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EVIDENCE-BASED ONCOLOGY

Insufficient evidence to compare clinical effectiveness and safety of self-expanding metal stents with other treatments for malignant colorectal obstruction

Abstracted from: Sebastian S, Johnston S, Geoghegan T, et al. Pooled analysis of the efficacy and safety of self-expanding metal stenting in malignant colorectal obstruction. *Am J Gastroenterol* 2004;99:2051–7.

Background

Self-expanding metal stents are used for palliative treatment or to control symptoms while awaiting subsequent surgery in people with malignant colorectal obstruction. However, there is uncertainty about the clinical effectiveness and safety of self-expanding metal stents in people with malignant colorectal obstruction.

Objective

To assess the clinical effectiveness and safety of self-expanding metal stents in people with malignant colorectal obstruction.

Method

Systematic review with narrative synthesis and meta-analysis.

Search strategy

MEDLINE, Cancerlit, Embase, Science Citation Index, and Cochrane Clinical Trial Register from Jan-

uary 1990 to May 2003; hand searches of selected conference proceedings.

Inclusion criteria

All English and foreign language studies on colorectal stenting, malignant colonic obstruction, colonic endoprosthesis, and endoluminal stenting included. Studies with inadequate data on outcome variables or adverse events, data included in a later publication, data on stenting for benign stenoses, case reports, letters and reviews were excluded.

Main outcomes

Clinical success or failure; technical success or failure; ability to perform further single-stage surgery; complications; mortality.

Main results

No randomised controlled trials were identified. Fifty-four studies (1198 people) met inclusion criteria. Stents were used for palliative treatment ($n = 791$, 66%), or as a bridge to further surgery

($n = 407$, 34%). Obstructions were due to primary colorectal tumours ($n = 1002$, 84%), external compression from non-gastrointestinal tumours ($n = 127$, 11%) or post-surgical tumour recurrences ($n = 69$; 5%). Thirty-four studies used Enteral Wallstents, but other stents were used in 20 studies.

Benefits. Overall, technical success was similar in the palliative and bridge to further surgery groups. Clinical success was higher in the palliative treatment group; although statistical significance was not stated. 71.7% of people in the bridge to surgery group were able to undergo subsequent single-stage surgery (see Evidence Profile: Benefits).

Adverse events. Major adverse events were bowel perforation or re-obstruction and stent migration (see Evidence Profile: Harms). Stent migration was reduced in the palliative treatment group (16/407 [3.9%] with stent placement for palliative treatment vs 116/791 [14.7%] with stent placement as a bridge to surgery).

Treatment-related mortality. Seven deaths overall: three from colonic perforation; two from gram-negative sepsis; two from colonic re-obstruction. Six deaths occurred in the palliative treatment group and one in the bridge to further surgery group.

Evidence Profile: Benefits

Outcome	Cumulative risk
Technical success for stent placement ^a	
Overall	93.2%
Palliative vs. bridge to surgery	93.4% vs. 91.9% ($P = 0.34$)
Clinical success for stent placement	
Overall ^b	88.6%
Palliative ^b vs. bridge to surgery ^c	91.0% vs. 71.7% ($P =$ not stated)

^a Successful stent placement at the first attempt and confirmed by radiological assessment.

^b Clinical success defined as clinical and radiological evidence of colonic decompression ≤ 48 hours, without a need for re-intervention.

^c Clinical success defined as the ability to perform single-stage surgery without stoma creation.

Evidence Profile: Harms

Adverse event with stent placement	Number of events (percentage of cases affected)
Perforation	45 (3.8)
Migration	132 (11.8)
Obstruction	82 (7.0)
Mortality	7 (0.6)

Authors' conclusions

Self-expanding metal stent placement is safe and effective for the palliation of malignant colorectal obstructions and facilitates single-stage surgery thereby providing a useful alternative to colostomy.

Method notes

Search method	Adequate
Selection criteria	Inadequate: methodological criteria for inclusion and exclusion not well specified
Assessment of study quality	Inadequate: all studies were non-randomised and subject to confounding and biased participant allocation. Most case series were retrospective and subject to recall bias. These issues were inadequately discussed
Data synthesis	Inadequate: unclear if studies assessed for quality. Limited data reported on outcomes, sub-group analysis of adverse events, and technical or clinical failures. Pooled data are unlikely to be reliable because of these factors
Heterogeneity	No tests for heterogeneity reported. Studies were heterogeneous for quality
Analysis	Given the methodological weaknesses of some of the included studies, and the variety of stents tested, narrative synthesis was appropriate. However, pooled analysis is of limited reliability, because of the methodological limitations of underlying studies

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Commentary

Colorectal cancer is the third most common cancer and the fourth most frequent cause of death from

cancer worldwide. The World Health Organization (WHO) estimates that 945,000 new cases occur yearly, with 492,000 deaths.¹ In developed countries, colorectal tumours are the second most common form of cancer, with a lifetime incidence of 5%.^{1,2}

In 8–29% of patients with colorectal carcinoma, obstruction is the main symptom at diagnosis,^{3,4} and 85% of patients who undergo emergency colorectal surgery have obstruction from colorectal carcinoma.⁵ Emergency surgery for obstruction from colorectal carcinoma is performed more often in elderly patients than in younger age categories.⁶

In patients who undergo emergency surgery for obstruction the prognosis is poorer, and the postoperative and long-term morbidity rates are higher compared with patients who have elective surgery.^{3,7–9} The higher postoperative mortality rate appears to be mainly linked to the increased surgical risk present in emergency conditions: the physical status of patients referred for surgery for obstruction is often poor, due to tumour growth and hydroelectrolytic imbalance which, moreover, exacerbates any underlying disease (e.g. hypertension, diabetes, heart and lung disease). In colorectal carcinoma patients, the 5-year survival rate is less than 20% in those with obstruction and 50% in those without obstruction.³

Surgery, considered standard treatment for patients with colorectal carcinoma, has a curative or palliative aim, depending on the disease stage. The surgical approach is either a single-stage resection and anastomosis, or a two-stage procedure, with a temporary stoma being created so that patients can be operated in an elective setting. In the latter case, quality of life may be compromised by the stoma, which, in approximately 50% of cases, becomes permanent.

Alternative approaches to emergency surgery include Nd:Yag laser therapy, endoscopic dilatation, insertion of decompression tubes and, since the early 1990s, the application of expandable metal stents.^{10–13} Although stent insertion appears a reasonable alternative, being used as a single procedure for palliation, or as a means to decompress the colon to allow an elective single-stage surgical procedure ('bridge to surgery'), the procedure has specific requirements. Stents are usually placed by gastroenterologists under endoscopic guidance with the aid of fluoroscopy or by interventional radiologists under fluoroscopic guidance alone. Moreover, in the literature, evidence of their safety and efficacy is scarce. Several observational studies have re-

ported low perioperative mortality and morbidity rates, with a high percentage of success in relieving the symptoms of colon obstruction, and in performing single stage resection in patients with curable disease. However, concern is still expressed regarding the cost-effectiveness of this procedure.

In their pooled analysis, Sebastian et al. evaluated the use of expandable metal stents for malignant colonic obstruction in 1198 patients enrolled in 54 trials. The outcome variables that the authors considered were related to efficacy (technical and clinical success rate, ability to carry out single-stage surgery when performed as a bridge to surgery), safety (early and late complications), and cost-effectiveness. Overall, metal stents were used as a definitive palliative procedure in 66% of cases and as a 'bridge to surgery' in the remaining 34%. Primary colon cancer was the cause of obstruction in 84% of cases, and recurrence or extrinsic compression accounted for the remaining 16%. A combined endoscopic and radiologic approach was used in 69% of cases, and several types of stent were used. Technical success was achieved in 93% (range 64–100%) of cases and, for this parameter, no statistically significant differences were found between the palliative group and the group that underwent metal stent placement in the 'bridge to surgery' setting. Clinical success was achieved in 89% (range 55–100%) of patients. In cases of ab extrinseco compression, the failure rate was significantly ($P=0.04$) higher (12%) than in cases of primary colon cancer (4%). In the 'bridge to surgery' group, the clinical success rate was 72% (range 45–84%). The cumulative mortality rate (0.6%) was mainly due to the occurrence of colonic perforation in the patients who underwent palliative surgery. Perforation, migration and re-obstruction were found in 4%, 12%, and 7% of cases, respectively. Cost-effectiveness studies, available for only three series, reported that costs in the metal stent group were lower than in the conventional surgery group. However, a wide range of cost reduction was found between series, and between palliative and 'bridge to surgery' approaches.

Some aspects of the review by Sebastian et al. deserve careful evaluation. Since no randomised trials were available, only single arm studies, presumably prospective and retrospective, with a probable patient selection bias, were included in the review. It is not known how many candidates for this approach were considered eligible, and finally underwent treatment. Thus the percentages for technical and clinical

success were probably overestimated. Moreover, a wide range of success was reported across the studies considered, indicating that patient selection may have an impact on procedure effectiveness.

Regarding outcome evaluation, no data have been reported on long-term efficacy, in terms of either mortality or safety; nor have patient-oriented measures been reported on. When used as a palliative procedure, stent insertion concerns canalisation alone, while its influence on bleeding and pelvic pain is only slight.

In view of the high incidence of colorectal cancer, and the high mortality and morbidity rates incurred by emergency surgery for bowel obstruction, alternative or adjunctive treatment modalities are warranted.

The endoscopic/radiologic approaches for expandable metal stent insertion certainly appear promising. However, the data available in the literature are far from conclusive and, above all, there is a lack of clinical randomised studies on stent insertion versus resection, and stent insertion versus other non-surgical treatment methodologies, such as external or high-dose endocavitary radiotherapy (HDR) and laser-therapy. Stent insertion calls for expert endoscopists and radiologists and logistical facilities.

Therefore, the use of expandable metal stents cannot yet be proposed as a safe and valid approach for use in routine clinical practice.

Quality assessment (1 = fair; 4 = excellent)	
Relevance	4
Validity	3
Applicability	3
Feasibility	2
Impact	2
Knowledge context	3

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