International Journal of Surgery 9 (2011) 595–599

Contents lists available at SciVerse ScienceDirect

International Journal of Surgery

journal homepage: www.theijs.com

Review

Colorectal stents: Do we have enough evidence?

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ARTICLE INFO

Article history:
Received 2 August 2011
Accepted 29 August 2011
Available online 13 September 2011

Keywords:
Colonic stents
Self-Expandable-Metal-Stents (SEMS)
Colonic obstruction
Colorectal cancer and endoluminal stenting

ABSTRACT

Background: The use of colonic stents has significantly evolved over the last few years. Emergency surgery for colonic obstructions is usually associated with significant mortality, morbidity and often stoma formation. Colonic stents provide an alternative way to relieve colonic obstruction, and hence avoiding the risks associated with emergency surgery. This literature review aims to summarize the important current evidence regarding colorectal stenting and show whether further evaluation of the procedure is required.

Results: The available large number of non-randomized studies suggests that Self-Expandable-Metal-Stents (SEMS) placement for acute colonic obstruction could be considered as safe and effective alternative to surgery in experienced hands either as a bridge to surgery or as a palliative measure. This evidence has led to SEMS being widely adopted. However, randomized evidence has begun to show the defects that are inherent in the low level evidence that has so far supported SEMS use and it may be that reports of randomized controlled trials may clarify the patient population where SEMS placement is appropriate.

Conclusion: While we are still waiting for the outcome of the multicentre randomized controlled trials in the UK and Europe, clinicians must be aware of the current evidence limitations and apply SEMS use pragmatically.

1. Introduction

Stenting of the colonic strictures was first proposed in the early nineties as a method of potentially converting emergency surgery for obstructing colorectal cancers (CRC), with its associated mortality and morbidity, to safer elective surgery.[1] Reports rapidly followed of colorectal stent placement to relieve malignant and benign strictures both as a bridge to definitive surgery or as palliative treatment for obstructing cancer.[2–4] Techniques have evolved to produce high clinical and technical success rates in a variety of settings.[5] This review aims to summarize the important current evidence regarding colorectal stenting and show where further evaluation of the technique is required.

1.1. Search methods

Electronic search of databases (Pubmed/Medline, Ovid, Blackwell Synergy and Cochrane database) in addition to the search engines Google/Google Scholar and Bing. The search was limited to articles published *mainly* over the last five years in English language. In addition, older publications were used to provide a background for the subject. Searches were screened and those studies thought to be relevant had full text versions retrieved. The references of all retrieved texts were searched for further relevant studies.

2. What is the role/evidence of colorectal stents in the emergency setting?

Eight to twenty nine percent of CRC patients are initially presented with acute colonic obstruction. Seventy percent already have an advanced cancer on presentation and only (50%) are candidates for curative surgery.[6,7] Emergency surgery for acute colonic obstruction is associated with a mortality of (15–20%) and a morbidity of (40–50%); both of which are significantly higher than the elective colorectal surgery, where the mortality rate ranges between (0.9–6%).[8]

The use of endoluminal colonic stents has significantly evolved over the last few years. They provide an alternative way to relieve colonic obstruction to emergency surgery, which is usually associated mortality, morbidity and often stoma formation. Successful

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doi:10.1016/j.ijsu.2011.08.010

colonic stent placement provides the necessary time needed to prepare patients with resectable cancer for definitive elective surgery. This time can be used for nutritional, organ and psychological support, tumor staging and neo-adjuvant therapy. It also allows the involvement of specialist colorectal surgeons. Several small retrospective series have examined the results of post-stent definitive surgery with morbidity and mortality similar to accepted elective surgical rates.[9,10] Recent reports suggest that laparoscopic surgery after colonic stenting appears to be successful and safe.[10–13]

Despite encouraging results from case series and case-controlled data, similar results have not been consistently replicated in the randomized controlled trials comparing emergency surgery vs. Self Expandable Metal Stent (SEMS) as a bridge to surgery. One multicentre trial was terminated early due to a high rate of technical failure in the SEMS arm (54%) and a high perforation rate (7%) Using an Intention to treat analysis, no difference was observed in the stoma creation rate between the SEMS and emergency surgery group. They suggested that the low rate of technical success may reflect the inability to choose suitable cases for stenting in a randomized trial setting.[14] In April 2011, the collaborative Dutch Stent-In study group has published a multi-centre randomized controlled trial to compare [colonic stenting ($n = 47$ patients) vs. emergency surgery ($n = 51$)]. This trial has shown that colonic stenting has no decisive clinical advantages to emergency surgery. The most common serious adverse events they have experienced are abscess (three in the colonic stenting group *vs.* four in the emergency surgery group), perforations (six *vs.* none), and anastomotic leakage (five *vs.* one), and the most common adverse events were pneumonia (three *vs.* one) and wound infection (one *vs.* three). The trial was stopped before reaching their calculated sample size of (110) patients because of the substantial morbidity and some mortality occurred in the colonic stenting after (30) days from the stenting time. They advised that colonic stents could be used as an alternative treatment in as yet undefined subsets of patients.[15]

In contrast, Cheung et al. specifically set out to compare laparoscopic surgery posts SEMS vs. Open emergency surgery. Their trial was smaller (48 patients) and did not report an *a priori* power calculation. Technical and clinical success was 83% after SEMS insertion and no perforations were reported. Subsequent laparoscopic resection was successful in all cases.[16] Two further trials are anticipated in this area; the Colo Rectal Stenting Trial (CReST) and the Enteral Stents for Colonic Obstruction (ESCO) trial. Both studies are currently recruiting participants.[17,18]

3. What is the role/evidence of colorectal stents in the palliative setting?

Colonic stents can also be used as a palliative measure for patients with advanced non-resectable CRC or for those who are considered to be medically unfit for surgery. They can alleviate obstructive related symptoms and avoid stoma formation.[19,20] As with bridge-to-surgery much of the evidence is in the form of retrospective case series which have been summarized in review articles, Khot et al. presented pooled data of 336 palliative stents reported in the literature and found the success rate was (90%) with a re-obstruction rate of 10%.[19] More recent pooled estimates, with larger patient numbers, report similar data.[8,20] Again the higher level evidence would initially appear to conflict with results from retrospective data. In 2006 the [Dutch In-stent 1 trial] closed after recruiting only 21 patients due to a perforation in 4 of 11 patients in the SEMS arm.[21] In a subsequent report this increased to 6 perforations (greater than 50%).[22] The perforations were not immediate (earliest 12 days) and as such unlikely to be due to technical problems with deployment. The authors suggested that they may be related to the type of stent selected for all participants in the trial or the combination of stenting and palliative chemotherapy increasing risk of late perforation.[22] The only other randomized controlled trial (22 participants) in this setting compared stenting with colostomy and reported equality in terms of morbidity and mortality.[23]

4. When is a colonic stent contraindicated?

The absolute contraindication for colonic stenting is clinical or radiological evidence of perforation, and low rectal tumors within (5 cm) of the anal verge where stenting is liable to cause severe anal pain, tenesmus or incontinence. Relative contraindications include anatomical difficulties such as long stricture segment, or strictures positioned in tortuous colonic segments and bowel ischemia.[24–27]

5. What is the role of stenting in the proximal colon?

In the early stages, the range at which a colonic stent could be deployed was limited by the fact that there were no dedicated colonic stents available. Oesophageal stents were adapted instead, but there relatively short length made the proximal colon inaccessible. The first case of proximal colonic stenting was reported in Aberdeen in 1997 for an obstructing cancer in the proximal transverse colon. At the time of developing the obstruction the patient was being treated for bilateral ilio-femoral thrombosis and was considered to be high risk for laparotomy. The stent remained in situ for 10 weeks whilst the thrombus was treated and the patient had an uneventful right hemicolectomy thereafter.[28]

Stenting in the proximal colon has not been as popular as surgery has been the standard management for proximal obstructive lesions. This is probably due to the fact that emergency right colonic resections were widely considered safer with fewer complications than emergency surgery for left colonic lesions. However data from large series do not support this assumption with mortality and leak rates equivalent to or increased after surgery for proximal compared to distal obstruction,[29,30] thus the benefits of stenting as a bridge to surgery may be similar to those seen for stenting in distal obstruction as discussed earlier. The evidence though is mainly limited to small retrospective case series which compare proximal to distal stenting but not surgery.

Elsberger et al. reported one of the first series of proximal stents. All but one were placed for palliation; four in the transverse colon and three at the splenic flexure. Technical and clinical success was achieved in six patients using a combined colonoscopic and radiological technique. However, all the lesions in this series were incompletely obstructed (confirmed by water soluble enema).[31]

Dronamraju et al. reported a series of 16 proximal stents; eight lesions in the transverse colon and eight in the ascending colon. Technical and clinical success remained high; 14/16 (87.5%) with proximal lesions vs. 60/81 (78.9%) with distal lesions stented in the same time. Complications were also equivalent in both groups (7.1% vs. 8.6%).[32]

Repici et al. report a slightly larger series of 21 patients with complete obstruction in eight and incomplete in 13. Technical success was achieved in 20 patients (95%) and clinical success in 17 (85%). There were no immediate complications and all eight patients who subsequently underwent resection had uneventful postoperative courses.[33]

Kim et al. examined the effects of stenting on later post resection outcomes depending on the location of the stent. Their definition of a proximal lesion was one proximal to the sigmoid colon. Their series was relatively large (57 patients) but even with the relatively 'distal' definition of proximal they only had 13 patients in this group. However there were no difference detected between the

two groups in the rate of one stage resection, post-operative complications, intensive care unit (ICU) stay, hospital stay and mortality.[34]

Although these series are individually small and hence represent low level evidence the heterogeneity of the results is reassuring. Technical and clinical success rates reported are similar to the pooled results reported in a 2002 meta-analysis of all stent results published of 92% and 88% respectively.[19] However there may be an element of reporting bias in the literature on proximal stents. Although several of the studies mention that proximal stent placement is no more difficult than distal placement, it is also likely that endoscopists or radiologists who attempt to stent proximal lesions already have significant expertise in stenting distal lesions. It is therefore likely that proximal stents are as successful and safe as distal stents in appropriately experienced hands.

6. What is the role of colorectal stents in extrinsic obstruction?

Whilst many case series include small numbers of SEMS place for extrinsic disease the only series to examine this specifically has been reported by Shin in et al.[35] They initially hypothesized that stent placement in this setting may be more difficult, as the colon is often immobilized due to extrinsic invasion, and unlike CRC, the interior of the colonic wall remains smooth making stent bedding-in more difficult and promote stent migration. In a multivariate analysis, underlying extracolonic malignancy was the predictor of failure for colonic stent placement whereas a history of radiation therapy was the sole predictor of complications.[36]

7. What are the different stent types of colorectal stents? what are their drawbacks and advantages?

Various types of self-expanding metal stent (SEMS) are available. Once deployed, SEMS expand over 24–72 h to become incorporated into both the tumor and surrounding tissue by pressure necrosis, anchoring the stent. SEMS can be covered or uncovered; both have similar technical and clinical success.[26,37] There has been suggestion that covered stents have higher rates of migration whilst they may resist tumor in-growth.[38] Covered stents can be used to close fistulae with generally good results reported.[39–41] Pragmatically the choice of stent will be made on the basis of the stent indication, anticipated time of placement as well as operator and institutional factors such as previous experience, facilities and cost.

8. How does colorectal stents insertion affect colonic imaging?

Computed Tomography (CT) colonography is a reasonably sensitive and specific pre-operative evaluation tool to rule out synchronous lesions in the proximal colon.[42] Sensitivity and specificity of CT colonography for synchronous lesions do not appear to be negatively affected by the placement of SEMS. Bowel preparation and colonic insufflation do not appear to cause migration of stents or other complications.[43]

Most SEMS materials appear safe for Magnetic Resonance Imaging (MRI); which is important for future rectal tumors staging, but factors such as stent shape, orientation to the magnetic field, and type of alloy composition influence signal intensity in vitro.[26] Despite the lack of specific colorectal stents MRI scan safety studies, extensive studies were carried out about their biliary, vascular and oesophageal relatives.[44,45] MRI has minimal degradation effects and neglected migration chances especially in the non-stainless steel stents.

9. What is post procedure care?

Post-procedural care is largely not evidence based. After successful stent insertion, patients are observed for at least 24 h. Plain abdominal X-ray is usually done to assess the position and expansion of the stent at 24 h. Any clinical suspicion of perforation mandates immediate imaging and surgery if confirmed. In clinically successful cases patients can resume oral intake immediately.[26] Although not evidence based it seems logical that where the indication is palliative patients should receive advice regarding low-residue diet and commence regular stool softeners to prevent stent occlusion.[25,26] Patients should be educated about the symptoms of re-obstruction and action to be taken if this occurs. Re-obstruction due to tumor invasion or overgrowth can be managed by laser re-canalization or re-stenting with or within the old stent. Currently, it seems that there is no strong evidence available that looked into timing of performing surgery after colonic stenting.

10. Overall what are the complications of colorectal stents deployment?

The occurrence of perforation varies greatly across the literature and can occur as an immediate or delayed complication. The usual risk is quoted is less than 4%[19]; however, recent randomized evidence has thrown this figure into doubt for unselected populations.[22,14] Perforations could immediate or delayed. The reason behind the perforation's mechanism is not very clear, and perhaps it is multifactorial like guide wire deployment, stricture dilatation, site and length of the obstructive lesion, chemotherapy and type of the stent. More studies are needed to look specifically into this matter.

Technical or clinical failure have both been low in most reported series[19]; however, randomized evidence is now being reported with much higher failure rates.[22,14]

Stent occlusion due to faecal impaction or tumor overgrowth is a particular problem in palliative patients where stents remain in situ for longer periods of time. Re-obstruction has been reported in 60% of cases at 300 days.[46] Song et al assessed the use of a dual-design stent, consisting of an outer stent and inner bare nitinol stent intended to reduce the delayed complications of in-growth obstruction and migration. One hundred and fifty one patients were included in the trial; initial technical success was over 90%, but the perforation rate was high (16/151-11%), this being more common in patients with complete obstruction. Tumor overgrowth occurred in 5 of the 95 patients treated with palliative intent (5.2%).[24]

Stent migration could happen in the early phase usually following pre-placement laser canalization, chemotherapy or in stented benign stricture lesions.[19] Migrated stents usually removed endoscopically with no further intervention as it indicates resolution of luminal stricture.[19]

11. Are stents economically viable?

Data using American insurance claim data suggest that SEMS placement economically viable compared with surgical creation of the colostomy with a shorter mean hospital stay (8 vs. 12 days) and reduced cost ($15.071 vs. $24.695).[47] These include all U.S. Medicare claims for either colonic stent placement or colostomy but importantly, claims for both procedures i.e. those likely to relate to failed stents were excluded.

12. Conclusion

The available large number of non-randomized studies suggests that SEMS placement for acute colonic obstruction due to cancer

could be considered as safe and effective alternative to surgery in experienced hands either as a bridge to surgery or as a palliative measure. This evidence has led to SEMS being widely adopted in many centers. However randomized evidence has begun to show the defects that are inherent in the low level evidence that has so far supported SEMS use and it may be that reports of randomized controlled trials may clarify the patient population where SEMS placement is appropriate. Meanwhile, the implementation of stents to relieve colonic obstruction in practice should only be done in centers where expertise is available. Clinicians must be aware of the current evidence limitations and apply SEMS use pragmatically. The patients should be selected carefully before the procedure. The procedure should be explained clearly to the patients; including the risks and benefits. Long term follow up plans should be implemented to assess the long term complications of the stents.

Conflicts of interest
None

Sources of funding
None

Ethical approval
N/A

Author contribution

1. Ahmad Al Samaraee: Design, Writing, Literature Search Collection, submission process
2. Iain McCallum: Writing, Design, Litrature search/collection
3. Louise Kenny: Writing, Grammar/language check
4. Siddek Isreb: Writing, communication
5. Louise McDougal: Writing, referencing style.
6. Mumtaz Hayat: Gastroenetlogist and endoscopist: comments/corrections and final approval before submission for publications
7. Seamus Kelly: Consultant Surgeon: comments/corrections and final approval before submission for publications

Acknowledgment

The authors would like to thank Mr B. McWiliams for his kind advice and support. Some parts of this review were based on studies for a Master degree of science (MSc), which was granted to the first author of this paper; Mr. Ahmad Al Samaraee (Cardiff University-UK, 2010). Approval for use this information for the purpose of publication has been obtained from the University related supervisor.

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