REVIEW

Colonic stenting: a practical update

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ABSTRACT

Colonic stenting is part of the UK service provision guidelines for colorectal cancer. However, there are issues about availability and expertise within the UK, and controversies remain regarding various clinical and technical aspects of the technique. Based on the current evidence, this article will provide a practical update on the indications, the clinical and technical considerations and the remaining unanswered questions regarding colonic stenting.

INTRODUCTION

Since the first description in 1991 of an oesophageal self-expanding metal stent (SEMS) to palliate large bowel obstruction from colorectal cancer (CRC),¹ the use of colonic stenting has grown extensively worldwide, and is now cited as the standard of care in CRC service provision guidelines within the UK.² There were greater than 70 Pubmed citations in 2011 alone on various aspects of colonic stenting, and despite this depth of interest the evidence still remains unclear in a number of important clinical and technical aspects of the technique. The aim of this article is to provide an update on current evidence for colonic stenting with a focus on the indications, clinical and technical considerations and the unanswered questions.

INDICATIONS**Colorectal cancer**

By far the commonest indication for SEMS is treating obstruction caused by CRC. This is performed in two different clinical scenarios: 'palliation' for surgically incurable or unfit patients and as a 'bridge to surgery' in surgically curable patients.

Despite advances in perioperative care and greater subspecialisation, emergency surgery for acute obstruction due to CRC is still associated with a high morbidity (45–50%) and mortality (15–45%).³ These poor outcomes are likely to be due to a combination of patient (poor bowel

preparation and patients in poor medical condition due to electrolyte disturbances and comorbidities) and operating factors (differences in operative techniques and operations performed by non-specialists out of hours). In addition, emergency surgical colostomy is associated with a high postoperative complication rate (34% reporting stenosis, partial prolapse and pain) and a poor quality of life (QOL).⁴ To negate the need for emergency surgery, successful stenting is an attractive alternative and has been shown to avoid emergency surgery in the vast majority of patients.⁵

Palliation

The most experience with SEMS has been treating colonic obstruction in patients with either stage IV CRC (in which median survival is only 17 months), or when significant comorbidities preclude surgery. The advantage of this approach is that it offers a single non-surgical procedure, which does not require general anaesthesia or intensive treatment unit stay, and potentially palliates the patient for the remainder of their life. The largest meta-analysis with nearly 800 patients reported a high technical success (radiological confirmation of correct SEMS deployment and placement at the first attempt) of 93% with good clinical success rates (clinical resolution of large bowel obstruction within 48 h of SEMS insertion without re-intervention) of 91%, although considerable variation between studies was reported⁵ (see table 1). Similar results have also been shown in UK practice from our recent multicentre series, with technical and clinical success rates of 87.4% and 84.6%, respectively.⁶

Direct comparisons of SEMS placement versus emergency surgery comes from only small studies. A recent retrospective case-controlled study (with less than 30 patients in each group) showed SEMS in a favourable light, with clinical success rates of 100% with no immediate complications in the SEMS group. In addition,

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Table 1 This summary table reports the main outcomes of self-expanding metal stents for the four major indications

	Palliation (%) (range)	Bridge (%) (range)	Extrinsic range (%)	Benign range (%)
Technical success	93.35 (67–100)	91.9 (33–100)	67–87	89–100
Clinical success	91 (62–100)	71.7 (45–84)	20–82	76–95
Re-intervention	10–15	–	18–73	13–33
Complication overall	15–22	10–22	11–39	11–43
Stoma rate	3–6	16–33	10–47	10–48
Perforation rate	3–5	2	0–13	9–11
Mortality (30-day)	1–14	1–8	3–36	0–5

For colorectal cancer; data are extracted from the largest study of pooled⁵ analysis of 791 palliative and 407 bridge patients with ranges found within this analysis in brackets. Due to the small number of patients in the reported studies for extrinsic and benign indications, only ranges are quoted from an accumulation of a number of studies found within the literature. This table highlights that technical success is worst for extrinsic indications and clinical success best for palliation indications. In addition, complications are significant in all groups, but are particularly high in the benign and extrinsic indications. Mortality is worst in the extrinsic group.

SEMS had a shorter length of stay in hospital by 10 days and significantly lower stoma (by over three-fold) and complication rates compared to surgery.⁷ Survival following the two treatments was comparable and this seems to be supported by a recent meta-analysis, which reported a mortality of 2% for both treatments.⁸ In addition, patient QOL improved following both treatments, but this seems to be more immediate and pronounced for SEMS due to the dip in QOL in the postoperative period.⁹ A US decision analysis study showed lower mean costs per patient favouring SEMS over surgery in palliative patients over a 6-month period, with costs of US\$27 255 and US\$57 398, respectively.¹⁰ This was likely to reflect the savings from inpatient costs of the shorter hospital stay by successful palliative SEMS placement,^{11 12} and these benefits are likely to continue into outpatient care, as stoma appliances are not required.

Despite these encouraging results for SEMS, significant doubt about its effectiveness and safety over emergency surgery comes from the only randomised trial in this field.¹³ This Dutch study compared these two treatments in palliative stage IV CRC and randomly assigned 11 of 21 patients recruited to SEMS. It was closed prematurely due to excessive perforations in the SEMS arm at an alarming 36%. Controversies surrounding this trial include the early closure without achieving the primary endpoints of the trial, the particular SEMS used, although two subsequent prospective studies using the same SEMS showed substantially lower perforation rates (<4%),^{14 15} and patient selection with only left-sided lesions causing variable degrees of obstruction recruited.

Nevertheless, until well-conducted randomised controlled trials (RCT) that reach their endpoints confirm otherwise, SEMS placement does seem like a moral and sensible alternative treatment to emergency surgery in patients with a limited lifespan. Data from systemic reviews, meta-analyses and a number of other studies have shown high technical and clinical success rates, good safety, reductions in length of hospital stay and stoma rates and cost effectiveness without adversely affecting mortality.

Bridge to surgery

The first description of a colonic SEMS used in a surgically curable patient as a 'bridge' to elective surgery was in 1994.¹⁶ The advantages of this approach includes: potentially avoiding the mortality and morbidity associated with emergency surgery; cost-effectiveness with an elective one-stage operation that avoids colostomy and is approximately 30% cheaper than a two-stage surgical approach;^{11 12} optimisation of medical management of patients with regard to their comorbidities and the correction of volume and electrolyte imbalance before major surgery; allowing full patient assessment for cancer management including discussion by multidisciplinary teams, full radiological staging and identifying synchronous lesions; elective surgery, which may potentially be minimally invasive (laparoscopic) on a decompressed and prepared colon with a greater chance of achieving a primary anastomosis; allowing future neo-adjuvant chemotherapy strategies in these locally advanced tumours. Preliminary results from the FoXTROT collaborative study shows dramatic tumour regression in almost a third of patients in the neo-adjuvant group compared to negligible amounts in the none neo-adjuvant arm.¹⁷ The long-term data from this trial are eagerly awaited, but the short-term data are encouraging for future strategies of SEMS placement as a bridge to neo-adjuvant chemotherapy and then surgery.

The site of obstruction seems to influence the management of these patients profoundly in both clinical practice and within the literature. This is because, in contrast to left-sided lesions, a colostomy can be avoided for right-sided obstruction (lesions proximal to the splenic flexure) because a primary resection with a right hemicolectomy and ileocolonic anastomosis can be successful on unprepared dilated colon.¹⁸ Conversely, SEMS placement in right-sided lesions is technically very challenging, and a number of studies have shown that right-sided SEMS placement is associated with high technical failure rates.¹⁹ For these reasons, it has been argued that SEMS placement in right-sided obstruction is unnecessary and surgery is the treatment of choice.

The use of SEMS in the treatment strategy for a bridge to surgery has been shown to be successful in a

number of retrospective and prospective series.^{20–26} They have shown technical and clinical success rates between 83% and 97%, avoidance of emergency surgery in between 70% and 95% of cases without compromising long-term survival, lower postoperative complications, shorten hospital stays and reductions in inpatient mortality compared to emergency surgery.

In contrast, the four main RCT that have compared SEMS placement with emergency surgery have not been so favourable.^{27–30} However, all trials were in just left-sided obstruction and the results were heterogeneous, with three of the four trials stopped prematurely for different reasons (two because of high perforation and morbidity rates in the SEMS group and one because of a high complication rate in the surgery group) before reaching their primary endpoints. A recent systematic review³¹ summarised the findings as follows: clinical success rates of just 69%; favourable outcome towards SEMS over emergency surgery, with a higher primary anastomosis rate (relative risk ratio of 1.5; see figure 1) and lower stoma rate (relative risk ratio of 0.7; see figure 1); no difference in the rates of inpatient mortality,^{31 32} surgical site infections, anastomotic leaks or re-operations between the two groups.

The UK Colorectal Stenting Trial (CReST) is a RCT for patients presenting with acute left-sided obstruction with CRC, for both palliation and bridge to surgery indications, is currently in the final stages of recruitment. This important study hopes to address the key questions of what is the overall net benefit with SEMS placement compared to surgery, and which sub-population of patients is most likely to benefit.

OTHER INDICATIONS

There is significantly less experience in using SEMS for treating colonic obstruction due to 'benign disease' and 'extrinsic malignancies' and for its use in treating colonic fistulas.

Benign disease

Benign strictures tend to be more insidious in nature and patients rarely present with total obstruction. The problems are that uncovered SEMS have limited patency, high complication rates and are difficult to remove, while covered SEMS are associated with high migration rates. In the largest published series that consisted of just 21 patients (mostly diverticular strictures), the clinical success rate was 76%, but the complication rate was 42% of which the perforation rate was 29%.³³ One study did show that the majority of complications occurred after 7 days, and supported a potential role as a temporising measure before definitive surgery in patients who may gain substantial medical benefit by short-term SEMS placement.³⁴

Extrinsic malignancies

Colonic obstruction due to extrinsic compression is usually as a result of advanced pelvic malignancy, especially ovarian and prostate,³⁵ and overall the outcomes are very poor. Studies have shown very low clinical success rates of only 20% with a high complication rate, and up to 45% of patients requiring a later colostomy.^{36 37} In addition, there was a substantial 30-day mortality rate of up to 36%,^{37 38} which is likely to reflect extensive carcinomatous disease in these patients.

Figure 1 Risk ratio tables for a systematic review³¹ of the four randomised control trials of self-expanding metal stents (SEMS) for a bridge to surgery versus emergency surgery. The results indicate that SEMS use is associated with higher primary anastomosis rates and lower stoma rates when compared to emergency surgery (permission from the publishers obtained).

Colonic fistulas

Single figure case series and case reports have used SEMS to manage for colonic fistulas. Long-term resolution is said to occur in a third to a half of the cases with eventual luminal reconstitution. Treatment requires a covered SEMS in which the prevalence of migration is high.

CLINICAL AND TECHNICAL CONSIDERATIONS

Clinical considerations

Colonic SEMS placement should be performed in accordance with the National Institute for Health and Clinical Excellence (NICE) guidelines, which stipulate that patients presenting with acute obstruction require decompression within 24 h.² However, there are issues around the availability of this technique within the UK. Hospital episode statistics data for acute trusts in England for 2006–8 found that while 10 331 patients were coded annually with emergency hospitalisation and a new diagnosis of CRC, only 513 colonic SEMS procedures were coded, with significant regional variation in activity rates and availability in individual hospitals.³⁹ This is a very low rate of colonic SEMS placement relative to the number of emergency presentations of CRC, even when accounting for potential problems within complete capture of procedures by routine coding. There may be multiple reasons to explain this apparent variation, including a lack of emergency provision and access to colonic SEMS placement, as well as the necessary expertise in performing the procedure. For these reasons, the need for regional networks and centres of expertise with agreed referral pathways may be necessary within the UK, to ensure that NICE guidelines for relieving obstruction are met.

Radiological support and imaging is very important for SEMS placement. Previous imaging with a contrast enema study is no longer considered adequate and CT scan is the imaging modality of choice as it aids diagnosis, confirms the site, type and degree of obstruction, aids staging and determines the presence or absence of metastatic disease, and determines the absence or presence of colonic perforation.⁴⁰ The latter is important for directing the patients to emergency surgery, and NICE guidelines do not recommend SEMS placement in the presence of perforation or peritonitis.²

The literature does not address important issues surrounding clinical presentations of obstruction, such as acute versus subacute obstruction (although the latter has been shown to be associated with fewer complications and better technical success),^{19–41} closed versus open loop obstruction and the degree of colonic dilation. The site is important even in left-sided obstruction as SEMS placement in strictures within 5 cm of the anal verge runs the risk of the patient developing troublesome tenesmus⁴² and potential interference in sphincter function leading to incontinence.

Prophylactic SEMS placement in ‘imminent obstruction’ (tight stricture without clinical evidence of obstruction) potentially exposes patients to procedural risks with negligible clinical benefits. This is because in the palliation group over 70% will die from disease progression, and in the bridge group the vast majority will receive definitive resection before developing clinical obstruction.⁴³

Other clinical considerations before stenting, such as optimal bowel preparation, prophylactic antibiotics and the management of anticoagulants/antiplatelet agents have seldom been studied. In our practice, oral bowel cleaning agents are not used due the risk of perforation, and we rely solely on two phosphate enemas regardless of the site of obstruction with good technical success rates even in proximal lesions. ASGE guidelines recommend antibiotic prophylaxis due to the high rate of bacteraemia,⁴⁴ which has been reported as approximately 8%.⁴⁵ However, our practice is in line with NICE guidance, which does not recommend the use of prophylactic antibiotics as colonic SEMS placement has no greater risk of bacteraemia than diagnostic colonoscopy.⁴⁶ The BSG guidelines classify stenting as a high-risk procedure for bleeding,⁴⁷ and while optimising the INR in patients on oral anticoagulants may be possible, stopping antiplatelet agents such as clopidogrel 7 days before the procedure is not, when complying with NICE guidance for relieving clinical obstruction.

Technical considerations

Pre-stent dilation should be avoided due to the risk of perforation. There are two standard techniques for SEMS insertion. The first is ‘over the wire’, which is principally a radiological technique that uses fluoroscopic guidance only. It allows the deployment of large diameter SEMS but is limiting for more proximal strictures. The second is ‘through the scope’ (TTS), and this is our preferred technique, which we perform with minimal air insufflation (see figure 2). This endoscopic technique allows SEMS to be delivered via an adequately sized biopsy channel and positioned with a combination of direct endoscopic visualisation and fluoroscopic guidance. TTS offers better control of deployment, improved access to right-sided lesions and the option to biopsy to aid diagnosis and management of the patient. In addition, it has been shown to have better technical outcomes,⁵ and in our study the clinical success of TTS was far superior at over 90% compared to just 75% with over the wire.⁶

Not surprisingly, studies have shown that experienced operators have higher rates of technical success,^{6–41} with improvements seen over the first 40 procedures.⁴⁸ In addition, operator experience in other interventional techniques such as endoscopic retrograde cholangiopancreatography has been shown to be associated with greater technical success and fewer complications.⁴¹ This, of course, makes training

Figure 2 Illustration of a colonic self-expanding metal stent (SEMS) placement using the through the scope technique courtesy of Dr Paul O'Toole. (i) Endoscopic image of the guidewire first being advanced across the obstructing colonic cancer. (ii) Endoscopic image of the SEMS delivery system passed through the biopsy channel over the guidewire and through the stricture. (iii) Radiological image of the SEMS being deployed with obvious wasting at the site of the stricture. (iv) Endoscopic image of the distal end of the SEMS successfully deployed and opened (technical success).

provision in the procedure very challenging and can potentially only be addressed in high volume centres where expertise is concentrated.

Post-procedure, full SEMS expansion usually takes 24 h, and a study has shown that insufficient SEMS expansion of less than 70% on abdominal x-ray at 48 h post-insertion⁴⁹ is a poor prognostic sign. It is advisable that the patient should be restricted to only fluids during this period, and a low residue diet is followed thereafter. We also recommend regular life-long use of laxatives usually one sachet of Movicol twice a day to reduce the chance of faecal impaction.^{50 51}

COMPLICATIONS

There is considerable variation in the complication rates between reported series and RCT. The recent Cochrane review reported a complication rate as high as 39%⁵² while our UK multicentre study reported rates between 10% and 15%. The risk factors that have been identified include male sex, complete obstruction, SEMS diameter less than 22 mm, stricture dilation

(perforation risk 10–18%),^{5 53} operator inexperience, and the use of the chemotherapy agent bevacizumab (20-fold increased risk of perforation).⁴¹ Age was considered unimportant in one study,⁵⁴ although a more recent series did report slightly worse outcomes with elderly patients in the 'bridge to surgery' group.⁵⁵

Perforation

A large review reported an overall overt perforation rate of 4.9% and this was similar regardless of whether it was for 'palliation' or 'bridge to surgery'.⁵⁶ The vast majority (84%) occurred immediately or within 24 h of the procedure. The recent Cochrane review reported a perforation rate of nearly 6%, while a recent systematic review and meta-analysis of RCT for 'bridge to surgery' found a clinical perforation rate of 6.9% and a silent perforation rate of 14%.^{31 52} Not surprisingly, perforation does seem to have a profound influence on patient survival, as illustrated by one study in which the 30-day mortality if

a perforation occurred was 16.2% compared to just 0.8% if it had not.⁵⁶

Bleeding

Bleeding occurs in approximately 5% of cases but this is usually very minor due to SEMS irritating friable tumour,⁵³ and conservative management is generally all that is necessary.⁵⁷

Migration

Migration occurs in between 2% and 11%,^{8 52 58} with the majority migrating distally, often with spontaneous expulsion. However, impaction can occur on the anal verge and then removal under general anaesthesia with anal retractors is often required. Specific risk factors for migration include use in benign strictures,³⁷ covered SEMS (migration reported in up to 40%), small diameter SEMS less than 22 mm⁵⁹ and following chemotherapy or radiotherapy.^{57 60}

Re-obstruction/SEMS occlusion

The median patency of SEMS placements in the palliation group is just under 5 months, and SEMS occlusion is reported at 2–12%,^{8 52 58} which increases with the time it remains *in situ*. The commonest cause of re-obstruction in palliative patients is tumour overgrowth but others include faecal impaction, stent migration and a benign indication.⁵³

Mortality

The procedure-related mortality ranges between 0.6% and 3%,^{8 52 61} with sepsis, perforation and re-occlusion being contributing factors.⁵ A number of studies now quote 30-day mortality as a guide for the futility of the procedure. A recent multicentre series of 447 patients reported a 30-day all-cause mortality of near 9%.¹⁵ Within the UK, the data from the national bowel cancer audit project in 2007 reported this mortality at 11%,⁶² and in our multicentre series it was 13.6% for 'palliation' and 7.7% for 'bridge to surgery'.⁶

UNANSWERED QUESTIONS

RCT have yet to show conclusively whether there is an overall net benefit with SEMS placement over emergency surgery for CRC, such as reductions in operative morbidity and mortality, reductions in stoma formation, cost effectiveness, improvements in QOL quality and safety profiles, and if so, which subpopulation will benefit. No RCT has addressed the role or efficacy of SEMS in treating right-sided obstruction (above splenic flexure) even though high clinical success rates have previously been reported.⁶³ All future studies need to have well-defined populations, be adequately powered and concluded to their endpoints. In addition, SEMS placement in these trials should be performed by experienced operators using the most optimal technique, that is, TTS.

Two important oncological issues with SEMS also need to be addressed. The first is safety and long-term outcomes in patients undergoing post-procedure chemotherapy, given the reported high incidence of micro perforations (up to 14%) and the poor outcomes seen with bevacizumab.^{41 64} The second is with regard to the promising results from FoXTROT,¹⁷ and the potential benefits of SEMS allowing patients to undergo neo-adjuvant chemotherapy in the bridge to surgery setting.

Comparisons between types of SEMS and their differing characteristics have yet to be systematically studied. With advancements in SEMS technology, the development of biodegradable⁶⁵ and drug-eluting stents,⁶⁶ this ever growing area needs ongoing systematic evaluation.

CONCLUSIONS

The use of SEMS to treat colonic obstruction is an attractive alternative to emergency surgery. However, from the literature, there is little to support the use of SEMS outside clinical large bowel obstruction from luminal CRC. Even in this setting, there is discordance between the reported series, in which the procedure seems to be a good safe technique and an effective alternative to emergency surgery, to that of randomised trials, in which the outcomes are much worse, with low success rates and high complication rates. With the current shortfalls within the literature, patient selection through multidisciplinary team working and methods of optimising outcomes, which include expertise in the clinical and technical aspects of the technique, is essential. As there seem to be issues within the UK surrounding both access and expertise in the procedure, regional referral networks with centres of excellence need to be developed in order to get the best patient outcomes and to comply with NICE and national CRC service provision guidelines.

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