The role of colonic stents in 2010

The management of left-sided malignant colonic obstruction is challenging. Despite active screening programmes, approximately 25% of colorectal cancers in the UK present with acute colonic obstruction.[1] Emergency surgery for acute malignant colonic obstruction is associated with significant morbidity and mortality, and the concept of a non-operative form of management is appealing.

Until the early 1990s surgery was the only method of relieving colonic obstruction. Right-sided colonic obstruction (obstruction proximal to the hepatic flexure) is dealt with straightforwardly by right hemicolectomy with a primary ileal-to-distal non-dilated colon anastomosis. In contrast, surgery for left-sided colonic obstruction is more complicated. The colon proximal to the obstruction is dilated and friable and provides poor tissue for anastomoses.[2] In addition, electrolyte imbalances, nutritional compromise and faecal loading all contribute to an increased risk of anastomotic failure. Patients with malignant large-bowel obstruction are clearly poor surgical candidates, and mortality rates can reach up to 30%.[1-5] Patients with perforation require immediate surgical intervention, and the focus of colonic stents is therefore on how to improve the management of patients with non-perforated left-sided malignant colonic obstruction.

Surgical strategies to deal with these difficulties have included three-, two- and one-stage procedures. Three-stage surgery involves a decompressive stoma at the first visit to theatre. The second operation is resection of the primary tumour. Finally the patient returns to theatre for closure of the stoma. The 5-year survival rate for patients completing all three operations is 19 - 38%.[1] Many patients are left with permanent stomas.

A two-stage procedure includes resection of the obstructing lesion with closure of the distal colon/rectum and an end colostomy proximal to the lesion. Re-establishment of bowel continuity is perfomed electively.

One-stage surgery involves resection of the colonic tumour and primary anastomosis. This is done either via total colonic resection with ileorectal anastomosis or by segmental resection with on-table colonic lavage for the unprepared bowel.

Emergency surgery has high morbidity[3] and mortality rates.[6] These rates are significantly higher than in the elective situation,[6] and emergency surgery often results in stoma creation. Stomas have a negative impact on quality of life scores,[7] are associated with significant morbidity (up to 34%[8]), and are often not reversed. The concept of non-operative management that avoids stoma formation is attractive.

The appeal of endoscopic management is that these high-risk patients avoid surgery and the risks associated with anaesthesia. These patients are poor surgical candidates because of bowel obstruction and its consequences rather than any immediate threat from the underlying colon carcinoma. Placement of colonic self-expanding metal stents (SEMS) has proved beneficial in two groups of patients – the 'bridge to surgery' and definitive palliation group. Successful decompression allows for thorough clinical evaluation and for the patient to undergo staging investigations before surgery.[9] The term 'bridge to surgery' was used in 1994 by Tejero *et al.*[10] to describe patients whose tumours were deemed surgically resectable. Stent placement in these patients allows optimisation for definitive surgery at a later stage. In patients deemed to have irresectable tumours after investigation, colonic SEMS may prove to be the definitive treatment.

The evidence for endoscopic management of left-sided colonic obstruction is evolving. Non-randomised cohort studies have provided support for the use of colonic stents. In the emergency setting, Martinez-Santoz *et al.*[11] compared surgery (N=29) with pre-operative stenting followed by elective surgery (N=26) in patients with obstructing colon cancer. Pre-operative stenting followed by elective surgery was associated with an increase in the primary anastomosis rate (84.6% v. 41.4%; p=0.0025) and a lower rate of stoma formation (15.4% v. 58.6%). Stenting was also associated with reduced hospital stay (14.23 v. 18.52 days; p=0.047), intensive care unit stay (0.3 v. 2.9 days; p=0.015) and postoperative complications (11.6% v. 41.2%; p=0.008). Sebastian *et al.*'s[12] pooled analysis of 1 198 patients from 54 non-randomised studies reported median technical and clinical success rates of 94% and 91%, respectively. Early complications related to stent placement included perforation (3.76%) and stent migration (11.81%). Stent-related mortality was 0.58%. Although long-term follow-up data were not available it was concluded that SEMS were safe and effective for both 'bridge to surgery' and palliative patients. A meta-analysis[13] of 10 studies involving 451 patients comparing colonic SEMS and open surgery concluded that colonic stenting was effective palliation for malignant colonic obstruction. SEMS were associated with shorter hospital stay and a low rate of stoma formation; however, there was no difference in overall survival between the stent and emergency surgery groups.

Patients undergoing emergency surgery are often unable to tolerate adjuvant chemotherapy, whereas patients undergoing SEMS placement have had less of a physiological insult. SEMS placed for palliation have been shown to be durable and these patients have lower morbidity rates compared with their counterparts undergoing emergency surgery and stoma creation.[14,15]

Studies from Canada and the UK indicate that colonic stent placement need not be limited to tertiary centres. Baerlocher and colleagues analysed stent placement in a community hospital (Oshawa, Ontario, Canada) and showed that all meaningful parameters were comparable to those from tertiary centres.[16] They had a stent success rate of 91.3% and a complication rate of 18%. A study from the Countess of Chester Hospital in the UK showed a success rate of 78% and a complication rate of 16%.[17] These authors contend that SEMS placement allows time to get these patients to a dedicated colorectal unit for resection.

Another advantage of pre-operative colonic stent placement is that it allows for a pre-operative colonoscopy to exclude synchronous lesions.[18] In Vitale's series, a synchronous cancer was detected in three patients (9.6%), hence changing the initial surgical plan.[18]

Unfortunately there is evidence of selection bias in the study populations in most of the non-randomised individual studies and meta-analyses that must call the conclusions into question. Of valid concern has been whether placing a SEMS can increase the risk of perforation and tumour dissemination, thus worsening patient prognosis.

In glaring contrast to the above data on colonic stent placement is one of the few randomised control trials (RCTs) ever attempted. The multicentre Dutch Stent-in 1[19] study aimed to assess whether colonic SEMS were superior to surgical treatment in patients with stage IV incurable left-sided colorectal cancer. Patients were randomly assigned to surgery or SEMS placement. A high number of unexpected adverse events in the non-surgical/SEMS arm led to premature closure of the trial by the safety monitoring committee. Four of 10 patients enrolled in the stent arm developed perforations. The authors conclude that this may be specifically related to the type of stent being piloted, chemotherapy, or a chance phenomenon. This study has now been re-launched as the Stent-in 2 study[20] with the entry criteria widened to include patients with potentially operable malignant colonic obstructions.

The only other RCT enrolled only 22 patients for palliative treatment of malignant rectosigmoid obstruction.[21] They concluded there were no statistically significant differences between the surgery and stent group in terms of morbidity and mortality.

The choice between stent and surgery therefore appears to be one that should be left up to the treating surgeon, as no clear evidence-based guidelines exist.

The use of colonic SEMS despite the lack of level I evidence for their use is considered unacceptable by some, and the proponents of SEMS have been hard pressed to justify it. To this end, the colorectal stenting trial (CReST) has been launched in the UK. CReST aims to investigate whether SEMS for obstructing colorectal cancer will result in decreased operative morbidity, length of hospital stay and rate of stoma formation and improved quality of life and survival compared with conventional treatment. All these have already been claimed by prospective and retrospective audits but are not backed by randomised level I evidence. Patients are to be randomised to either SEMS or surgical decompression with or without resection of the primary tumour.

Further research in the area of SEMS in the colon is going to require at least one well-structured RCT. Of concern is that one of the only attempts at a RCT was terminated early because of complications in the SEMS group. This casts a shadow over the pooled data from prospective and retrospective reviews, which overwhelmingly favour SEMS placement. More studies focusing on the long-term impact and complications of colonic stents are required. The impact of chemotherapy on perforation rates needs to be assessed further.

Colonic SEMS are a promising therapy in the armamentarium in the fight against colon cancer. However, it would be unwise to encourage their use without careful prospective audit of outcomes and long-term follow-up, as with any new technology.

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