional complications such as recurrent obstruction or perforation.

In a retrospective study at a tertiary referral university hospital, Song et al. investigated the technical feasibility, clinical effectiveness, and safety of expandable metallic stent placement in patients with malignant rectal obstruction within 5 cm of the anal verge. Sixteen patients had rectal obstructions within 5 cm (range, 25–50 mm) of the...
anal verge (Group A) and 14 patients had rectal obstructions > 5 cm (range, 53-74 mm) from the anal verge (Group B). Stent migration occurred in 1 patient in group A and in 3 patients in group B. All four stents were removed due to intolerable anal pain, despite analgesic use, secondary to stent migration.\textsuperscript{9}

In another retrospective study, the authors aimed to investigate the clinical outcomes of SEMS in malignant rectal obstruction in comparison to left colonic obstruction. Of 573 patients enrolled in the study, 154 (26.9\%) underwent SEMS placement for rectal obstruction. In 39/154 patients, rectal obstruction was located ≤5 cm from the anal verge. Stent migration was the second most common complication in this study (n = 22; 4.6\%). Four patients with rectal obstruction experienced early and late stent migration, 2 of whom had obstructions <5 cm from the anal verge. In one of these cases, the patient had received a covered stent for obstruction located 4 cm from the anal verge; stent migration caused pain, requiring removal and reinsertion. In the second case, the tumor was located 5 cm from the anal verge and the patient received an uncovered SEMS-this patient ultimately underwent curative surgery. In the left colonic obstruction group, 4 and 10 patients experienced early and late stent migration, respectively.\textsuperscript{15}

The overall complication rate was higher in patients with rectal obstruction (37.4\% vs 25.1\%; \( p = 0.01 \)). However, most of the complications in patients with rectal obstruction were managed successfully with endoscopic treatment (41.3\%). In this study, the majority of the patients (77.1\%) received uncovered stents, which differs from the previously mentioned study by Song et al.\textsuperscript{15}

Yet another retrospective analysis was performed with 55 patients who underwent placement of uncovered SEMS for palliative treatment of malignant colorectal obstruction. The obstruction site was located in the rectum in 23 patients (41.8\%). Stent migration was the second most common complication (10.9\%, 6/55). Early stent migration (<1 week after stent placement) developed in 5 patients, 2 of whom had partial distal migration and received additional stent insertion and 3 of whom had complete migration in which the stent was expelled out of the anus. Two of the latter patients required no further intervention and the other patient underwent stent reinsertion. Late stent migration (≥1 week after stent placement) developed in only 1 patient with sigmoid colon cancer and in no patients with rectal obstruction.\textsuperscript{30}

In a prospective study of a dual-design colorectal stent (consisting of an outer stent and an inner bare nitinol stent) placement was performed in 151 patients with malignant colorectal obstruction. Stent migration did not occur in the bridge-to-surgery group, but occurred in 4 patients in the palliative group, 1 of whom had obstruction specific to the rectum.\textsuperscript{22}

Perforation

Perforation is a rare but serious complication of colorectal stent placement, often related to the tortuosity of the rectosigmoid junction, insertion technique, or the endoscopists’ experience.\textsuperscript{3,7,23,33} Other risk factors include balloon predilation, excessive manipulation of stent wires, laser recanalization prior to SEMS placement (which is rarely performed in the current era), and possibly related to concomitant bevacizumab use, an angiogeneic inhibitor.\textsuperscript{3} However, a recent study by Lee et al. suggests that bevacizumab may no longer be a risk factor for perforation.\textsuperscript{34} Perforation typically requires surgical intervention.\textsuperscript{3}

While these are commonly cited risk factors, in one study, the authors conducted a multivariate logistic analysis with forward stepwise selection and found that complete obstruction was the only significant independent factor for perforation (odds ratio 6.88, 95 % CI 2.04 - 23.17, \( p = 0.002 \)); age, sex, site and length of the obstruction, the source of the malignancy, and balloon dilation before and after stent placement were not related to the likelihood of perforation.\textsuperscript{22} Stent placement due to obstruction in the lower rectum does not appear to increase the risk for perforation.

In a different prospective study, 49 patients underwent uncovered SEMS placement for malignant colorectal obstruction, 15 (30.6\%), of whom had rectal obstruction. Perforation occurred in 1 patient with rectal cancer 87 days after SEMS placement proximal to the stent placement site, which required a Hartmann’s operation. It is unclear how low in the rectum the stent was placed. For comparison, the only other perforation in this study occurred immediately after stent deployment.
in a patient with a sigmoid colonic obstruction, and the patient received emergent palliative left hemicolectomy. In a retrospective study at a tertiary hospital, Song et al. investigated the technical feasibility, clinical effectiveness, and safety of SEMS in patients with malignant rectal obstruction within 5 cm of the anal verge. Sixteen patients had rectal obstructions within 5 cm (range, 25-50 mm) of the anal verge (Group A) and 14 patients had rectal obstructions > 5 cm (range, 53-74 mm) from the anal verge (Group B). The perforation rate was 6.7% (2/30). Colonic perforation occurred in 8% (2/25) of patients with dual stents at 10 and 50 days after stent placement. In one case, perforation was related to the stent wiring, and the site of perforation could not be detected. In the other patient, the perforation occurred in the colon, proximal to the tumor bed, due to pressure necrosis from flared ends of the inner bare stent of the dual stent. In one patient, the length between the lower margin of obstruction and the anal verge before stent placement was 50 mm. The length between the lower margin of the placed stent and the anal verge 1 to 3 days after stent placement was 25 mm. In the other patient, the length between the lower margin of obstruction and the anal verge before stent placement was 70 mm. The length between the lower margin of the placed stent and the anal verge 1 to 3 days after stent placement was 40 mm. Both patients required emergent colostomy. No perforations occurred in patients with fully covered retrievable stents. The authors concluded that stent placement is safe in the lower rectum and that the diameter of flared ends of dual stents should be reduced to decrease risk for perforation.

In another retrospective study, authors investigated the clinical outcomes of SEMS in malignant rectal obstruction in comparison to left colonic obstruction. Of 573 enrolled patients, 154 (26.9%) underwent SEMS placement for rectal obstruction. In 39/154 patients, rectal obstruction was located ≤5 cm from the anal verge. Perforation occurred in 1 patient with upper rectal obstruction, but did not occur in any patients with lower rectal obstruction.

**Lumen Apposing Metal Stents (LAMS)**
Initially designed for the drainage of pancreatic fluid collections, the Axios stent (Boston Scientific, Natick MA) is a 1 cm long, fully covered LAMS available in 10, 15, and 20 mm dm in the United States. Axios stents may be beneficial to patients with complex, severe, and refractory stenosis located within 5 cm of the anal verge.

Many reports of Axios stents being used to treat luminal obstruction in the large bowel exist. There are a few reports of the use of the Axios stent in an off-label manner to treat low-lying rectal obstruction. In one report, a 49 year old male with sigmoid adenocarcinoma developed severe, filiform, eccentric stenosis 5 cm from the anus that could not be resolved by traditional endoscopic dilation. After successive dilations failed (using a through-the-scope, over-the-wire balloon under fluoroscopic guidance), a 15 mm wide Axios stent was placed across the stricture under endoscopic and radiologic guidance. The patient tolerated the stent without further complication and with adequate intestinal transit at his two month follow-up.

In another case report, a 66 year old male, who underwent a low anterior resection with loop ileostomy for colorectal malignancy, developed complete obstruction of the rectal anastomosis. Recanalization of the lumen was successfully performed with a 15 mm wide Axios stent. While this stent was designed for transenteric drainage, in this case, it functioned to maintain patency after total rectal anastomotic stenosis.

**Risk-Benefit Analysis**
While the risk for certain adverse effects may be increased when stenting in the case of low-lying rectal obstruction, complications are rare.
and can often be managed through endoscopic intervention including stent reinsertion, balloon dilatation, and hemostasis.\textsuperscript{15} Argon plasma coagulation (APC) has also been utilized when complications arise after stent placement for rectal obstruction. It may be used to trim malpositioned or migrated endoscopic SEMS. Molina-Infante et al. described a case of APC endoscopic transection of an embedded segment from a distally migrated, uncovered rectal stent, complicated by ulcerations due to impaction against the rectal wall after failed removal via endoscopic en bloc due to diffuse tumoral ingrowth.\textsuperscript{37} In another case, APC was used successfully to trim a stent in an 86-year-old female with obstructing rectal cancer who underwent placement of a colonic SEMS with a portion of free flange in the distal rectum.\textsuperscript{38}

Anal pain, a feared complication with stent placement so close to the anal verge, is tolerable to most patients with or without analgesics, although patients may choose to undergo palliative radiotherapy to reduce pain, which is also experienced by patients whose tumors are >5 cm from the anal verge.\textsuperscript{15} Tumor ingrowth can be managed with APC, ablation of the obstruction, or (most commonly) via placement of a second stent while tumor overgrowth can be managed with an additional stent.\textsuperscript{2,3} Perforations, while rare, can occur and often require surgery. In some instances, conservative medical therapy may be utilized including nasogastric tube insertion, antibiotics, and total parenteral nutrition while allowing perforations to spontaneously resolve.\textsuperscript{3}

Stent placement in patients with obstructions <5 cm from the anal verge allows patients to avoid surgical intervention and colostomy/stoma while maintaining continence and with minimal adverse impact on quality of life.\textsuperscript{3-5,33} Stent placement is also more cost-effective than stoma creation for patients with inoperable malignant colonic obstructions and results in shorter hospital stay.\textsuperscript{5}

\section*{Conclusions}

Can we stent within 5 cm of the anal verge? Yes. Stenting within 5 cm of the anal verge is possible and should be considered in certain patients. Complications may not occur as often as what was once thought and can often be resolved without additional adverse events. Ultimately, patients may avoid colostomy or invasive surgical procedures and have improved quality of life. In conclusion, stent placement within 5 cm of the anal verge is safe, feasible, and efficacious, and a reasonable alternative to surgery as palliative care or as a bridge to surgery in carefully selected patients.

\section*{References}

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