

Self-expanding Metallic Stents for Relieving Malignant Colorectal Obstruction

A Systematic Review

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Objective: To assess the safety and efficacy of self-expanding metallic stents (SEMS) placement for the relief of malignant colorectal obstruction in comparison to surgical procedures through a systematic review of the literature.

Summary Background Data: Conventional therapies for relieving colorectal obstructions caused by cancer have high rates of morbidity and mortality, particularly when performed under emergency conditions, and palliative procedures resulting in colostomy creation can be a burden for patients and caregivers.

Methods: A systematic search strategy was used to retrieve relevant studies. Inclusion of papers was established through application of a predetermined protocol, independent assessment by 2 reviewers, and a final consensus decision. Eighty-eight articles, 15 of which were comparative, formed the evidence base for this review.

Results: Little high-level evidence was available. However, the data suggested that SEMS placement was safe and effective in overcoming left-sided malignant colorectal obstructions, regardless of the indication for stent placement or the etiology of the obstruction. Additionally, SEMS placement had positive outcomes when compared with surgery, including overall shorter hospital stays, and a lower rate of serious adverse events. Postoperative mortality appeared comparable between the 2 interventions. Combining SEMS placement with elective surgery also appeared safer and more effective than emergency surgery, with higher rates of primary anastomosis, lower rates of colostomy, shorter hospital stays, and lower overall complication rates.

Conclusions: Stenting appears to be a safe and effective addition to the armamentarium of treatment options for colorectal obstructions. However, the small sample sizes of the included studies limited the validity of the findings of this review. The results of additional comparative studies currently being undertaken will add to the certainty of the conclusions that can be drawn.

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Colorectal cancer can result in malignant obstruction of the colon or rectum, through the presence of either intrinsic or extrinsic tumors. Acute or subacute bowel obstruction can lead to abdominal pain, nausea, vomiting, bowel rupture, and eventual death if left untreated.

Conventional therapies for relieving malignant colorectal obstruction include surgical resection (potentially curative) or palliative colostomy. Resection is more frequently an option in patients with less advanced cancer, and is ideally carried out as a single-stage procedure, with anastomosis to restore bowel continuity. Multistage procedures may also be undertaken, with resection and stoma formation in one procedure, followed by restoration of continuity in another procedure.¹ However, a significant proportion of patients receiving a staged procedure never undergo reversal of the colostomy.²

Permanent stoma creation is the standard treatment of bowel obstruction caused by nonresectable tumors, relieving the symptoms of bowel obstruction. Although it is the standard treatment modality, stoma creation is associated with high morbidity and mortality rates, particularly when undertaken under emergency conditions.¹ Furthermore, stoma creation is recognized as having a highly negative impact on patients' psychosocial well-being³ and can be a burden to caregivers as well as the patient during the final months of their life.

Endoscopic treatments to palliate rectal obstruction have also been developed in recent years but are not yet a standard treatment option. Medical management, including the use of opioids, anticholinergics, and antiemetics, is most commonly used in hospices and palliative care settings to assist in maintaining an acceptable quality of life in patients with terminal illness.

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The full Australian Safety and Efficacy Register of New Interventional Procedures—Surgical (ASERNIP-S) systematic review of this procedure with data extraction tables can be found at the ASERNIP-S Web site: www.surgeons.org/asernip-s/.

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Self-expanding metallic stents (SEMS) are expandable metallic tubes that are advanced to the site of the obstruction along a guidewire in a collapsed state, under fluoroscopic and/or endoscopic guidance. Once deployed, the stents slowly expand radially to their maximum diameter under their own force, thereby achieving patency of the obstructed anatomy. Almost all stenting procedures are carried out transanally, and are generally well tolerated by patients with only conscious sedation, or no anesthesia. The value of stent placement is as a minimally invasive alternative to open surgical techniques, such as resection or stoma creation. SEMS may be used as a definitive palliative measure or can be used as a “bridge to surgery” to allow stabilization of the patient’s condition before surgery is carried out as an elective procedure at a later date.

A number of stents have been designed specifically for use in the lower gastrointestinal tract and are available in a variety of lengths and diameters, so that the appropriate stent can be selected based on factors such as the length of the obstructed section of bowel and anatomic location of the obstruction.

While stenting procedures are becoming a more frequent treatment modality, it is currently unclear whether stenting represents a safe and effective alternative to surgical procedures for the treatment of malignant colorectal obstructions. The aim of this review is to assess the safety and efficacy of SEMS placement for the relief of malignant colorectal obstruction in comparison to surgical procedures through a systematic review of the literature.

METHODS

Literature Search Strategies

A systematic search was conducted of MEDLINE, EMBASE, CINAHL, Current Contents, PubMed, the Cochrane Library and Science Citation Index, from the inception of the databases until April 2005. The York (UK) Centre for Reviews and Dissemination databases, www.Clinicaltrials.gov, National Research Register, Australian Clinical Trials Registry, American College of Physicians (ACP) Journal Club, relevant online journals and the Internet were searched in February 2006. Updated searches were performed in July 2006 to include any new randomized controlled trials (RCTs). Searches were conducted without language restriction. The search terms were: (intestinal obstruction and stent), (stent and colorectal), ((intestinal obstruction/radiography [MeSH] OR intestinal obstruction/surgery [MeSH] OR intestinal obstruction/therapy [MeSH]) AND stents [MeSH]).

Inclusion Criteria

Articles were selected if the abstract contained safety and efficacy data on SEMS placement in the form of RCTs, other controlled or comparative studies or case series. Case reports detailing complications were also included. Conference abstracts were included if they contained relevant safety and efficacy data. Foreign language articles and/or English abstracts from foreign language articles were included if they met the review inclusion criteria and contained safety and

efficacy data. In the case of duplicate publications, the latest and most complete study was included.

Data Extraction and Synthesis

Data were extracted by one researcher and checked by another using standardized extraction tables developed a priori. Included studies were assigned a level of evidence according to the National Health and Medical Research Council Hierarchy of Evidence, and all comparative studies were critically appraised for study quality according to the guidelines in the Cochrane Reviewer’s Handbook⁴ and the CONSORT statement⁵ on a number of methodologic parameters. Because of its heterogeneity, the data specific to SEMS placement were presented grouped to provide a clinical picture with a larger data set and also split by indication to illustrate in more detail the safety and efficacy of SEMS placement for specific patient populations. The range of values (rates or study means) across included studies and the median of the study rates or means were calculated for each outcome in this data set. The results for the surgical comparators were not pooled due to the diversity of outcome measures reported but were reported in groups that were as homogeneous as possible based on the reported data.

RESULTS

Included Studies

Nine studies compared SEMS with surgery: 2 RCTs (level II),^{6,7} 2 comparative studies with concurrent controls (level III-2),^{8,9} and 5 comparative studies with historical controls (level III-3).^{10–14} Three studies compared the outcomes of SEMS followed by elective surgery to those of emergency surgery without prior stenting; one level III-2 study,¹⁵ and 2 level III-3 studies.^{16,17} Three studies with internal comparisons were also included.^{18–20}

In addition to the data on SEMS placement extracted from the 15 comparative studies, a further 73 case series (level IV) reporting safety and efficacy data of SEMS placement alone were identified and included.^{21–93} These studies ranged widely in both population size and duration of follow-up. Six case reports detailing complications were also included.^{94–99}

This resulted in outcomes being reported for 1785 patients, with 1845 stents placed. Of the 1785 patients, 762 (43%) had SEMS placed as a palliative treatment, while 363 (20%) patients had stents placed as a bridge to surgery. The intended clinical pathway was not clearly defined for 660 (37%) patients.

A total of 1600 (90%) patients had SEMS placed to overcome left-sided obstructions and 20 (1%) for right-sided obstructions. Thirty-nine (2%) patients had an obstructive lesion in the transverse colon and the location of the obstruction was not stated for 126 (7%) patients.

The quality of the available evidence was rated as poor. Very few studies described adequate methodologic detail, sample sizes were frequently small and there was a lack of uniform outcome measures reported.

SEMS Placement

Efficacy

Technical success was defined as the passing of a guidewire and appropriate placement of the stent. In the 88 included studies, the median rate of technical success was 96.2%, ranging from 66.6% to 100%. The definitions of clinical success varied among the 85 studies reporting this outcome, but all included colonic decompression with resolution of obstructive symptoms within 72 hours of stent placement. The median rate of clinical success was 92%, ranging from 46% to 100%. Sample sizes in the studies reporting these efficacy parameters varied widely, from 3 to 89 patients, with a median sample size of 15 patients and 16 stents.

When separated by indication (palliation or bridge to surgery), there was little difference in the overall rates of technical and clinical success. Similarly, the etiology of the primary obstruction (eg, primary/recurrent colorectal, urogenital, or pancreatic cancer) appeared to have little effect on the overall rates of technical and clinical success. Technical failure was most commonly caused by an inability to pass a guidewire, particularly through torturous anatomy.

In the palliative population, stent patency was reported as either a duration of patency or as a proportion of patients with a patent stent either at time of death or end of follow-up. In the 14 studies that reported duration of patency, the median of reported study mean durations was 106 days (range, 68–288 days). The median rate of patency at the end of follow-up (or time of death) in the 11 studies reporting this outcome was 100% (range, 53%–100%). In total, 90.7% (118 of 130) of patients that had a rate of patency reported either died or ended follow-up with a patent stent.

The mean time for progression to surgery after stent placement in the bridge to surgery population was reported in 25 studies. The median of these reported mean times was 7 days (range, 2–12 days).

The median rate of reintervention that was required in the 45 studies reporting this outcome for palliative stent placements was 20%, with a range of rates from 0% to 100%, with 1 patient requiring 2 separate reinterventions. Reintervention was considered to include unplanned surgical intervention, placement of a second or subsequent stent or interventions to maintain stent patency, such as laser ablation or colonic irrigation/enemas. Only 7 studies reported incidences of reintervention in patients with stents placed as a bridge to surgery, reflective of the shorter time that the stent remained in the colon. Among this group, the median rate of reintervention was 7%, with a range of rates from 0% to 20%.

Safety

Among the 54 studies for all indications that reported on incidences of stent migration, both within the immediate postoperative period and over the duration of follow-up, the median rate of migration was 11%, ranging from 0% to 50%. The studies reporting outcomes for stents placed for palliation reported similar results. However, it was not possible to determine what percentage of total stents placed in each area

of the colon migrated, as very few studies reported the initial location of the stents in adequate detail. Bridge to surgery patients had fewer cases of stent migration, due to the stent remaining in the colon for a shorter time.

Perforation, caused by either the guidewire or stent, was reported on in 50 studies. Among the entire SEMS population, the median rate of perforation was 4.5% (range, 0%–83%). The indication for stent placement did not appear to influence the rate of perforation.

Colonic reobstruction was primarily reported in patients with stents placed for palliation. Thirty-one studies reported this outcome, with a median rate of reobstruction of 12% (range, 1%–92%). The majority of reobstructions were as a result of tumor invasion ingrowth and/or overgrowth. Stent obstructions occurred from 48 hours to 480 days after placement and treatments included laser therapies to ablate obstructing tissue, restenting, surgery, and colonic irrigation.

Other reported complications of stent placement included rectal bleeding, anal/abdominal pain, and tenesmus. These complications were relatively rare and generally well tolerated by patients.

SEMS Versus Surgery

Efficacy

Technical and clinical success rates could not be meaningfully compared for SEMS placement versus surgery, as surgery is rarely defined as “unsuccessful.” Technical and clinical success rates for stent placement in this population^{6–14} were comparable to those already described for placement overall.

The reported length of hospital stay required after SEMS placement and surgery (emergency or elective) in the 9 studies varied considerably. However, all but one study reported shorter hospital stays after SEMS placement than surgery, and this was found to be significant ($P < 0.05$) in 6 of the 7 studies that analyzed this outcome statistically.^{6,8–11,14}

Safety

Complication rates were difficult to compare due to the differing levels of complexity involved in the respective procedures, and the lack of a standardized definition of a complication, particularly in the SEMS population. However, the complications reported after surgical interventions were generally of a more serious nature, reflecting the more complex procedure. The most serious complication after SEMS placement was perforation, and the most frequent complications were minor bleeding/pain and stent migration. The most common complications after surgery were respiratory and cardiac complications, followed by infection.

The postoperative mortality figures were difficult to interpret, as they may reflect more on the progression of the patients underlying malignant disease than the surgical/SEMS intervention. Also confounded by the underlying malignancy are the survival rates; however, the 5 studies that addressed this outcome did not find a significant difference in survival between the 2 patient groups.^{7–9,11,12}

Elective Surgery with SEMS Versus Emergency Surgery

Efficacy

Rates of progression to surgery after stent placement ranged from 60% to 93% in individual studies, with some patients not meeting the criteria for resectability after decompression with SEMS. Patients progressed to surgery from 2 to 16 days post-stenting, with a median of study means of 5.8 days between stenting and elective surgery.

Rates of primary anastomosis after elective surgery following stenting were at least twice that of those after emergency surgery. Colostomy rates were notably higher in cases of emergency surgery than elective surgery.

Two of the 3 studies reported on length of hospital stay, and both found that a shorter stay was required after SEMS and elective surgery than emergency surgery.^{15,16} This was reported to be statistically significant ($P = 0.047$) in one study.¹⁵

Safety

All 3 studies reported more cases of complications, or a higher overall complication rate, in the emergency surgery groups than the elective surgery groups.

Mortality was poorly reported in these studies; however, one author reported that mortality was significantly higher ($P < 0.001$) in the emergency surgery group at 30 days postoperatively, although the causes of mortality were not stated.¹⁷ Long-term prognosis (overall survival) was not found to differ significantly between the 2 groups at either 3 or 5 years.¹⁷

Covered Versus Uncovered Stents

Efficacy

In total, only 18 studies specifically reported the use of covered or uncovered stents: 124 covered stents were placed in 120 patients and 171 uncovered stents were placed in 168 patients.^{9,18,19,21,27,36,39–41,47,48,51,69,75,79,82,87,92} There were only minor differences between the reported technical and clinical success rates when comparing covered and uncovered stents.

Safety

Rates of perforation were not appreciably altered by the type of stent used. The benefit of the covered stent appeared to be its ability to resist tumor ingrowth, reflected in lower reobstruction rates compared with uncovered stents, although covered stents appeared more prone to migration than uncovered stents due to their more rigid nature.

Cost Considerations

Seven studies reported a variety of costing data, utilizing both predictive modeling and clinical data. The use of SEMS followed by emergency surgery was found to result in a lower cost overall than emergency surgery by the 4 studies that addressed this comparison.^{13,59,100,101} Two studies^{13,14} compared the cost of stent placement to surgery and found that SEMS placement was the less costly option than surgery, while another study¹⁰² concluded that the cost of stents for

both palliation and as a bridge to surgery were virtually identical to the cost of colostomy in either circumstance.

DISCUSSION

This review examining the safety and efficacy of SEMS for relieving malignant colorectal obstructions was limited by the quantity and quality of the available evidence. There were only 2 RCTs included; and of the 15 comparative studies, many suffered from lack of methodologic rigor, which made assessing the validity of the data difficult. The majority of included studies were retrospective case series (73 of 88), which do not provide comparative data and are affected by inherent biases in study design.

Although SEMS have been used in the colon since the early 1990s, there were only 3 studies that compared elective surgery after decompression with SEMS to emergency surgery. It was difficult to draw valid comparisons among the study groups in the 9 comparative studies that examined the outcomes of stenting compared with surgery, particularly when examining adverse events, as the reported complications were significantly different among stenting and surgery patient populations.

The majority of studies had a small sample size: only 7 studies had 50 or more participants. The length of follow-up was also short for the majority of patients, primarily due to the fact that many patients died as a result of their underlying malignant disease before long-term safety and efficacy outcomes could be determined.

The size of the evidence base for individual outcomes was also limited as not all studies reported similar outcomes in a consistent manner, or did not report results separately for different indications. None of the studies reported on key psychosocial outcomes related to stoma creation, such as quality of life, despite the fact that these have been found to be of considerable importance to patients.¹⁰³

There were significant differences in the treatments used in the studies, particularly as many authors used different stent types; however, it was not possible to analyze the safety and efficacy profile for individual stent types as many studies did not report the stent types used, or used multiple stent types and did not report outcomes separately. It is also possible that in studies where a number of different stents were used, the treating physicians selected particular stents to suit the specific needs of individual patients. Technological advances over time have also resulted in construction and composition changes to many stents, and accurate descriptions of the older stents have not been possible to obtain. Several authors also used stents designed for use in other areas of the gastrointestinal or cardiovascular systems before dedicated colonic stents became available. Additionally, there was no standardization of the type of surgery performed on patients in the comparative studies, which adds an extra dimension of heterogeneity to the outcomes reported.

It was not possible to draw conclusions regarding the suitability of SEMS placement for particular patient populations, as details such as age and ASA grades were not consistently reported. Furthermore, since the majority of studies reported stent placement for left-sided colonic ob-

structions, no conclusions regarding stent placement for right-sided or transverse colonic obstruction could be made.

Despite the poor quality evidence base, the available data suggested that SEMs placement was effective in overcoming left-sided malignant colorectal obstructions, with high levels of technical and clinical success regardless of the indication for stenting or etiology of the obstruction. Stent placement also appeared to be safe, with a relatively low rate of serious complications, although the need for minor re-intervention was common among stented patients. Stents placed for palliation have the potential to maintain colonic patency until the patient's death from underlying disease.

Compared with surgery, SEMs placement resulted in overall shorter hospital stays and a lower rate of serious adverse events. However, adverse events were difficult to compare due to the differing levels of complexity involved in the respective procedures, and the lack of a standardized definition of a complication. Despite this, the complications reported after surgical intervention were generally of a more serious nature, reflecting the increased complexity of the procedure. Postoperative mortality and survival appeared comparable between the 2 interventions.

Combining SEMs placement with elective surgery also appeared safer and more effective than emergency surgery. The majority of patients progressed to elective surgery after stent placement, with rates of primary anastomosis much higher in the SEMs group. Colostomy rates were higher in cases of emergency surgery than in post-SEMs elective surgery, indicative of the increased difficulty of the operative course in the emergency situation. Length of hospital stay was shorter in the SEMs groups and complication rates were also lower.

Future Research

An RCT comparing the outcomes of elective surgery after SEMs placement with emergency surgery would be informative, although issues of clinical equipoise and other ethical considerations would need to be addressed adequately.

Additionally, studies evaluating patient-related outcomes, such as the differences in quality of life measures between patients with a stoma and those avoiding stoma creation through stenting, may provide further impetus for increased levels of stenting in appropriate patient populations.

CONCLUSION

The safety and efficacy of SEMs placement compared with surgery cannot be determined from this evidence base. However, considered in isolation, the evidence included in this review (primarily from case series) suggests that SEMs placement is both a safe and effective technique for relieving left-sided malignant colorectal obstructions. The results of current ongoing trials should assist in more clearly defining the safety and efficacy of SEMs placement compared with surgery. The undertaking of a multicenter RCT of stent placement as a bridge to surgery is both feasible and desirable. However, the difficulties inherent in randomizing patients seeking palliative

treatment may preclude the possibility of conducting a RCT of palliative stent placement.

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