Insertion of colonic stents for the management of malignant large bowel obstructions

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This report is a contracted technical report for use by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee which has been established to provide advice to the Minister for Health and Ageing on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of colonic stents for the management of large bowel obstruction was received from the Colorectal Surgical Society of Australia and New Zealand (CSSANZ) by the Commonwealth Department of Health and Ageing ('the department') in October 2010.

Colonic stents are indicated for patients who suffer colonic obstruction, stricture or stenosis of a known or unknown diagnosis. Stents can be metallic or non-metallic (eg plastic). A self-expanding metallic stent (SEMS), the colonic stent most commonly used in Australia, is an expandable metallic tube adopted for the relief of malignant colorectal obstruction as a minimally invasive alternative procedure to open surgical techniques. All stents have a mesh design and are available in covered (full or partial) or uncovered compositions. The majority of stents used in Australia are of the uncovered type. A SEMS self-expands due to radial force following deployment with a delivery catheter (Small and Baron 2008; Watt et al 2007).

For the purpose of the current assessment, SEMS deployment is indicated for two distinct patient groups. Firstly, a SEMS can be deployed as a bridge to surgery for cases in which an emergency resection of the obstructed colon could lead to serious complications, such as patients who are frail and/or suffering from significant comorbidities (NICE 2004a). This allows for management of the emergency and provides time to plan elective surgery. Secondly, placement of a SEMS can be used for the palliative management of a colonic obstruction in patients who suffer from incurable metastatic disease and/or are medically unfit for surgery (ACPGBI 2007). A SEMS can obviate the need for stoma or resection and may be effective for over a year, potentially providing palliation until death. Even though these patient populations are distinct in terms of their baseline morbidity, it is possible that some patients who initially receive a SEMS for palliative purposes improve over time as a result of chemotherapy and, accordingly, become eligible for resection. Conversely, some patients who initially received SEMS as a bridge to surgery may unexpectedly deteriorate in condition and die, rendering the inserted SEMS as palliative. Based on this, four patient populations are indicated for the placement of a SEMS, outlined in Table 1.

Table 1 Patient populations indicated for SEMS placement

Diagnosis	Patient population
Large bowel obstruction, stricture or stenosis caused by **confirmed diagnosis** of colorectal cancer or cancer of an organ adjacent to the bowel	**Bridge to surgery:** Patient condition expected to improve after insertion of SEMS, with subsequent surgical management indicated.[a] **Palliative:** SEMS as a palliative measure for patients with incurable malignant large bowel obstruction with either chronic or acute comorbidities, with or without metastasis.
Large bowel obstruction, stricture or stenosis caused by **unknown diagnosis**[b]	**Bridge to surgery:** Patient condition expected to improve after insertion of SEMS, with subsequent surgical management indicated.[a] **Palliative:** SEMS as a palliative measure for patients with incurable malignant or non-malignant obstruction with either chronic or acute comorbidities, with or without metastasis.

a The subsequent surgical management of any patient who has received a SEMS may be any type of surgical intervention, including curative surgery or non-curative surgery, single-stage resection or a multi-stage procedure.
b This group may include less than 25% of patients with colonic obstructions of non-malignant aetiologies, such as diverticulitis and Crohn's disease.

For the purposes of the current assessment, SEMS placement is not advocated to treat benign obstructions caused by conditions such as diverticular and Crohn's disease. SEMS insertion is proposed as an extension of current management of malignant colorectal obstruction which is at present surgical resection.

Proposal for public funding

The proposed MBS item descriptor for SEMS insertion for the management of malignant colorectal obstruction is presented in Table 2.

Table 2 Proposed MBS item descriptor for insertion of colonic stents for large bowel obstruction, stricture or stenosis

Category 3 – Therapeutic procedures
MBS [item number] Endoscopic insertion of stent or stents for large bowel obstruction, stricture or stenosis, where cause of the obstruction is due to: • a pre-diagnosed colorectal cancer, or cancer of an organ adjacent to the bowel • an unknown diagnosis. (Anaes.) Fee: $650.00 Explanatory notes: • The fee for the insertion of a colonic stent covers the colonoscopy to the point of obstruction, stricture or stenosis, passage of a guide wire under fluoroscopy and deployment of a colonic stent. • Two colonic stents are listed on the ARTG for use in colonic obstruction caused by malignancy (ARTG numbers 119517, 157191). The remaining three colonic stents are listed for use in strictures caused by colorectal cancer (ARTG numbers 139317, 144564, 167223). • The fee to be indexed by 2012/2013 Wage Cost Index 5 rate that is Cabinet-in-Confidence information. • Anaes. item numbers 20810 and 23063 (or 23031, 23032, 23033, 23041, 23042, 23043, 23051, 23052, 23053, 23061, 23062) to be charged with the service accordingly. • The procedure is undertaken by a colorectal surgeon or gastroenterologist appropriately trained in this procedure and certified by the Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy.

MBS: Medicare Benefits Schedule.

The proposed item fee includes colonoscopy to the point of obstruction, passage of a guide-wire across the obstruction under fluoroscopy and deployment of a colonic stent. The procedure is to be undertaken by a colorectal surgeon or gastroenterologist appropriately trained in this procedure and certified by the Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy. The technical difficulty of this procedure exceeds that for deployment of an oesophageal or biliary stent, and procedural

duration ranges from 30-90 minutes. The relief of obstruction is accompanied by immediate and often dramatic passage of stool, which can be extremely unpleasant for the proceduralist and other team members. The fee utilised for this report shall be indexed by 2012/2013 Wages Cost Index rate (Cabinet-in-Confidence).

It is suggested that the MBS item descriptor should not limit repeat use of stents. One stent may be placed within another (re-stenting) if the initial stent has become obstructed by granulation tissue or tumour. However, re-stenting is usually attempted only twice; after two or more unsuccessful attempts, an alternative approach would likely be taken. However, it may be that stents need to be inserted in separate locations in the same individual.

In the case of a failed attempt at stent insertion, there is a generic MBS item (MBS item 30001) to cover failed surgical interventions, where 50 per cent of the usual fee could be claimed. If an obstruction or stenosis becomes reduced in size, a stent will likely simply fall out, as stents generally require an obstruction to stay in place. This may also occur in the case of stent migration, where reintervention involving the removal of the migrated stent and the deployment of a new SEMS is required. Therefore, there is no need to have a specific MBS item number for stent removal.

The procedure is contraindicated when the obstruction is suspected to be associated with bowel perforation, intestinal ischemia or intra-abdominal infections such as abscesses or peritonitis (Watt et al 2007). Stenting should be cautiously considered when the obstruction is complete and the stricture does not allow passage of a guide-wire, as forceful attempts could lead to bowel perforation.

A team from the Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) was contracted to conduct a systematic review of the literature and an economic evaluation of colonic stents for the management of malignant colorectal obstruction for MSAC consideration..

Current arrangements for public reimbursement

Although not currently listed on the MBS, the placement of SEMS for the treatment of malignant colorectal obstruction is performed widely throughout Australia. The current arrangements for reimbursement of the SEMS procedure itself are paid for out of pocket by the patient.

Background

The intervention has not previously been considered by the Medical Services Advisory Committee (MSAC), and no related reviews have been conducted that have examined the specific patient population defined in the current assessment.

Prerequisites to implementation of any funding advice

The colonic stenting devices approved for use in Australia by the Therapeutic Goods Administration (TGA) are outlined in Table 3. The SEMS which has been named as part of the current submission is based on Ultraflex™, Wallstent® and WallFlex® stents manufactured by Boston Scientific Pty Ltd (ARTG 119517), which is estimated to have 85 per cent of Australian market share. Expert clinical opinion suggests that there is little clinical difference between the stents currently available in the Australian market.

However, while some of the listed stents may be used for obstruction caused by unspecified malignancy (ARTG 119517, 157191), other stents are restricted to use specifically in the case of obstructions caused by colorectal cancer (ARTG 139317, 144564, 167223). Duodenal stents are also listed on the ARTG; however, these are not appropriate for use in the treatment of colorectal obstructions.

Table 3 TGA approved stenting devices and systems for treating colorectal obstruction

ARTG no	Manufacturer/importer/ sponsor	Device name[b]	GMDN	Intended purpose
119517	Boston Scientific Pty Ltd[a]	Ultraflex™ Precision Colonic Stent System	38442 Unclassified	Palliative treatment of gastro-duodenal obstructions and colonic strictures produced by malignancy.
119517	Boston Scientific Pty Ltd[a]	Wallstent® Enteral colonic Endoprosthesis		
119517	Boston Scientific Pty Ltd[a]	WallFlex® Colonic Stents		
157191	William A. Cook Australia Pty Ltd	Cook Colonic Z-Stent® with induction system	37847 Colonic Stent	Palliative treatment for colonic, duodenal or gastric obstruction or strictures caused by malignant neoplasm, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.
139317	William A. Cook Australia Pty Ltd		37847 Colonic Stent	Maintain patency of malignant colonic strictures.
144564	Endotherapeutics Pty Ltd.		37847 Colonic Stent	Palliative treatment of colonic strictures caused by malignant neoplasm in the rectum, sigmoid colon and descending colon.
167223	Device Technologies Australia Pty Ltd.		37847 Colonic Stent	Implanted for pre-operative obstruction relief prior to removal of colo-rectal carcinoma, designed to maintain the patency of colo-rectal strictures caused by malignant tumour.

a Boston Scientific Pty Ltd WallFlex® Colonic Stents are new generation stents and account for 85% of Australian market share. Ultraflex™ and Wallstent® are first generation stents
b All the devices are metallic stents, mainly SEMS. They can be both covered and uncovered; nevertheless uncovered stents are most commonly deployed in Australia
ARTG: Australian register of Therapeutic Goods; GMDN: Global Medical Device Nomenclature.

Consumer impact statement

No input has been received from external craft or consumer groups addressing potential advantages (or disadvantages) to consumers if treatment with SEMS becomes available through the public healthcare system.

Clinical need

In the management of malignant colorectal obstruction, SEMS is to be used as alternative modality in addition to the current management procedures. For patients who are medically fit for surgery, SEMS can serve as a bridge to surgery, which would avoid the need for emergency surgery and allow time to plan appropriate elective surgery. It can also serve as an alternative to surgery for palliative purposes in patients suffering from incurable metastatic disease. For patients who are medically unfit for surgery, SEMS insertion provides an additional option; otherwise, best supportive care is the only

treatment available at present. SEMS is used to provide palliation until deaths in this group of patients.

According to data from the Australian Institute of Health and Welfare (AIHW), colorectal cancer is the second most common form of cancer in Australia, making up 13.1 per cent (males: 12.6%, females: 13.9%) of all reported incidences of cancer in 2007. In addition, the incidence rate of colorectal cancer and corresponding utilisation of resources have dramatically increased from 1982 to 2007 (AIHW 2010; AIHW 2011).

Based on data from the Australian Cancer Registry (AIHW 2004), CSSANZ has calculated that approximately 1,100 patients per year would be suitable for the placement of a SEMS. Allowing for local variation in expertise and facilities, and individual surgeon or patient bias and preference, CSSANZ has proposed an annual SEMS deployment rate of 575 to 625 patients as a fair estimate.

Current clinical management of intestinal obstruction caused by colorectal cancer is outlined in Figure 1. outlined in Figure 1. The proposed clinical management algorithm with the addition of the SEMS procedure as an option follows in

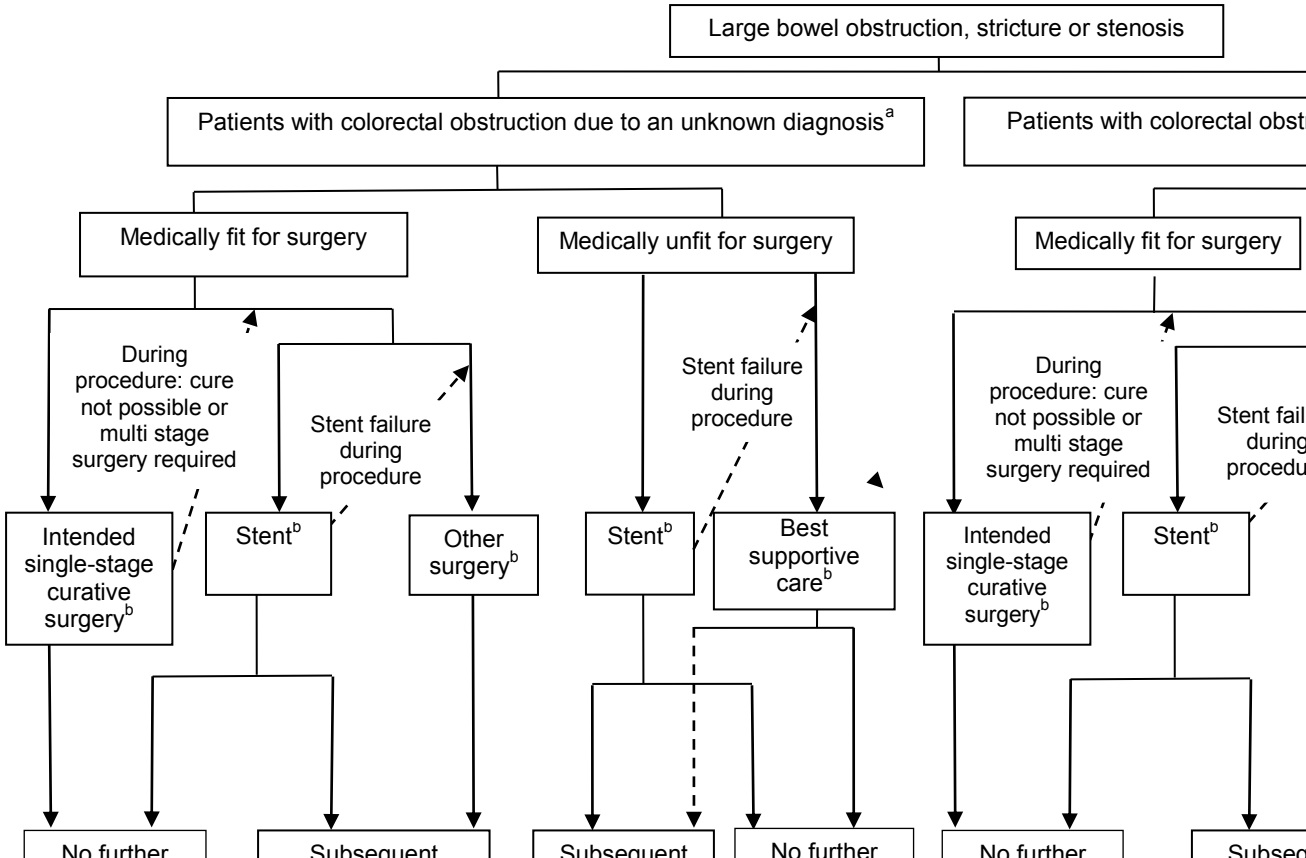
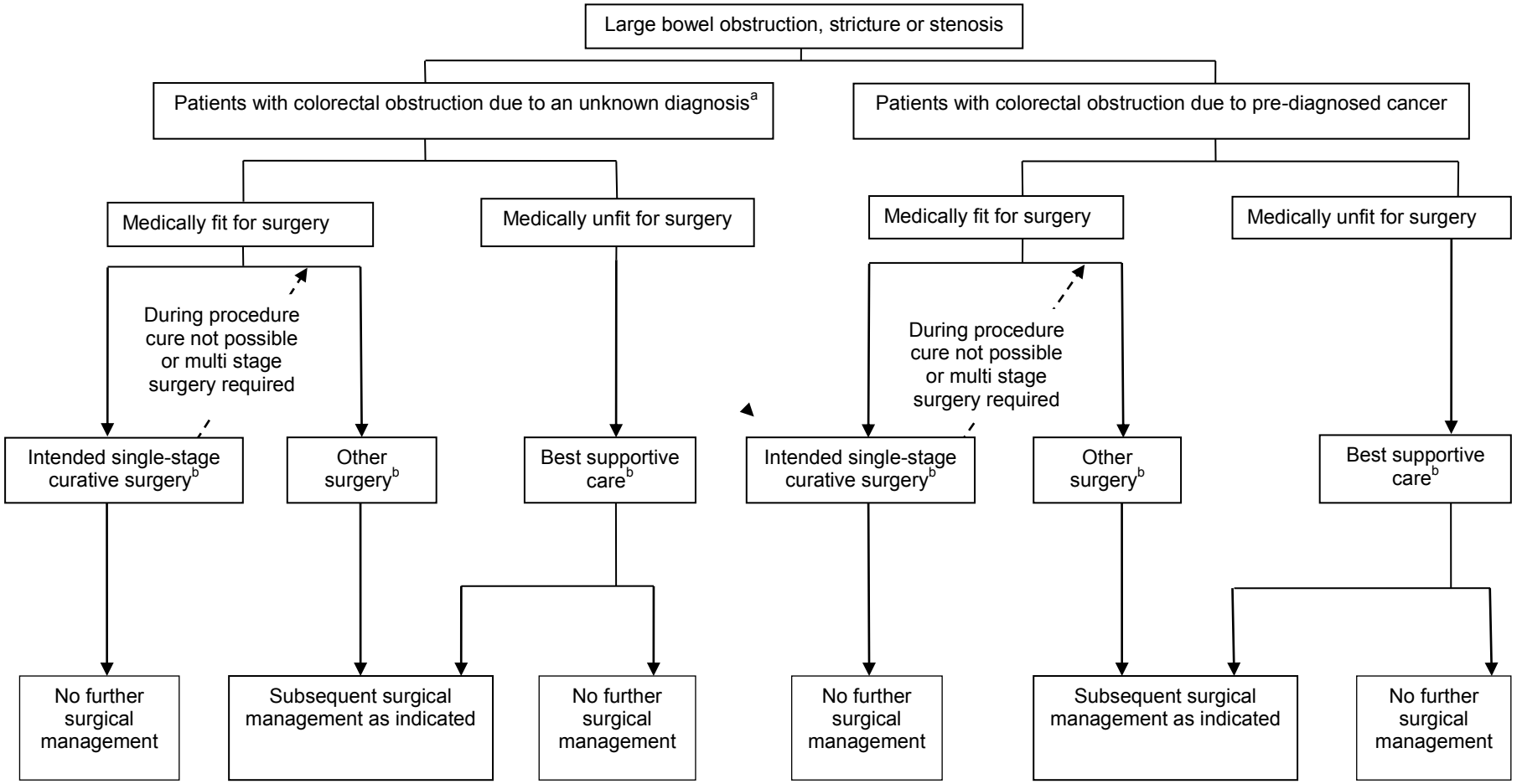


Figure 2.

Figure 1 Current clinical management algorithm of intestinal obstruction caused by colorectal cancer



Other surgery: Two- and three-staged resection techniques used in managing colorectal obstructions, strictures or stenosis. Hartmann's procedure and primary anastomosis could be performed by itself or together with staged surgical resections. Current MBS-listed surgical resection techniques are listed in Table 2.
Subsequent surgical management: Any surgical intervention including single-stage surgery and 'other surgery'.
Best supportive care: Conservative/clinical management of symptoms without surgical interventions.
a This group may include less than 25% of patients with colonic obstructions of non-malignant aetiologies such as diverticulitis and Crohn's disease
b Patients would receive chemotherapy, radiotherapy and/or palliation in addition to ongoing medical management. The type and combination of medical management received is individually based.

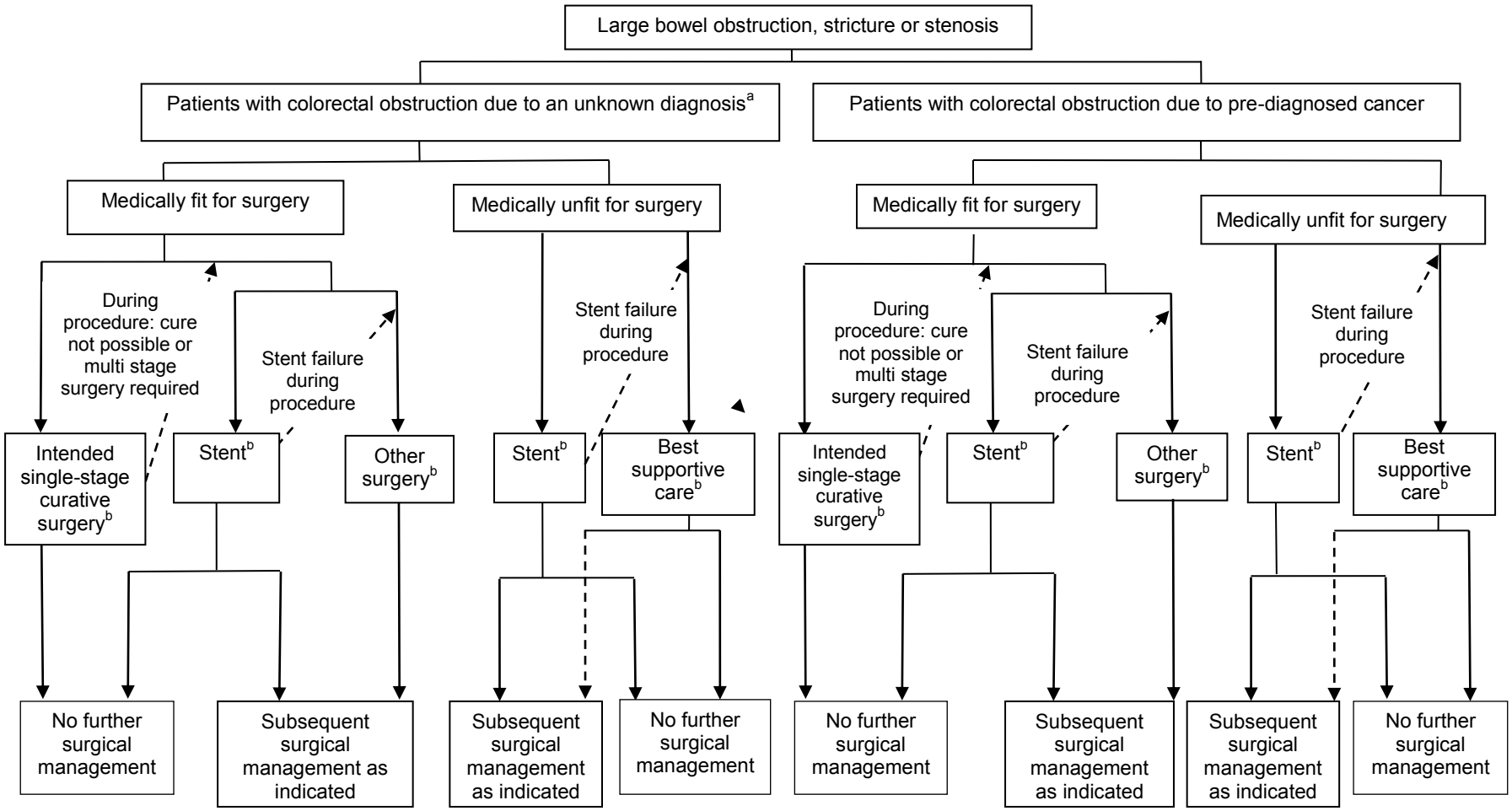


Figure 2 Proposed clinical management algorithm (once SEMS insertion introduced)

Other surgery: Two- and three-staged resection techniques used in managing colorectal obstructions, strictures or stenosis. Hartmann's procedure and primary anastomosis could be performed by itself or together with staged surgical resections. Current MBS-listed surgical resection techniques are listed in Table 4.
Subsequent surgical management: Any surgical intervention including single-stage surgery and 'other surgery'.
Best supportive care: Conservative/clinical management of symptoms without surgical interventions.
a This group may include less than 25% of patients with colonic obstructions of non-malignant aetiologies such as diverticulitis and Crohn's disease
b Patients would receive chemotherapy, radiotherapy and/or palliation in addition to ongoing medical management. The type and combination of medical management received is individually based.

Comparator to the proposed intervention

Two comparators were considered relevant to the assessment of SEMS in this review, namely, surgical management and best supportive care. Surgical management is indicated for patients who are medically fit for surgery and are able to tolerate general anaesthesia. Surgical management can be used as both a curative and non-curative measure. Best supportive care is the alternative intervention for patients who are in terminal stages of the underlying cancer and medically unfit for surgery, including those with comorbidities which would prevent the use of general anaesthesia.

Surgical management

Currently, surgical resection is the gold standard treatment in managing colorectal obstruction. It may be carried out as a one-stage, two-stage or three-stage procedure. For right- and left-sided (curative) malignancies, a hemi-colectomy with primary anastomosis is preferably performed as a one-stage procedure. Single-stage resection, also known as resection with primary anastomosis, is performed under general anaesthesia using an open laparotomy technique; the diseased section of bowel is excised and removed, and the free ends of the bowel are re-joined during the same procedure to restore bowel function (Breitenstein et al 2007). However, not all patients are candidates for single-stage surgery due to various factors including patient comorbidity, tumour stage or size, and surgeon experience and expertise (Dauphine et al 2002). Single-stage surgical resection of colorectal obstruction was not considered as a valid comparator procedure for the purpose of this assessment. Expert clinical input indicated that patients who are eligible to undergo a single-stage procedure should receive that surgery, and should not be considered for stenting.

Patients who are medically fit for surgery, but not suitable to undergo a single-stage resection, would undergo a two- or three-staged resection. For the purpose of the current assessment, these patients are also considered suitable for SEMS insertion and to receive reimbursement under the proposed MBS item.

Colostomy and Hartmann's resection are the most commonly employed multi-staged procedures for the management of colorectal obstructive lesions. Colostomy and Hartmann's resection can both be performed using either an open laparotomy or laparoscopic technique. Colostomy is the procedure generally performed if the cancer is too advanced for single-stage resection, the obstruction is right sided, and/or the patient is medically unfit for single-stage resection due to severe comorbidities. Hartmann's resection is commonly indicated for distal (left-sided) obstruction, less advanced cancer, and/or when the patient is comparatively fitter than the patients who would be indicated for colostomy. In general, a two-stage procedure involves resection of the bowel and the formation of a stoma, followed by a second operation to restore bowel continuity. Alternatively, the stoma may be closed during a third procedure (De Salvo et al 2002). Stoma creation can be performed under the influence of general or regional anaesthesia.

The disadvantages of surgical management over stenting include the need for general anaesthesia, the potential requirement for stoma creation and subsequent re-intervention, and a potentially prolonged hospital and intensive care unit (ICU) stay. The majority of patients who undergo a staged resection while in the terminal stage of their underlying malignancy never undergo reversal of the colostomy (stoma) (Mauro et al 2000). Stoma

creation has a poor impact on the psychological wellbeing of patients and can be a burden to carers during the final months of the patient's life (Karadag et al 2003). Common adverse events following surgical management include bleeding, anastomotic leakage of bowel content, wound dehiscence, infection, intra-abdominal abscesses, peritonitis, parastomal hernia, paralytic ileus, fistulisation, prolapse, necrosis, retraction of stoma, skin irritation around stoma and damage to neighbouring organs (eg urethral injury). Stoma creation has a mortality risk of up to 24 per cent (Martinez-Santos et al 2002; Deans et al 1994).

Table 4 shows current MBS item numbers related to resection and management of colorectal obstruction. Clinical expert opinion states that some of these items may be applicable for both single-stage and multi-stage resection procedures.

Table 4 Types of resection procedures listed on the MBS for managing colorectal obstructions

MBS item no	Type of resection procedure
30375	Caecostomy, Enterostomy, Colostomy, Enterotomy, Colotomy, Cholecystostomy, Gastrostomy, Gastrotomy, Reduction of intussusception, Removal of Meckel's diverticulum, Suture of perforated peptic ulcer, Simple repair of ruptured viscus, Reduction of volvulus, Pyloroplasty (adult) or Drainage of pancreas Fee: $501.50 Benefit: 75% = $376.15
32009	TOTAL COLECTOMY AND ILEOSTOMY Fee: $1,312.90 Benefit: 75% = $984.70
32024	RECTUM, HIGH RESTORATIVE ANTERIOR RESECTION WITH INTRAPERITONEAL ANASTOMOSIS (of the rectum) greater than 10 centimetres from the anal verge excluding resection of sigmoid colon alone not being a service associated with a service to which item 32103, 32104 or 32106 applies Fee: $1,312.90 Benefit: 75% = $984.70
32025	RECTUM, LOW RESTORATIVE ANTERIOR RESECTION WITH EXTRAPERITONEAL ANASTOMOSIS (of the rectum) less than 10 centimetres from the anal verge, with or without covering stoma not being a service associated with a service to which item 32103, 32104 or 32106 applies Fee: $1,756.15 Benefit: 75% = $1,317.15
32026	RECTUM, ULTRA LOW RESTORATIVE RESECTION, with or without covering stoma, where the anastomosis is sited in the anorectal region and is 6 cm or less from the anal verge Fee: $1,891.20 Benefit: 75% = $1,418.40
32033	RESTORATION OF BOWEL following Hartmann's or similar operation, including dismantling of the stoma Fee: $1,450.30 Benefit: 75% = $1,087.75

MBS: Medicare Benefits Schedule.
Note: All fees as of April 2011.

Best supportive care

Currently, patients medically unfit for surgical management receive best supportive care. Placement of a SEMS serves as a minimally invasive intervention for these patients. The best supportive care for cancer patients is the multidisciplinary attention to the patient's overall physical, social, psychosocial, spiritual and cultural needs, regardless of the current intention of any anti-cancer treatment (NICE 2004a; NICE 2004b). The objective of best supportive care is to improve the quality of life for patients and prolong survival, through a combination of chemotherapy, radiotherapy, palliation and ongoing medical management which is tailored to each patient's needs (Ahmed et al 2004; Ahmedzai et al 2001; NICE 2004b).

Scientific basis of comparison

The evidence base of the current assessment consisted of 40 primary studies that examined the use of SEMS for management of malignant colorectal obstruction. This included two randomised controlled trials (RCTs) and five non-randomised comparative studies that compared SEMS placement to multi-stage surgical resection. The comparative study data were used in the evaluation of both relative safety and effectiveness as appropriate. The majority of retrieved studies were case series, and their pooled data supplemented and substantiated the available comparative evidence regarding the safety of SEMS. No systematic reviews or health technology assessments (HTAs) were identified that examined the safety and effectiveness of colorectal SEMS in patients specifically indicated for multi-stage surgical resection.

In general, the studies included in this review were of relatively poor quality. Patients and procedures were heterogenous, procedural details were inconsistently or poorly reported, the majority of studies lacked methodological rigour, and possible confounders that may have affected study outcomes were not addressed.

Comparative safety

All primary studies included in this assessment were reviewed for data related to adverse events occurring after treatment with SEMS. No studies that compared stents to best supportive care were retrieved; as such, no assessment or comparison of the relative safety for these two treatments could be made.

Six studies comparing SEMS placement to multi-stage surgical treatment, including one RCT, reported on procedure-related mortalities occurring within their patient cohort. While very few procedure-related deaths were reported in these studies and there was little apparent difference between treatments, the small patient populations precluded the ability to accurately determine mortality rates and conduct statistical comparisons between treatments. A procedure-related mortality rate of 1.6 per cent after SEMS placement was found within lower-level evidence. However, this figure is likely to be an over-inflation, as it does not include data from the majority of studies retrieved, for which no explicit statement regarding patient mortalities was made but it was implied that no patient mortality occurred. It also includes mortality statistics from studies that stated it was unclear whether patients died due to SEMS placement or their underlying disease.

Adverse events arising as an outcome of SEMS placement and as a result of surgical resection vary considerably in nature and severity, complicating the direct comparison of the relative safety of SEMS and multi-stage resection. Potential adverse events following the SEMS procedure were commonly stent-related or tumour-related. Adverse events following surgery were generally stoma-related or infection-related. In terms of severity, bowel perforation is likely to be the most severe stent-related event. Due to the potential for serious pelvic infection and peritonitis to develop, this outcome can be considered a life-threatening medical emergency, requiring immediate hospital admission as well as multi-stage surgical resection of the bowel. Any other infectious event, be it following SEMS placement or surgical resection, also needs to be considered and managed as a medical emergency.

With regards to comparative evidence, six non-randomised studies comparing SEMS placement to multi-stage surgical treatment, including two RCTs, reported on procedure-related adverse events occurring within their patient cohort. The only statistically significant difference found with respect to adverse event occurrence was a higher rate of patient readmission for complications after multi-stage surgical treatment, reported in one comparative study.

The majority of information on safety outcomes after SEMS placement was obtained from level IV evidence. The relatively severe event of bowel perforation was reported in over four per cent of SEMS patients. Data suggested that occurrence of perforation may be higher when dilators are used. Adverse events related to tumour growth were the most common, reported in seven to nine per cent of patients. Tumour ingrowth or overgrowth is not an immediate adverse event, and therefore is unlikely to interfere with the direct relief that a stent may provide. However, it does increase the likelihood that treatment for re-obstruction will be required in the future. Re-obstruction and stent migration were reported in six to seven per cent of patients. It is possible that rates of stent migration may have been inflated by studies that used stents not specifically designed for the colon (eg oesophageal stents); although every effort was made to exclude such studies, some authors did not explicitly state the type of stent used. Other minor adverse events were reported in less than five per cent of patients.

From the evidence available, it was difficult to make a definitive determination of the relative safety of SEMS placement compared to multi-stage surgery. Based on this evidence, which was largely low-level and of questionable methodological quality, SEMS placement appeared to be approximately equivalent to multi-stage surgical resection in terms of safety, albeit with the prospect of severe medical consequences arising from issues such as bowel perforation and tumour growth-related events.

Comparative effectiveness

For the purpose of the current assessment, relative effectiveness of SEMS placement can only be determined through evidence directly comparing the procedure of interest to a relevant comparator procedure. No studies that compared stents to best supportive care were retrieved; as such, no assessment or comparison of the relative effectiveness for these two treatments could be made. Seven comparative studies that met the necessary criteria, including two RCTs, were used to determine the relative effectiveness of SEMS compared to multi-stage surgical resection. However, these studies were subject to significant confounders and sources of bias in their methodology, such as inconsistency in reporting of clinical outcomes, heterogeneous patient populations, lack of statistical comparisons and small sample size.

With regards to specific effectiveness outcomes, the available evidence showed few significant differences between SEMS placement and multi-stage surgery, with the potential exception of post-procedural hospital and ICU stay, where patients who received SEMS commonly experienced significantly better outcomes than those who underwent surgical resection. However, it is important to remember that readmission is often necessary in an instance of an adverse event such as stent migration. Patients who received SEMS as a bridge to surgery may be able to undergo planned surgery significantly sooner and require a

shorter hospital stay after planned surgery than those who initially underwent surgery with temporary stoma; however, this finding was based on results from a single small study.

Relative quality of life following treatment, defined as the primary effectiveness outcome of interest to the present assessment, could not be determined based on the available evidence. One comparative study assessed this outcome; the results of this study did not show any benefit for SEMS placement over surgical resection. While a lack of universal definitions and direct statistical comparisons made evaluation of the relative procedural success between the two treatments difficult, the majority of studies reported equivalent or slightly higher rates of initial clinical success in patients who underwent surgical resection compared to those who received SEMS. Need for re-intervention after SEMS placement generally varied from zero to 10 per cent of patients, but no comparison to multi-stage surgery was made within the available evidence. When treatment occurred with definitive palliative intent, no significant difference in length of patient survival was found between SEMS placement and multi-stage surgery.

With respect to relative effectiveness, SEMS placement appeared to be non-inferior to multi-stage surgical resection. However, this conclusion was based on a small number of studies with considerable methodological deficiencies and should be accepted with caution.

Economic evaluation

For the purpose of conducting the economic evaluation of SEMS insertion for the management of malignant bowel obstructions, it was assumed that colonic stents are suitable for two groups of patients (all of whom are ineligible for single-stage bowel resection) with an obstruction caused by either pre-diagnosed cancer or unknown diagnosis:

- patients medically fit for multi-stage surgery; and
- patients medically unfit for multi-stage surgery.

These two patient populations were modelled separately as the comparator(s) differed based on the baseline risk for multi-stage surgery.

Patients fit for multi-stage surgery

Patients who were initially fit to undergo a multi-stage surgery to resolve the malignant colonic obstruction could receive such a surgery (eg colostomy) for palliation or with an intention for re-anastomosis (eg second stage of a two-stage surgery) at a later date. Accordingly for the purpose of determining cost-effectiveness:

- The patients who received palliative or definitive SEMS were compared with patients who were not medically fit for re-anastomosis, which included colostomy for palliative purposes.
- The patients who received SEMS as a bridge to surgery were compared with patients who were medically fit for a second stage of a two-stage surgery. The comparative multi-stage surgeries included colostomy or Hartmann's procedure.

The previous literature demonstrated that the use of colonic SEMS for malignant bowel obstruction is usually cost saving relative to colostomy or Hartmann's procedure. The main differences in healthcare costs were largely driven by the length of hospital stay, which was significantly shorter in patients receiving colonic stents. In addition, there was some evidence to suggest that colonic stent insertion was more effective, in terms of gains in quality of life.

Patients unfit for multi-stage surgery

There was insufficient published evidence regarding patients considered unfit to receive any type of emergency surgery to resolve the obstruction. Therefore for the purposes of the economic evaluation, the incremental cost of treating these patients with a SEMS compared to palliation alone (resembling best supportive care) was estimated.

Rationale for cost-effectiveness

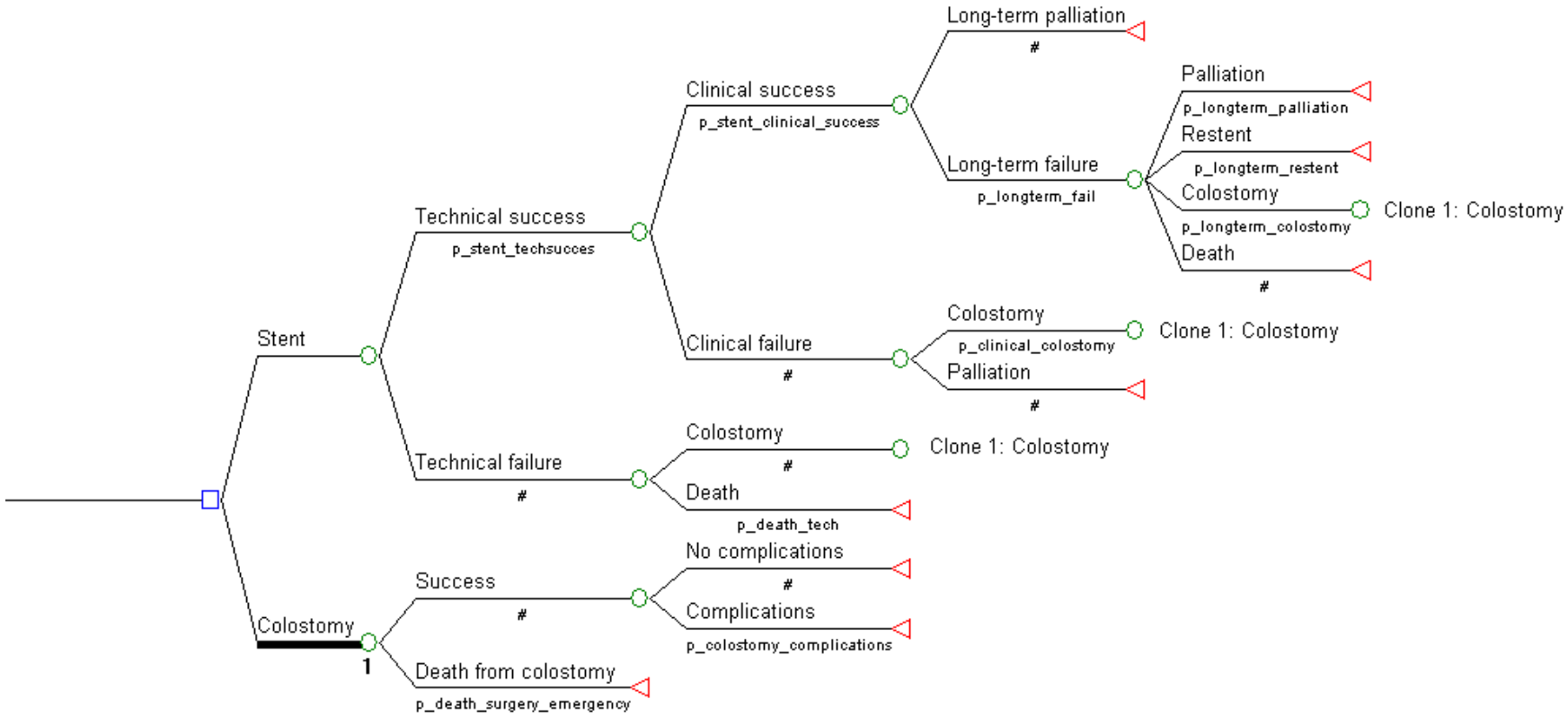
There were only two RCTs that measured the effectiveness of SEMS relative to colostomy for colonic obstruction for palliative purpose. Both RCTs compared palliation with SEMS versus stoma creation for the management of inoperable malignant colonic obstruction. The results from Xinopolous et al (2004) found that 14 out of 15 patients (93.3%) had successful SEMS placement without serious complications compared with 15 patients (100%) who underwent surgery. Fiori et al (2004) reported technical and clinical success rates of 100 per cent in the 11 patients that had SEMS placed and also for the 11 patients who underwent colostomy.

Given the low number of patients in both RCTs and the lack of follow-up data regarding outcomes after SEMS insertion, a systematic review of clinical studies and case series by Khot et al (2002) was used to form the basis of the transitions through the model. Both models adopted a cost-utility analysis framework. Decision trees were developed to estimate the costs and benefits of SEMS versus the comparators over a one-year time period. The decision trees incorporated all pre-procedural, surgical, hospital, ICU, post-procedural, palliative and procedure failure costs. Quality of life was also incorporated into the model based on the estimated survival. A cost per QALY for both models was estimated.

The decision tree for patients requiring palliation is presented in Figure 3. A separate decision tree was developed to compare SEMS with multi-stage surgery (diverting colostomy or a Hartmann's procedure) as a bridge to surgery. This decision tree is presented in Figure 4. The incremental cost-effectiveness ratio (ICER) was calculated using the following ratio:

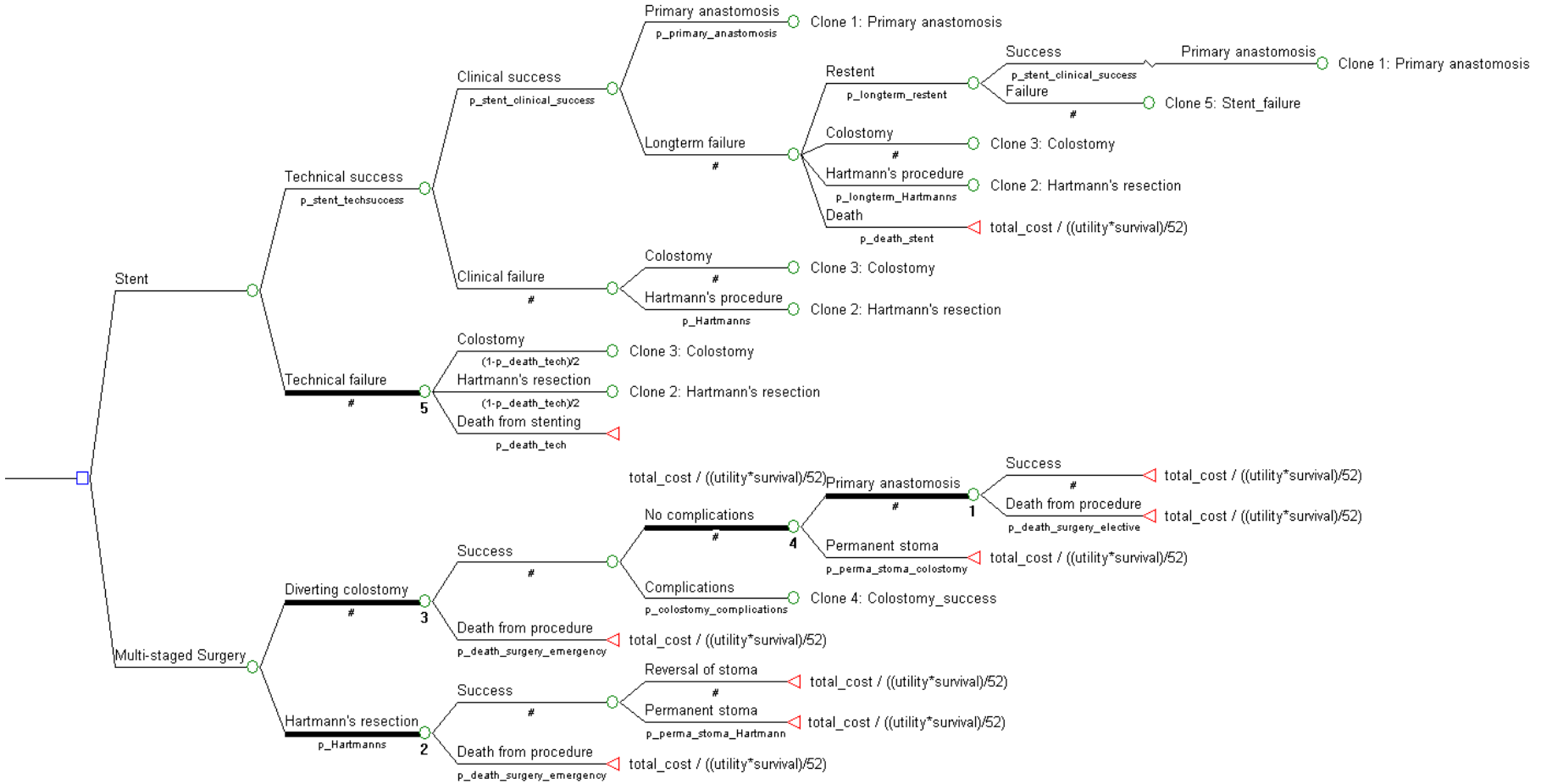
$$ICER = \frac{Cost_{New} - Cost_{Comparator}}{Effectiveness_{New} - Effectiveness_{Comparator}}$$

Figure 3 Decision tree for patients requiring palliation (SEMS versus colostomy)



□ represents a decision node between the two treatment options; ○ represents a chance node with a probability of various events occurring; ◁ represents a terminal node where the pathway ends. The bold line represents a clone of the substree which is replicated elsewhere in the tree. p: Probabilities that were determined by the literature; #: 1-p.

Figure 4 Decision tree for patients requiring a bridge-to-surgery (SEMS versus colostomy/ Hartmann's procedure)



□ represents a decision node between the two treatment options; ○ represents a chance node with a probability of various events occurring; ◁ represents a terminal node where the pathway ends.
The bold line represents a clone of the substree which is replicated elsewhere in the tree. p: Probabilities that were determined by the literature; #: 1-p

Main results of economic evaluation

Patients fit for multi-stage surgery (receiving SEMS for palliation)

For the base case analysis the total cost of a SEMS insertion was estimated to be $17,809. This value includes the costs of palliation and the cost of colostomy for those with stent failure. The total average cost for patients that received a palliative colostomy was estimated to be $20,516. This represented a cost savings of $2,707 for stent placement over palliative colostomy.

The estimated average patient receiving a SEMS would gain 0.099 quality-adjusted life years (QALYs) compared to 0.089 QALYs in the palliative colostomy group. This yields an incremental benefit of 0.010 QALYs per patient. This benefit is due to difference in mortality rates between colostomy and stenting.

In terms of cost-effectiveness, the SEMS insertion for palliation dominated palliative colostomy. In other words it provided additional benefit at lower costs (See Table 5).

Table 5 Summary of cost-effectiveness analysis for palliation (stent vs. colostomy)

	Average cost	Incremental cost	QALYs	Incremental QALYs	ICER
Stent	$17,809		0.099		
Colostomy	$20,516	-$2,707	0.089	0.010	Dominated

QALY: Quality-adjusted life year; ICER: Incremental cost-effectiveness ratio.

Patients fit for multi-stage surgery (receiving SEMS as a bridge to surgery)

For the base case analysis, the total cost of SEMS insertion was estimated to be $29,729. This value included the costs of re-stenting, stoma creation or Hartmann's procedure in the case of a stent failure. The total average cost for patients that received multi-stage surgery (either a colostomy or a Hartmann's procedure) was estimated to be $30,169. This represented a cost savings of $440.

The estimated average patient receiving a SEMS as a bridge to surgery would gain 0.510 quality-adjusted life years (QALYs) compared to 0.458 QALYs in the multi-stage surgery group. This yields an incremental benefit of 0.052 QALYs per patient. This benefit is due to the difference in mortality rates between an emergency procedure and an elective procedure.

In terms of cost-effectiveness, the SEMS insertion as a bridge to surgery dominated colostomy. In other words it provided additional benefit at lower costs (See Table 6).

Table 6 Summary of cost-effectiveness analysis for bridge to surgery (stent vs. multi-stage surgery)

	Average cost	Incremental cost	QALYs	Incremental QALYs	ICER
Stent	$29,729		0.510		
Colostomy	$30,169	-$440	0.458	0.052	Dominated

QALY: Quality-adjusted life year; ICER: Incremental cost-effectiveness ratio.

Patients unfit for multi-stage surgery

For patients who are unfit for any type of resection to resolve the colonic obstruction, a SEMS insertion procedure could substitute palliation (best supportive care); the cost of providing the stent procedure rather than palliation alone was estimated to be $9,659.

Estimate of costs

The proposed MBS fee was provided by the applicant ($650). In the base-case analysis the co-payment was estimated to be 25 per cent of the MBS fee. Higher co-payment fees were tested in the sensitivity analysis. Under this scenario SEMS is a cost saving. In the sensitivity analysis different MBS fees and co-payments were tested.

For patients requiring SEMS for palliation

If the total cost of the MBS schedule benefit and co-payment is over $3058, SEMS is no longer cost-saving, relative to colostomy.

For patients requiring SEMS as a bridge to surgery

If the total cost of the MBS schedule benefit and co-payment is over $1249, SEMS is no longer cost-saving, relative to multi-stage surgery (colostomy or Hartmann's surgery).

Financial/budgetary impacts

An epidemiological approach, based on the incidence of colorectal cancer in Australia, was used to estimate the cost per annum of providing SEMS instead of colostomy or Hartmann's resection for treatment of malignant colorectal obstruction.

The estimated number of patients eligible for SEMS for palliation ranged between 134 and 487. The estimated number of patients eligible for SEMS as a bridge to surgery ranged between 314 and 1,137 (See Table 7).

Table 7 Estimated number of patients to receive treatment

	Incidence of obstruction	
	LOW (8%)	HIGH (29%)
Estimated number of colorectal cancer cases	14,940	14,940
Incidence of obstruction (8%-29%)	1,195	4,333
Percentage of left-sided malignancies (75%)	896	3,249
Percentage eligible for curative surgery (single-stage) (50%)	448	1,625
Estimated patients for palliative treatment (30%)	**134**	**487**
Estimated patients fit for surgery (bridge to surgery)	**314**	**1,137**

It was estimated that most patients would only receive one SEMS placement procedure. However a small proportion of patients (<10%) could require re-stenting because of stent failure, re-obstruction or migration of the initial stent insertion.

Patients fit for multi-stage surgery

For patients requiring palliative SEMS

The overall average cost of a SEMS versus a palliative colostomy is presented in Table 8 (allowing for stent failures, complications and palliation costs).

Table 8 Estimated total costs of SEMS versus colostomy (palliation)

	SEMS	Colostomy
Consumables	$3,902	$690
MBS items & hospital fees	$9,659	$11,285
Patient/insurer costs	$4,248	$8,541
Total post-operative	**$17,809**	**$20,516**

SEMS: Self-expanding metallic stent.

For patients requiring SEMS as a bridge to surgery

The total average costs for SEMS versus multi-stage surgery is summarised in Table 9. These costs include those patients who would receive a resection with primary anastomosis after receiving a SEMS as bridge to surgery and also any re-stenting or multi-stage surgeries due to a stent failure. The costs also include a proportion of patients who received palliation.

Table 9 Estimated total costs of SEMS versus multi-stage surgery

	SEMS	Multi-stage surgery
Consumables	$5,211	$1,908
MBS items & hospital fees	$9,848	$11,852
Patient/insurer costs	$14,670	$16,409
Total post-operative	**$29,729**	**$30,169**

SEMS: Self-expanding metallic stent; MBS: Medicare Benefits Schedule.

Patients unfit for multi-stage surgery

The total average cost of a SEMS versus palliation (best supportive care) is presented in Table 10. The average costs do not take into account any costs for deaths due to the procedure or re-stenting.

Table 10 Estimated total costs of SEMS versus palliation only (BSC)

	SEMS	Palliation only (BSC)
Consumables	$3,535	$0
MBS items & hospital fees	$2,988	$963
Patient/insurer costs	$4,817	$719
Other healthcare costs (palliation)	$6,073	$6,073
Total post-operative	**$17,413**	**$7,755**

SEMS: Self-expanding metallic stent; BSC: Best supportive care; MBS: Medicare Benefits Schedule.

For patients requiring palliative SEMS

Table 11 and Table 12 present the overall estimated impact of SEMS placement in lieu of a palliative colostomy. If all patients who would have received palliative colostomy received a SEMS instead, the overall cost savings would be between $363,981 (lower estimate) and $1,319,430 (upper limit).

Table 11 Estimated total costs of SEMS versus palliative colostomy (lower limit)

	SEMS	Colostomy
Total cost per patient	$17,809	$20,516
Number of patients	134	134
Breakdown of financial implications		
Consumables	$524,659	$92,777
MBS items & hospital fees	$1,298,740	$1,517,371
Patient out-of-pocket	$571,182	$1,148,415
Total financial implications	**$2,394,582**	**$2,758,562**
Incremental costs		
Consumables		$431,883
MBS items & hospital fees		-$218,630
Patient out-of-pocket		-$577,233
Total cost		**-$363,981**

SEMS: Self-expanding metallic stent; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Table 12 Estimated total costs of SEMS versus palliative colostomy (upper limit)

	SEMS	Colostomy
Total cost per patient	$17,809	$20,516
Number of patients	487	487
Breakdown of financial implications		
Consumables	$1,901,890	$336,316
MBS items & hospital fees	$4,707,933	$5,500,468
Patient out-of-pocket	$2,070,535	$4,163,004
Total financial implications	**$8,680,358**	**$9,999,788**
Incremental costs		
Consumables		$1,565,574
MBS items & hospital fees		-$792,535
Patient out-of-pocket		-$2,092,469
Total cost		**-$1,319,430**

SEMS: Self-expanding metallic stent; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

For patients requiring SEMS as a bridge to surgery

Table 13 and Table 14 present the overall estimated impact of SEMS placement in lieu of either a colostomy or a Hartmann's procedure. If all patients who would have received a colostomy or Hartmann's resection received a SEMS, the overall cost savings would be between $138,045 (lower estimate) and $500,412 (upper limit).

Table 13 Estimated total costs of SEMS versus multi-stage surgery (lower limit)

	SEMS	Multi-stage surgery
Total cost per patient	$29,729	$30,169
Number of patients	314	314
Breakdown of financial implications		
Consumables	$1,634,888	$598,612
MBS items & hospital fees	$3,089,690	$3,718,421
Patient out-of-pocket	$4,602,534	$5,148,124
Total financial implications	**$9,327,112**	**$9,465,157**
Incremental costs		
Consumables		$1,036,276
MBS items & hospital fees		-$628,731
Patient out-of-pocket		-$545,590
Total cost		**-$138,045**

SEMS: Self-expanding metallic stent; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Table 14 Estimated total costs of SEMS versus multi-stage surgery (upper limit)

	SEMS	Multi-stage surgery
Total cost per patient	$29,729	$30,169
Number of patients	1,137	1,137
Breakdown of financial implications	0	0
Consumables	$5,926,468	$2,169,968
MBS items & hospital fees	$11,200,127	$13,479,275
Patient out-of-pocket	$16,684,186	$18,661,950
Total financial implications	**$33,810,781**	**$34,311,193**
Incremental costs		
Consumables		$3,756,501
MBS items & hospital fees		-$2,279,148
Patient out-of-pocket		-$1,977,764
Total cost		**-$500,412**

SEMS: Self-expanding metallic stent; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Patients unfit for any surgery

Table 15 and

Table 16 present the overall estimated impact of SEMS in addition to palliation alone (best supportive care). If all patients received a SEMS rather than palliation alone (best supportive care), the overall additional cost would be between $1,294,154 (lower estimate) and $4,703,201 (upper limit).

Table 15 Estimated total costs of SEMS versus BSC (lower limit)

	SEMS	Palliation only (BSC)
Total cost per patient	$17,413	$7,756
Number of patients	134	134
Breakdown of financial implications		
Consumables	$473,690	$0
MBS items & hospital fees	$1,214,174	$942,831
Patient out-of-pocket	$645,478	$96,407
Total financial implications	**$2,333,342**	**$1,039,237**
Incremental costs		
Consumables		$473,690
MBS items & hospital fees		$271,343
Patient out-of-pocket		$549,071
Total cost		**$1,294,104**

SEMS: Self-expanding metallic stent; BSC: Best supportive care; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Table 16 Estimated total costs of SEMS versus BSC (upper limit)

	SEMS	Palliation only (BSC)
Total cost per patient	$17,413	$7,756
Number of patients	487	487
Breakdown of financial implications		
Consumables	$1,721,545	$0
MBS items & hospital fees	$4,412,707	$3,426,556
Patient out-of-pocket	$2,345,879	$350,374
Total financial implications	**$8,480,131**	**$3,776,930**
Incremental costs		
Consumables		$1,721,545
MBS items & hospital fees		$986,151
Patient out-of-pocket		$1,995,505
Total cost		**$4,703,201**

SEMS: Self-expanding metallic stent; BSC: Best supportive care; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

If MBS funding is granted for SEMS insertion to manage colorectal obstruction it is unlikely to impact the extended Medicare safety net. This is because the majority of MBS services are provided in the inpatient setting.

Overall conclusion with respect to comparative cost-effectiveness

Patients fit for multi-stage surgery

The results of the economic evaluation demonstrated that:

- *For patients requiring palliative SEMS versus palliative colostomy:* SEMS placement dominated colostomy (more effective and less costly).

- *For patients requiring SEMS as bridge to surgery versus multi-stage resection:* SEMS placement dominated colostomy or Hartmann's procedure (more effective and less costly).

The sensitivity analysis demonstrated that:

- The main drivers of both models were the technical and clinical success of the SEMS insertion, and length of hospital stay following the procedures.
- The probability of a resection with primary anastomosis after insertion of a SEMS and the cost of stenting were also drivers in the bridge to surgery model.

Financial implications suggested that:

- SEMS insertion would be a cost savings versus the comparators for both palliation and bridge to surgery. An estimated cost savings ranges from $363,981 to $1,319,430 in the palliation group and $138,045 to $500,412 in the bridge to surgery group based on the lowest and highest estimate of the number of patients eligible to be treated with SEMS for malignant bowel obstruction.

Patients unfit for multi-stage surgery

The results of the economic evaluation demonstrated that:

- *For patients requiring definitive SEMS:* SEMS placement instead of palliation (best supportive care) had an incremental cost of $9,659.

Financial implications suggested that:

- If all patients received SEMS rather than palliation alone (best supportive care), the overall additional cost would be between $1,294,104 (lower limit) and $4,703,201 (upper limit).

Overall, the economic evaluation demonstrated that if SEMS were used in lieu of a colostomy for patients requiring palliation, SEMS would result in cost savings. If the majority of these patients were treated with palliation alone (standard best supportive care), there would be an incremental cost in providing SEMS. The results for those patients who received SEMS as a bridge to surgery in lieu of a diverting colostomy or Hartmann's procedure also showed that a SEMS would result in cost savings.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of colonic stents, a therapeutic device for the management of malignant large bowel obstruction. MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Schedule (MBS) in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer health and health administration.

This report for MSAC consideration summarises the assessment by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) of the available clinical evidence at the time of the assessment for insertion of colonic stents for the management of malignant large bowel obstruction.

Background

Colorectal cancer (ICD-10:C18-C20), also known as large bowel cancer, is one of the most common cancers in the world. The large bowel consists of the ascending colon, transverse colon, descending colon, sigmoid colon and rectum. In the United Kingdom, colorectal cancer is the third most common cause of deaths related to cancer and the Association of Colo-proctology of Great Britain and Ireland states that approximately 100 new cases are diagnosed each day in the United Kingdom (ACPGBI 2007). According to the National Institute for Health and Clinical Excellence in the United Kingdom, the five-year survival rate after diagnosis of colorectal cancer is about 45 per cent, while the remaining 50 to 60 per cent of patients eventually develop metastases (NICE 2004a; NCCN 2011).

Although there is no definitive cause for the disease, approximately 20 per cent of patients diagnosed with colorectal cancer have a familial association. Genetic abnormalities such as Lynch syndrome, hereditary non-polyposis colorectal cancer, familial adenomatous polyposis syndromes, and MYH-associated polyposis can lead to familial colorectal malignancy (Longmore et al 2004). The disease is also associated with risk factors such as previous colonic polyps, diabetes mellitus, an unbalanced diet (eg red meat, high-fat diet, inadequate fibre intake), obesity, sedentary lifestyle, smoking and excessive consumption of alcohol (Amersi et al 2005). Colorectal cancer is also more common in patients with ulcerative colitis or Crohn's disease (Eaden et al 2001; Itzkowitz and Harpaz 2004; von Roon et al 2007).

Intestinal obstruction is a common complication and medical emergency among patients with colorectal cancer. Obstruction is usually accompanied by colic, abdominal pain and symptoms such as constipation, distension, anorexia, nausea and vomiting. Constipation is absolute if the obstruction is complete, whereas flatus or faeces may pass when the obstruction is only partial or incomplete. If colonic obstruction is not treated early, it can lead to intestinal strangulation, paralysis, ischaemia, perforation, peritonitis and even death (Winslet 2004).

Cancer is the second most common cause of intestinal obstruction in adults after adhesions resulting from prior laparotomy. Colorectal and ovarian cancers are the most common causes of malignant colorectal obstructions (Davis and Nouneh 2001; Watt et al 2007). Intestinal obstructions may also be caused by non-malignant conditions such as Crohn's disease and diverticulitis. The incidence of intestinal obstructions due to primary intestinal malignancy ranges from 10 to 28 per cent (Davis and Nouneh 2001; Tilney et al 2007). Mandava et al (1996) stated that about 30 per cent of patients with colon cancer and 10 per cent of patients with rectal cancer present as emergencies and 80 per cent of these episodes are related to colorectal obstruction. Xinopoulos et al (2004) observed that 10 to 20 per cent of patients with colorectal cancer develop partial colonic obstruction, and a further 8 to 29 per cent progress to complete obstruction. At least 70 per cent of such obstructions occur in the left side of the colon, the descending colon and the recto-sigmoid region, making them accessible by endoscopic means (Sebastian et al 2004).

Colonic stents

The first use of colonic stents was reported in 1991 in Japan (Dohmoto et al 1991), and colonic stents have been used to manage colorectal obstruction since the last decade.

Colonic stents are classified as metallic or non-metallic (eg plastic stents). Generally, in Australia only metallic stents are used, particularly the self-expanding metallic stent (SEMS). SEMS are expandable metal mesh tubes. Different types of metals or alloys are used, which can be either covered or uncovered. Covered SEMS are fully or partially covered with chemical compounds such as polyethylene, polytetrafluoroethylene and polyurethane (Park et al 2010; Repici et al 2000). The majority of stents used in Australia are of the uncovered type.

Stent migration, obstruction, tissue ingrowth and bowel perforation are adverse events that may be associated with stent deployment. According to expert clinician input, uncovered SEMS may reduce post-operative complications, such as tissue reactions, and therefore minimise the risk of stent migration. In contrast, tissue granulation and tumour ingrowth may be less common with covered SEMS (Watt et al 2007).

Recently, absorbable stents are being used for colonic indications. These have the benefit of reduced migration because they are absorbed within approximately one month of insertion (McLoughlin and Byrne 2008).

The procedure

Firstly, a clinical diagnosis of bowel obstruction should be confirmed by either a computed tomography scan or an abdominal radiograph. Contrast enema or endoscopic examination (sigmoidoscopy) may be useful for excluding pseudo-obstruction.

Once bowel obstruction is confirmed, the bowel is prepared using rectal cleansing enemas, especially if the obstruction is complete and no bowel movement has been recorded in the previous few days. In cases of incomplete distal obstruction, bowel preparation can be achieved by oral administration of polyethylene glycol (Cho et al 2011; Garcia-Cano et al 2006). Administration of prophylactic antibiotics is recommended when the obstruction is complete and severe, because 'the introduction of air during the procedure may lead to micro-perforation and bacteraemia' (Reza et al 2009).

Stents are deployed with a delivery catheter or wire that is positioned using fluoroscopic or endoscopic visualisation techniques, or both (Boorman et al 1999; Camunez et al 2000; Liberman et al 2000; Saida 1996). Radial force causes the stent to self expand once it is released (Small and Baron 2008; Watt et al 2007). Two methods of stent deployment are used: through the scope and over the wire. The through the scope method is used in less severe cases of obstruction, whereas the over the wire technique is used, often with fluoroscopic guidance, for severe lesions that do not permit the passage of an endoscope (Reza et al 2009).

Manual dilation of the colon using a balloon dilator may be required to facilitate stent deployment when the lesion does not allow passage of the stent deployment system or adequate stent expansion immediately after placement (Jost et al 2007; Small and Baron 2008). However, peri-interventional dilation may be associated with an increased risk of bowel perforation (Garcia Cano et al 2006; Khot et al 2002; Sebastian et al 2004).

Stenting of malignant colonic strictures is a minimally invasive endoscopic procedure that does not require an incision. Usually, colorectal stenting is carried out under conscious sedation without general anaesthesia and takes between 30 and 90 minutes (Watt et al 2007). Stent insertion is not suitable for obstructions of the most proximal large bowel. Deployment of the stents in other parts of the colon is usually performed at hospitals equipped with resources for managing bowel obstructions. In Australia, the procedure is undertaken by a colorectal surgeon or gastroenterologist appropriately trained and certified by the Conjoint Committee for Recognition of Training in Gastrointestinal Endoscopy . Thus, colonic stenting should only occur in facilities with appropriately trained endoscopists, operating theatres, anaesthetists and radiology services.

The SEMS requires an obstruction to hold it in place; if the obstruction becomes reduced as a result of medical management, then the stent is likely to fall out (Camunez et al 2000).

Abdominal radiography may be used at intervals in the first few days after stent placement to ascertain whether the stent remains correctly placed and the obstructing lesion is patent. In case of migration, the stent would be removed, and a new stent is inserted across the obstructed part of the bowel. Placing one stent within another (re-stenting) is also possible, if the initial stent becomes obstructed by granulation or tumour tissue. Re-stenting is usually attempted only twice: a third attempt is unlikely if the initial two attempts are unsuccessful.

Following the insertion of a colonic stent, patients are likely to receive ongoing active medical management for curative or palliative purposes consisting of chemotherapy, radiotherapy or both (Harrisa et al 2001). The exact type or combination of medical management received is individually tailored to the patient's disease status.

Intended purpose

SEMS are a minimally invasive alternative to open surgical technique for patients with malignant colorectal obstruction (Watt et al 2007). Placing a stent at the obstructed part of the colon serves as a 'bridge to surgery', allowing time to manage the emergency situation and plan for elective surgery. Emergency resection can lead to serious complications when performed in patients who are already frail and suffering from significant comorbidities (NICE 2004a). In addition, SEMS can be used for the palliative management of bowel obstruction in patients with incurable metastatic disease or those who are medically unfit for major resection (eg patients who are unable to receive anaesthesia) (ACPGBI 2007). A stent can obviate the need for surgery and may be effective for over a year, potentially providing palliation until death.

Colonic stenting can also be used to treat benign obstructions caused by conditions such as diverticular and Crohn's disease, even though colonic stents are not listed on the Australian Register of Therapeutic Goods (ARTG) for these conditions.

Colonic stents are proposed for the treatment of large bowel obstruction, stricture or stenosis in the following patient populations:

- Patients diagnosed with colorectal cancer or cancer of an organ adjacent to the bowel:

- stent used as a palliative measure for patients with incurable malignant large bowel obstruction and either acute or chronic comorbidities, with or without metastasis;

- stent used as a bridge to surgery in cases where the patient's condition improves after insertion of a stent and subsequent surgical management is indicated.

- Patients with large bowel obstruction of unknown diagnosis. This group of patients may not always be known to have cancer at the time of the bowel obstruction. Thus, patients with non-malignant causes of obstruction such as Crohn's disease and diverticulitis may also form part of this population;

  - stent used as a palliative measure for patients with incurable malignant or non-malignant obstruction with either acute or chronic comorbidities, with or without metastasis;

  - stent used as a bridge to surgery, in cases where the patient's condition improves after insertion of a stent and subsequent surgical management is indicated.

The subsequent surgical management of any patient receiving a colonic stent may include curative surgery, non-curative surgery, single-stage resection or a multi-stage procedure.

For the purposes of this assessment, patients who are eligible for single-stage colorectal resection should receive this option, where appropriate; therefore, the use of stents is not indicated in this population.

Clinical need

Colorectal cancer is the second most common cancer in Australia. In 2007, prostate cancer was the most common cancer reported (19,403 new cases), followed by bowel cancer (14,234 new cases) and breast cancer (12,670 new cases) (AIHW 2010). In the same year, lung cancer was the leading cause of death from cancer in Australia, causing 7,626 deaths, while colorectal cancer took the lives of 4,047 Australians. The incidence of colorectal cancer in 2007 was 13.1 per cent (12.6% for men and 13.9% for women) of the overall cancer incidences. According to the Australian Institute of Health and Welfare (AIHW), the incidence of colorectal cancer increased from 67 to 75 cases per 100,000 in men and from 50 to 55 cases per 100,000 in women during the period from 1982 to 2007 (AIHW 2010). The Interactive National Hospital Morbidity Data confirms the utilisation of 12,919 patient days for malignant neoplasm of the colon during the 1998 to 1999 period. This has increased annually to 19,037 patient days during the 2007 to 2008 period (AIHW 2011).

Potential utilisation

The Colorectal Surgical Society of Australia and New Zealand (the applicant) has calculated an annual rate of stent deployment using data from the Australian Cancer Registry (AIHW 2004). Accordingly, out of the 14,000 new cases of colorectal cancer diagnosed annually, approximately 2,800 (about 20%) are estimated to present with obstruction. Nearly 2,100 (approximately 75%) of these patients will have malignancies in the left colon, which are amenable to endoscopic management. Among this group of patients, approximately 700 would have metastatic disease and another 400 would be medically unfit for single-stage surgery. Thus, approximately 1000 patients would be

eligible for colonic stenting each year. Allowing for local variability in expertise and facilities, as well as individual surgeon and patient preferences, it is reasonable to assume an annual stent deployment rate of between 575 and 625.

According to the Colorectal Surgical Society of Australia and New Zealand, colonic stenting would replace emergency abdominal surgery in 90 per cent of cases. After stenting, about 10 per cent of patients would require surgery for failed stent placement, while a further 10 per cent will return for definitive surgery after initial decompression. Assuming a technical success rate of 90 per cent, it is estimated that there would be 550 fewer emergency abdominal procedures performed for large bowel obstruction per year. Approximately 10 per cent of the stents currently deployed are used as a bridge to surgery, these patients will ultimately return for single-stage resection. Previously, the majority of these patients would have required two separate surgeries.

Existing procedures

Surgical management

Surgical resection is currently the gold standard treatment for managing colorectal obstruction. It may be carried out as a one-stage, two-stage or even three-stage procedure. For right- and left-sided malignancies, a hemi-colectomy with primary anastomosis is preferably performed as a one-stage procedure: the diseased section of bowel is excised, and the free ends of the bowel are re-joined during the same procedure to restore bowel function (Breitenstein et al 2007).

Single-stage resection and anastomosis (primary anastomosis) is the preferred treatment option for large bowel obstruction, but not all patients or tumours are candidates for single-stage surgery (Dauphine et al 2002). This may relate to various factors including patient comorbidity, tumour stage or size, and the expertise of the surgeon.

In general, a two-stage procedure involves resecting the diseased bowel (Hartmann's resection) and creating a stoma, in which one end of the colon is drawn through the abdominal wall and sutured in place (colostomy). A second operation is then performed at a later date to restore bowel continuity. Hartmann's resection is commonly performed when the obstruction is left-sided, the patient is comparatively fit for surgery or the cancer is not too advanced. Colostomy is generally performed when the obstruction is right-sided, the patient is unfit for single-stage resection due to severe comorbidities or the cancer is too advanced. Hartmann's resection and colostomy are usually employed as staged procedures for palliative purposes in patients with obstructive colonic lesions. Alternatively, the stoma may be closed during a third procedure (De Salvo et al 2002). The three-stage procedure involves diversion of faecal matter by colostomy to decompress the dilated bowel (isolated stoma formation), followed by colonic resection and, as a third step, closure of the colostomy (Breitenstein et al 2007).

Single-staged resection (primary anastomosis) is performed under general anaesthesia as open surgery (laparotomy). Hartmann's resection is performed under general anaesthesia, whereas stoma creation can be performed under general or regional anaesthesia. Hartmann's resection and colostomy can be performed via laparotomy or laparoscopy.

Patients with colorectal obstruction that is secondary to a malignancy usually present as a surgical emergency. Consequently, these patients are often already frail as a result of their underlying disease and are not eligible to undergo an invasive single-stage procedure

without adequate bowel preparation. Single-stage resection performed in an emergency setting also carries a greater risk of morbidity than an elective procedure (De Salvo et al 2002; McArdle and Hole 2004). Therefore, surgery to relieve colonic obstruction is usually performed in two or three stages when possible, particularly for patients who have non-resectable metastatic disease or are unfit for single-stage resection (Gainant 2012).

Most patients who are in the terminal stage of cancer and have received a staged resection never have the colostomy reversed (Mauro et al 2000). Nonetheless, stoma creation has a deleterious effect on the psychological wellbeing of patients and can be a burden to patients, as well as their carers, during the final months of life (Karadag et al 2003).

Common adverse events associated with surgical resection include bleeding, leakage, wound dehiscence, infection, abscess, peritonitis, parastomal hernia, paralytic ileus, fistulisation, prolapse, necrosis, stoma retraction, skin irritation around the stoma and damage to neighbouring organs (eg urethral injury). Stoma creation has a mortality risk of up to 24 per cent (Deans et al 1994; Martinez-Santos et al 2002).

Best supportive care

While the majority of patients with malignant colonic obstruction are eligible for surgical intervention, patients who are medically unfit for surgery would receive best supportive care. Supportive care for cancer patients comprises multidisciplinary attention to a patient's overall physical, social, psychosocial, spiritual and cultural needs regardless of whether the anti-cancer treatment being administered as curative or palliative. This helps patients to maximise the benefits of their treatment and to live as comfortably as possible (Ahmedzai et al 2001; NICE 2004a; NICE 2004b). For patients with advanced gastrointestinal cancer, best supportive care aims to prolong survival and improve quality of life through a combination of chemotherapy, radiotherapy, palliation and ongoing medical management (Ahmed et al 2004; NICE 2004b) that is based on individual needs. Thus, it is possible for some patients receiving best supportive care to improve during this treatment.

Other management

Endoscopic ablation techniques, such as cryotherapy, electrocoagulation, argon plasma coagulation, photodynamic therapy and neodymium-yttrium-argon-garnet laser therapy have also been used to treat colorectal obstruction (Kimmey 2004). Laser therapy can restore bowel patency when used on its own, but obstruction usually reoccurs quite rapidly. Balloon dilation and decompression drainage tubes are other alternative treatments for managing colorectal obstruction (Tanaka et al 2001). However, the Protocol Advisory Sub-Committee (PASC) and Health Expert Standing Panel (HESP) confirmed that these treatment options are rarely used in Australia, and, hence, were not considered as comparators for this review.

Marketing status of metallic stents

The metallic stents approved for use in Australia are listed in Table 17. The stent that was named as part of the current submission is ARTG 119517, which is estimated to have an 85 per cent share of the Australian market. Expert clinical opinion suggests that there is little clinical difference between the stents currently available in Australia.

However, while some of the listed stents may be used for obstruction caused by unspecified malignancy (ARTG 119517 and 157191), other stents are restricted to use in the case of obstructions caused specifically by colorectal cancer (ARTG 139317, 144564 and 167223). Duodenal stents are also listed on the ARTG, but these are not appropriate for use in the treatment of colorectal obstructions.

Table 17 TGA approved stenting devices and systems for treating colorectal obstruction

ARTG No.	Manufacturer/ importer/sponsor	Device name[b]	GMDN	Intended purpose
119517	Boston Scientific Pty Ltd[a]	Ultraflex™ Precision Colonic Stent System	38442 Unclassified	Palliative treatment of gastro-duodenal obstructions and colonic strictures produced by malignancy.
119517	Boston Scientific Pty Ltd[a]	Wallstent® Colonic Endoprosthesis		
119517	Boston Scientific Pty Ltd[a]	WallFlex™ Colonic Stent		
157191	William A. Cook Australia Pty Ltd	Cook Colonic Z-Stent® with induction system	37847 Colonic stent	Palliative treatment for colonic, duodenal or gastric obstruction, or strictures caused by malignant neoplasm, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.
139317	William A. Cook Australia Pty Ltd	N/R	37847 Colonic stent	Maintain patency of malignant colonic strictures.
144564	Endotherapeutics Pty Ltd	N/R	37847 Colonic stent	Palliative treatment of colonic strictures caused by malignant neoplasm in the rectum, sigmoid colon and descending colon.
167223	Device Technologies Australia Pty Ltd	N/R	37847 Colonic stent	Implanted for pre-operative obstruction relief prior to removal of colo-rectal carcinoma, designed to maintain the patency of colo-rectal strictures caused by malignant tumour.

a WallFlex™ Colonic Stents are new generation stents and account for 85% of the Australian market share. Ultraflex™ and Wallstent® are first generation stents
b All the devices are metallic stents, mainly SEMS. They can be covered or uncovered-uncovered stents are most commonly used in Australia.
GMDN: Global Medical Device Nomenclature; N/R: not reported.
Source: Watt et al 2007

Current reimbursement arrangements

Surgical resection is currently the standard treatment for managing colorectal obstruction. Acute obstruction secondary to colorectal cancer is considered a surgical emergency. When undertaken in the emergency setting, surgery for colorectal obstruction is associated with a higher risk to the patient than comparable elective surgery (McArdle and Hole 2004). Approximately 50 per cent of patients with malignant colorectal obstruction are eligible for curative surgical resection (Xinopoulos et al 2004).

The current MBS item numbers related to resection and management of colorectal obstruction are listed in Table 18; the number of services claimed for each of these items is listed in Table 19.

Table 18 Types of resection procedures listed on the MBS for managing colorectal obstruction

MBS item no	Type of resection procedure
30375	Caecostomy, Enterostomy, Colostomy, Enterotomy, Colotomy, Cholecystostomy, Gastrostomy, Gastrotomy, Reduction of intussusception, Removal of Meckel's diverticulum, Suture of perforated peptic ulcer, Simple repair of ruptured viscus, Reduction of volvulus, Pyloroplasty (adult) or Drainage of pancreas Fee: $501.50 Benefit: 75% = $376.15
32009	TOTAL COLECTOMY AND ILEOSTOMY Fee: $1,312.90 Benefit: 75% = $984.70
32024	RECTUM, HIGH RESTORATIVE ANTERIOR RESECTION WITH INTRAPERITONEAL ANASTOMOSIS (of the rectum) greater than 10 centimetres from the anal verge excluding resection of sigmoid colon alone not being a service associated with a service to which item 32103, 32104 or 32106 applies Fee: $1,312.90 Benefit: 75% = $984.70
32025	RECTUM, LOW RESTORATIVE ANTERIOR RESECTION WITH EXTRAPERITONEAL ANASTOMOSIS (of the rectum) less than 10 centimetres from the anal verge, with or without covering stoma not being a service associated with a service to which item 32103, 32104 or 32106 applies Fee: $1,756.15 Benefit: 75% = $1,317.15
32026	RECTUM, ULTRA LOW RESTORATIVE RESECTION, with or without covering stoma, where the anastomosis is sited in the anorectal region and is 6cm or less from the anal verge Fee: $1,891.20 Benefit: 75% = $1,418.40
32033	RESTORATION OF BOWEL following Hartmann's or similar operation, including dismantling of the stoma Fee: $1,450.30 Benefit: 75% = $1,087.75

MBS: Medicare Benefits Schedule.
Note: All fees as of April 2011.

There has been an increase in the utilisation of services related to colonic obstruction from 1997 to 2010 (See Table 19). However, the MBS item numbers for these services could also be used for other indications, including diverticular disease, pelvic abscess, Crohn's disease and trauma, in addition to malignant bowel obstructions. The Colorectal Surgical Society of Australia and New Zealand (the applicant) has stated that the vast majority of bowel resections are performed for elective resection of non-obstructive bowel cancer. As the same item numbers are used for emergency procedures, there is no way of determining from these data the specific number of bowel resections performed for malignant colorectal obstruction, or the proportion performed in the emergency or elective setting. Use of each item number could also depend on the degree of obstruction and its cause, the condition of the patient, the severity of disease and the preferences and expertise of the surgeon.

Table 19 The number of services claimed for each MBS item number

Financial year	30375	32024	32033	32009	32025	32026	Total
2009/10	2,316	1,698	324	128	1,032	821	6,319
2008/09	2,196	1,717	332	129	995	808	6,177
2007/08	2,073	1,793	329	107	1,005	885	6,192
2006/07	1,987	1,714	291	119	988	828	5,927
2005/06	1,902	1,692	310	108	949	753	5,714
2004/05	1,931	1,624	298	113	964	719	5,649
2003/04	1,882	1,541	267	110	890	668	5,358
2002/03	1,934	1,559	281	90	879	665	5,408
2001/02	1,969	1,502	283	98	852	641	5,345
2000/01	2,041	1,378	220	97	836	597	5,169
1999/2000	2,032	1,300	233	64	686	459	4,774
1998/99	1,948	1,249	237	80	650	516	4,680
1997/98	1,981	1,152	286	84	687	434	4,624

Approach to assessment

Objective

The objective of this assessment is to determine whether there is sufficient evidence in relation to safety, effectiveness and economic considerations for the use of metallic colonic stents in patients with malignant colorectal obstruction.

Clinical decision pathway

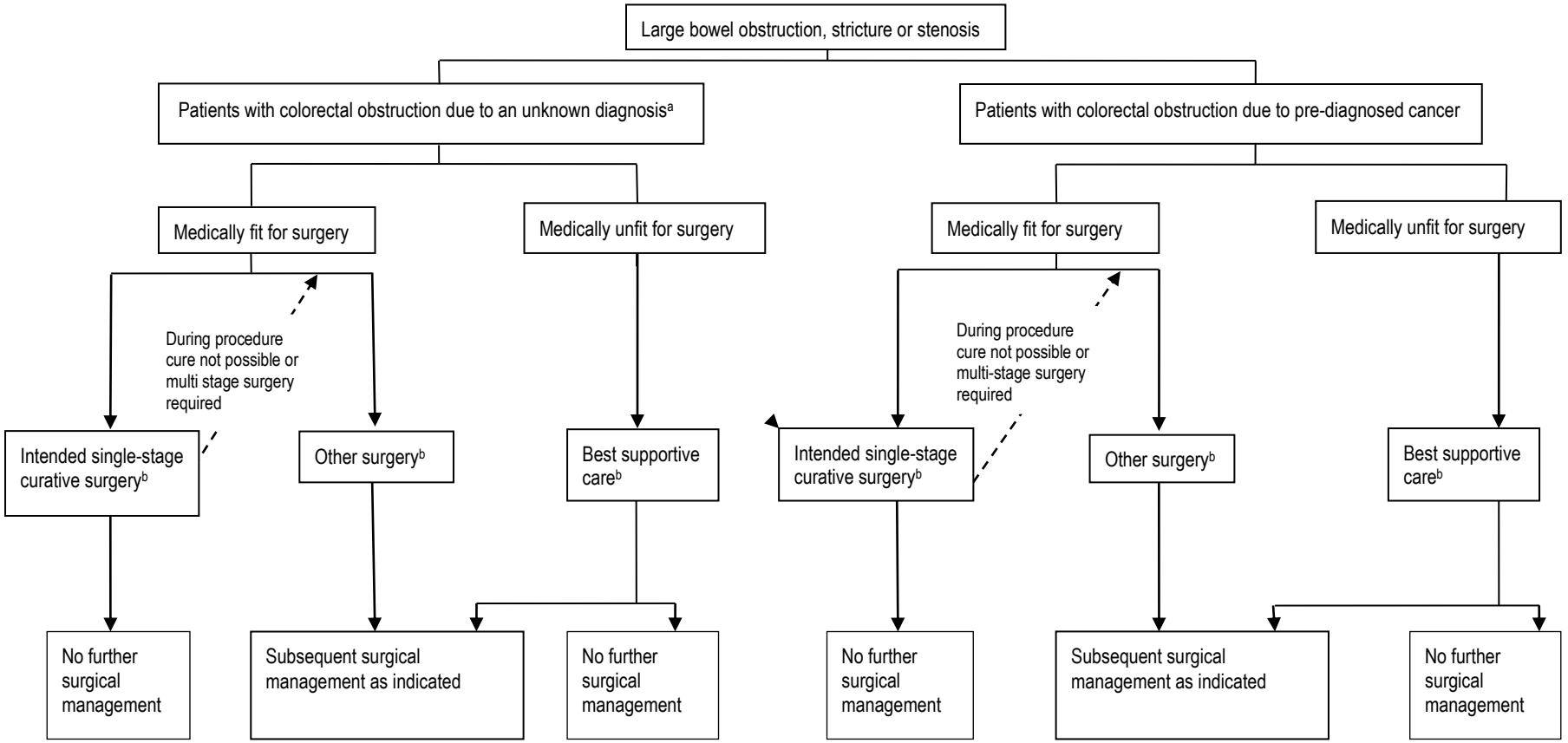
The current clinical management algorithm for patients with intestinal obstruction caused by colorectal cancer is shown in **Error! Reference source not found.**. The proposed clinical management algorithm with the addition of stenting follows in Figure 6. To make interpretation of the flowcharts meaningful, the population with the relevant medical condition is divided into those with colorectal obstruction (stricture or stenosis) due to a previously diagnosed cancer, and those with obstruction (stricture or stenosis) due to an unknown cause. Although the clinical management algorithms appear similar for these two patient populations, this division helps reflect differences in the proportion of patients suitable for each individual pathway.

In the flowcharts, each population has been further divided into two sub-populations: those who are medically fit for surgery and those who are not. Among patients who are medically fit for surgery, two groups have been identified: patients for whom single-stage surgery (resection) is performed as a curative procedure and those for whom some other form of surgery is required. However, the algorithms include the possibility of movement to another form of surgery if the intended single-stage surgery needs to be changed for some reason during the procedure. Insertion of a stent is not an alternative for patients who are cured through single-stage surgery (Figure 6). Insertion of a stent is included as a relevant option for all other patients who are medically fit for surgery.

Best supportive care (with any combination of chemotherapy, radiotherapy or palliation) is currently the only option for patients who are medically unfit for surgery. Insertion of a stent is an alternative to best supportive care (Figure 6). Patients receiving best supportive care could still improve due to ongoing active medical management.

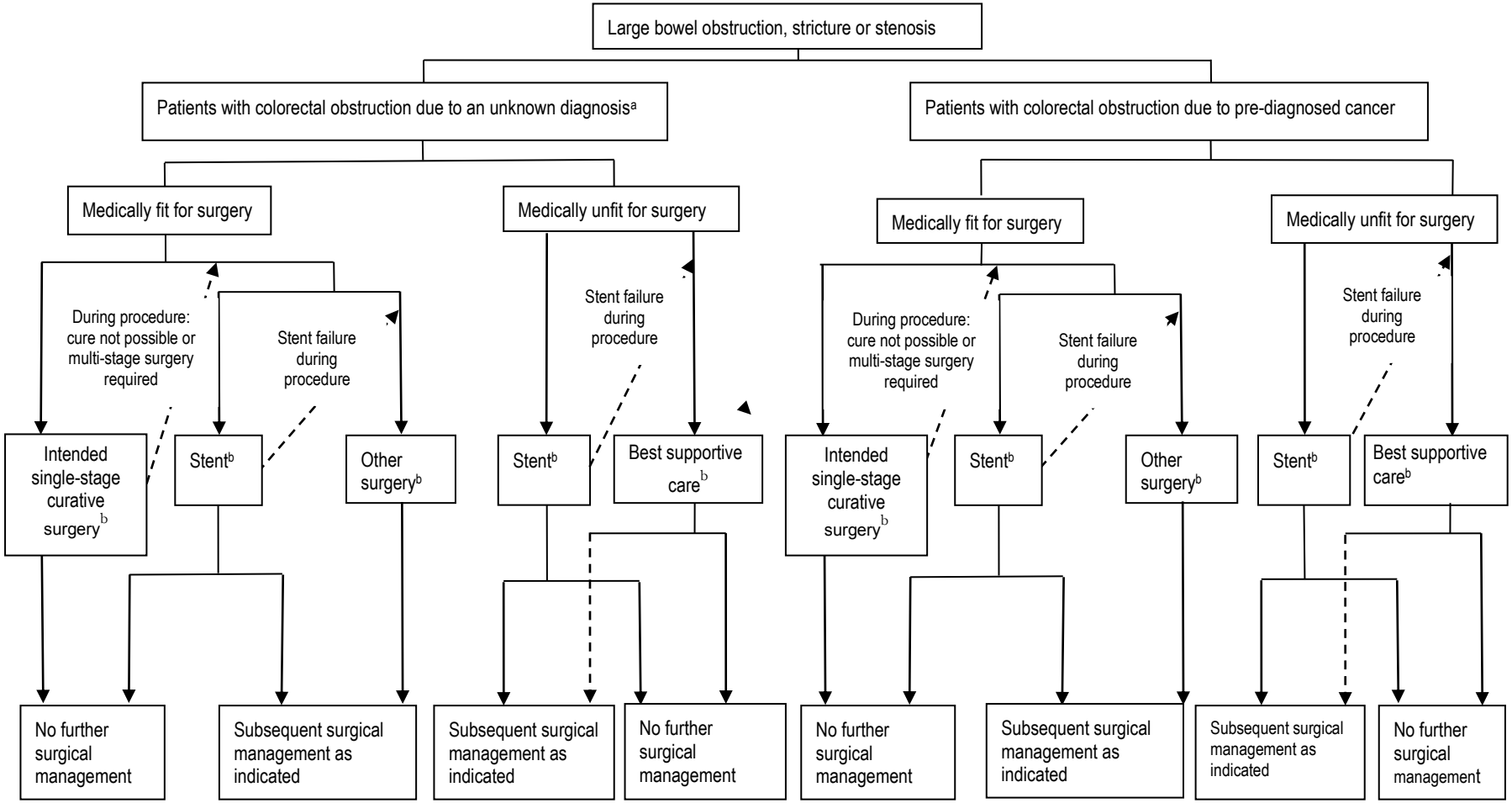
It is important to note that patients are likely to receive or continue receiving medical management following stent deployment, which consists of chemotherapy, radiotherapy, palliation and/or a combination of various medical treatments. The type and combination of medical management received is individually based and depends on the patient's medical status. Following an unsuccessful stent deployment, patients usually receive a colostomy or Hartmann's resection if they were to undergo surgery. When stent deployment is unsuccessful due to bowel perforation, the patient would undergo a corrective Hartmann's resection. If the stent needs to be removed because of a complication, this is also charged as a Hartmann's resection. Alternatively, if the stent migrates beyond the obstruction then it is likely to simply fall out.

Figure 5 Current clinical management algorithm



Other surgery: Two- and three-stage resection techniques used to treat colorectal obstructions, strictures or stenosis. Hartmann's procedure and primary anastomosis could be performed alone or together with staged surgical resection. Current MBS-listed surgical resection techniques are listed in Table 4.
Subsequent surgical management: Any surgical intervention including single-stage surgery and 'other' surgery.
Best supportive care: Conservative or clinical management of symptoms without surgical intervention.
a This group may include up to 25% of patients with colonic obstruction due to non-malignant aetiologies, such as diverticulitis and Crohn's disease.
b Patients receive chemotherapy, radiotherapy and/or palliation in addition to ongoing medical management. The type and combination of treatments received is individually based.

Figure 6 Proposed clinical management algorithm



Other surgery: Two- and three-stage resection techniques used to treat colorectal obstructions, strictures or stenosis. Hartmann's procedure and primary anastomosis could be performed alone or together with staged surgical resection. Current MBS-listed surgical resection techniques are listed in Table 4. Subsequent surgical management: any surgical intervention including single-stage surgery and 'other' surgery.
Best supportive care: Conservative or clinical management of symptoms without surgical intervention.
a This group may include up to 25% of patients with colonic obstructions due to non-malignant aetiologies such as diverticulitis and Crohn's disease.
b Patients receive chemotherapy, radiotherapy and/or palliation in addition to ongoing medical management. The type and combination of treatment received is individually based.

Comparator

Insertion of colonic stents as bridge to surgery or definitive palliative procedure was compared with the following two major branches of surgical and medical management:

- Surgical management (other surgery)

  Surgical resection can be carried out as a one-, two- or even three-stage procedure. Hemi-colectomy with primary anastomosis is ideally performed as a one-stage procedure, where appropriate, and is not a comparator to colonic stenting.

  When single-stage resection is not an option, 'other surgery', which includes two- or three-stage resection, mainly colostomy (stoma creation) and Hartmann's procedure, is performed (De Salvo et al 2002).

- Best supportive care

  Best supportive care regimens comprise a suitable combination of chemotherapy, radiotherapy and/or palliation. Patients receiving supportive care may still improve sufficiently to become eligible for surgery at a later date.

Research questions

Population 1

In patients (>17 years of age) with colorectal obstruction due to an unknown diagnosis who are medically fit for surgery, what is the safety, effectiveness and cost-effectiveness of colonic stenting with or without active medical management (eg chemotherapy) compared with 'other surgery' (with or without chemotherapy)?

Population 2

In patients (>17 years of age) with colorectal obstruction due to an unknown diagnosis who are medically unfit for surgery, what is the safety, effectiveness and cost-effectiveness of colonic stenting with or without active medical management (eg chemotherapy) compared with best supportive care (with or without chemotherapy)?

Population 3

In patients (>17 years of age) with colorectal obstruction due to confirmed cancer who are medically fit for surgery, what is the safety, effectiveness and cost-effectiveness of colonic stenting with or without active medical management (eg chemotherapy) compared with other surgery (with or without chemotherapy)?

Population 4

In patients (>17 years of age) with colorectal obstruction due to confirmed cancer who are medically unfit for surgery, what is the safety, effectiveness and cost-effectiveness of colonic stenting with or without active medical management (eg chemotherapy) compared with best supportive care (with or without chemotherapy)?

Review of literature

Literature sources and search strategies

Medical literature searches were conducted in five bibliographic databases: PubMed, EMBASE, CINAHL, *The Cochrane Library* and the Centre for Reviews and Dissemination (CRD) of the University of York databases. In addition, the websites of health technology assessment (HTA) agencies were also searched, a complete list of these websites is provided in Appendix C. Potentially relevant studies were identified from the inception of the databases to 15 September 2011. The bibliographies of all included studies were hand-searched for any relevant references that may have been missed by the literature searches (pearling).

The search terms used to identify relevant literature from the databases on the safety and effectiveness of colonic stents are listed in Appendix B. Similar text words, indexing terms and Boolean operators were employed when searching HTA websites.

Table 20 Search terms used to identify relevant literature

Area of enquiry	Search terms
Intervention	MeSH headings Stents Text words Stent*, SEMS, Ultraflex, Wallstent, Wallflex, Z-stent, Z stent, Zstent
Medical condition	MeSH headings Intestinal obstruction Constriction, pathologic Text words Obstruct*, stricture*, stenos*, narrow*
Localisation	MeSH headings Intestine, Large Text words Intestin*, bowel, colorectal, colon*, rectal, rectum

MeSH: Medical Subject Headings; SEMS: self expanding metallic stent;

Selection criteria

The inclusion and exclusion criteria used in this assessment are listed in Table 21. These criteria were formulated in consultation with clinical experts, who provided input throughout the process of protocol development and assessment based on preliminary scoping searches.

Table 21 Selection criteria for included studies

Characteristic	Inclusion criteria	Exclusion criteria
Study design and publication type	Systematic reviews, meta-analyses, and comparative clinical studies (including randomised and non-randomised comparative studies). Pre-test/post-test case series (level IV evidence) studies of relevance to the Australian context with consecutive patient enrolment and a minimum of 50 participants will be included to address safety.	Case series (level IV studies) reporting on use of conventional treatment without deployment of stent, case series (level IV studies) with non-consecutively selected patients, narrative reviews, case reports, articles identified as preliminary reports where results are published in later versions, articles in abstract form, letters, editorials, and animal, in vitro and laboratory studies.
Population	Patients with colorectal obstruction, stricture or stenosis caused by an **unknown diagnosis**[a], **medically fit** for emergency surgery, but single-staged emergency resection is not appropriate or not successful. Patients with colorectal obstruction, stricture or stenosis caused by an **unknown diagnosis**[a], **medically unfit** for surgery. Patients with colorectal obstruction, stricture or stenosis caused by **confirmed cancer**, **medically fit** for surgery, but single-staged resection is not appropriate or unsuccessful. Patients with colorectal obstruction, stricture or stenosis caused by **confirmed cancer**, **medically unfit** for surgery.	Patients who are deemed medically fit for single-stage resection.
Intervention	Metallic stents, including SEMS and uncovered stents, either as a bridge to surgery, or as a definitive procedure (that is stent is used as a palliative intervention).	Non-metallic stents Absorbable stents Oesophageal stents Gastric stents Duodenal stents Anal stents/tubes
Comparator	Other surgery: Two- and three-staged resection techniques used in managing colorectal obstructions, strictures or stenosis. Hartmann's procedure and anastomosis could be performed by themselves or together with staged surgical resections. Best supportive care: Any combination of ongoing medical management (chemotherapy, radiotherapy or palliation) is included.	Single-stage resection
Outcome	Effectiveness: Primary outcome: Quality of life (QALY). Secondary outcomes: Survival/mortality (eg at 30 days), technical/clinical success, morbidity, avoidance of emergency surgery, hospital and ICU stay, operating time, avoidance of multi-stage surgery, temporary or permanent relief of obstruction, patency, re-stenting. Safety: all complications and adverse events.	None
Language	English language articles.	None

a This group may include less than 25% of patients with colonic obstructions of non-malignant aetiologies such as diverticulitis and Crohn's disease

Systematic reviews were included only if they met all of the following criteria (Cook et al 1997):

- focused clinical question;

- comprehensive sources and explicit search strategy;
- use of explicit, reproducible and uniformly applied criteria for article selection;
- rigorous critical appraisal of included studies; and
- qualitative or quantitative data synthesis.

Comparative evidence was considered regardless of the presence or absence of randomisation. Both prospective and retrospective comparative studies were included in the assessment.

Case series (level IV) studies were included for the safety analysis only. Case series studies with a minimum of 20 participants were considered to be of relevance to the Australian context. Literature that also suggested 'there is a steep learning curve for use of SEMS in the management of colorectal obstruction, and therefore at least 20 cases required for the operator to be considered as experienced' (Williams et al 2010). Since there were an unmanageable number of case series studies with a minimum of 20 participants, only those with a minimum of 50 patients were included for this assessment. To be included, the case series studies also needed to assess the outcomes of consecutively enrolled patients within a definite time frame.

Case reports were excluded.

Search results

The numbers of reference citations retrieved from each bibliographic database is listed in Table 22.

These citations were imported into a Reference Manager database (ISI ResearchSoft). A total of 4,074 results were imported and 1,115 duplicates were removed. Of the remaining 2,959 citations, 476 non-English articles were excluded and 2263 studies were excluded by one reviewer based on their abstracts. If there was any doubt about whether to include a study after reading the abstract, the full text article was retrieved for further examination. Most of the narrative reviews, case reports, preliminary reports, conference abstracts, letters, editorials and animal, in vitro and laboratory studies were removed from the database at this stage. The full-text versions of the remaining 220 citations were retrieved for further analysis.

Table 22 Search results from electronic databases searched

Database	No of search results
PubMed	1,597
Embase	2,286
CINAHL*	98
The Cochrane Library	69
CRD	24
Total no of papers	4,074

CINAHL: Cumulative Index to Nursing and Allied Health Literature; CRD: Centre for Reviews and Dissemination

Study selection process

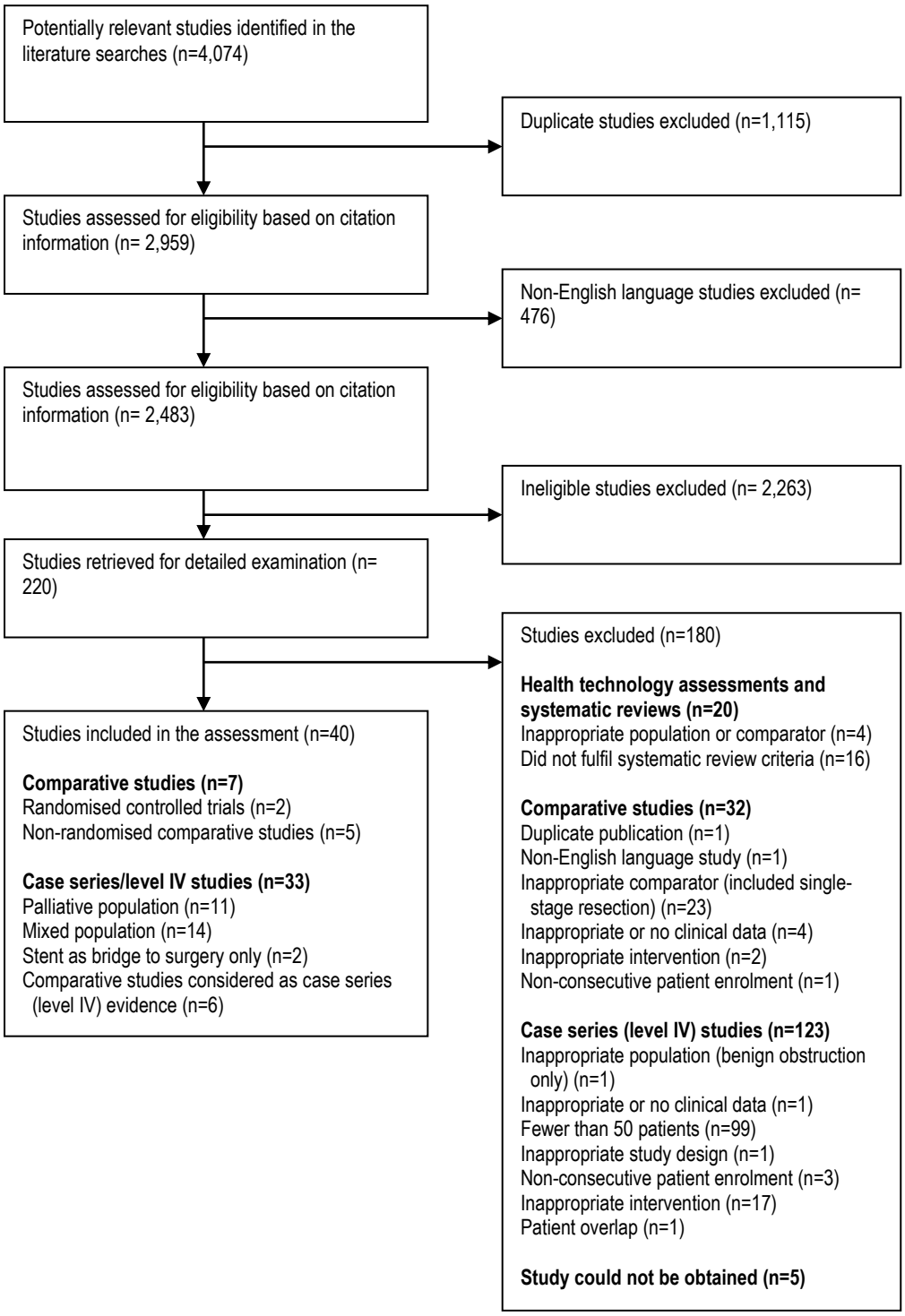
Full-text articles were carefully assessed against the inclusion criteria by one reviewer. If there was any doubt about whether to include a study, it was referred to a second reviewer for assessment. In such cases, decisions about inclusion were made by consensus after discussion between the two reviewers. The study selection process is depicted in Figure 7.

Where there were two or more systematic reviews with identical comparators and patient populations, only the most recently published systematic review was included unless it was less comprehensive than the earlier review. In addition, eligible randomised controlled trials (RCTs) that were published after the search end date of the most recent systematic review were included.

If no suitable systematic reviews on the topic were available, RCTs and non-randomised comparative studies were selected for inclusion. When multiple publications of the same study were identified, the latest and most comprehensive version was retrieved and the duplicates were excluded.

The 40 studies that met all of the inclusion criteria are listed in Appendix D. Ineligible studies and the reasons for their exclusion are listed in Appendix H. The reasons for excluding 180 studies at the final stage of the selection process are listed in Appendix I.

Figure 7 Summary of the process used to identify and select studies for the review



Adapted from Liberati et al 2009

Data extraction and analysis

Data from each study were extracted into standardised data extraction tables by one reviewer and then checked by a second. Data for each of the safety and effectiveness outcomes were only extracted if they were stated in the text, tables, graphs or figures of the article, or could be accurately extrapolated from the data presented. If no data were

reported for a particular outcome, then no value was tabulated. This was done to avoid the bias caused by incorrectly assigning a value of zero to an outcome measurement on the basis of an unverified assumption by the reviewer. For example, if the procedure-related mortality rate was not reported, the result was not assumed to be zero.

Appraisal of the evidence

Appraisal of the evidence was conducted at 3 stages:

- Stage 1: Appraisal of the applicability and quality of individual studies included in the review;
- Stage 2: Appraisal of the precision, size and clinical importance of the primary outcomes used to determine the safety and effectiveness of the intervention;
- Stage 3: Integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

Validity assessment of individual studies

The evidence presented in the selected studies was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC 2009).

These dimensions consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence (See Table 23). The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of its determination.

Table 23 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.[a]
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *p*-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

a See Table 24.

Strength of the evidence

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence.

Level

The level of evidence reflects the effectiveness of a study design to answer a particular research question. Effectiveness is based on the probability that the design of the study has reduced or eliminated the impact of bias on the results.

The NHMRC evidence hierarchy provides a ranking of various study designs ('levels of evidence') by the type of research question being addressed (see Table 24).

Table 24 Designations of levels of evidence according to type of research question.

Level	Intervention[a]
I[b]	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (ie alternate allocation or some other method)
III-2	A comparative study with concurrent controls: ▪ non-randomised, experimental trial[c] ▪ cohort study ▪ case-control study ▪ interrupted time series with a control group
III-3	A comparative study without concurrent controls: ▪ historical control study ▪ two or more single arm study[d] ▪ interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

Source: NHMRC (2009)

a Definitions of these study designs are provided in NHMRC (2000) on pages 7-8.

b A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

c This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie utilise A vs B and B vs C, to determine A vs C with statistical adjustment for B).

d Comparing single-arm studies ie case series from two studies. This would also include unadjusted indirect comparisons (ie utilise A vs B and B vs C, to determine A vs C but where there is no statistical adjustment for B).

Note A: Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms are rare and cannot feasibly be captured within randomised controlled trials; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note B: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question eg level II intervention evidence, level IV diagnostic evidence, level III-2 prognostic evidence.

Quality

Included comparative studies were critically appraised for study quality according to the guidelines in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (eds Higgins and Green 2011). Included RCTs were examined with respect to the adequacy of allocation concealment and blinding (if appropriate), handling of losses to follow-up, and any other aspect of study design or execution that may have introduced bias, with reference to the Consolidated Standards of Reporting Trials (CONSORT) statement (Altman et al 2001). Non-randomised comparative studies and case series were evaluated for the method of patient selection, completeness of follow-up and any other feature of the study design or execution that may have introduced bias.

Two reviewers independently appraised each of the included studies, and any differences in interpretation were resolved through discussion. A quality score was not assigned; instead the quality of the included studies was described in a narrative fashion, and any important quality issues were highlighted in the discussion of outcomes.

Statistical precision

Statistical precision was determined using statistical principles. Small confidence intervals and *p*-values give an indication as to the likelihood that the reported effect is real and not attributable to chance (NHMRC 2000). Studies needed to be appropriately powered to ensure that a real difference between groups would be detected in the statistical analysis.

Size of effect

For the comparative studies, it was important to assess whether statistically significant differences between the treatments were also clinically important. The minimum effect size and whether the 95 per cent confidence interval included only clinically important effects were determined for each study by the study authors.

Relevance of evidence

The outcomes being measured should be appropriate and clinically relevant. Inadequately validated (predictive) surrogate measures of a clinically relevant outcome should be avoided (NHMRC 2000).

Quality of life was considered as the primary effectiveness outcome for this review. Owing to the nature of the disease, the majority of secondary effectiveness and safety outcomes evaluated were also clinically relevant.

Assessment of the body of evidence

Appraisal of the body of evidence was conducted along the lines suggested by the NHMRC in their guidance on clinical practice guideline development (NHMRC 2009). Five components are considered essential by the NHMRC when judging the body of evidence:

- the evidence base – which includes the number of studies sorted by their methodological quality and relevance to patients;
- the consistency of the study results – whether the better quality studies had results of a similar magnitude and in the same direction ie homogenous or heterogeneous findings;
- the potential clinical impact - appraisal of the precision, size and clinical importance or relevance of the primary outcomes used to determine the safety and effectiveness of the test;
- the generalisability of the evidence to the target population; and
- the applicability of the evidence - integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

A matrix for assessing the body of evidence for each research question, according to the components above, was used for this assessment (See Table 25) (NHMRC 2009).

Table 25 Body of evidence assessment matrix

Component	A Excellent	B Good	C Satisfactory	D Poor
Evidence base[a]	One or more level I studies with a low risk of bias or several level II studies with low risk of bias.	One or two level II studies with low risk of bias or an SR/multiple level III studies with low risk of bias.	One or two level III studies with low risk of bias, or level I or II studies with moderate risk of bias.	Level IV studies, or level I to III studies with high risk of bias.
Consistency[b]	All studies consistent.	Most studies consistent and inconsistency may be explained.	Some inconsistency reflecting genuine uncertainty around clinical question.	Evidence is inconsistent.
Clinical impact	Very large.	Substantial.	Moderate.	Slight or restricted.
Generalisability	Population/s studied in body of evidence are the same as the target population.	Population/s studied in the body of evidence are similar to the target population.	Population/s studied in body of evidence different to target population for guideline but it is clinically sensible to apply this evidence to target population.	Population/s studied in body of evidence different to target population and hard to judge whether it is sensible to generalise to target population.
Applicability	Directly applicable to Australian healthcare context.	Applicable to Australian healthcare context with few caveats.	Probably applicable to Australian healthcare context with some caveats.	Not applicable to Australian healthcare context.

a Level of evidence determined from the NHMRC evidence hierarchy (See Table 24).
b If there is only one study, rank this component as 'not applicable'.
Adapted from NHMRC (2009).

Expert advice: Health Expert Standing Panel (HESP)

HESP has been established as a panel of the Medical Services Advisory Committee (MSAC) and is a pool of experts collated from various medical fields who are nominated by their associated professional body or by applicants.

HESP members are engaged to provide practical, professional advice to evaluators which directly relates to each application and the service being proposed for the MBS. HESP members are not members of either MSAC or its subcommittees ESC and PASC. Their role is limited to providing input and guidance to the assessment groups to ensure that the pathway is clinically relevant and takes into account consumer interests. HESP member's advice is to inform the deliberations MSAC presents to the Minister.

Results of assessment

Health technology assessment and systematic review

There were no systematic reviews identified directly addressing the research question of the present review.

Characteristics of included studies

Table 26 and Table 27 summarised study characteristics of each included study. Appendix F, Appendix G and Appendix H summarise the data extraction.

A total of 40 primary studies were included in this assessment, of which seven were comparative and 33 were level IV studies. In no instance was a conflict of interest mentioned by the study authors.

Comparative evidence included two RCTs (Fiori et al 2004; Xinopoulos et al 2004), one level III-2 study (Nagula et al 2010) and four level III-3 studies. Three of the comparative studies were prospective while the rest were retrospective. SEMS cohorts were small in general and ranged from 11 to 30 patients only. Most authors did not specify follow-up durations. All seven comparative studies compared stents to surgical procedures. No study compared stents to best supportive care or conservative management.

Of the seven comparative studies, six included only patients with a diagnosis of confirmed malignancy, whilst one study did not report diagnosis. Additionally, of the seven studies, five did not report whether balloon dilation was performed nor whether covered or uncovered stents were used. One study reported that balloon dilation was not performed and that mixed stent types were used; a second study employed balloon dilation in all patients and only uncovered stents were used (Xinopoulos et al 2004). None of these studies reported whether adjunct medical treatment such as chemotherapy was used. The detailed inclusion criteria and patient characteristics of the studies are summarised in Appendix F and Appendix G.

A statistical analysis of the pre-operative parameters of the study groups was not carried out in any of the non-randomised comparative evidence.

The level IV evidence base included six studies that were originally designed as comparative. Their comparators were not considered relevant to our research questions and were therefore considered as level IV evidence for this assessment. Of the level IV evidence, 27 were case series. The authors of 15 studies did not indicate specific follow-up periods; while for the remaining studies, follow-up periods ranged from a few days to 1.5 years.

Within the level IV evidence base there was a large degree of variation in reporting of study patient characteristics and procedures. The present review included patients who received SEMS insertion for palliative reasons or as a bridge to surgery. These populations are generally distinct in terms of baseline morbidity and prognosis, making it difficult to generalise outcomes across all relevant patient populations. Furthermore, few authors reported whether patients were indicated for palliative treatment or as a bridge to

surgery at the time of SEMS insertion. It is possible that a number of patients initially receiving SEMS as a bridge to surgery may have died with the SEMS in place, while some patients initially receiving palliative treatment may have improved and received surgery at a later stage. Of the 33 studies, seven reported patients with both benign and malignant diagnoses, while the remainder reported patients with a malignant diagnosis only. Within those seven studies mentioned, the percentage of treated patients with a benign diagnosis did not exceed 22.4 per cent.

Nineteen of the 33 studies did not report whether the stents used were uncovered or covered, six reported using exclusively uncovered stents, while eight studies included both covered and uncovered stents. Balloon dilation was not performed in seven studies, while in 12 studies the use of balloon dilation was referred to in terms of patients undergoing balloon dilation or the type of balloon dilation used (n = NR). The remaining 14 studies did not report whether balloon dilation was performed. Of the 33 studies, 19 reported that some patients received chemotherapy as well as stenting, and a further five reported the use of stool softeners and/or laxatives post procedure. In the remaining nine studies, no co-interventions were reported. The level of detail in the reporting of these co-interventions varied significantly between studies. The characteristics of these studies are presented in detail in Appendix H.

In general, study dates of the included 40 studies spanned from 1993 to 2009, with more than half conducted during the last decade. It is noted that studies were inconsistent as to whether the diagnosis of cancer was established prior to the treatment or after. This is especially apparent when the authors did not specify their inclusion criteria for enrolment.

Table 26 Summary of included comparative studies

Study	Level of evidence[a]	Study design	Study period	N	Diagnosis of cancer[b]	Indication for the intervention	Length of follow-up
Fiori et al 2004	II	Prospective	Jan 2001 to May 2003	SEMS: 11 Colostomy: 11	11 11	Pal: 11/11 Pal: 11/11	SEMS: NR Surgery: NR
Xinopoulos et al 2004	II	Prospective	Mar 1998 to Apr 2002	SEMS: 15 Colostomy: 15	15 15	Pal: 15/15 Pal: 15/15	SEMS: mean 11 weeks (range 6-18) Surgery: NR
Nagula et al 2010	III-2	Prospective	Feb 2002 to Jul 2006	SEMS: 30 Colostomy or internal bypass: 14	30 14	Pal: 30/30 Re-anastomosis: 14/14	SEMS: 24 weeks Surgery: 24 weeks
Varadarajulu et al 2011	III-3	Retrospective	2007 to 2008	SEMS: 12 Colostomy: 24	12 24	Pal: 6/12 BTS: 6/12 Pal: NR Re-anastomosis: 5/24	SEMS: NR Surgery: Median 29 months (range 13-46 months)
Baik et al 2006	III-3	Retrospective	Apr 2000 to Jul 2008	SEMS: 18 Colostomy: 19	18 19	BTS: 18/18 Re-anastomosis: 19/19	SEMS: NR Surgery: NR
Johnson et al 2004	III-3	Retrospective	SEMS: NR Surgery: Jan 1998 to Dec 1999	SEMS: 20 Colostomy: 18	20 18	Pal: 20/20 Pal: 18/18 Re-anastomosis: 0/18	SEMS: NR Surgery: NR
Osman et al 2000	III-3	Retrospective	Apr 1997 to Apr 1998	SEMS: 16 Hartmann or dysfunctional caecostomy: 10	16 10	Pal: 10/16 BTS: 6/16 Pal: 3/10 Re-anastomosis: 7/10	SEMS: NR Surgery: NR

a NHMRC level of evidence (see Table 24).

b In some instance it is not clear whether patients were diagnosed with cancer prior to the treatment or diagnosis was established after the intervention.

BTS: Insertion of a stent/s as a bridge to surgery; N: Number of patients enrolled in the study and received a stent/s. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NA: Not applicable; NR: Not reported; Pal: Palliative/definitive stent.

Table 27 Summary of included level IV evidence

Study	Study design	N	Study period	Diagnosis of cancer[a]	Indication for the intervention	Length of follow-up
Cho et al 2011	Retrospective	136	Jan 2004 to Mar 2009	136	Pal: 96/136 BTS: 40/136	NR
De Gregorio et al 2011	Prospective	467	Jan 1998 to Dec 2007	467	Pal: NR BTS: NR	Pal: mean 15.6 months (range 1 - 25.3) BTS: NR
Karanen et al 2011	Retrospective	101	Jan 1998 to Dec 2009	101	Pal: 90/101 BTS: 11/101	Mean 91 days (range 0 - 1035)
Lee et al 2011	Retrospective	71	Jan 2000 to Dec 2008	71	Pal: 71/71	Median: 9.63 months (SD ± 10.14) (range 0.6 - 43.14)
Lepsenyi et al 2011	Retrospective	71	6-year period	NR	Pal: 64/71 BTS: 11/71	Pal: mean 18 months; BTS: NR
Mackay et al 2011	Retrospective	82	Jan 2002 to Jan 2008	67	Pal: 71/82 BTS: 11/82	NR
Meisner et al 2011	Prospective	447[b]	23 months to 33 months[c]	447	Pal: 255/447 BTS: 182/447; other: 10/447	Pal: until death BTS: 12 months
Park et al 2011	Retrospective	103	Nov 2001 to Aug 2008	103	Pal: 103/103	NR
Selinger et al 2011	Retrospective	96[d]	2000 to 2008	NR (94.8%)	Pal: 48/57 BTS: 9/57	Median: 6 months (mean 15, range 1-72)
Yoon et al 2011	Retrospective	412	Nov 2005 to Dec 2009	412	Pal: 276/412 BTS: 136/412	Pal: Mean 135 days (range 1-1160) BTS: 9 days (range 1-352)
Young et al 2011	Prospective	100	Aug 1999 to Dec 2005	93	Pal: 89/100 BTS: 11/100	Median 34.5 months (range 1-64)
Branger et al 2010	Prospective	93	Feb 2002 to Aug 2009	93	Pal: 66/93 BTS: 27/93	Pal: median 7 months (range 3 days - 37 months) BTS: median 15 months (range 12-42 months)
Kim et al 2010	Retrospective	99	May 2003 to Jan 2008	99	Pal: 52/99 BTS: 47/99	Pal: mean 100 ± 129 days (range 2-455) BTS: mean 10.3 days
Li et al 2010	Prospective	52	Apr 2001 to Oct 2007	52	BTS: 52/52	Pal: median 36 ± 12 months (range 3-70)
Moon et al 2010	Prospective	68	Jan 2004 to Feb 2006	68	Pal: 38/68 BTS: 30/68	Pal: range 23-847 days
Park et al 2010	Prospective	151	Oct 2007 to Jul 2009	151	Pal: 107/151 BTS: 44/151	NR
Small et al 2010	Retrospective	233	Apr 1999 to Apr 2008	233	Pal: 168/233 BTS: 65/233	Pal: mean 129 ± 273 days (range 1-2837) BTS: 554 ± 566.46 (range 14-2488)
Kim et al 2009	Prospective	122	Sep 2001 to Jun 2008	122	Pal: 80/122 BTS: 42/122	Mean 453 ± 512 days (range 3-2370)
Suh et al 2010	Retrospective	55	Feb 2004 to Apr 2007	55	Pal: 55/55	NR

Study	Study design	N	Study period	Diagnosis of cancer[a]	Indication for the intervention	Length of follow-up
Baraza et al 2008	Prospective	71	May 2001 to Dec 2006	NR	Pal: 56/71 BTS: 7/71	NR (5 years)
Demarquy et al 2008	Prospective	204	Sep 1994 to Sep 2006	185	Pal: 187/204 BTS: 17/204	Mean 8 months (range 1 week - 6 years)
Masci et al 2008	Prospective	72	Jan 2004 to Jul 2005	72	Pal: 54/72 BTS: 18/72	NR (30, 90 & 180 days)
Shrivastava et al 2008	Retrospective	91	Sep 1998 to Sep 2006	91	Pal: 91/91	Median 63 days (IQR 20-270 days)
Small and Baron 2008	Retrospective	85	Apr 1999 to Jun 2006	NR	NR	Mean 93 days (range 7-691)
Stenhouse et al 2009	Prospective	72	Apr 1999 to Oct 2006	72	Pal: 56/72 BTS: 16/72	NR
Alcantara et al 2007	Prospective	95	Nov 1997 to Nov 2006	92	Pal: 28/95 BTS: 67/95	NR
Jost et al 2007	Retrospective	67	Apr 1996 to Dec 2004	NR	Pal: 22/67 BTS: 45/67	NR
Lee et al 2007	Prospective	80	Jul 1998 to Sep 2005	80	Pal: 37/80 BTS: 43/80	NR
Mucci-Hennekinne et al 2007	Retrospective	67	Feb 2002 to May 2006	67	Pal: 55/67 BTS: 12/67	NR
Athreya et al 2006	Retrospective	102[e]	1998 to 2004	99	Pal: 90/102 BTS: 12/102	NR
Garcia-Cano et al 2006	Retrospective	175	Oct 2003 to Sep 2004	175	Pal: 79/175 BTS: 96/175	NR
Vitale et al 2006	Prospective	57	Jan 2002 to Sep 2004	57	BTS: 57/57	NR
Mainar et al 1999	Prospective	71	Oct 1993 to Dec 1996	71	BTS: 71/71	Mean 10.3 days (range 6-35 days)

a In some instances it is not clear whether patients were diagnosed with cancer prior to the treatment or whether diagnosis was established after the intervention.
b 463 patients enrolled in the study, but only 447 were evaluated. 16 patients were excluded due to inability to place a stent.
c Wallflex Colonic Spanish Registry were assessed over one year and 11 months, and Wallflex Colonic International Registry for two years and nine months.
d 96 patients 104 stenting attempts. Follow-up data were available only for 57 patients.
e 118 enrolled in the study, but only 102 were evaluated. 16 patients' records were not available.
BTS: Insertion of a stent/s as a bridge to surgery; IQR: Interquartile range; N: Number of patient enrolled in the study and received a stent/s. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NR: not reported; Pal: palliative/definitive stent; SD: Standard deviation.

Critical appraisal of randomised controlled studies

Participants

Within the group of seven comparative studies there were two RCTs which compared stenting with SEMS to surgical treatment as a palliative measure (Fiori et al 2004; Xinopoulos et al 2004). Total patient enrolment was 22 patients (11 in each group) in one study, and 30 patients (15 in each group) in the other.

Diagnosis and pathological analysis

In both studies the inclusion criteria was non-resectable malignancy. In Xinopoulos et al (2004), the malignancy was confirmed histologically. Fiori et al (2004) examined all patients by colonoscopy and CT-scan. In both studies, the aetiology of obstructing tumours and the locations of obstructions were reported.

Allocation and blinding

Fiori et al (2004) reported randomisation using random number tables. No details of blinding or allocation concealment were mentioned. Xinopoulos et al (2004) reported randomisation and double-blinding; however, the method and nature of the double-blinding was not specified and no allocation concealment was mentioned.

Interventions and outcomes

Both RCTs reported the type of stents (all SEMS) used and the surgical procedures performed. In one study cost effectiveness was assessed, whilst technical success of the procedure was reported in both studies. Fiori et al (2004) reported the following pre-specified outcomes for assessment: mean operative time, morbidity and mortality rate, canalisation of the gastrointestinal tract, restoration of oral intake and median hospital stay. Only a cost analysis was pre-specified by Xinopoulos et al (2004) in the methods. In both studies, complications of the procedure were reported; however, Fiori et al (2004) limited the reporting to the hospital stay of patients (range 2-4 days in the stenting group and 7-10 in the colostomy group), whilst Xinopoulos et al (2004) was limited due to poor reporting of outcomes.

Statistical methods

In both RCTs the pre-specified significance level, *p* values and statistical tests carried out were reported. Fiori et al (2004) analysed patient baseline demographics and concluded that the two groups did not differ significantly across Australian Society of Anaesthetists (ASA) criteria, sex or age. Xinopoulos et al (2004) compared survival distribution curves by a log-rank test. Both studies analysed results on an intention-to-treat basis.

Follow-up and losses to follow-up

Fiori et al (2004) did not report losses to follow-up, nor total follow-up time; however, median hospital stay was reported. Xinopoulos et al (2004) reported that patients underwent endoscopic surveillance every eight weeks. Patients appeared to have been followed until death for both groups and no losses to follow up were reported (See Table 26).

The length of follow-up undertaken by Xinopoulos was sufficient to capture relevant outcomes as it would appear that patients were followed until death. The follow-up period in Fiori et al (2004) was limited, as patients did not appear to have been followed after discharge; hence, the reporting of complications was restricted to the length of hospital stay.

Critical appraisal of other comparative studies

Participants

The remaining five comparative studies that were not RCTs had total patient enrolment ranging from 26 to 44 with treatment arm enrolment ranging from 12 to 30 in stenting groups and from 10 to 24 in the surgical groups. Of these five studies, one was designed prospectively and the remaining four were retrospective.

Patient selection criteria were described across all studies and were not so specific as to limit the generalisability of study results. Variance across studies was evident but in all cases included colonic obstruction with clinical signs and symptoms, with exclusion of patients with signs of peritonitis or perforation (Appendix F and Appendix G). In the studies considering only palliative patients, the inclusion criteria encompassed only patients with un-resectable or incurable malignancies.

Allocation

A non-randomised study, Osman et al (2000), compared patients treated with SEMS to a historical surgical group admitted to the author's institution under the same consultant with a similar diagnosis during the preceding 12 months.

In the prospective study by Nagula et al (2010), patient enrolment into the stenting arm or surgical arm was done on the basis of patient and physician preference for either stenting or surgery.

In a study by Johnson et al (2004), patients treated with stenting were matched to historical controls for disease and sex, in this instance the baseline demographics of the patient groups differed across age (p=0.0065) and ASA score (p=0.01). Patients in the surgical group were on average younger and with lower ASA scores.

Interventions and outcomes

All five studies detailed the stenting procedure and type of stents used (all SEMs). Similarly, all studies specified the type of surgical procedures being performed; however, procedural details were not provided. The assessed outcomes varied slightly amongst the studies; the majority of studies reported the mean survival of patients and procedural complications. All studies reported the technical success rate of stenting, and one of the five studies assessed patient quality of life (Nagula et al 2010). The cost effectiveness of stenting versus surgery was reported in two studies. All studies reported procedure-related complications (safety) and length of hospital stay (effectiveness). Similarly, in the two studies that included patients treated both palliatively and as a bridge to surgery, outcomes were not separated accordingly, making interpretation of results difficult.

Statistical methods

Four of the five studies specified the statistical tests carried out and four studies reported *p* values for selected results or patient demographics. One study gave a pre-specified significance level.

Two studies analysed results on a per protocol basis (Johnson et al 2004; Nagula et al 2010) and the remaining studies assessed patients on intention-to-treat basis. Osman et al (2000) did not specify statistical methods or provide *p* values for results or patient demographics.

Follow-up and losses to follow-up

Of the five comparative studies, two included only patients treated as a palliative measure (Johnson et al 2004; Nagula et al 2010). Nagula et al (2010) specified a follow-up period of 24 weeks with losses to follow-up of 28 patients, of which 24 were due to death. Johnson et al (2004) did not report a follow-up period.

Within the five studies, two included patients being treated as a palliative measure and as a bridge to surgery (Varadarajulu et al 2011; Osman et al 2000). Varadarajulu et al (2011) reported a mean follow-up time of 29 months (range 13-46 months), with two patients lost to follow-up in each group. Loss of follow-up in the SEMS group was due to death, whilst the reasons for loss were not reported for the surgical group. Osman et al (2000) did not report on the duration of follow-up or losses to follow-up.

In the final study (Baik et al 2006) which included only patients treated as a bridge to surgery, no follow-up or mean survival data was provided. This study did, however, provide time to surgery and duration of hospital stay after surgery or decompression.

In some instances, where patients appeared to have been followed until death, follow-up periods can be deemed appropriate; however, overall follow-up was inconsistent and poorly-reported, especially when stents were used as bridge to surgery.

Appraisal of level IV studies

Sixteen of the 33 studies included as level IV evidence were prospective and the remaining 17 were retrospective. All 33 studies were pre-test/post-test case series that enrolled subjects consecutively; six were multicentre studies. Patient enrolment ranged from 52 patients to 467 patients with patient ages ranging from 17 to 102 years of age. Mean patient age ranged from 58.84 years to 74 years and median patient age ranged from 62.2 to 78 years.

Safety and efficacy data was presented in all 33 studies; however, in terms of present assessment only safety data of level IV studies were considered.

Duration of follow-up was not consistently reported across all studies. Length of follow-up as a mean, median or range was stated definitively in 16 of the 33 studies. Amongst 14 studies where range of follow-up was specified, the duration of follow-up ranged from two days to 2,370 days. Where median follow-up times were given (five studies), the shortest median length of follow-up was seven months and the longest was 15 months. In studies that reported a mean length of follow-up (five studies) the mean ranged from 36 days to 453 days. Six studies indicated the length of follow-up as discrete time frames

(ranging from 72 hours to 18 months). In four studies, the length of follow-up was not specified; however, it was stated that patients were followed until death, subsequent surgery, complication requiring re-operation or the study end point. Of the 13 remaining studies, six appeared to have followed patients until death, subsequent surgery or study end point and in the remaining seven studies, the duration of follow-up could not be determined (See Table 27).

Within the level IV evidence, the duration of follow-up varied widely among studies. Follow-up periods of more than six months were common; however, there were a significant number of studies in which interpretation of the follow-up period was difficult, the length of follow-up may have been insufficient to capture stent-related complications, or the duration of follow-up was not apparent.

Most of the studies (27 of 33) were explicit on inclusion or exclusion criteria, while six did not specify the selection criteria. In general, patients with malignant colorectal obstruction with signs of peritonitis, severe neoplastic bleeding, suspicion of colonic perforation, colonic ischemia or stricture/cancer extending <5 cm from the anal valve were excluded from study cohorts (Appendix H).

Is it safe?

Comparative evidence (Level II & III)

Procedure-related mortality

No studies that compared stents to best supportive care were retrieved; as such, no assessment or comparison of relative mortality rates for these two treatments could be made.

Six studies comparing SEMS placement to surgical treatment (such as colostomy, Hartmann's resection and internal bypass), including one RCT, reported on procedure-related mortalities occurring within their patient cohort (See Table 28). Procedure-related mortalities were defined differently across studies. Some authors reported post-procedural mortalities, others 30-day mortality, while others described mortalities in the same hospital admission as treatment.

No post-operative mortalities were reported in the one RCT (Fiori et al 2004) and in two of the non-randomised studies that compared SEMS placement to colostomy (Baik et al 2006; Nagula et al 2010). Osman et al (2000) reported one 30-day mortality following surgery (Hartmann's resection or dysfunctional caecostomy), but no cause of death was reported. No SEMS patients were reported to have died in the post-operative period. Johnson et al (2004) reported two in-hospital deaths after SEMS placement: one was the result of a myocardial infarction in a patient with congestive cardiac failure, whilst the other was cerebrovascular-related. Two in-hospital deaths occurred following surgery, as a result of carcinomatosis. All mortalities were reported to have occurred within seven days of treatment. In the study by Varadarajulu et al (2011), one patient in the surgical cohort died of sepsis 28 days after undergoing colostomy; no mortalities after SEMS placement were reported.

Table 28 Mortality after treatment with SEMS placement and surgery: comparative studies

Study	Level of evidence	SEMS placement		Surgery		*P*-value
		n/N	Cause of mortality	n/N	Cause of mortality	
Fiori et al (2004)	II		No mortalities		No mortalities	NR
Study total		**0/11**		**0/11**		
Nagula et al (2010)	III-2		No mortalities		No mortalities	NR
Study total		**0/30**		**0/14**		
Varadarajulu et al (2011)	III-3		No mortalities	1/24	Sepsis	NR
Study total		**0/12**		**1/24**		
Baik et al (2006)	III-3		No mortalities		No mortalities	NR
Study total		**0/18**		**0/19**		
Johnson et al (2004)	III-3	1/20	Myocardial infarction with congestive cardiac failure[a]	2/18	Carcinomatosis[a]	NR
		1/20	Cerebrovascular accident[a]			
Study total		**2/20**		**2/18**		
Osman et al (2000)	III-3		No mortalities	1/10	Cause not reported	NR
Study total		**0/16**		**1/10**		

a Did not occur as a result of the intervention.
n: Events of mortality; N: Based on all patients for whom safety data was reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; SEMS: Self-expanding metallic stent.

Adverse events

No studies that compared stents to best supportive care were retrieved; as such, no assessment or comparison of relative adverse event rates for these two treatments could be made.

Six studies comparing SEMS placement to multi-stage surgical resection, including two RCTs, reported on adverse event outcomes. Types of adverse events reported varied considerably between the treatment groups, making direct comparison difficult. Adverse events reported after placement of SEMS were generally stent-related, such as migration, fracture or occlusion from tumour invasion. Adverse events after surgery were generally wound- or stoma-related, such as infection and abscess formation. Data on these events are summarised in Table 29.

Table 29 Adverse events after treatment with SEMS placement and surgery: comparative studies

Study	Level of evidence	SEMS placement		Surgery		*P* value
		n/N	Adverse event	n/N	Adverse event	
Fiori et al (2004)	II		None	1/11	Colostomy prolapse	NS
Study total		**0/11**		**1/11**		
Xinopoulos et al (2004)	II	9/15	Minor bleeding and pain	2/15	Mild leucocytosis and fever	NR
		6/15	Stent occlusion from tumour invasion			
		1/15	Stent migration			
Study total		**16/15**		**2/15**		
Nagula et al (2010)	III-2	3/30	Small bowel obstruction	3/14	Small bowel obstruction	NR
		2/30	Stent occlusion from tumour invasion	1/14	Abscess	
		1/30	Stent migration			
Study total		**6/30**		**4/14**		
Varadarajulu et al (2011)	III-3	1/12	Minor bleeding	1/24	Sepsis	0.081
				1/24	Parastomal hernia	
				1/24	Anastomotic leak	
				1/24	Peristomal abscess	
				1/24	Intra-abdominal abscess	
				1/24	Small bowel obstruction	
				1/24	Enterocutaneous fistula	
				1/24	Pelvic abscess	
Study total		**1/12**		**8/24**		
Baik et al (2006)	III-3	1/18	Perforation with abscess formation	2/19	Wound infection	0.660
		1/18	Stent migration with severe tenesmus and haemorrhage			
		1/18	Stent migration			
Study total		**3/18**		**2/19**		
Johnson et al (2004)	III-3	2/18	Stent occlusion from tumour invasion	1/18	Wound infection	NR
		1/18	Tenesmus from stent fracture			
		1/18	Perforation and peritonitis from stent fracture			
Study total		**4/20**		**1/18**		

n: Adverse events; N: Based on all patients for whom safety data was reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NS: Not stated; NR: Not reported; SEMS: Self-expanding metallic stent.

Only three studies reported a statistical comparison between treatment groups with regard to occurrence rates of adverse events, with none reporting a statistically significant

difference. Fiori et al (2004) reported that one stoma prolapsed in a surgical patient three days post-colostomy, with no statistically significant difference between the two groups concerning morbidity. Baik et al (2006) reported three occurrences of adverse events after SEMS placement compared to two after temporary stoma formation (p=0.66). Varadarajulu et al (2011) found one of 12 (8.3%) SEMS patients experienced complications compared to eight of 24 patients (33.3%) in the surgery group, which only approached statistical significance (p=0.08). However, the authors noted that no patient who underwent SEMS placement required readmission for a complication, compared to six patients who had received surgery (0% vs 25%, p=0.019).

Among the remaining studies, results were somewhat mixed. Xinopoulos et al (2004) and Johnson et al (2004) reported a higher incidence of adverse events after SEMS placement compared to surgery, while Nagula et al (2010) reported a lower rate of adverse event occurrence after SEMS placement compared to surgery. However, none of these results were compared statistically.

Non-comparative evidence (Level IV)

Procedure-related mortality

Fifteen studies reported on procedure-related mortality, while the remaining 18 studies did not report on mortalities and/or did not acknowledge explicitly that there were no mortalities. Of the 1674 patients included in these studies, 27 incidences of procedure-related mortality were reported. The procedure had a mean mortality risk of 1.6 per cent (median 1.0%; range 0-9.2%). The majority of studies, 13 out of 15 (86.7%), reported an occurrence rate for stenting-related deaths of ≤4.5 per cent (See Table 30). Athereya et al (2006), however, recorded a mean occurrence of 9.2 per cent but indicated that it is unclear whether all of these 8 patients died within 30 days due to stent related complications or other comorbidities.

According to 15 of the level IV studies, only 27 of the 75 mortalities that occurred within 30 days resulted from the procedure. These results indicate that more than 36 per cent of the mortalities reported were procedure related; however, this may overestimate the actual risk as some of the 15 level IV studies assessed may have reported only procedure-related mortalities without giving non-procedure-related deaths.

It was apparent in some cases that mortality was caused as a consequence of bowel perforation (Lepsenyi et al 2011; Mackay et al 2011; Demarquay et al 2008; Stenhouse et al 2009). Among the 27 patients who died from the procedure, five deaths appeared to be directly due to perforation. Authors did not disclose causes of the remaining 22 mortalities. Bowel perforation appeared to be the most serious adverse event of the intervention that led to procedure-related mortality.

Table 30 Summary of procedure-related mortality events reported by level IV primary studies

Study	N	n	Occurrence (%)	Details
Lee et al (2011)	71	0	0	No incidences of 30-day mortality.
Lepsenyi et al (2011)	65[a]	2[b]	3.1	Only procedure-related deaths were reported.
Mackay et al (2011)	82	1[b]	1.2	Did not list 31 long-term (>7 days) complications, and therefore could not be incorporated.
Meisner et al (2011)	447	3	0.7	3 stent-related mortalities, among 30 deaths occurred within 6 hours.
Selinger et al (2011)	80	0	0	2 deaths within 5 days, but none related to stenting.
Young et al (2011)	100	1	1.0	Out of seven 30-day mortalities, one was related to stenting.
Branger et al (2010)	93	5	5.4	Out of 11 mortalities, 5 were related to stenting.
Kim et al (2009)	116	2	1.7	Procedure-related mortality.
Suh et al (2010)	55	0	0	No stent-related mortality.
Baraza et al (2008)	63	0	0	No stent-related mortalities among 6 that occurred within 30 days and 48 that occurred within 2-40 months.
Demarquay et al (2008)	204	1[b]	0.5	Potentially due to perforation.
Stenhouse et al (2009)	64	1[b]	1.6	Potentially due to perforation.
Lee et al (2007)	80	0	0	No procedure-related deaths occurred within 7 days.
Mucci-Hennekinne et al (2007)	67	3	4.5	Stent-related mortality.
Athreya et al (2006)	87	8	9.2	It is unclear whether these 8 patients died (within 30 days) due to the stenting or comorbidity.
TOTAL (15 studies)	**1674**	**27**	**1.6**	

a N is based on the number of stenting procedures or attempts performed.
b Potentially occurred due to perforation.
n: Events of procedure-related mortality; N: Based on all patients for whom safety data were reported, regardless of the number of patients enrolled in a study, or their technical/clinical success.

Morbidity

This includes the peri-operative and post-operative morbidity of patients. Tumour growth-related adverse events were the most common, while re-obstruction, migration and bowel perforation were prominent stent-related events with an occurrence rate of more than 4 per cent. The remaining morbidities can be categorised as sensation-related events, bleeding events, infectious events, and other events such as erosion (and/or ulcer), fistula formation and adhesions. Table 31 summarises adverse events identified among the included 34 level IV studies.

Table 31 Summary of adverse events reported by studies included for assessment

Adverse event	Studies	N	n (Incidence)	Rate where reported[a] (%)	Range among reported[a] (%)
Tumour growth-related events					
Tumour ingrowth	8	925	81	8.8	3.7-12.7
Tumour overgrowth	7	469[b]	33	7.0	1.8-22.5
Stent-related events					
Re-obstruction/occlusion[c]	23	3302[b]	216	6.5	0.5-32.4
Stent migration	32	4032[b]	259	6.4	0.9-21.9
Bowel perforation[d]	32	4032[b]	167	4.1	0-14.1
Sensation-related events					
Pain and/or discomfort	11	1711[b]	70	4.1	0.5-30.0
Tenesmus[e]	6	1151[b]	35	3.0	1.0-15.4
Bleeding events					
Bleeding (minor)[f]	12	1457[b]	64	4.4	0-16.1
Bleeding (general)	9	1474[b]	8	0.5	0-2.5
Infectious events					
Bacteremia	2	318	8	2.5	1.2-3.0
Peritonitis	1	71	1	1.4	NA
Abscess	2	185	2	1.1	1.0-1.2
Sepsis	2	257	2	0.8	0.6-1.2
Other events					
Adhesions	1	71	2	2.8	NA
Erosion and/or ulcer	4	447[b]	10	2.2	1.6-3.5
Fistula formation	4	313[b]	6	1.9	1.0-4.2
TOTAL	**33**	**4103**	**NA**	**NA**	**NA**

a Calculated by pooling all studies that addressed the event
b In some studies the number of stenting attempts or procedures performed has been considered as N instead of the number of patients.
c Was a result of faecal/mucosal impaction, tumour ingrowth, tumour overgrowth, stent blockage or migration.
d In a minority of cases this could be a result of pre-interventional balloon dilation rather than the stent itself.
e A feeling of incomplete emptying of the rectum.
f Bleeding events that were explicitly noted to be minor, which had resolved spontaneously, with conservative management and/or appeared in the form of haematochezia. Haematochezia is the passage of fresh blood per anus, usually in or with stools.
n: Any stenting-related events that lead to technical or clinical failures were also incorporated where data was available; N: Based on all patients for whom safety data was reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NA: Not applicable.

Bowel perforation

Bowel perforation is a potentially serious adverse event of stenting which demands emergency surgical management. As such, it appears to be one of the three major complications related to the intervention. The majority of the level IV studies (32 of 33, 97%) addressed the event (See Table 32).

Out of the 4032 total cases incorporated, 167 perforations were noted reflecting an occurrence rate of 4.1 per cent. The median occurrence was 3.4 per cent with an

occurrence range from 0 to 14.1 per cent. In most of the studies (29 of 32, >90%) the rate of bowel perforation was below 10 per cent, and in 22 studies ≤ 5 per cent.

Out of 32 studies that recorded incidences of bowel perforation, six studies used uncovered stents only, seven studies used both uncovered and covered stents, and 19 studies did not mention the type of stent that was used. Within the six studies that used only uncovered stents, 38 perforations were recorded (n=763), while 31 perforations were reported in the studies that used both uncovered and covered stents (n=977).

It is noted that some studies did not incorporate bowel perforation into their safety analysis, if the occurrence was immediate and/or led to technical or clinical failure. However, during our analysis, such incidences were considered as adverse events and incorporated into the calculation. For example, in their safety assessments, Moon et al (2010), Cho et al (2011) and Yoon et al (2011) did not incorporate nine incidences of bowel perforation (1, 1 and 7 respectively) that occurred almost immediately after the procedure and led to technical/clinical failure.

Pre- and peri-interventional dilation appears to be associated with bowel perforation (Watt et al 2007). Fourteen studies used dilation by a balloon, Bougie or Savary-Gillard dilator, when the obstruction did not allow passage of the stent deployment system and when the stent did not expand adequately after deployment. Studies that used dilation recorded 5.1 per cent bowel perforation (n=2104), while the six studies that did not use dilation recorded a 3.4 per cent bowel perforation rate (n=522). No studies used dilation routinely.

Table 32 Summary of bowel perforation events reported by included primary studies

Author	N	Events of perforation (n)	Occurrence (%)	Type of stent (covered vs uncovered)	Dilation
Cho et al (2011)	136	3[a]	2.2	Mix	Used in ≥1
De Gregorio et al (2011)	467	11	2.4	NR	NR
Keränen et al (2011)	100	6[b]	6.0	NR	1
Lee et al (2011)	71	9[c]	12.7	Mix	Not used
Lepsenyi et al (2011)	65[d]	4	6.2	NR	NR
Mackay et al (2011)	82	2	2.4	NR	NR
Meisner et al (2011)	382	15	3.9	Uncovered	14
Park et al (2011)	103	1	1.0	Mix	1
Selinger et al (2011)	80	2	2.5	NR	NR
Yoon et al (2011)	412	15[e]	3.6	Mix	16
Young et al (2011)	100	6	6.0	NR	Used in some
Branger et al (2010)	93	3	3.2	NR	NR
Kim et al (2010)	110[d]	0	0.00	Uncovered	Not used
Li et al (2010)	50	0	0	NR	Not used
Moon et al (2010)	68	2	2.9	Mix	NR
Park et al (2010)	107	0	0	Mix	1
Small et al (2010)	233	19[f]	8.2	NR	Used in some
Kim et al (2009)	116	7	6.0	NR	55
Suh et al (2010)	55	1	1.8	Uncovered	Not used
Demarquay et al (2008)	204	8	3.9	NR	NR
Masci et al (2008)	72	1	1.4	NR	NR
Shrivastava et al (2008)	81	10	12.4	NR	2
Small and Baron (2008)	85	12	14.1	Uncovered	7
Stenhouse et al (2009)	64	4	6.2	Uncovered	NR
Alcantara et al (2007)	95	4	4.2	NR	4
Jost et al (2007)	67	6	9.0	Uncovered	10
Lee et al (2007)	80	1[g]	1.2	Mix	NR
Mucci-Hennekinne et al (2007)	67	2	3.0	NR	NR
Athreya et al (2006)	87	4	4.6	NR	1
Garcia-Cano et al (2006)	175	7	4.0	NR	Not used
Vitale et al (2006)	54	1	1.8	NR	NR
Mainar et al (1999)	71	1	1.4	NR	Not used
TOTAL (32 studies)	**4032**	**167**	**4.1**	**-**	**-**

a Includes one immediate bowel perforation that led to technical failure and two post-interventional perforations.
b Includes two early (≤7 days) perforations and four late (>7 days) events.
c Includes 4 early (<30 days) complications and 5 late (>30 days) complications.
d N based on number of stenting procedures or attempts performed.
e Includes 7 immediate (<96hrs) perforations which lead to clinical failure and 8 long-term perforations.
f Includes one intraprocedual perforation and 18 late (>7 days) perforations.
g Occurred within 7 days.
N: Based on all patients for whom safety data are reported, regardless of number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients.

Re-obstruction

Re-obstruction was the most common reported adverse event related to the intervention. Table 33 lists the studies that reported peri- and post-operative events that appear to lead to re-obstruction, stent blockage and/or occlusion. While in most cases, tumour growth and faecal (and mucosal) impactions appeared to be the leading cause for re-obstruction, there were incidences of stent migration and intestinal debris facilitating re-obstruction (Lee et al 2011; Meisner et al 2011; Li et al 2010; Moon et al 2010; Park et al 2010; Suh et al 2010; Alcantara 2007).

Re-obstructions were reported in 23 studies which consisted of a total patient base of 3302 patients. The occurrence of re-obstruction ranged from 0.5 per cent (Yoon et al 2011) to 32.4 per cent (Lee et al 2011) with a mean of 6.5 per cent, and a median of 7.7 per cent. The majority of studies, 17 of 23 (74%), reported an occurrence rate of <15 per cent. Four studies reported an incidence rate between 16 and 21 per cent (Moon et al 2010 – 16.2%; Small and Baron 2008 – 16.5%; Cho et al 2011 – 18.4%; Jost et al 2007 – 20.9%). Among the occurrences of re-obstruction, 44 were reported in the four studies that used uncovered stents only (n=589), while 73 re-obstructions were reported in the six studies that used both covered and uncovered stents (n=897).

The results of Mackay et al (2011) have not been incorporated into our calculation as the authors do not specify the number of patients who had this event during the long-term (>7 days) follow-up. The authors mentioned 31 patients who experienced long-term complications that included stent migration, stent obstruction, tenesmus, diarrhoea and faecal incontinence (Mackay et al 2011).

Lee et al (2011) reported an exceptionally high incidence of re-obstruction (32.4%). This study was followed-up for 9.63 ± 10.14 months (range, 0.6-43.14), which is considerably longer than other included studies. The authors also noted 21 events of re-obstructions caused by stent migration (7 patients), tumour outgrowth (15 patients) and ingrowth (3 patients). Six patients in whom re-obstruction developed needed palliative surgery, and another 15 patients (21.1%) were treated with a second stenting. Two patients were managed conservatively.

Three studies compared incidences of re-obstructions that occurred within seven days with those that occurred after seven days (Keränen et al 2011; Selinger et al 2011; Small and Baron 2008). Among the 27 reported events, four re-obstructions occurred within a week, and 22 occurred afterwards. This indicated that the late re-obstructions (>7 days) were nearly five times more likely to occur than the early events (<7 days). This may be due to the fact that re-obstructions occur as a result of tumour growth and stent migration, which is likely to occur over a period of time (Lee et al 2011).

In some cases re-obstruction has been managed by re-stenting. For instance, Alcantara et al (2007) managed all four incidences of re-obstruction through re-insertion of stents. Another case of re-obstruction manifested by faecal impaction was also resolved by re-stenting (Young et al 2011). The majority of patients that experienced re-obstructions were managed by re-stenting, which has been clinically successful. If re-stenting were not successful, surgical correction would be necessary to resolve the obstruction (Lee et al 2011).

Table 33 Summary of re-obstruction events reported by included primary studies

Author	N	Events of re-obstructions n	Occurrence (%)	Type of stent (covered vs uncovered)
Cho et al (2011)	136	25[a]	18.4	Mix
De Gregorio et al (2011)	467	22	4.7	NR
Keränen et al (2011)	100	8	8.0	NR
Lee et al (2011)	71	23[b]	32.4	Mix
Lepsenyi et al (2011)	65[c]	5	7.7	NR
Meisner et al (2011)	382	8	2.1	Uncovered
Park et al (2011)	103	10	9.7	Mix
Selinger et al (2011)	80	5	6.2	NR
Yoon et al (2011)	412	2	0.5	Mix
Young et al (2011)	100	6	6.0	NR
Branger et al (2010)	93	11	11.8	NR
Li et al (2010)	50	1	2.0	NR
Moon et al (2010)	68	11[d]	16.2	Mix
Park et al (2010)	107	2	1.9	Mix
Small et al (2010)	233	18	7.7	NR
Suh et al (2010)	55	8	14.6	Uncovered
Demarquay et al (2008)	204	6	2.9	NR
Small and Baron (2008)	85	14[e]	16.5	Uncovered
Alcantara et al (2007)	95	4	4.2	NR
Jost et al (2007)	67	14	20.9	Uncovered
Mucci-Hennekinne et al (2007)	67	8	11.9	NR
Athreya et al (2006)	87	2	2.3	NR
Garcia-Cano et al (2006)	175	3	1.7	NR
TOTAL (23 studies)	**3302**	**216**	**6.5**	**-**

a Includes 2 early stent re-occlusions, 1 faecal impaction and 22 late re-occlusions.
b Includes 2 cases of faecal impactions which occurred within 30 days and 21 stent obstructions which occurred after 30 days. Late obstructions caused by stent migration (n=7), tumour outgrowth (n=15), and ingrowth (n=3). Fifteen patients were treated by re-stenting and six needed palliative surgery.
c N Based on the number of stenting procedures or attempts performed.
d Includes 3 cases of faecal impactions (one of them lead to clinical failure) and 8 stent occlusions (1 within 7 days and 7 after 7 days).
e Includes 3 early (<7 days) stent occlusions, 10 late (>7 days) stent occlusions and one distal obstruction.
N: Based on all patients for whom safety data was reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients.

Stent migration

Out of the 33 level IV studies included in the safety analysis, 32 stated incidences of stent migration. This incorporated 4032 of the total 4103 patients that were included in the level IV evidence base. A total of 259 incidences of stent migration following stent insertion were reported within the follow-up periods that data was provided for (See Table 34).

The occurrence rate of migration ranged from 0.9 per cent (Kim et al 2010) to 21.9 per cent (Stenhouse et al 2009), where the mean occurrence of the event was calculated at 6.4 per cent among the 32 studies. The median rate of stent migration was 7.1 per cent. Twenty two (>68%) studies reported <10 per cent rate of migrations. The majority of studies (30 of 32; >93%) recorded <15 per cent incidence of stent migration, while Lee

et al (2007) and Stenhouse et al (2009) experienced the highest incidence rates, 16.2 per cent and 21.9 per cent respectively.

The majority of studies (18 of 32) did not mention the type of stents used. Six studies used only uncovered stents and eight studies used both uncovered and covered types. Among the studies that used uncovered stents only, 44 incidences of stent migrations occurred (n=763; 5.8% occurrence). In contrast, among the eight studies (n=1048) that used both covered and covered stents, 95 incidences of stent migration were reported (9.1% occurrence).

Ten studies provided data on time until stent migration (n=1058). Among 96 total migrations, 40 occurred within a week of stent insertion (early migration), and 56 occurred after seven days (late migration). This indicated a 41.7 per cent tendency for early occurrence, if the stent is patent to migration.

Distal migration of the stents was the most common, with the potential for spontaneous expulsion via the anus (Li et al 2010). However, the possibility of proximal migration was also noted. Garcia-Cano et al (2006) recorded two incidences of proximal migration from a total of seven incidences.

It should be noted that some studies have not incorporated stent migration into their safety analysis, if the occurrence was immediate and/or resulted in technical or clinical failure. However, during our assessment such incidences were considered as adverse events and incorporated into the calculation. For instance, Cho et al (2011) reported three incidences of stent migration leading to clinical failures and we have considered that the study experienced a total of 14 incidences of stent migration including the 11 post-interventional complications (n=136). In the same manner, Mucci-Hennekinne et al (2007) reported three cases of stent migration including one immediate migration which has been incorporated into our calculation.

Table 34 Summary of stent migration events reported by included primary studies

Author	N	Events of migration (n)	Occurrence (%)	Type of stent (covered vs uncovered)	Length of follow-up	Time of migration[a]	
						Early	Late
Cho et al (2011)	136	14[b]	10.3	Mix	NR	3	11
De Gregorio et al (2011)	467	32	6.8	NR	Pal: mean 15.6 months (range 1 - 25.3); BTS: NR	NR	NR
Keränen et al (2011)	100	4	4.0	NR	Mean 91 days (range 0 - 1035)	0	4
Lee et al (2011)	71	9[c]	12.7	Mix	Median 9.63 months (SD ± 10.14)(range 0.6 - 43.14)	NR	NR
Lepsenyi et al (2011)	65[d]	1	1.5	NR	Pal: mean 18 months; BTS: NR	NR	NR
Mackay et al (2011)	82	6	7.3	NR	NR	NR	NR
Meisner et al (2011)	382	7	1.8	Uncovered	Pal: until death; BTS: 12 months	NR	NR
Park et al (2011)	103	15	14.6	Mix	NR	NR	NR
Selinger et al (2011)	80	10[e]	12.5	NR	Median 6 months, mean 15 (range 1 - 72)	3	7
Yoon et al (2011)	412	21	5.1	Mix	Pal: mean 135 days (range 1 - 1160); BTS: 9 days (range 1 - 352)	NR	NR
Young et al (2011)	100	1	1.0	NR	Median 34.5 months (range 1 - 64)	NR	NR
Branger et al (2010)	93	3	3.2	NR	Pal: median 7 months (range 3 days - 37); BTS: median 15 months (range 12 - 42)	NR	NR
Kim et al (2010)	110[d]	1	0.9	Uncovered	Pal: mean 100 ± 129 days (range 2 – 455); BTS: mean 10.3 days	NR	NR
Li et al (2010)	50	4[f]	8.0	NR	Pal: median 36 ± 12 months (range 3 - 70)	NR	NR
Moon et al (2010)	68	7	10.3	Mix	Pal: range 23 - 847 days	3	4
Park et al (2010)	107[g]	12	11.2	Mix	NR	NR	NR
Small et al (2010)	233	18	7.7	NR	Pal: mean 129 ± 273 days (range 1 – 2837); BTS: 554 ± 566.46 days (range 14 - 2488)	2	16
Kim et al (2009)	116	7	6.0	NR	Mean 453 ± 512 days (range 3 - 2370)	NR	NR
Suh et al (2010)	55	6	10.9	Uncovered	NR	5	1

Author	N	Events of migration (n)	Occurrence (%)	Type of stent (covered vs uncovered)	Length of follow-up	Time of migration[a]	
						Early	Late
Baraza et al (2008)	71[d]	4	5.6	Mix	NR (5 years)	NR	NR
Demarquay et al (2008)	204	4	2.0	NR	Mean 8 months (range 1 week - 6 years)	NR	NR
Masci et al (2008)	72	1	2.3	NR	NR (30, 90 & 180 days)	NR	NR
Shrivastava et al (2008)	81	7	8.6	NR	Median 63 days (IQR 20 - 270)	NR	NR
Small and Baron (2008)	85	10	11.7	Uncovered	Mean 93 days (range 7 - 691)	NR	NR
Stenhouse et al (2009)	64	14	21.9	Uncovered	NR	14	NR
Alcantara et al (2007)	95	4	4.2	NR	NR	NR	NR
Jost et al (2007)	67	6	9.0	Uncovered	NR	NR	NR
Lee et al (2007)	80	13	16.2	Mix	NR	7	6
Mucci-Hennekinne et al (2007)	67	3[h]	4.5	NR	NR	1	2
Athreya et al (2006)	87	5[i]	5.8	NR	NR	NR	NR
Garcia-Cano (2006)	175	7	4.0	NR	NR	2	5
Vitale et al (2006)	54	3	5.6	NR	NR	NR	NR
TOTAL (32 studies)	**4032**	**259**	**6.4**	-	-	40	56

a Early migration: Incidences of migrations occurred within 7 days post-operatively. This includes any event of stent migration lead to technical/clinical failure as well; Late migration: stent migrations recorded after 7 days.
b Includes 3 early stent migrations that lead to clinical failure, and another 11 occurred during the follow-up.
c Includes 2 complications that occurred within 30 days and 7 after 30 days.
d N: Based on the number of stenting procedures or attempts performed.
e Includes 3 events which occurred within 5 days and 7 events that occurred thereafter.
f Distal partial migration (2) and expulsion from anal canal (2).
g Only 107 (of a total 151) patients who received stents with a palliative intention were assessed for long-term complications.
h Includes 1 immediate stent migration that required re-stenting.
i Occurred after 30 days
BTS: Insertion of a stent/s as a bridge to surgery; IQR: Interquartile range; N: Based on all patients for whom safety data was reported, regardless of the number of patients enrolled in the study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NR: Not reported; Pal: Palliative/definitive stent; SD: Standard deviation.

Tumour growth-related events

In total, 11 studies recorded tumour ingrowth or overgrowth, with a total of 114 incidences reported (n=1169; occurrence rate 9.8%). Most of these studies recorded tumour growth-related events when the patients had been followed for more than seven days. Shrivastava et al (2008) noted median time to tumour ingrowth as 242 days (IQR 234-628 days). In some instances, tumour growths led to re-obstruction or occlusion (Suh et al 2010).

A total of 81 tumour growth-related events were reported across eight studies (n=925; occurrence rate 8.8%) (See Table 35). Seven studies, with a total of 469 patients, reported tumour overgrowth with a mean occurrence of 7 per cent (See Table 36).

Tumour growth-related events appeared more common among patients who received uncovered stents. Suh et al (2010) used uncovered stents only and reported a 14.5 per cent rate of tumour growth-related events, while the six studies that used both uncovered and covered stents reported 92 occurrences of tumour growths (12.1%, n=760). This supports earlier findings (Watt et al 2007).

Table 35 Summary of tumour ingrowths reported by included primary studies

Author	N	Events of tumour ingrowth (n)	Occurrence (%)	Type of stent (uncovered vs covered)
Lee et al (2011)	71	3[a]	4.2	Mix
Yoon et al (2011)	412	46	11.2	Mix
Young et al (2011)	100	5	5.0	NR
Moon et al (2010)	68	4[b]	5.9	Mix
Park et al (2010)	107	10	9.4	Mix
Suh et al (2010)	55	7	12.7	Uncovered
Shrivastava et al (2008)	81	3[c]	3.7	NR
Lee et al (2007)	31	3	9.7	Mix
TOTAL (8 studies)	**925**	**81**	**8.8**	**-**

a No tumour ingrowths occurred within 30 days following the procedure, nevertheless 3 incidences occurred thereafter lead to stent obstruction.
b All occurred after 7 days. One patient experienced both ingrowth and overgrowth.
c All 3 cases were recorded after 30 days follow-up. Median time to ingrowth was 242 days (Interquartile range 234-628 days).
N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success.

Table 36 Summary of tumour overgrowths reported by included primary studies

Author	N	Events of tumour overgrowth (n)	Occurrence (%)	Type of stent (uncovered vs covered)
Lee et al (2011)	71	16[a]	22.5	Mix
Selinger et al (2011)	57	3[b]	5.3	NR
Moon et al (2010)	68	3[c]	4.4	Mix
Kim et al (2009)	116	3	2.6	NR
Suh et al (2010)	55	1	1.8	Uncovered
Baraza et al (2008)	71[d]	6	8.4	Mix
Lee et al (2007)	31	1	3.2	Mix
TOTAL (7 studies)	**469**	**33**	**7.0**	**-**

a One incident of tumour outgrowths was recorded 30 days following the procedure, and another 15 thereafter. Later tumour outgrowths lead to stent obstruction.
b No overgrowths were detected within 5 days post-operatively; however 3 incidences were reported among 57 patients followed for late (>5 days) complications.
c All incidences occurred after 7 days. One patient experienced both ingrowth and overgrowth.
d N based on the number of stenting procedures or attempts performed.
N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients.

Sensation-related events

Two main sensation-related adverse events, pain (and/or discomfort) and tenesmus, were assessed. Tenesmus is a sensation of incomplete bowel emptiness leading to ineffective painful straining to empty the bowels without producing a significant quantity of stool.

Abdominal, rectal or anal pain were encountered among 70 patients in the 11 studies that reported such incidences (n=1711; incidence rate 4.1%) (See Table 37). Small and Baron (2008) reported four cases of severe pain or tenesmus which have also been incorporated into these results.

Typically, the pain experienced appeared to range from moderate to severe, and in some instances required analgesia (Li et al 2010). Pain associated with the procedure resolved within 30 days (Shrivastava et al 2008).

Table 37 Summary of pain (and/or discomfort) reported by included primary studies

Author	N	n	Occurrence (%)	Details
Keränen et al (2011)	100	1	1.0	One late (>7 days) pain (general)
Meisner et al (2011)	382	7	1.8	
Yoon et al (2011)	412	2	0.5	Stent insertion-related serious pain
Young et al (2011)	100	5	5.0	Anal pain
Kim et al (2010)	110[a]	33	30.0	Abdominal or anal pain
Li et al (2010)	50	2	4.0	Moderate anal pain requiring analgesia
Kim et al (2009)	116	4	3.4	Rectal pain
Demarquay et al (2008)	204	1	0.5	Severe abdominal pain
Shrivastava et al (2008)	81	7	8.6	Post-procedural increased pain (all occurred within 30 days)
Small and Baron (2008)	85	4	4.7	Tenesmus or severe pain
Mainar et al (1999)	71	4	5.6	Rectal pain
TOTAL (11 studies)	**1711**	**70**	**4.1**	

a N based on number of stenting procedures or attempts performed.
N: Based on all patients for whom safety data are reported, regardless of number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead number of patients.

Tenesmus was reported in six studies, with 35 events among the 1151 patients (incidence rate of 3%; range 1.0 – 15.4%). Five studies had occurrence rates ≤ 2.8 per cent, while Kim et al (2010) recorded an exceptionally high occurrence of 15.4 per cent (See Table 38.

Even-though Mackay et al (2011) reported 31 long-term complications which also included incidences of tenesmus, these could not be incorporated into our calculation as the authors did not quantify them separately from the aggregate data (Mackay et al 2011). Another study combined four events of tenesmus and severe pain (See Table 22). In some instances, tenesmus was an intra-procedural or early event (De Gregorio et al 2011).

Table 38 Summary of events of tenesmus reported by included primary studies

Author	N	Events of tenesmus (n)	Occurrence (%)
De Gregorio et al (2011)	467	6[a]	1.3
Kim et al (2010)	110[b]	17	15.4
Small et al (2010)	233	5	2.2
Baraza et al (2008)	71[b]	2	2.8
Alcantara et al (2007)	95	1	1.0
Garcia-Cano et al (2006)	175	4	2.3
TOTAL (6 studies)	**1151**	**35**	**3.0**

a Intra-procedural events.
b N based on number of stenting procedures or attempts performed.
N: Based on all patients for whom safety data are reported, regardless of number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients.

Bleeding events

Overall, 19 studies reported 72 bleeding events among 2813 patients (occurrence rate of 2.6%; range 0-16.1%) (See Table 39). This includes an incidence of haematoma which occurred seven days after the intervention. It is noted that out of the 72 total bleeding events, 56 events (78%) were mild to moderate which resolved spontaneously or with conservative management. Mild bleeding events (64) included 14 events of haematochezia (19.4 per cent of all bleeding events). The occurrence rate of haematochezia was 3.6 per cent (n=386).

It is noted that some studies only reported on incidences which needed blood transfusion (Young et al 2011). As such, the total incidence of post-operative bleeding may be greater than what has been calculated here.

Table 39 Summary of bleeding events reported by included primary studies

Author	N	Bleeding events (n)	Occurrence (%)
De Gregorio et al (2011)	467	16[a]	3.4
Karanen et al (2011)	100	1	1.0
Lepsenyi et al (2011)	65[b]	3[a]	4.6
Meisner et al (2011)	382	2	0.5
Selinger et al (2011)	80	2	2.5
Yoon et al (2011)	412	1	0.2
Young et al (2011)	100	0	0
Kim et al (2010)	110[b]	13[a]	11.8
Li et al (2010)	50	0	0
Moon et al (2010)	68	2[c]	2.9
Park et al (2010)	107	0	0
Small et al (2010)	233	2[c]	0.9
Kim et al (2009)	116	4[a]	3.4
Shrivastava et al (2008)	81	3[a]	3.7
Small and Baron (2008)	85	11[c]	12.9
Lee et al (2007)	80	1[a]	1.2
Garcia-Cano et al (2006)	175	1	0.6
Vitale et al (2006)	31	5[a]	16.1
Mainar et al (1999)	71	5[a]	7.0
TOTAL (19 studies)	**2813**	**72**	**2.6**

a Post-interventional anal/rectal bleeding (mild) which ceased spontaneously or with conservative management.
b N based on the number of stenting procedures or attempts performed.
c Haematochezia.
N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients.

Infectious events

Infectious events such as bacteraemia, sepsis, abscess and peritonitis were also reported. Overall, six studies with 746 patients reported 13 such events, with a mean occurrence of 1.7 per cent (See Table 40). This includes eight cases of bacteraemia accompanied with fever (n=318, 2.5%), two cases of abscess (n=185, 1.1%) and two cases of sepsis (n=257, 0.8%). Mainar et al (1999) reported a case of peritonitis (n=71, 1.1%). Some incidences

of sepsis could not be incorporated into our calculation as authors did not quantify their occurrence separately from the aggregated data (Mackay et al 2011).

Table 40 Summary of infectious events reported by included primary studies

Author	N	Infectious events (n)	Occurrence (%)
Keränen et al (2011)	100	1	1.0
Mackay et al (2011)	82	1	1.2
Small et al (2010)	233	7	3.0
Small and Baron (2008)	85	1	1.2
Garcia-Cano et al (2006)	175	1	0.6
Mainar et al (1999)	71	1	1.4
TOTAL (6 studies)	**746**	**12**	**1.7**

N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success.

Other events

Other adverse events that resulted from the intervention were erosion (and/or ulcer), fistula formation and adhesions. Four studies reported 10 cases of erosion (and/or ulcer) with an occurrence rate of 2.2 per cent. Fistula formation was reported at a mean occurrence rate of 1.9 per cent (6 of 313). Two cases of adhesions were also noted (2.8%, n=71) (See Table 31).

Is it effective?

No studies comparing stents to best supportive care were retrieved; as such, no assessment of the relative effectiveness of these two treatments could be made. All data presented within this section relates to the relative effectiveness of SEMS insertion compared to multi-stage surgical resection.

Technical and clinical success

Treatment outcomes of SEMS placement are commonly reported as either technical or clinical. Technical success is generally defined as the successful placement and deployment of a SEMS. Whilst there is no universal definition, clinical success is often regarded as colonic decompression without endoscopic or surgical reintervention after successful SEMS placement. The authors of different studies have often used their own criteria to define clinical success. The Cochrane review by Sagar (2011) noted that definitions of clinical success included relief of colonic obstruction symptoms, return of bowel function and resumption of oral intake, and stated that the outcomes of studies comparing SEMS to surgery may be impacted by these different definitions. This is reflected in the studies included to assess clinical treatment outcomes in the current review, where definitions of clinical success after SEMS placement included successful colonic decompression (Osman et al 2000), relief from obstructive symptoms (Johnson et al 2004; Varadarajulu et al 2011), improvement of obstructive symptoms within 48 hours (Nagula et al 2010) and resumption of bowel function and oral intake (Fiori et al 2004).

Definitions of clinical success after surgery also varied, and included relief from obstructive symptoms (Johnson et al 2004; Varadarajulu et al 2011), and resumption of bowel function and oral intake (Fiori et al 2004). Nagula et al (2010) and Osman et al (2000) did not provide explicit definitions of clinical success for surgery, and Xinopoulos et al (2004) did not provide explicit definitions of clinical success for either SEMS placement or surgery.

Data on rates of technical and clinical success after SEMS placement and surgery are summarised in Table 41. Both of the RCTs provided some data on technical and clinical success outcomes of SEMS placement. Xinopoulos et al (2004) reported technical and clinical success in 14 of 15 patients (93.3%) that had SEMS placed. In the remaining patient, stenting was not possible because the guide-wire could not be passed through the lesion; the patient subsequently underwent palliative stoma formation surgery. The colostomy procedure was reported to have been performed successfully and without serious complications in the comparator group of 15 patients (100%) who underwent surgery. Fiori et al (2004) reported technical and clinical success rates of 100 per cent in the 11 patients that had SEMS placed, as well as successful interventions (classified as restoration of canalisation of the gastrointestinal tract) for all 11 patients who underwent colostomy surgery.

Four of the five non-randomised comparative studies reported on technical and clinical success outcomes of SEMS placement. Nagula et al (2010) reported the lowest rate of technical success, with 32 of 38 patients (84.2%) receiving successful SEMS placement and deployment. A further two patients had inadequate symptom resolution within 48 hours of stent placement, resulting in a clinical success rate of 78.9 per cent. The authors made no statement about the clinical success of surgery in the comparator group of 14 patients. This group included the eight patients who experienced clinical failure after

SEMS placement, all of whom received surgical palliation. Johnson et al (2004) reported a SEMS technical and clinical success rate of 90.0 per cent in 20 patients. Both of the patients who experienced technical failure were subsequently managed by palliative stoma formation. In the comparator group, 16 of 18 surgery patients (88.9%) were reported to have gained a benefit from stoma formation, while the remaining two patients had extensive peritoneal disease and died soon after treatment. Osman et al (2000) reported a technical and clinical success rate of 93.8 per cent in 16 SEMS patients, but did not report definitive success rates of intervention in surgical patients. Varadarajulu et al (2011) reported technical and clinical success in all 12 patients treated with SEMS, and successful treatment for all 24 patients who underwent surgery.

Table 41 Technical and clinical success rates of SEMS placement and surgery: comparative studies

Study	Level of evidence	SEMS placement				Surgery	
		Technical success		Clinical success		Clinical success	
		n/N	%	n/N	%	n/N	%
Fiori et al (2004)	II	11/11	100	11/11	100	11/11	100
Xinopoulos et al (2004)	II	14/15	93.3	14/15	93.3	15/15	100
Nagula et al (2010)	III-2	32/38	84.2	30/38	78.9	NR/14[a]	NR
Varadarajulu et al (2011)	III-3	12/12	100	12/12	100	24/24	100
Johnson et al (2004)	III-3	18/20	90.0	18/20	90.0	16/18[b]	88.9
Osman et al (2000)	III-3	15/16	93.8	15/16	93.8	NR/10	NR

a Includes eight patients who initially received SEMS placement, but did not experience clinical success.
b Two patients who did not experience benefit from stoma formation were found to have extensive peritoneal disease.
NR: Not reported; SEMS: Self-expanding metallic stent.

Duration of stent patency and need for reintervention

Two comparative studies, including the RCT by Xinopoulos et al (2004), reported on stent patency as either a proportion of patients with a patent SEMS at time of death, or as duration of patency; both studies incorporated only patients receiving palliative treatment. Xinopoulos et al (2004) reported that 100 per cent of patients achieving clinical success after SEMS placement (n=14) had patent stents at time of death (median time to mortality 21.4 weeks). Johnson et al (2004) also reported that 100 per cent of patients achieving clinical success after SEMS placement (n=18) had patent stents at time of death (median time to mortality 92 days). In both studies, patient mortality was reported to be primarily a result of progression of the underlying malignant disease, not loss of stent patency.

Four comparative studies reported on the need for reintervention after clinically successful SEMS placement in patients treated for palliative purposes. The RCT by Xinopoulos et al (2004) reported six of 14 patients (42.9%) subsequently underwent laser treatment of tumour ingrowth for maintenance of stent patency. Johnson et al (2004) reported that two of 18 patients (11.1%) received a second stent placement for treatment of obstruction due to tumour ingrowth. Nagula et al (2010) stated that three of 30 patients (10.0%) patients required repeat colonoscopy with second stent placement, two for treatment of obstruction due to tumour ingrowth and one for stent migration. Varadarajulu et al (2011) reported that all of the four palliative SEMS patients for whom

follow-up data were available had died without requiring re-intervention; none of the 19 patients who underwent colostomy or internal bypass experienced complications which required re-intervention. No study discussed need for re-intervention after surgical treatment.

Quality of life outcomes

The prospective, non-randomised comparative study by Nagula et al (2010) reported on measures of patient quality of life using the Functional Assessment of Cancer Therapy – Colorectal (FACT-C) survey instrument, and the Colon Obstruction Score. The FACT-C is a validated tool for the assessment of quality of life in cancer patients through physical, functional, social and emotional well-being subscales, with an additional subscale that evaluates quality of life related to gastrointestinal function. The Colon Obstruction Score is a novel, seemingly non-validated questionnaire that semi-quantitatively assesses the presence and severity of a range of symptoms of colonic obstruction. Patients were asked three additional individual questions to evaluate global quality of life, global health and the effort they required to cope with the illness, but no further detail on these questions was provided. The authors did not report any statistical comparisons of patients who received SEMS and those who underwent surgery. Quality of life scores at follow-up were only compared to baseline scores within the same treatment cohort. Results are shown in Table 42.

In the SEMS treatment group (i.e. patients who achieved technical and clinical success), the overall FACT-C score improved progressively from two weeks after treatment through the study period (six months post-treatment), but this improvement did not reach statistical significance. In the surgery group, the overall FACT-C score declined two weeks after treatment, but returned to baseline for the remainder of the study period. Improvements in the various subscales were minimal at best for both treatment groups, with the exception of the Colon - Symptoms subscale. Scores on this subscale were reported to have improved significantly in the SEMS group ($p<0.05$ compared with baseline at 1- and 6-month follow-up) and in the surgery group ($p<0.05$ compared with baseline at 1-month follow-up).

Colon Obstruction Scores indicated the presence of an improvement in obstructive symptoms in both the SEMS and surgical groups compared with baseline throughout the study period ($p<0.05$ for both treatment groups at 1- and 6-month follow-up); however, it should be noted that this was a novel and non-validated measure that does not appear to have been employed in any other clinical study. Self-rated global quality of life was shown to improve significantly in patients who underwent surgery at 4- and 8-week follow-up ($p<0.05$ at both time points), but declined after this time point. Patients in the SEMS group had a significant improvement in their ability to cope with their illness at 2-week follow-up only ($p<0.03$, data not shown by authors).

It should be noted that the authors acknowledged that substantial losses of patients to follow-up, particularly due to the high mortality rate related to advanced malignancy, limited their capacity to draw statistical conclusions at later time points. At 8-week follow-up, only 25 of 44 enrolled patients (56.8%) were available, dropping to 16 patients (36.4%) at 24-week follow-up. The authors noted that statistically significant differences at those later time points should be interpreted cautiously.

Table 42 Quality of life in patients after SEMS placement and surgery

Outcome	Subscale (where applicable)	Follow-up	SEMS placement median (IQR)	Surgery median (IQR)	*p*-value
FACT-C	Overall	Baseline	72.3 (65.5-80.0)	74.6 (60.7-83.2)	
		1 month	89.7 (72.0-99.3)	79.5 (66.5-86.2)	NR
		6 months	95.5 (74.0-99.8)	77.5 (68.7-105.2)	
	Physical	Baseline	11.7 (9.3-14.0)	11.7 (5.8-16.3)	
		1 month	15.2 (10.5-22.2)	13.4 (10.5-17.5)	NR
		6 months	18.7 (14.0-21.0)	17.5 (10.5-22.2)	
	Emotional	Baseline	12.0 (9.0-18.0)	12.0 (10.0-15.0)	
		1 month	18.0 (12.0-20.0)	12.5 (9.0-17.0)	NR
		6 months	16.0 (12.0-22.0)	16.0 (14.0-16.0)	
	Functional	Baseline	13.0 (11.0-16.0)	11.5 (10.0-16.0)	
		1 month	15.0 (12.0-18.0)	14.0 (12.0-16.0)	NR
		6 months	16.0 (12.0-18.0)	15.0 (11.0-23.0)	
	Social	Baseline	23.0 (22.0-25.0)	25.0 (21.0-25.0)	
		1 month	24.5 (23.0-24.5)	25.0 (23.0-25.0)	NR
		6 months	23.0 (19.0-24.0)	25.0 (23.0-25.0)	
	Colon - symptoms	Baseline	11.0 (9.0-14.0)	10.0 (8.0-13.0)	
		1 month	14.5 (12.0-20.0)[a]	13.0 (11.0-21.0)[a]	NR
		6 months	21.0 (15.0-22.0)[a]	16.0 (14.0-19.0)	
Colon Obstruction Score		Baseline	6.0 (4.0-9.0)	6.5 (5.0-10.0)	NR
		1 month	3.5 (2.0-5.0)[a]	2.5 (1.0-6.0)[a]	
		6 months	2.0 (1.0-3.0)[a]	4.0 (0.0-5.0)[a]	
Self-reported global quality of life [b]		Baseline	4 (2-6)	2.5 (1-6)	NR
		1 weeks	5 (3-6)	3 (1-4)	
		2 weeks	4 (4-7)	3 (2-5)	
		4 weeks	5 (3-6)	5.5 (3-7)[a]	
		8 weeks	5 (3-7)	7 (6-8)[a]	
		12 weeks	6 (5-7)	6 (3-7)	
		24 weeks	6 (5-7)	4 (4-7)	

a Denotes statistically significant improvement ($p < 0.05$) compared with baseline.
b Data not shown by authors; values derived from figure.
FACT-C: Functional Assessment of Cancer Therapy – Colorectal; IQR: interquartile range; NR: Not reported; SEMS: Self-expanding metallic stent.
Source: Nagula et al (2010).

Hospital and intensive care unit stay

With regards to hospital and intensive care unit stay, outcomes were generally found to favour SEMS placement over surgery (see Table 43 for details). The RCT of Fiori et al

(2004) reported a median hospital stay of 2.6 days after SEMS placement, while the 11 patients who underwent colostomy had a median hospital stay of 8.1 days post-surgery. This difference in length of stay was found to be statistically significant in favour of SEMS placement (p<0.001). In their RCT, Xinopoulos et al (2004) reported a total hospital stay of 28 days for the 15 patients undergoing SEMS placement (mean 1.9 days) and a total hospital stay of 60 days for the 15 patients who underwent colostomy surgery (mean 4 days, no statistical comparison reported).

All five non-randomised comparative studies reported on length of hospital stay following SEMS placement. Osman et al (2000) reported a mean hospital stay of 2.5 days after SEMS placement and 13.5 days after Hartmann's procedure or defunctioning caecostomy surgery (no statistical comparison reported). One surgery patient required admission to the intensive care unit for 24 hours. Johnson et al (2004) found no significant difference in the duration of hospital stay between patients receiving SEMS placement and those receiving palliative stoma formation (median 17.5 days vs 18 days, p=0.65); however, the authors stated that patients who received a stoma (median 2.5 days in eight patients) required a significantly longer stay in the intensive care unit than SEMS patients (no patients requiring stay) (p=0.003). Baik et al (2006) found SEMS patients to have a significantly shorter post-procedural hospital stay than colostomy patients (median 5 days vs 14 days, p<0.001), as did Varadarajulu et al (2011) (mean 2.17 days vs 10.58 days, p = 0.004). Nagula et al (2010) compared only SEMS patients who underwent treatment as inpatients and achieved clinical success (22 patients; eight patients were treated as outpatients) to those patients receiving surgery, reporting that median length of stay was 4 days after SEMS placement and 7.5 days after surgery (no statistical comparison reported).

Table 43 Length of hospital stay after SEMS placement and surgery: comparative studies

Study	Level of evidence	SEMS placement		Surgery		*p*-value
		n	LOS (days)[a]	n	LOS (days)[a]	
Fiori et al (2004)	II	11	2.6 (range 2-4)	11	8.1 (range 7-10)	<0.0001
Xinopoulos et al (2004)	II	15	1.9[b] (mean)	15	4[b] (mean)	NR
Nagula et al (2010)	III-2	22[c]	4 (mean)	14	7.5 (mean)	NR
Varadarajulu et al (2011)	III-3	12	2.17 (mean)	24	10.58 (mean)	0.004
Baik et al (2006)	III-3	18	5 (range 1-16)	19	14 (range 7-27)	<0.0001
Johnson et al (2004)	III-3	20	18 (range 9-132)	18	17.5 (range 9-65)	0.65
Osman et al (2000)	III-3	16	2.5 (mean) (range 2-6)	10	13.5 (mean) (range 10-15)	NR

a Median values unless otherwise stated.
b Study reported total days of hospital stay per treatment group; means were calculated through division by number of patients.
c Study reported results only for SEMS patients treated as inpatients.
LOS: Length of hospital stay; NR: Not reported; SEMS: Self-expanding metallic stent.

Procedural operating time

Only one study compared the length of operating time for the placement of SEMS compared to surgery. The RCT by Fiori et al (2004) found procedural time to be significantly shorter for SEMS placement (mean 36 ± 15.0 minutes (range 15-55)) than for surgery (mean 75.4 ± standard deviation of 26.1 minutes (range 35-110), p<0.003).

Patient survival – palliative stent placement

Three comparative studies, including the RCT by Xinopoulos et al (2004), reported on length of patient survival after palliative treatment with SEMS placement or surgery. No significant differences in median length of survival were reported between treatment groups in any of the studies (Johnson et al 2004; Nagula et al 2010; Xinopoulos et al 2004) (See Table 44). While the study by Johnson et al (2004) found no significant difference between treatment groups, the patient cohort receiving SEMS placement was found to be significantly older (p=0.0065) and have more severe disease (determined via American Society of Anesthesiologists physical status classification; p=0.04) than the cohort who underwent surgery, and could potentially have been expected to experience worse survival outcomes than patients who underwent surgery.

Table 44 Patient survival after palliative treatment with SEMS placement and surgery: comparative studies

Study	Level of evidence	SEMS placement		Surgery		*p*-value
		n	Median survival	n	Median survival	
Xinopoulos et al (2004)	II	14	21.4 weeks	15	20.9 weeks	NS
Nagula et al (2010)	III-2	30	6 months	14	6 months	NS
Johnson et al (2004)	III-3	18	92 days	18	121 days (range 89-281)	0.5

NS: Not significant; SEMS: Self-expanding metallic stent.

Progression to surgery – bridge to surgery treatment

Three non-randomised comparative studies reported on outcomes related to progression to surgery in patients who received SEMS as a bridge to surgery. The study by Baik et al (2006) provided the most detailed information on this outcome, comparing outcomes of planned curative surgical procedures for patients receiving SEMS placement and emergency surgery with temporary stoma formation (see Table 45). Patients who received SEMS placement were able to undergo planned surgery significantly sooner (p=0.005) and required a shorter duration of hospital stay after planned surgery (p=0.002) than those who initially underwent surgery with temporary stoma.

With regards to the types of planned surgery performed after the initial decompression procedure, at least four of the 18 patients (22.2%) who underwent SEMS placement subsequently required multi-stage surgery (abdominoperineal resection, Hartmann's procedure). It could not be definitively determined how many of the remaining 14 patients who underwent SEMS placement avoided multi-stage surgery, as the authors did not state whether other planned surgeries performed (anterior resection, low anterior resection, left hemicolectomy) were conducted as single-stage or multi-stage procedures. No outcomes regarding the success of these planned procedures were reported.

Table 45 Bridge to surgery outcomes after SEMS placement and surgery with temporary stoma

Outcome	SEMS placement	Surgery	*p*-value
Duration from decompression procedure to planned surgery (days)	Median 7 (range 2-74)	Median 17 (range 7-138)	0.005
Duration of hospital stay after planned surgery (days)	Median 11 (range 8-22)	Median 16 (range 10-41)	0.002
Planned surgeries performed after decompression procedure	Abdominoperineal resection (2) Anterior resection (5) Hartmann's procedure (2) Low anterior resection (6) Left helicolectomy (3)	Abdominoperineal resection (5) Anterior resection (6) Hartmann's procedure (0) Low anterior resection (7) Left helicolectomy (1)	NA

NA: Not applicable; SEMS: Self-expanding metallic stent.
Source: Baik et al (2006).

In the study by Varadarajulu et al (2011), six of the 12 patients enrolled received SEMS placement as a bridge to surgery. The authors stated that all six patients went on to receive elective single-stage operations for tumour resection, but did not provide any further details on the procedure. All patients in the comparative surgical group had undergone multi-stage Hartmann's procedure. In the study by Osman et al (2000), five of the 16 patients who received SEMS placement were enrolled with the intent of undergoing planned surgery at a later date. These patients were re-admitted four to six weeks after SEMS placement for curative anterior resection; however, the authors did not state whether these were performed as single-stage or multi-stage procedures, and no outcomes were reported. All patients in the comparator group had undergone Hartmann's procedure or defunctioning caecostomy.

Ongoing clinical trials

Both clinicaltrail.gov and controlled-trials.com were searched on 22 November 2011 and a number of ongoing clinical trials focusing on the safety and effectiveness of stenting were identified (Appendix E). It could not be guaranteed whether all nine studies are based on the patient population of interest to our assessment, and whether the safety and effectiveness of stenting with patients who are ineligible to receive single-stage resection will be compared. Nevertheless most of these studies consider quality of life after the treatment as an effectiveness outcome, hence trying to address one of the major lacks in the present evidence base.

Other relevant considerations

The Colorectal Surgical Society of Australia and New Zealand (the applicant) made two comments on the protocol (decision analytical protocol) of the present assessment:

- Single-stage resection and anastomosis is the preferred option for management of the large bowel; however, not all patients or tumours are candidates for this surgery. This may relate to patient comorbidity, tumour stage or size, or surgeon experience. Single-stage resection requires greater surgical expertise (more than elective surgery) and morbidity is potentially greater.

- The vast majority of bowel resections performed are in the setting of non-obstructing elective resection of bowel cancer (Table 18). These are the same item numbers used in the emergency setting and there is no way to determine from these figures the frequency with which resection is performed for acute or sub-acute obstruction (Table 19).

The clinical need calculations relevant to the Australian context are vastly based on the applicants' assumptions and statistical records, which the evaluators of this assessment have not been able to support with the resources available.

What are the economic considerations?

Economic evaluation of new healthcare technologies is important when determining whether the new initiative offers additional benefits and at what cost. Economic evaluations are able to determine whether the new initiative is dominated by (or dominates) the existing technology, such that the costs are higher (lower) and the effectiveness is less (greater). Economic evaluation is particularly important where the new initiative offers health benefits at additional costs. Within a constrained healthcare budget, determining the additional cost that would be paid for a given health gain is important when ascertaining whether such incremental costs represent value for money.

The usual process for an economic evaluation is first to determine the incremental effectiveness, which is the additional benefits associated with the new technology relative to current practice. The second step is to determine the incremental costs, which is the difference in costs between the new initiative and current practice. Finally the incremental cost-effectiveness ratio (ICER) can be calculated using the following ratio:

$$ICER = \frac{Cost_{New} - Cost_{Comparator}}{Effectiveness_{New} - Effectiveness_{Comparator}}$$

To allow comparison of effectiveness across interventions and/or across settings, it is preferable for an economic evaluation to take the form of a cost-utility analysis. This analysis generates an ICER as described which can then be compared to a threshold, or range of thresholds, to determine whether the health system should invest in the new technology. The most common generic outcome measure is the quality-adjusted life year (QALY). This is a measure of effectiveness which combines morbidity and mortality dimensions into one composite measure of outcome. The use of cost-utility analysis, while preferable to disease-specific outcome measure, is reliant on the existence of appropriate published data.

Where the new technology demonstrates equal effectiveness to the existing technology (ie it is non-inferior) then a cost-minimisation approach is warranted.

Objective

The objective of this section is to conduct an economic evaluation of SEMS insertion for the management of malignant bowel obstructions. SEMS are indicated for four patient populations, all of which are not eligible for single-stage resection:

- patients with large bowel obstruction (strictures or stenosis) of an unknown diagnosis who are medically fit for multi-stage surgery;
- patients with large bowel obstruction (strictures or stenosis) of an unknown diagnosis who are medically unfit for multi-stage surgery;
- patients with large bowel obstruction (strictures or stenosis) caused by colorectal cancer or cancer of an organ adjacent to the bowel who are medically fit for multi-stage surgery;

- patients with large bowel obstruction (strictures or stenosis) caused by colorectal cancer or cancer of an organ adjacent to the bowel who are medically unfit for multi-stage surgery.

The overwhelming majority of the published literature was based on patients with a confirmed colorectal cancer. Therefore, in terms of economics and cost-effectiveness, patients with an unknown diagnosis of cancer who presented with colorectal obstruction are assumed to be equivalent to the patients with pre-diagnosed cancer. The appropriate comparators are listed in Table 46.

Table 46 Appropriate comparators relevant to patient populations

Patient population	Comparator
Patients medically fit for multi-stage surgery (with or without pre-diagnosed cancer)	Multi-stage surgical management, which mainly includes colostomy and Hartmann's resection
Patients medically unfit for multi-stage surgery (with or without pre-diagnosed cancer)	Best supportive care which includes palliation, ongoing medical management, chemotherapy and/or radiotherapy

SEMS could be used as bridge to surgery or for palliation to avoid emergency resection of the obstructed colon in patients who suffer from cancer. Patients who are medically fit for multi-stage surgery could receive a SEMS as a bridge to elective surgery as well as for palliative purposes. Patients who are unfit for multi-stage surgery who are at the terminal stage of their cancer are more likely to receive a SEMS for palliation.

Search strategies

Any study investigating the use of SEMS for the management of malignant large bowel obstructions was systematically identified (See 'Approach to assessment').

Peer-reviewed literature was searched in PubMed, EMBASE, CINAHL, The Cochrane Library and CRD databases. Additionally web-based search engines, such as 'Google' and 'Google scholar' were also searched to identify relevant economic studies. New search terms 'Cost$' or 'Econ$' were added to the previously used search strategy (See Table 20 and Appendix B) to identify any cost-effectiveness analyses.

The bibliographies of all included publications were hand-searched for any relevant references that may have been missed by the database search. A comprehensive description of the search strategy was provided earlier (See 'Review of literature').

Background – evidence of cost-effectiveness

Eight studies were identified addressing the cost-effectiveness of colonic SEMS in the management of malignant colonic obstructions. The inclusion criteria determined a priori for assessing the economic analyses of SEMS insertion are outlined in Table 47.

Table 47 Criteria for selecting studies to assess the cost-effectiveness of colonic SEMS in patients with a colorectal obstruction, stricture or stenosis

Selection criteria	Inclusion criteria
Population	Patients (>17 years) with an unknown cancer diagnosis, medically fit for multi-stage surgery. Patients (>17 years) with an unknown cancer diagnosis, medically unfit for multi-stage surgery Patients (>17 years) known to have pre-diagnosed cancer, medically fit for multi-stage surgery. Patients (>17 years) known to have pre-diagnosed cancer, medically unfit for multi-stage surgery
Intervention	SEMS insertion (as a bridge to surgery or a palliative intervention)
Comparator(s)	1.Multi-stage surgery – colostomy (stoma creation), Hartmann's resection 2.Best supportive care
Outcomes	Total average cost Cost per relevant health outcome (eg LYG, QALY)
Publication type	Cost studies, cost-effectiveness studies, cost-utility studies
Language	English language articles only.

LYG: Life year gained; QALY: Quality-adjusted life year.

Decision analytic models of cost-effectiveness

The following cost-effectiveness studies were identified:

- Targownik et al (2004) noted that colonic stent insertion followed by elective surgery (SEMS as a bridge to surgery) was more effective and less costly than emergency surgical resection followed by diversion (Hartmann's procedure) or anastomosis. SEMS insertion resulted in fewer operative procedures per patient, reduction in stoma creation rate and lower procedure related mortality. Overall, colonic stenting was associated with a lower mean cost per patient (US$45,709 vs US$49,941).

- Singh et al (2006) noted that SEMS insertion followed by elective surgery and reanastomosis resulted in fewer total operative procedures, lower mortality rate and the likelihood of requiring a permanent stoma. Colonic SEMS insertion was less costly than emergency surgery, creation of a colostomy or primary anastomosis but more costly than emergency diverting colostomy followed by elective surgery and reanastomosis. The resulting ICERs of colonic stenting versus diverting colostomy followed by elective surgery and reanastomosis were CAN$1,415 to prevent a stoma and CAN$1,516 to prevent an additional death.

- Govindarajan et al (2007), using a Markov chain Monte Carlo model, found that colonic SEMS insertion was more effective (9.2 quality adjusted life months benefit) and less costly (CAN$3,763) than emergency surgery. The results were driven by the rate of stenting-related complications and the surgical mortality.

Costing studies

The following costing studies were identified:

- Binkert et al (1998) noted that stenting cost 29 per cent less than surgical treatment, due to shorter hospitalisation.

- Xinopoulous et al (2004) stated that the average cost of SEMS insertion was marginally more expensive than colostomy (€2,224 vs €2,092). Although the SEMS itself

was costly, the overall costs were offset due to shorter hospitalisation and the overall simplicity of the stenting procedure.

- The Technology Assessment Unit of The McGill University Health Centre found that the costs of SEMS insertion compared to colostomy for palliation were equivalent (CAN$3,064 and CAN$2,991). This trend was maintained when a SEMS was used as a bridge to surgery (CAN$2,872 and CAN$2,992).

Retrospective claims study

The following retrospective costs analyses were identified:

- Osman et al (2000) retrospectively compared a group of patients who were managed with SEMS with an unselected group of patients managed by surgical decompression. The use of stents resulted in a significant reduction in hospital stay compared to colostomy (2.5 days vs 13.5 days). This resulted in an average savings of £1760 per patient receiving a SEMS. For those patients who proceeded to either a post-stent resection or Hartmann's operation, the mean net savings was £685 per patient.

- Varadarajulu et al (2011) demonstrated that the mean hospital costs were less for the SEMS cohort than for the colostomy group (US$21,771 vs US$33,383). Additionally, the total length of hospital stay from admission to discharge was eight days for the SEMS group and 12 days for the colostomy group.

In summary, the published literature demonstrated that the use of colonic SEMS to treat malignant bowel obstruction was usually a cost saving compared to colostomy or Hartmann's procedure. The main differences in healthcare cost are largely driven by length of hospital stay, which is significantly shorter in patients receiving colonic stents. In addition, there is some evidence to suggest that SEMS insertion is more effective, in terms of gains in quality of life.

Rationale for cost-effectiveness analysis

Patients medically fit for multi-stage surgery

There is limited evidence pertaining to patients with an unknown diagnosis; therefore, it is assumed that those with an unknown or known diagnosis would have the same treatment pathway. Consequently these populations are not dealt with separately in the analysis. The populations considered medically fit for surgery will be costed in two distinct groups:

- SEMS compared to palliative colostomy, in patients where SEMS is used as a palliative option;

- SEMS compared to multi-staged surgery (which includes colostomy or Hartmann's procedure) in patients where SEMS is used as a bridge to surgery.

Two RCTs compared SEMS to colostomy as discussed in the preceding section on efficacy and safety. Data from these studies were used for the economic analysis. In both RCTs, only patients who had incurable (unresectable) malignant colonic obstructions were included. The only significant differences between SEMS and multi-stage surgical

groups were: length of hospital stay, operation time and number of complications following the procedure.

For patients who were medically fit for surgery, there was a lack of comparative evidence for SEMS as a bridge to surgery compared to multi-stage surgery using randomised controlled trials. Therefore a cost-utility analysis was conducted using data extracted from systematic reviews of case-series studies.

Patients medically unfit for multi-stage surgery

There was insufficient published evidence regarding patients who were unfit for multi-stage surgery. Therefore, for the purposes of the economic evaluation, the incremental cost of treating these patients with SEMS compared to palliation alone was estimated. The palliation alone assumed to resemble best supportive care in this instance.

Estimate of costs

The estimated costs of SEMS and colostomy were taken from a number of sources. These included: the MBS, Australian Refined Diagnostic Related Group (AR-DRG) (version 5.1 round 13 – Private and Public), manufacturer's costs and the average charged Medicare fee. Resource use and MBS item numbers were determined with the aid of expert clinical advice.

Costs were estimated from the perspective of the Australian society; however, patient's travel costs or costs associated with loss of/or reduction in productivity were not included.

MBS items

The MBS item fees, which represent the Australian Government contribution to each procedure, were obtained from MBS online (See Table 48). The patient receives a reimbursement of 75 per cent of the schedule fee for inpatient services and 85 per cent for outpatient services. Consequently the benefit amount and not the full Medicare schedule fee were used in the model. Using the full fee would double count some of the co-payment contribution.

Average co-payments

Average co-payments were provided by the Department of Health and Ageing (See Table 48). The co-payment component is calculated as the MBS fee charged minus the MBS benefit paid plus any additional specialist fees. The co-payment may not be the exact patient contribution, since it may also include some insurance contribution (up to 25% of the MBS fee). To avoid double counting, the 25 per cent insurance contribution is not included as a separate cost. The co-payments are calculated as averages of all procedures claimed under the item number. Consequently, there may be a degree of heterogeneity; therefore, the accuracy of the co-payment is dependent on the other procedures that are also claimed under the same item number.

Table 48 MBS item numbers, fees and co-payments

MBS item	Item#	MBS fee	MBS benefit[a]	Co-payment
Specialist consultation	104	$84	$71	$68
Subsequent specialist consultation	105	$42	$36	$37
Consultant attendance	110	$148	$126	$67
Subsequent consultant attendance	116	$74	$63	$34
Colostomy/laparotomy	30375	$512	$384	$217
Resection with anastomosis	32024	$1,339	$1,004	$977
Rectosigmoidectomy	32030	$1,012	$759	$579
Restoration of bowel	32033	$1,479	$1,110	$946
Resection with primary anastomosis	32025	$1,791	$1,343	$1,292
Fibreoptic colonoscopy	32090	$328	$246	$198
Fluoroscopy with general anaesthesia	60500	$43.40	$32.55	$12
Fluoroscopy without general anaesthesia	60503	$30	$22	$24
Plain abdominal radiography	58900	$36	$27	$12
CT scan	56507	$480	$360	$197
Opaque enema	58921	$135	$101	$71
Full blood count	65070	$17	$13	$7
Electrolyte count	66512	$18	$13	$8
Pre-anaesthesia consultation	17610	$42	$32	$44
Initiation of anaesthesia for bowel resection	20841	$156	$117	$501
Initiation of anaesthesia for laparoscopic procedures	20806	$136	$102	$341
Initiation of anaesthesia for lower intestinal endoscopic procedures	20810	$78	$58	$120
Initiation of anaesthesia for fluoroscopy	21926	$97	$73	$209
Assistance - fee < 547.90	51300	$85	$64	$64
Assistance - fee > 547.90	51303	$0	$0	$198
Anaesthesia 1:56 to 2:00 hours	23083	$156	$117	NA[b]
Anaesthesia 1:11 to 1:15 hours	23053	$97	$73	NA[b]
Anaesthesia 56 min to 1:00 hour	23043	$78	$58	NA[b]
ICU attendance (first day)	13870	$355	$267	$153
ICU attendance	13873	$264	$198	$106

ICU: Intensive Care Unit; MBS: Medicare Benefits Schedule; NA: not available
a All procedures are undertaken as inpatient procedures with 75% of the scheduled fee reimbursable, with the exception of items 104, 105, 110, 116 which are undertaken in an outpatient setting with 85% of the scheduled fee reimbursable.
b There are no available data for MBS codes pertaining to anesthesia time blocks.

Cost of pre-operative treatment

The estimated average cost of pre-operative treatment for SEMS, colostomy and Hartmann's procedure are presented in Table 49. The pre-operative procedures are assumed to be identical for all three procedures. Overall pre-operative treatment is expected to cost $1,683 per patient ($963 MBS contribution).

Table 49 Pre-operative treatment costs

	MBS codes	Costs	Units	Total
Colonoscopy	32090	$246	1	$246
MBS 32090 co-payment	32090	$198	1	$198
Plain abdominal x-ray	58903	$36	1	$36
MBS 58903 co-payment	58903	$22	1	$22
CT scan of abdomen and pelvis	56507	$360	1	$360
MBS 56507 co-payment	56507	$197	1	$197
Barium swallow/enema	58921	$101	1	$101
MBS 58921 co-payment	58921	$71	1	$71
Pre-anaesthesia consultation	17610	$32	1	$32
MBS 17610 co-payment	17610	$44	1	$44
Initiation of anaesthesia (4 units)	20810	$58	1	$58
MBS 20810 co-payment	20810	$120	1	$120
Anaesthesia - 56 min to 1:00 hour	23043	$58	1	$58
Surgery consultation	104	$71	1	$71
MBS 104 co-payment	104	$68	1	$68
Total consumables				$0
Total MBS fees				$963
Total patient/insurer costs				$719
Total cost				**$1,682**

MBS: Medicare Benefits Schedule.

Cost of SEMS procedure

The costs associated with the insertion of the SEMS are summarised in Table 50. The average cost of the theatre was taken from AR-DRG G05B (minor small and large bowel procedures without complications). The insertion procedure is expected to cost $5,968 ($3,535 of which is consumables, largely the cost of the SEMS). The proposed MBS fee was provided by the applicant ($650).The co-payment was estimated to be 25 per cent of the MBS fee in the base case analysis. Higher co-payment fees are tested in the sensitivity analysis.

Table 50 Cost of SEMS insertion

	MBS code	Costs	Units	Total
Equipment				
Stent (prostheses list - BS071)		$3,060	1	$3,060
Contrast liquids[a]		$25	1	$25
Guide wire[a]		$375	1	$375
Cannula/ catheter[a]		$75	1	$75
Operation				
Insertion of stent (proposed MBS fee at 75%)		$488	1	$488
Estimated MBS co-payment (25% fee)		$163	1	$163
Fluoroscopy	60503	$22	1	$22
MBS 60503 co-payment	60503	$24	1	$24
Initiation of anaesthesia (5 units)	21926	$73	1	$73
MBS 21926 copayment	21926	$209	1	$209
Anaesthesia - 1:11 to 1:15 hours	23053	$73	1	$73
Assistance with insertion of stent	51303	$98	1	$98
MBS 51303 co-payment	51303	$198	1	$198
Theatre (AR-DRG G05B)		$1,087	1	$1,087
Total consumables				$3,535
Total MBS fees				$1,840
Total patient/insurer costs				$593
Total cost				**$5,968**

a Based on expert advice, 'Contrast liquids, guidewires and catheters are used to aid stent placement. A guidewire is inserted initially for stent placement then a catheter is placed over the guidewire. The contrast liquids are used to monitor the placement by x-ray'.
AR-DRG: Australian Refined Diagnostic Related Group; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Cost of colostomy

The costs associated with stoma creation (colostomy) are presented in Table 51. Surgical theatre costs for colostomy are estimated from AR-DRG G02B (major small and large bowel procedures without complications).

Table 51 Cost of colostomy

	MBS code	Costs	Units	Total
Equipment				
Single use stoma bags		$5	1	$5
Operational				
Colostomy procedure	30375	$384	1	$384
MBS 30375 co-payment	30375	$217	1	$217
Initiation of anaesthesia	20841	$117	1	$117
MBS 20841 co-payment	20841	$501	1	$501
Anaesthesia -1:56 to 2:00 hours	23083	$117	1	$117
Assistance	51300	$64	1	$64
MBS 51300 co-payment	51300	$64	1	$64
Theatre (AR-DRG G02B)		$1,679	1	$1,679
Total consumables				$5
Total MBS fees				$2,360
Total patient/insurer costs				$781
Total cost				**$3,146**

AR-DRG: Australian Refined Diagnostic Related Group; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Cost of Hartmann's procedure

The costs associated with Hartmann's procedure are presented in Table 52. The theatre costs were taken from AR-DRG G01B (rectal resection without complications).

Table 52 Cost of Hartmann's procedure

	MBS code	Costs	Units	Total
Equipment				
Linear cutting stapler		$470	1	$470
Staples		$244	3	$732
Operational				
Hartmann's operation	32030	$759	1	$759
MBS 32030 co-payment	32030	$579	1	$579
Initiation of anaesthesia (8 units)	20841	$117	1	$117
MBS 20841 co-payment	20841	$501	1	$501
Anaesthesia -1:56 to 2:00 hours	23083	$117	1	$117
Assistance	51303	$152	1	$152
MBS 51303 co-payment	51303	$198	1	$198
Theatre (AR-DRG G01B)		$2,578	1	$2,578
Total consumables				$1,202
Total MBS fees				$3,722
Total patient/insurer costs				$1,278
Total cost				**$6,202**

AR-DRG: Australian Refined Diagnostic Related Group; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Second stage of a two-stage surgery (re-anastomosis of the bowel and reversing the stoma) may be considered in 50-70 per cent of patients with a primary colostomy. The costs associated with re-anastomosis are presented in Table 53. Patients considered unsuitable for re-anastomosis would have a permanent stoma. For these patients ongoing costs include the cost of stoma bags and visits to astomal therapist.

Table 53 Cost of re-anastomosis

	MBS code	Costs	Units	Total
Equipment				
Linear cutting stapler		$470	1	$470
Staples		$244	3	$732
Operation				
Restoration of bowel	32033	$1,110	1	$1,110
MBS 32033 co-payment	32033	$946	1	$946
Initiation of anaesthesia (8 units)	20841	$117	1	$117
MBS 20841 co-payment	20841	$501	1	$501
Anaesthesia -1:56 to 2:00 hours	23083	$117	1	$117
Assistance	51303	$222	1	$222
MBS 51300 co-payment	51303	$198	1	$198
Theatre (AR-DRG G01B)		$2,578	1	$2,578
Total consumables				$1,202
Total MBS fees				$4,143
Total patient/insurer costs				$1,645
Total cost				**$6,990**

AR-DRG: Australian Refined Diagnostic Related Group; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Cost of resection and primary anastomosis

For those patients who have a successful bridge to surgery, a single-stage surgery with resection and primary anastomosis is ideally conducted. The costs associated with resection and primary anastomosis are presented in Table 54. The theatre costs were taken from AR-DRG G01B (rectal resection without complications).

Table 54 Cost of resection and primary anastomosis

	MBS codes	Costs	Units	Total
Equipment				
Linear cutting stapler		$470	1	$470
Staples		$244	3	$732
Operational				
Resection with primary anastomosis	32025	$1,343	1	$1,343
MBS 32025 co-payment	32025	$1,292	1	$1,292
Initiation of anaesthesia (8 units)	20841	$117	1	$117
MBS 20841 co-payment	20841	$501	1	$501
Anaesthesia -1:56 to 2:00 hours	23083	$117	1	$117
Assistance	51303	$269	1	$269
MBS 51303 co-payment	51303	$198	1	$198
Theatre (AR-DRG G01B)		$2,578	1	$2,578
Total consumables				$1,202
Total MBS fees				$4,424
Total patient/insurer costs				$1,991
Total cost				**$7,616**

AR-DRG: Australian Refined Diagnostic Related Group; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

Hospitalisation and intensive care costs

The average per diem costs of hospitalisation used in the model were calculated from AR-DRG codes (version 5.1 round 13 – Private and Public). To avoid double-counting, hospitalisation costs were assumed equal to the total cost of the AR-DRG minus the operating room, critical care and prostheses costs. Nursing costs and pharmaceutical costs were retained in this value, since these are not explicitly captured elsewhere in the model. To derive a daily cost, the total hospitalisation cost was divided by the average length of hospital stay (LOS). This cost was then imputed into the model as a single cost multiplied by the estimated LOS for each procedure. The daily cost of intensive care was taken from the current fees and charges for acute health services in Victoria ($2,138). Table 55 summarises the hospital costs used in the analysis.

Table 55 Hospital stay costs used in the model

	MBS code	Costs	Units	Total
Hospital stay stent – palliation (AR-DRG G05B)		$672	2.6	$1,746
Hospital stay stent – bridge to surgery (AR-DRG G05B)		$672	5	$3,358
Hospital stay colostomy – palliation (AR-DRG G02B)		$800	8.1	$6,484
Hospital stay colostomy – bridge to surgery (AR-DRG G02B)		$800	10	$8,004
Intensive care unit (ICU)		$2,138	1	$2,138
ICU attendance – colostomy	13870	$267	1	$267
MBS 13870 co-payment	13870	$153	1	$153
Hospital stay – Hartmann's procedure (AR-DRG G01B)		$796	10	$7,964
Intensive care unit (ICU)		$2,138	2	$4,276
ICU attendance – Hartmann's procedure	13870	$267	1	$267
MBS 13870 co-payment	13870	$153	1	$153
ICU subsequent attendance – Hartmann's procedure	13873	$198	1	$198
MBS 13873 co-payment	13873	$106	1	$106
Hospital stay – Hartmann's second stage (AR-DRG G01B)		$796	10	$7,964
Hospital stay – Resection / primary anastomosis (AR-DRG GO1B)		$796	7	$5,574

AR-DRG: Australian Refined Diagnostic Related Group; ICU: intensive care unit; MBS: Medicare Benefits Schedule.
Note: Numbers may not sum to total due to rounding.

For the base case analysis (palliation group), the LOS for each procedure was taken from Xinopoulos et al (2004). In this study, patients receiving a colonic SEMS for palliation had a significantly shorter LOS than the palliative colostomy group (2.6 versus 8.1 days). For the sensitivity analysis and the bridge to surgery analysis, expert opinion was used. The expert clinical advice estimated that a colostomy would require 10 days hospital stay plus one day in intensive care. A Hartmann's procedure would require 10 days in hospital and two days in intensive care and then a 10-day stay without intensive care for the second stage of a two-stage surgery. The hospital stay for resection and primary anastomosis would require a one-week hospital stay without intensive care.

Post-procedural costs

Table 56 summarises the costs incurred post surgery.

Table 56 Post-procedural costs used in the model

	MBS code	Costs	Units
Full blood count	65070	$12.80	X LOS
MBS 65070 co-payment	65070	$7.33	X LOS
Liver function test	66512	$13.35	X LOS
MBS 66512 co-payment	66512	$7.70	X LOS
Plain abdominal x-ray	58903	$71.40	2
MBS 58903 co-payment	58903	$43.02	2
Subsequent specialist consult	105	$35.90	X LOS stent
MBS 105 co-payment	105	$37.31	X LOS stent
Stoma bag		$5.30	1 X survival
Stomal therapist		$ 42.00	2

LOS: length of hospital stay; MBS: Medicare Benefits Schedule

All procedures include a full blood count and liver function test per day in hospital. In addition, for the procedure, patients would require two plain abdominal x-rays (MBS 58903) and a specialist visit each day of hospitalisation. The specialist fee is explicitly added to the model because the proposed fee for the procedure does not include post-surgical specialist visits (unlike the other surgical procedures).

The MBS codes for colostomy, Hartmann's procedure and resection with primary anastomsis include post-surgical specialist visits. Therefore to avoid double-counting post-procedural specialist visits are not included.

For permanent colostomy the daily cost of a stomal bag is included. This is incorporated in the model as a function of survival. The cost of stoma bags used in the model is based on the stomal appliance scheme reimbursement ($5.30). It is assumed that patients would also receive two stomal therapist visits during the year (expert opinion).

For patients that receive a temporary colostomy or a Hartmann's procedure, it is assumed that stoma bags would be required for four weeks and eight weeks, respectively. This is to account for the period until re-anastomosis could be conducted and the bowel function restored (expert opinion).

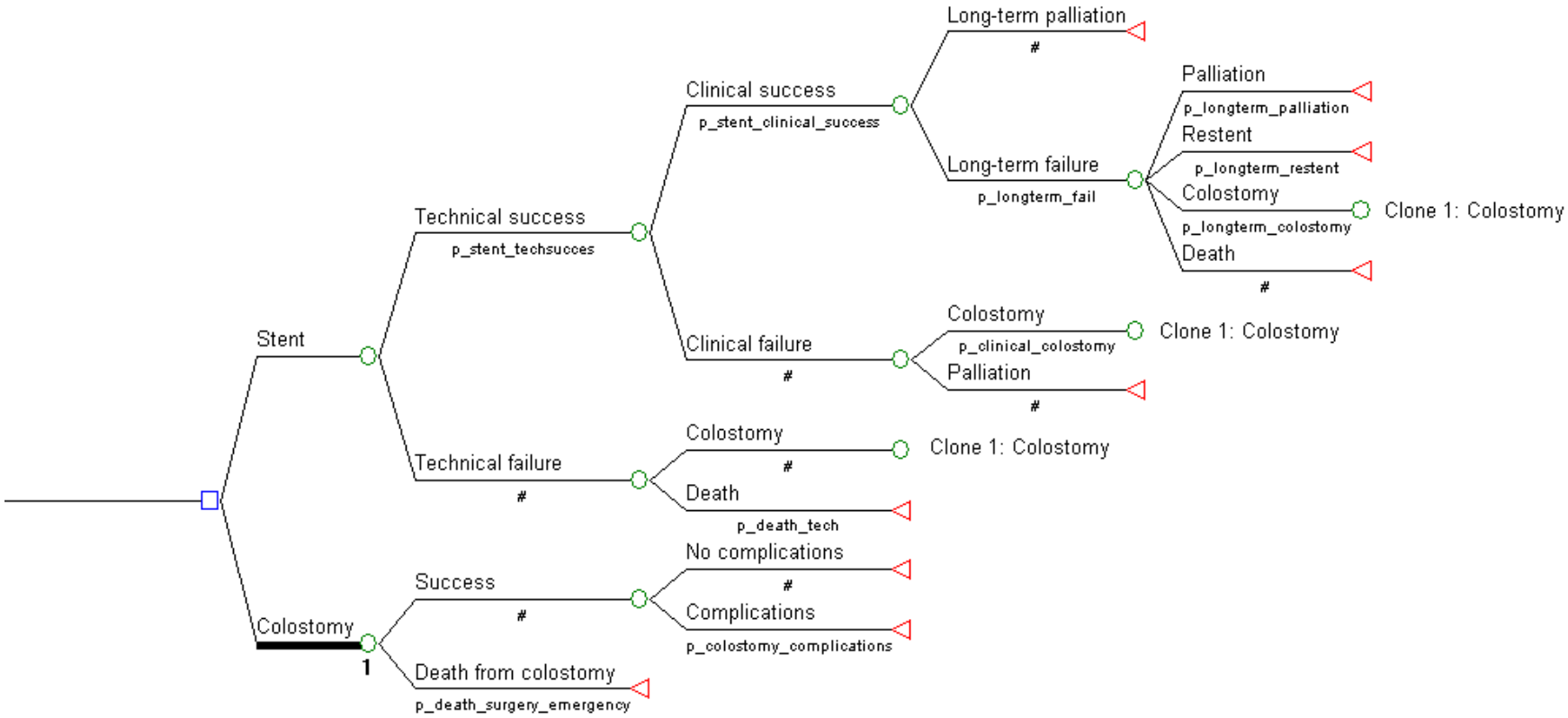
Patients fit for multi-stage surgery (receiving SEMS for palliation)

Economic model

A decision tree was developed for estimating the costs and benefits of using palliative SEMS compared to palliative colostomy for patients fit for surgery.

The decision tree incorporates the median survival of the patients and differences in length of stay in hospital, intensive care requirements, overall costs and quality of life (Figure 8).

Figure 8 Decision tree used in the economic model for patients requiring palliation (stent vs. colostomy)



□ represents a decision node between the two treatment options; ○ represents a chance node with a probability of various events occurring; ◁ represents a terminal node where the pathway ends.
The bold line represents a clone of the substree which is replicated elsewhere in the tree. p: Probabilities that were determined by the literature; #: 1-p.

Table 57 summarises the model inputs in the decision tree for the palliation group.

Table 57 Summary of cost analysis for palliation (stent vs colostomy)

Parameter	Value	Min	Max	Source
Probabilities				
Technical success – stent	0.92	0.47	1.00	Khot et al (2002)
Clinical success (| technical success) – stent	0.95	0.47	1.00	Estimated from Khot et al (2002)
Probability death (| technical failure) – stent	0.04	0.02	0.06	Estimated from Khot et al (2002)
Probability long-term failure (| clinical success)	0.20	0.10	0.30	Estimated from Khot et al (2002)
Failure requiring palliation (| long-term failure)	0.47	0.24	0.70	Estimated from Khot et al (2002)
Failure requiring re-stent (| long-term failure)	0.47	0.24	0.70	Estimated from Khot (et al 2002)
Failure requiring colostomy (| long-term failure)	0.06	0.03	0.09	Estimated from Khot et al (2002)
Failure causing death (| technical success)	0.01	0.01	0.02	Estimated from Khot et al (2002)
Clinical failure requiring colostomy (| technical success)	0.69	0.35	1.00	Estimated from Khot et al (2002)
Probability of death from emergency surgery – colostomy	0.12	0.06	0.18	Tinley et al (2007)
Probability of complications from colostomy	0.25	0.13	0.38	Varadarajulu et al (2011)
Length of stay in hospital (days)				
LOS stent	2.6	1.3	3.9	Fiori et al (2004)
LOS colostomy	8.1	4.1	12.2	Fiori et al (2004)
LOS for colostomy complications (additional)	2.0	1.00	3.0	Expert advice
LOS ICU for colostomy	1.0	0.00	1.5	Expert advice
Survival (weeks)				
Survival after stent	21	10.5	31.5	Xinopolous et al (2004)
Survival after colostomy	21	10.5	31.5	Xinopolous et al (2004)
Utility				
Utility stage IV colorectal cancer with stent	0.25	0.20	0.31	Ness et al (1999)
Utility stage IV colorectal cancer with colostomy	0.25	0.20	0.31	Ness et al (1999)
Costs				
Cost of pre-operative procedures	$1,683	$842	$2,525	See costing section for further details and cost estimates
Cost of stent procedure	$5,968	$2,984	$8,952	
Cost of colostomy procedure	$3,146	$1,573	$4,719	
Cost per diem hospital stay colostomy	$800	$400	$1,201	
Cost per diem hospital stay stent	$672	$336	$1,007	
Cost of intensive care	$2,557	$1,279	$3,836	
Cost of palliation	$6,073	$3,037	$9,110	
Cost of daily post operative procedures	$28	$14	$42	
Cost of post-operative radiographs	$71	$36	$107	
Cost of post-operative specialist visits stent	$93	$47	$140	
Cost of stoma bag (per bag)	$5	$3	$8	
Cost of stomal therapist	$42	$21	$63	

LOS: Length of hospital stay; ICU: Intensive care unit.
Note: '|' denotes that the value is a conditional probability either conditional on clinical success, technical success or long-term failure.

Estimate of effectiveness

There were only two RCTs that measured the effectiveness of SEMS relative to colostomy for colonic obstruction for palliation (Xinopolous et al 2004; Fiori et al 2004).

Both RCTs compared SEMS with colostomy (stoma creation) for palliation in the management of inoperable malignant colonic obstruction. As previously reported, the results from Xinopolous et al (2004) found that 14 out of 15 patients (93.3%) had successful SEMS insertions without serious complications compared with 15 patients (100%) who underwent surgery. Fiori et al (2004) reported technical and clinical success rates of 100 per cent in the 11 patients who had SEMS placed and also for the 11 patients who underwent colostomy.

Given the low number of patients in both RCTs and the lack of follow-up data regarding outcomes after SEMS insertion, a systematic review of clinical studies and case series by Khot et al (2002) was used to form the basis of the transitions through the model. This study was chosen because individual outcomes were clearly identified from the data presented. A second systematic review by Watt et al (2007) was considered, but the information presented was difficult to interpret within the model framework.

Technical success was achieved in 551 of 598 patients (92%) and clinical success was achieved in 525 patients (88%) (Khot et al 2002). The probability of clinical success used in the model was 95 per cent, which is the probability of clinical success conditional on technical success. This estimate is similar to the review by Watt et al (2007) that reported a technical success rate of 96 per cent and a clinical success rate of 92 per cent.

Long-term SEMS failure (within 21 weeks) was noted to occur in 20 per cent of patients who had immediate clinical success (Khot et al 2002). Of these patients, 47 per cent required no further treatment (due to stent migration), 47 per cent required a re-stent (due to migration or perforation) and 6 per cent required a colostomy.

Mortality

There was no statistically significant difference in the median survival of patients reported between the palliative SEMS group (21.4 weeks) and the palliative colostomy group (20.9 weeks) reported in Xinopolous et al (2004). In the model, a median survival time of 21 weeks was applied to both arms.

The overall mortality rate in the SEMS group was 0.5 per cent, calculated as a total of three deaths from 598 SEMS attempted (Khot et al 2002). The probability of death following a colostomy was also included in the model. A value of 12.1 per cent was used to represent death from an emergency surgery, which has been reported in the literature to range from 10 to 20 per cent and can be as high as 30 per cent (Farrell 2007; Katsanos et al 2011; Targownik 2004; Tilney 2007).

Length of hospital stay

Length of hospital stay was statistically different in both studies. Fiori et al (2004) reported a median hospital stay of 2.6 days after SEMS insertion compared to 8.1 days for the surgery group ($p<0.001$). Xinopoulos et al (2004) reported a total hospital stay of 28 days (sum of patients) for those undergoing SEMS placement and 60 days for those who underwent colostomy surgery; however, no statistically significant results were reported. Therefore, the median hospital stays from Fiori et al (2004) were used in the model.

Complications

In the colostomy arm, it was assumed that 25 per cent of patients would experience complications that would require an additional two days of hospitalisation. This figure is derived from Varadarajulu et al (2011), in which no patient who underwent stenting required readmission for a complication; however, 25 per cent of patients who received surgery did require readmission (p=0.019).

Utility

The model incorporates quality of life into the model by assigning a utility of zero for those who immediately die from the surgical procedure. For those who survive and are treated with palliation, the utility value of 0.25 was assigned to both groups. This value was accrued over the estimated survival of 21 weeks in both arms. The utility value was sourced from Ness et al (1999), which represent stage IV metastatic/unresectable colorectal cancer.

Cost-effectiveness results

For the base case analysis the total cost of a SEMS procedure was estimated to be $17,809. This value includes the costs of palliation and the cost of colostomy for those with SEMS failure. The total average cost for patients that received a colostomy was estimated to be $20,516. This represents a cost savings of $2,707 with SEMS instead of colostomy when used for palliation.

The estimated average patient receiving a SEMS would gain 0.099 QALYs compared to 0.089 QALYs in the colostomy group. This yields an incremental benefit of 0.010 QALYs per patient. This benefit is due to the difference in mortality rates following SEMS insertion and colostomy.

In terms of cost-effectiveness, SEMS dominated colostomy. In other words, it provided additional benefit at lower costs (See Table 58).

Table 58 Summary of cost-effectiveness analysis for palliation (stent vs colostomy)

	Average cost	Incremental cost	QALYs	Incremental QALYs	ICER
Stent	$17,809		0.099		
Colostomy	$20,516	-$2,707	0.089	0.010	Dominated

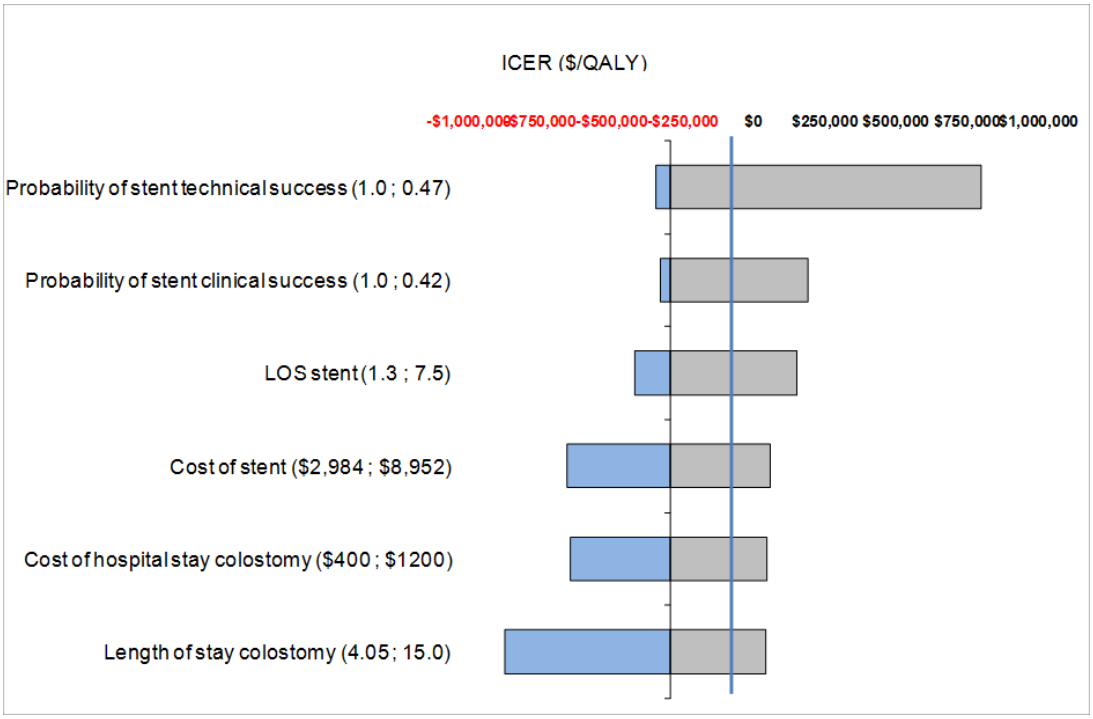
ICER: Incremental cost-effectiveness ratio; QALY: Quality-adjusted life year.

Sensitivity analysis

A univariate sensitivity analysis was conducted to test the robustness of the model and identify the parameters that were driving the results of the model. The parameters were tested using a confidence interval if available and if unavailable the estimate was increased and decreased by 50 per cent (See Table 59). The results of the sensitivity analysis follow in Figure 9. The vertical axis on the graph represents the incremental cost of SEMS insertion relative to colostomy (in this case it is cost saving). The bars to the left of the vertical axis represent a larger cost-saving (SEMS insertion relative to colostomy) and the bars to the right represent a reduction in the cost-saving (or more costly when past the $0 line). Figure 9 only displays those parameters in which the SEMS

procedure becomes more costly than a colostomy. The other parameters have little impact on the model. A full list of all of the variables can be found in Appendix J.

Figure 9 One-way sensitivity analysis (SEMS vs. colostomy)



ICER: Incremental cost-effectiveness ratio; QALY: Quality adjusted life year

Based on the sensitivity analysis, it can be seen that the efficacy of the SEMS procedure (both technical and clinical success) is a main driver in the model. Also, the overall cost of SEMS and the LOS for insertion of SEMS also influence the overall results.

The critical point in which the parameter causes SEMS to be more costly than a colostomy (in other words when the cost per QALY = $0) can be seen in Table 59. For example, when the technical (clinical) success of the SEMS procedure is below 0.67, (0.58) colostomy is the cheaper option.

Table 59 Critical point for parameters (Cost SEMS ≥ Cost of colostomy)

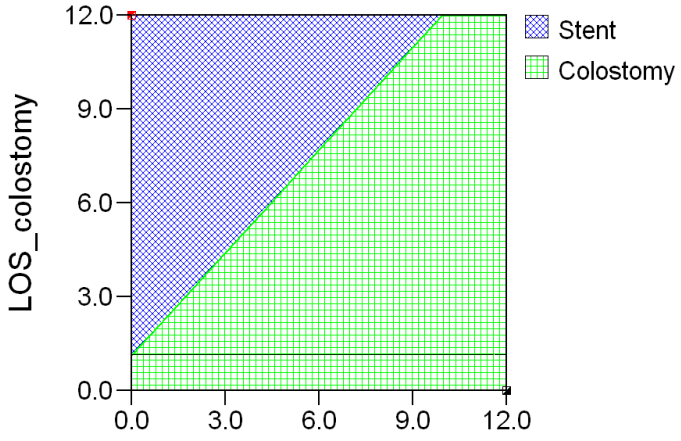
Parameter	Critical point (SEMS vs. colostomy)
Probability of stent technical success	≤ 0.67
Probability of stent clinical success	≤ 0.58
Length of stay stent	≥ 5.84
Length of stay colostomy	≤ 4.55
Cost of stent	≥ $8,200

SEMS: Self-expanding metallic stent

The cost savings due to reduced length of hospital stay was also a main driver of the model. Holding all other variables constant, if the LOS for SEMS was 5.84 days, the average cost of SEMS (including failure) would be equal to the average cost of

colostomy. If the LOS based on expert opinion (5 days for SEMS and 10 days for colostomy) was used, SEMS still dominates colostomy. Figure 10 demonstrates the relationship between LOS for SEMS and a colostomy. Given the linear relationship between the two procedures, as long as the LOS for a colostomy is at least 1.3 days greater than the LOS for SEMS, a SEMS is more cost-effective than a colostomy for palliation at a willingness to pay (WTP) threshold of $50,000 per QALY.

Figure 10 LOS stent versus LOS colostomy (WTP=$50,000/QALY)



LOS: Legnth of hospital stay; WTP: Willingness-to-pay

Sensitivity analysis around the stent procedure copayment

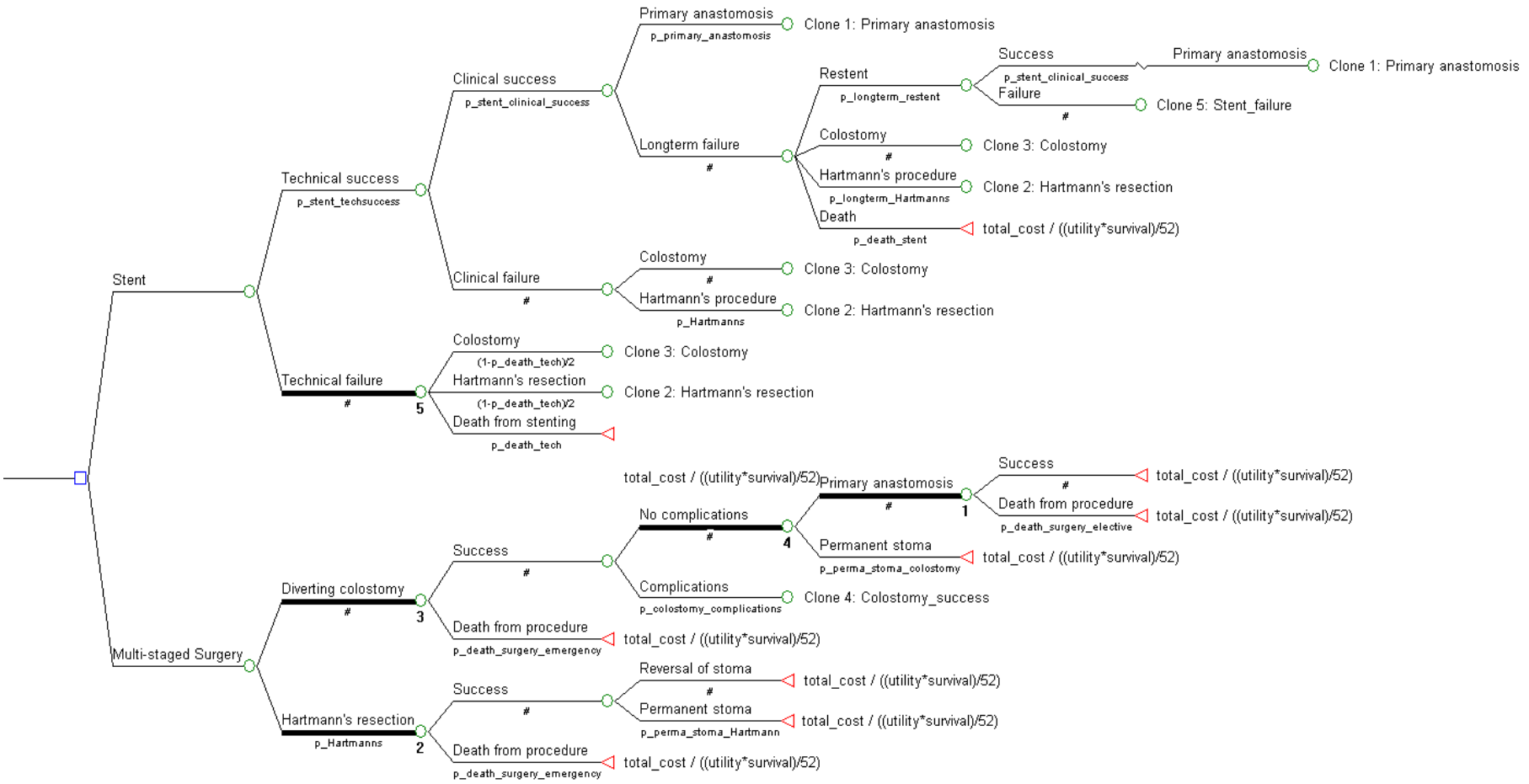
In the model, the co-payment for SEMS procedure is estimated to be 25 per cent of the schedule fee given the absence of co-payment data. It is likely that this value is underestimated and the total fee charged to the patient may be higher than $650 (100% proposed fee). In the palliation group, when the value of the copayment is greater than $2570, SEMS does not represent a cost savings (relative to colostomy). Furthermore, if the copayment is greater than $3000 the cost-effectiveness becomes questionable (assuming a WTP threshold of $50,000 per QALY).

Patients fit for multi-stage surgery (receiving SEMS as a bridge to surgery)

Economic model

A decision tree was developed for estimating the costs and benefits of using SEMS as a bridge to surgery compared to 'multi-stage surgery'. The 'multi-stage surgery' procedures are colostomy or Hartmann's procedure. Figure 11 illustrates the decision tree for those patients receiving multi-stage surgery.

Figure 11 Decision tree for bridge-to–surgery (SEMS vs multi-stage surgery)



□ represents a decision node between the two treatment options; ○ represents a chance node with a probability of various events occurring; ◁ represents a terminal node where the pathway ends. The bold line represents a clone of the substree which is replicated elsewhere in the tree. p: Probabilities that were determined by the literature; #: 1-p

Model inputs

The probabilities used in the decision tree were obtained from a variety of sources including published literature and expert clinical advice. At the decision node it was assumed that the split between those who would receive a Hartmann's resection and a colostomy in the 'multi-stage surgery' arm would be a 50/50 split (expert clinical advice). Table 60 summarises the model inputs in the decision tree for the bridge to surgery population.

Table 60 Summary of model inputs for the bridge to surgery group

Parameter	Value	Min	Max	Source
Probabilities				
Technical success – stent	0.92	0.47	1.00	Khot et al (2002)
Clinical success (| technical success) – stent	0.95	0.47	1.00	Estimated from Khot et al (2002)
Probability long-term failure (| clinical success)	0.20	0.10	0.30	Estimated from Khot et al (2002)
Failure requiring Hartmann's (| long-term failure)	0.41	0.21	.62	Estimated from Khot et al (2002)
Failure requiring restent (| long-term failure)	0.47	0.24	0.70	Estimated from Khot et al (2002)
Failure causing death (| long-term failure)	0.01	0.01	0.02	Estimated from Khot et al (2002)
Clinical failure requiring colostomy (| long-term failure)	0.69	0.35	1.00	Estimated from Khot et al (2002)
Probability of resection with primary anastomosis	0.80	0.40	1.00	Estimated from Khot et al (2002)
Probability of a permanent stoma	0.40	0.30	0.50	Tinley et al (2007), Expert advice
Split between Hartmann's and Colostomy	0.50	0.25	0.75	Expert advice
Probability of death from stenting	0.04	0.02	0.06	Estimated from Khot et al (2002)
Probability of death from elective surgery	0.04	0.02	0.06	Osman et al (2000), Tarogownik et al (2004), Feo and Schaffzin (2011)
Probability of death from emergency surgery	0.12	0.06	0.18	Tinley et al (2007)
Probability of complications from colostomy	0.25	0.13	0.38	Varadarajulu et al (2011)
Length of stay in hospital				
LOS stent	5	2.5	7.5	Expert advice
LOS colostomy	10	5	15	Expert advice
LOS for colostomy complications	2	1	3	Expert advice
LOS ICU for colostomy	1	0	1.5	Expert advice
LOS Hartmann's procedure	1	5	15	Expert advice
LOS ICU for Hartmann's procedure	2	1	3	Expert advice
LOS resection with primary anastomosis	7			Expert advice
Other inputs				
Survival after stent (weeks)	48.36	24.18	52	Estimated from American Cancer Society (2007)[a]
Weeks with a bridge to surgery colostomy	4	2	6	Singh et al (2006)
Weeks till second stage Hartmann's	8	4	12	Singh et al (2006)
Utility				
Utility stage II / III without colostomy	0.59	0.54	0.64	Ness et al (1999)
Utility stage II / III with permanent ostomy	0.50	0.44	0.56	Ness et al (1999)
Utility of death	0	0	0	Assumption
Costs				
Cost of pre-operative procedures	$1,683	$842	$2,525	See costing section for further details for all cost estimates
Cost of second pre-operative procedure	$753	$377	$1,130	
Cost of stent procedure	$5,968	$2,984	$8,952	
Cost of colostomy procedure	$3,146	$1,573	$4,719	
Cost of Hartmann's procedure	$6,202	$3,101	$9,303	

Parameter	Value	Min	Max	Source
Cost of second stage Hartmann's	$6,990	$3,495	$10,049	
Cost of resection and primary anastomosis	$7,616	$3,808	$11,424	
Cost per diem hospital stay colostomy	$800	$400	$1,201	
Cost per diem hospital stay stent	$672	$336	$1,007	
Cost per diem hospital stay Hartmann's/primary anastomosis or second stage	$796	$398	$1,195	
Cost of intensive care and attendance	$2,557	$1,279	$3,836	
Cost of palliation	$6,073	$3,037	$9,110	
Cost of daily post operative procedures	$28	$14	$42	
Cost of post-operative radiographs	$71	$36	$107	
Cost of post-operative specialist visits stent	$93	$47	$140	
Cost of stomal bag	$5	$3	$8	
Cost of stomal therapist	$42	$21	$63	

a See details of calculation below under mortality

Estimate of effectiveness

The clinical and technical success of the SEMS procedure was taken from Khot et al (2002). The mortality rate of Hartmann's procedure or colostomy was 12 per cent, which represents death from emergency surgery. The probability of death from an elective surgery (bridge to surgery following either a colostomy or SEMS) was 4 per cent in the model. The probability of having a permanent stoma after a Hartmann's procedure was 40 per cent (Tilney et al 2007). This was supported by expert advice (range 30-50%).

Mortality

There is no evidence of differences in long-term survival between patients that receive SEMS and those receiving resection or emergency surgery (Tilney et al 2007). Overall survival (in addition to procedure related mortality) was incorporated into the model using the five-year survival rates for Duke's stage B colorectal cancer. The five-year survival rate of 70 per cent was converted into a one-year probability of death of 7 per cent. The number of weeks applied in the model was 48.36 [52 weeks*(1-0.07)] to take into account the 7 per cent expected to die from cancer in that year. A palliation cost was also attributed to those patients expected to die in the first year.

Length of hospital stay

All of the LOS values were sourced from expert opinion. The estimated LOS used in the base case analysis was 5 days (SEMS), 10 days (colostomy), 10 days (Hartmann's) and 7 days (resection with primary anastomosis). An additional ICU stay of one day and two days was attributed to colostomy and Hartmann's procedure, respectively.

Complications

For those receiving a colostomy, it was assumed that 25 per cent of patients would experience a complication that would require an additional two days stay in hospital. This figure is derived from Varadarajulu et al (2011).

Utility

Quality of life was incorporated into the model by assigning a utility of zero for those who immediately die from the surgical procedure.A utility of 0.59 was assigned to those who had a resection with primary anastomosis or Hartmann's procedure that was successfully completed in two stages (this represents stage II/III rectal cancer treated with resection/chemotherapy/radiation therapy). For those patients with a permanent stoma, a utility of 0.50 was assigned to account for the quality of life decrement for living with a permanent stoma. This value represents stage II/III rectal cancer treated with resection/chemotherapy/radiation therapy and permanent ostomy. All of the utility values were taken from Ness et al (1999).

Cost-effectiveness results

For the base case analysis, the total cost of a SEMS procedure was estimated to be $29,729. This value includes the costs of a re-stent procedure, stoma creation or Hartmann's procedure in cases of a stent failure. The total average cost for patients that received 'multi-stage surgery' (either a colostomy or a Hartmann's procedure) was estimated to be $30,169. This represents a cost savings of $440.

The estimated average patient receiving SEMS would gain 0.510 QALYs compared to 0.458 QALYs in the 'multi-stage surgery' group. This yields an incremental benefit of 0.052 QALYs per patient. This benefit is due to difference in mortality rates between an emergency procedure and an elective procedure.

In terms of cost-effectiveness, SEMS dominated colostomy. In other words it provided additional benefit at lower costs (See Table 61).

Table 61 Summary of cost-effectiveness analysis for bridge to surgery (SEMS vs multi-stage surgery)

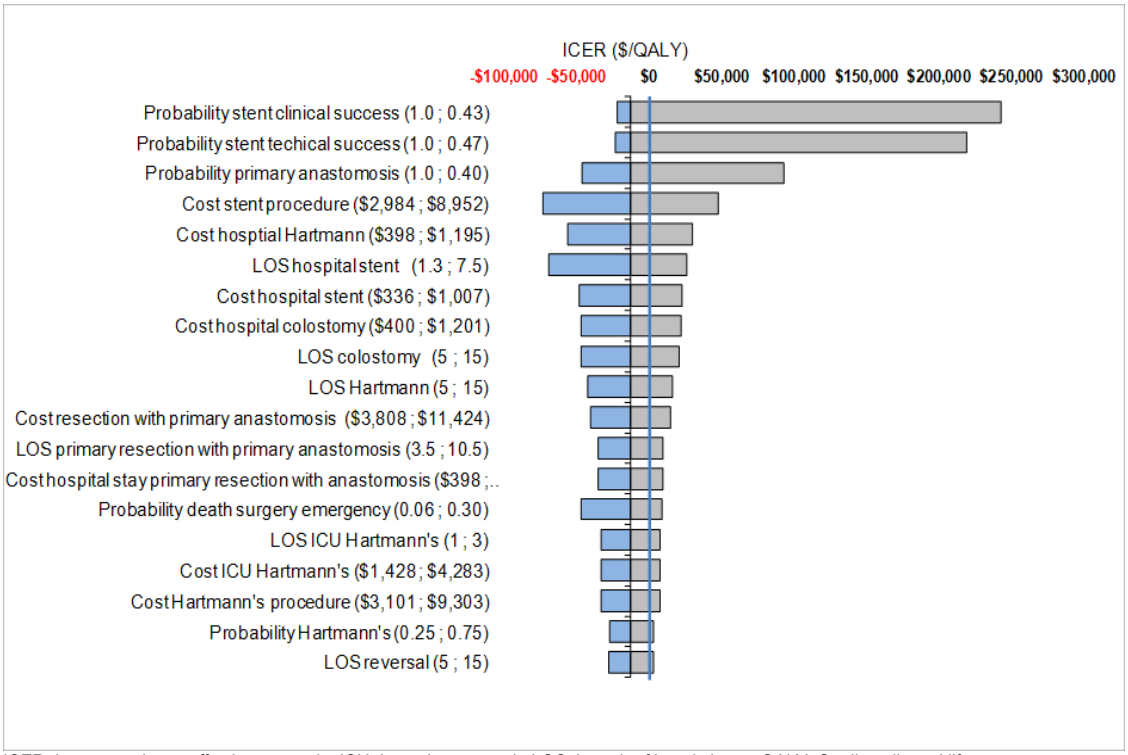
	Average cost	Incremental cost	QALYs	Incremental QALYs	ICER
Stent	$29,729		0.510		
Colostomy	$30,169	-$440	0.458	0.052	Dominated

ICER: Incremental cost-effectiveness ratio; QALY: Quality-adjusted light year.

Sensitivity analysis

The results of this one-way sensitivity analysis can be seen in Figure 12. Only those parameters that crossed the $0 line are displayed; all other parameters can be found in Appendix J.

Figure 12 One-way sensitivity analysis (SEMS vs multi-stage surgery)



ICER: Incremental cost-effectiveness ratio; ICU: Intensive care unit; LOS: Length of hospital stay; QALY: Quality adjusted life year

Based on the sensitivity analysis, it can be seen that the efficacy of the SEMS procedure (both technical and clinical success) is a main driver in the model.

The critical point at which the parameter causes SEMS to be more costly than the comparator (in other words when the cost per QALY = $0) can be seen in Table 62. At any values greater than these critical points, there is an associated cost per QALY gained.

Table 62 Critical point for parameters (Cost SEMS = Cost of multi-stage surgery)

Parameter	Critical point (SEMS vsmulti-stage surgery)
Probability of stent technical success	≤ 0.86
Probability of stent clinical success	≤ 0.47
Length of stay stent	≥ 5.8
Length of stay colostomy	≤ 8.2
Length of stay Hartmann's procedure	≤ 7.8
Length of stay primary anastomosis	≤ 8.9
Length of stay ICU Hartmann's	≤ 1.4
Length of stay for Hartmann's reversal	≤ 5.9
Cost of hospital stay colostomy	≤ $655
Cost of hospital stay stent	≤ $791
Cost of hospital stay Hartmann's procedure	≤ $680
Cost of hospital stay resection with primary anastomosis	≤ $1,020
Cost of ICU Hartmann's	≤ $1,968
Cost of stent	≥ $6,392
Cost of resection with primary anastomosis	≤ $8,503
Cost of Hartmann's procedure	≤ $4,509
Probability of resection with primary anastomosis	≤ 0.40
Probability of Hartmann's (split between Hartmann's/ colostomy)	≤ 0.70
Probability of death from emergency surgery	≤ 0.18

ICU: Intensive care unit; SEMS: Self-expanding metallic stent.

Sensitivity analysis regarding the SEMS procedure co-payment

As previously discussed, the co-payment is likely to be underestimated and the total cost of the SEMS procedure and co-payment are likely to be higher than an estimated $650 (100% MBS fee). If the co-payment in the bridge to surgery group is greater than $761, SEMS is not a cost savings compared to multi-stage surgery. At a value greater than $761 and less than $3,150, SEMS is still considered cost-effective at a willingness-to-pay threshold of $50,000 per QALY.

Patients unfit for multi-stage surgery who receive palliation only (best supportive care)

For patients who are unfit for surgery, a cost analysis was conducted to compare the incremental cost of SEMS compared to best supportive care (in this case, the treatment costs of palliation) (See Table 63). Based on expert opinion, patients receiving SEMS would require five days in hospital with no ICU.

Table 63 Summary of cost analysis for palliation only (BSC)

	SEMS	Palliation only (BSC)

Pre-operative costs		
Consumables	$0	$0
MBS fees	$963	$963
Patient/insurer costs	$719	$719
Total pre-operative	$1,683	$1,683
Procedural costs		
Consumables	$3,535	
MBS fees and theatre costs	$1,840	
Patient/insurer costs	$593	
Total procedural costs	$5,968	
Hospital stay costs		
Consumables	$0	
MBS fees	0	
Patient/insurer costs	$3,358	
Total hospital stay	$3,358	
Post-operative costs		
Consumables	$0	
MBS fees	$185	
Patient/insurer costs	$147	
Total post-operative	$333	
Palliative costs		
Total estimated costs of palliation	$6,073	$6,073
Total costs	$17,415	$7,756

BSC: Best supportive care; MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Financial implications

Patients fit for multi-stage surgery

An epidemiological approach, based on the incidence of colorectal cancer in Australia, was used to estimate the cost per annum of providing SEMS instead of colostomy or Hartmann's procedure for treatment of malignant colorectal obstruction. The data sources used in the estimation of the eligible population are shown in Table 64.

Table 64 Data sources used in estimating the number of colorectal cancer cases

Parameter	Value	Source
Australian population	Males: 11,268,679 Females: 11,378,785	Australian Bureau of Statistics data by age (Series B, 3222.0)
Incidence rate of cancers of the colon, rectum and anus	Males: 78.6 per 100,000 Females: 56.3 per 100,000	Australian Institute of Health and Welfare: Cancer incidence projection Australia 2002 to 2011
Proportion of anal cancers	Males: 1.5% Females: 2.7%	AIHW Australian Cancer incidence and Mortality (ACIM) books (Excel pivot table)
Incidence of obstruction	8-29%	Varadarajulu et al (2011)
Incidence of left-sided malignancies	75%	Application for SEMS
Percentage eligible for curative surgery (single-stage)	50%	Xinopoulos et al (2004)
Percentage who are treated for palliation	30%	Assumption

Estimated number of colorectal cancer cases

The total estimated Australian population for 2011 was taken from the Australian Bureau of Statistics projected population statistics. The estimated incidence of colon cancer was sourced from the AIHW Cancer Incidence Projections 2001 to 2011. The estimates include ICD-10: C18-C21. For the purposes of this report, we excluded C21 from the estimation, as this code represents anal cancers. The percentage of cases of anal cancer was taken from the AIHW cancer incidence data cubes and subtracted off the total estimate. Table 65 summarises the approach to estimate the number of colorectal cancer cases.

Table 65 Estimated number of colorectal cancer cases

	2012
Population males (2012)	11,268,679
Incidence rate of colon, rectal and anal cancer	8,857
Estimated number of anal cancers	151
Estimated number of colorectal cancers	8,707
Population females (2012)	11,378,785
Incidence rate of colon, rectal and anal cancer	6,406
Estimated number of anal cancers	173
Estimated number of colorectal cancers	6,233
Total estimated number of colorectal cancer cases	**14,940**

Estimated number of patients requiring treatment

The estimated incidence of bowel obstruction in patients with colorectal cancer varies widely. Varadarajulu et al (2011) reported an incidence of between 8 to 29 per cent. A report by the Royal College of Surgeons reported that between 15 to 20 per cent of patients with colonic cancer present with symptoms of acute bowel obstruction (Trompetas 2008), whereas Tinley et al (2007) and Osman et al (2000) reported 15 per cent and 30 per cent, respectively.

The estimated number of patients requiring the procedure for bowel obstruction is presented in Table 66. The low (and high) estimate is based on 8 per cent (29%) of colorectal cancer patients with bowel obstruction. Of these patients, 75 per cent would be expected to have left-sided malignancies (as per the applicant) and 50 per cent would be eligible for single-stage surgery (Xinopoulos et al 2004). Of those not eligible for single-stage surgery, 30 per cent would be treated with palliative treatment and the rest would be eligible for a second stage of a two-stage resection (Deans et al 1994).

In summary, the number of patients eligible for SEMS insertion for palliation ranges between 134 and 487. The number of patients eligible for SEMS for bridge to surgery ranges between 314 and 1,137.

Table 66 Estimated number of patients to receive treatment

	Low (8%)	High (29%)
Estimated number of colorectal cancer cases	14,940	14,940
Incidence of obstruction (8%-29%)	1,195	4,333
Percentage of left sided malignancies (75%)	896	3,249
Percentage eligible for curative surgery (single-stage) (50%)	448	1,625
Estimated patients for palliative treatment (30%)	134	487
Estimated patients fit for surgery (bridge to surgery)	314	1,137

Table 67 presents the total cost of a SEMS insertion compared to a colostomy, excluding the costs of palliation, stent failures or complications. These costs include the pre-operative costs, surgical costs, hospitalisation costs and post-operative costs. As can be seen, a SEMS insertion has much higher surgical costs compared to a colostomy. However, overall the colostomy costs are higher due to the hospital costs incurred because of increased length of stay.

Table 67 Estimated costs of SEMS versus colostomy (palliation)

	SEMS	Colostomy
Consumables	$0	$0
MBS fees	$963	$963
Patient/insurer costs	$719	$719
Total pre-operative	**$1,683**	**$1,683**
Consumables	$3,535	$5
MBS fees and theatre costs	$1,840	$2,360
Patient/insurer costs	$593	$781
Total surgical	**$5,968**	**$3,146**
Consumables	$0	$0
MBS fees	$0	$267
Patient/insurer costs	$1,746	$8,774
Total hospital stay	**$1,746**	**$9,041**
Consumables	$0	$779
MBS fees	$185	$105
Patient/insurer costs	$147	$7
Total post-operative	**$333**	**$891**
Total costs	**$9,790**	**$14,760**

MBS: Medicare Benefits Schedule; SEMS: self-expanding metallic stents
Note: Numbers may not sum to total due to rounding.

Once stent failures, complications and palliation costs are accounted for, the overall average cost of a SEMS versus a colostomy still favours stenting (See Table 68).

Table 68 Estimated total costs of SEMS versus colostomy (palliation)

	SEMS	Colostomy
Consumables	$3,902	$690
MBS fees	$9,659	$11,285
Patient/insurer costs	$4,248	$8,541
Total post-operative	**$17,809**	**$20,516**

MBS: Medicare Benefits Schedule; SEMS: self-expanding metallic stents

Table 69 and Table 70 show the overall estimated impact of SEMS placement in lieu of a colostomy. If all patients who would have received colostomy received SEMS, the overall cost savings would be between $363,981(lower estimate) and $1,319,430 (upper limit). The cost savings are mainly due to lower MBS costs and lower patient/private health insurance costs due to short hospitalisation. However, the cost savings are offset somewhat by an increased cost in consumables, given the high costs of the stent itself.

Table 69 Estimated total costs of SEMS versus colostomy (lower limit)

	SEMS	Colostomy
Total cost per patient	$17,809	$20,516
Number of patients	134	134
Breakdown of financial implications		
Consumables	$524,659	$92,777
MBS items	$1,298,740	$1,517,371
Patient/insurer costs	$571,182	$1,148,415
Total financial implications	**$2,394,582**	**$2,758,562**
Incremental costs		
Consumables		$431,883
MBS items		-$218,630
Patient/insurer costs		-$577,233
Total cost		**-$363,981**

MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Table 70 Estimated total costs of SEMS versus colostomy (upper limit)

	SEMS	Colostomy
Total cost per patient	$17,809	$20,516
Number of patients	487	487
Breakdown of financial implications		
Consumables	$1,901,890	$336,316
MBS items	$4,707,933	$5,500,468
Patient / insurer costs	$2,070,535	$4,163,004
Total financial implications	**$8,680,358**	**$9,999,788**
Incremental costs		
Consumables		$1,565,574
MBS items		-$792,535
Patient / insurer costs		-$2,092,469
Total cost		**-$1,319,430**

MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Estimated costs for treating patients as a bridge to surgery

The total average costs for SEMS versus multi-stage surgery is summarised in Table 71. These costs include those patients who would receive a resection with primary anastomosis after a bridge to surgery and also any re-stenting or multi-stage surgeries due to a SEMS failure. The costs also include a proportion of patients who receive palliation. The overall cost savings is driven by lower costs in the MBS fees and costs to the patient and private health insurance. If SEMS were to replace multi-stage surgery, there would be an increased cost in consumables, given the high costs of the SEMS itself.

Table 71 Estimated total costs of SEMS versus multi-stage surgery

	SEMS	Multi-stage surgery
Consumables	$5,211	$1,908
MBS items	$9,848	$11,852
Patient/insurer costs	$14,670	$16,409
Total post-operative	**$29,729**	**$30,169**

MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Table 72 and Table 73 present the overall estimated impact of SEMS placement of either a colostomy or a Hartmann's procedure. If all patients who would have received a colostomy or Hartmann's received SEMS, the overall cost savings would be between $138,045 (lower estimate) and $500,412 (upper limit).

Table 72 Estimated total costs of SEMS versus multi-stage surgery (lower limit)

	SEMS	Multi-stage surgery
Total cost per patient	$29,729	$30,169
Number of patients	314	314
Breakdown of financial implications		
Consumables	$1,634,888	$598,612
MBS items	$3,089,690	$3,718,421
Patient/insurer costs	$4,602,534	$5,148,124
Total financial implications	**$9,327,112**	**$9,465,157**
Incremental costs		
Consumables		$1,036,276
MBS items		-$628,731
Patient/insurer costs		-$545,590
Total cost		**-$138,045**

MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Table 73 Estimated total costs of SEMS versus multi-stage surgery (upper limit)

	SEMS	Multi-stage surgery
Total cost per patient	$29,729	$30,169
Number of patients	1,137	1,137
Breakdown of financial implications:	0	0
Consumables	$5,926,468	$2,169,968
MBS items& hospital fees	$11,200,127	$13,479,275
Patient out-of-pocket	$16,684,186	$18,661,950
Total financial implications	**$33,810,781**	**$34,311,193**
Incremental costs:		
Consumables		$3,756,501
MBS items		-$2,279,148
Patient / insurer costs		-$1,977,764
Total cost		**-$500,412**

SEMS: Self-expanding metallic stent; MBS: Medicare Benefits Schedule.

Patients unfit for multi-stage surgery

No evidence was identified regarding the number of patients who currently receive best supportive care for malignant bowel obstruction. It is most likely that a proportion of those treated for palliative purposes would receive best supportive care. In the analysis the low and high estimates from the fit for surgery (palliation group) were used. If all patients received SEMS rather than best supportive care, the overall additional cost would be between $1,294,105 (lower estimate) (See Table 74) and $4,703,201 (upper limit) (See Table 75).

Table 74 Estimated total costs of SEMS versus palliation only (BSC) (lower limit)

	SEMS	Palliation only (BSC)
Total cost per patient	$17,413	$7,756
Number of patients	134	134
Breakdown of financial implications		
Consumables	$473,690	$0
MBS items	$1,214,174	$942,831
Patient/insurer costs	$645,478	$96,407
Total financial implications	**$2,333,342**	**$1,039,237**
Incremental costs		
Consumables		$473,690
MBS items		$271,343
Patient/insurer costs		$549,071
Total cost		**$1,294,105**

BSC: Best supportive care; MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

Table 75 Estimated total costs of SEMS versus palliation only (BSC) (upper limit)

	SEMS	Palliation only (BSC)
Total cost per patient	$17,413	$7,756
Number of patients	487	487
Breakdown of financial implications		
Consumables	$1,721,545	$0
MBS Items	$4,412,707	$3,426,556
Patient/insurer costs	$2,345,879	$350,374
Total financial implications	**$8,480,131**	**$3,776,930**
Incremental costs		
Consumables		$1,721,545
MBS Items		$986,151
Patient/insurer costs		$1,995,505
Total cost		**$4,703,201**

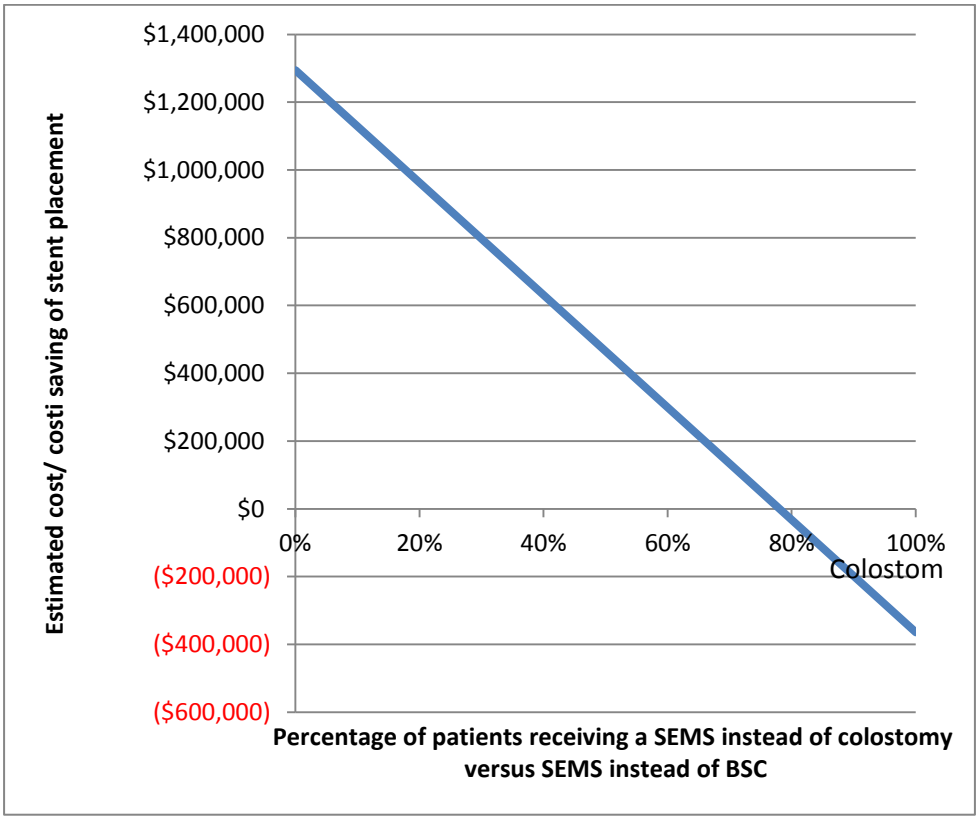
BSC: Best supportive care; MBS: Medicare Benefits Schedule; SEMS: Self-expanding metallic stent.

In the palliation setting there are effectively two patient populations:

- those who receive colostomy for palliation in addition to best supportive care; and
- those who receive best supportive care only.

The proportion of patients who receive best supportive care only is unknown. Figure 13 represents the trade-off between replacing colostomy with SEMS versus replacing best supportive care only with SEMS. The figure demonstrates that if the majority of patients received best supportive care only (<80%) there would be an increased cost to the health system, if SEMS was used instead of best supportive care. However, if >80 per cent of palliative patients were offered a (palliative) colostomy instead of best supportive care only, then there would be a cost saving if SEMS was used for these patients.

Figure 13 Estimated cost/cost savings of treating palliative patients



BSC: Best supportive care; SEMS: Self-expanding metallic stent.

Implication to the extended Medicare safety net

If MBS funding is granted for SEMS insertion to treat colorectal obstruction, it is unlikely to impact the extended Medicare safety net. This is because the majority of MBS services are provided in the inpatient setting.

Private/Public split

The proportion of patients that would have SEMS placement in the private sector relative to the public sector is unknown. Using AR-DRGs G01B, G02B and G05B as references, the percentage of private patients was 64 per cent, 67 per cent and 36 per cent respectively. Assuming this range of private patients (36% to 67%), the total cost savings (in the case of SEMS versus colostomy or as a bridge to surgery) or total cost (in the case of SEMS versus best supportive care), would be lower than previously estimated.

The total cost savings for using a SEMS instead of colostomy:

- For palliation - the total cost savings range from $131,033 to 474,994 with 36 per cent private patients, or range from $243,867 to $884,018 with 67 per cent private patients.

- For bridge to surgery - the total cost savings range from $49,696 to $180,148 with 36 per cent private patients or range from $92,490 to $335,276 with 67 per cent private patients.

The total cost increases if all patients receive SEMS instead of best supportive care:

- Total cost ranges from $465,877 to $1,693,153 if the percentage of private patients is 36 per cent and from $867,050 to $3,151,145 with 67 per cent private patients.

Discussion

Limitations of evidence

The capacity of the current assessment to draw definitive conclusions regarding the relative safety and effectiveness of SEMS for colonic obstruction is somewhat hampered by both the quantity and quality of available evidence. While a total of 40 studies were included in this assessment, only two were RCTs (level II evidence), while five were non-randomised comparative studies (level III evidence). Each of these studies compared SEMS placement to multi-stage surgical resection. No definitive primary research study was found that compared SEMS placement to best supportive care. Hence, the current assessment was unable to address the relative safety, effectiveness and cost-effectiveness of these two treatments.

For the purposes of the current assessment, it was determined a priori that patients eligible to receive single-stage colorectal resection should receive this treatment. As such, any studies that included and did not differentiate clinical outcomes for patients who were eligible for, or had received, single-stage surgical resection were excluded. This was to maximise the probability that the included evidence base addressed only the pre-defined population of interest. As Table 76 illustrates, a considerable number of comparative studies were retrieved for full-text review and subsequently excluded on this basis (Appendix I). Only one study was excluded due to cited patient overlap, so as to prevent duplication or misrepresentation of results. However, in a small number of low-level studies it was unclear whether patient overlap was present, providing a source of potential bias in the results.

The two RCT studies contained significant methodological issues. Only one study reported the method of randomisation used. Bias may have been introduced by the inability to blind patients, physicians and outcome assessors as to whether a patient received a stent or surgical treatment.

With regards to the comparative evidence as a whole (RCTs and non-randomised studies), only two of the seven studies conducted statistical comparisons to determine potential baseline differences in patient demographic and clinical characteristics. Some important clinical characteristics, such as whether the obstruction was partial or complete, were reported poorly or not at all. All comparative studies incorporated small sample sizes; all but one study had 20 or fewer patients in the SEMS group, and all but one had 20 or fewer patients in the surgical group. Few prospectively specified the clinical outcomes of interest. Lengths of patient follow-up were reported inconsistently or not at all, and where they were reported they were commonly limited in duration, limiting the capacity of the study to capture all potential long-term events following treatment. Four of the five non-randomised comparative studies used a retrospective study design, and two of the non-randomised studies pooled results from patients receiving palliative treatment and those receiving SEMS as a bridge to surgery. Health status could differ in patients receiving SEMS as a bridge to surgery compared to those receiving SEMS as a palliative measure; pooling these two patient groups could affect treatment outcomes. Although regarded as a clinical outcome of primary interest, only one comparative study addressed quality of life outcomes; the only validated tool used to assess quality of life was the Functional Assessment of Cancer Therapy – Colorectal survey instrument.

Limitations in study quality for the level IV evidence included the common use of retrospective study design, and poor reporting of the nature and duration of follow-up. Nearly half of the level IV studies did not explicitly mention study follow-up duration. Baseline patient characteristics were also poorly reported in these studies, and palliative and bridge to surgery patient populations and outcomes were often pooled, which may have resulted in considerable heterogeneity within the results. A further concern was the inconsistent reporting of safety outcomes, a key example of which is post-procedural mortality. It was unclear from many studies whether mortality occurred and was not reported, or did not actually occur. This uncertainty made defining the denominator for determining occurrence of this important outcome difficult, and has the potential to skew occurrence rates considerably.

Across all studies, patient selection and inclusion criteria were poorly specified. The majority of studies did not specify in their methodology whether they intended to report outcomes on an intention to treat (ITT) or per-protocol basis. None of the included comparative studies reported results on an ITT basis, and within the level IV evidence only six studies reported findings on an ITT basis. The majority of studies reported outcomes on a per-protocol basis, which is another potential shortcoming of the evidence base. Important procedural factors with the potential to impact on clinical outcomes, such as concurrent treatments, fabrication of stent (ie covered or uncovered), use of anaesthesia, and whether pre-operative dilation was used before SEMS placement, were reported poorly or not at all across included studies. For example, adjuvant chemotherapy, radiation therapy, and/or medical management can all cause the shrinkage of tumours and reduction of the obstruction. While a positive outcome for the patients, this can affect the patency of a stent or increase the propensity for stent migration. Three studies disclosed that author(s) were affiliated with, or they were funded by, a SEMS manufacturer (Meisner et al 2011; Varadarajulu et al 2011; Small and Baron 2008).

In conclusion, the included studies of the present assessment lacked methodological rigor, are potentially subject to a high risk of bias, and are potentially quite heterogeneous in their patient populations and approach to treatment. In general, the included studies were poor or inconsistent in their reporting of important patient and procedural details, their definition and reporting of outcome measures, and the way they addressed possible confounders that could have a considerable effect on clinical outcomes.

Table 76 Completed body of evidence assessment matrix

Body of evidence	A	B	C	D
Component	**Excellent**	**Good**	**Satisfactory**	**Poor**
Evidence base				Level IV studies, or level I to III studies with high risk of bias
Consistency			Some inconsistency reflecting genuine uncertainty around clinical question	
Clinical impact			Moderate	
Generalisability				Population/s studied in body of evidence different to target population and hard to judge whether it is sensible to generalise to target population
Applicability			Probably applicable to Australian healthcare context with some caveats	

Adapted from NHMRC (2008)

Is it safe?

Procedure-related mortality was variously defined and described across studies, such as post-procedural mortalities, 30-day mortality, or mortality within the same hospital admission as treatment. Very few procedure-related deaths were reported in the comparative evidence, with the small patient populations in these studies precluding the ability to accurately determine mortality rates and conduct statistical comparisons between treatments. A procedure-related mortality rate of 1.6 per cent after SEMS placement was found within the level IV evidence; however, this figure is likely an over-inflation, as it does not include data from the majority of studies retrieved, for which no explicit statement regarding patient mortalities was made although it was implied that no patient mortality occurred. It also includes mortalities from studies that reported it was unclear whether patients died due to SEMS placement or their underlying disease.

The nature of adverse events following SEMS placement compared to surgical resection was found to vary considerably. Tumour ingrowth or over-growth, bowel perforation, stent migration, bleeding, sensation-related events, infections and re-obstruction were found to occur after SEMS placement. In contrast, infections, anastomotic leak, and stoma-related adverse events were found to occur following surgical resection. In terms of the severity of adverse events, bowel perforation is likely the most severe stent-related event. Due to the potential for serious pelvic infection and peritonitis to develop, this outcome can be considered a life-threatening medical emergency, requiring immediate hospital admission, as well as multi-stage surgical resection of the bowel. Any other infectious event, be it following SEMS placement or surgical resection, also needs to be considered and managed as a medical emergency. Pain, tenesmus and minor bleeding are considered to be more manageable and unlikely to be life threatening.

Only three studies reported a statistical comparison between treatment groups with regard to adverse event occurrence, although none made a comparison of the relative

severity of these events. The only significant difference reported was a higher rate of readmission for complications after surgical treatment, reported in one study.

The majority of information on safety outcomes after SEMS placement was obtained from level IV evidence. The most severe adverse event following SEMS placement was perforation of the bowel, reported in over 4 per cent of SEMS patients. Data suggested that occurrence of perforation may be higher when dilators are used. Adverse events related to tumour growth (such as stent ingrowth or overgrowth) were the most common, reported in 7 to 9 per cent of patients. Tumour ingrowth or overgrowth is not an immediate adverse event, and therefore is unlikely to interfere with the direct relief that a stent may provide. Clinically, these are not considered as severe or significant adverse events, as in most of cases they are resolved by re-stenting. However, it does increase the likelihood that treatment for re-obstruction will be required in the future. Re-obstruction and stent migration were reported in between 6 and 7 per cent of patients. It is possible that rates of stent migration may have been inflated by studies that used stents not specifically designed for the colon (eg oesophageal stents); although every effort was made to exclude such studies, some authors did not explicitly state the type of stent used. Other adverse events were reported in less than 5 per cent of patients.

It is important to note that the level IV evidence rarely included reports on whether the patients who received SEMS were appropriate for single-stage resection. As a result, some patients in these studies may have been healthier than those who required multi-stage resection, potentially lowering the rate of adverse events found after SEMS placement.

Based on the available evidence, which was largely low-level and of questionable methodological quality, SEMS placement appeared to be approximately equivalent to multi-stage surgical resection in terms of safety. Due to the lack of good quality comparative evidence, it was not possible to determine whether SEMS placement was superior to multi-stage surgical resection with regards to safety.

Is it effective?

Due to the potential for stoma creation to have a significant negative impact on a patient's psychological wellbeing, and a burden to the patient and carers, the protocol of the current assessment defined quality of life after SEMS placement and surgical resection (measured by QALYs) as the primary effectiveness outcome of interest. A major deficiency of the evidence base in the current assessment is that of the seven comparative studies included, only one reported on patient quality of life as an effectiveness outcome. These outcomes were poorly reported, with no statistical comparison between the two treatment groups provided. Instead, outcomes were compared with baseline data. The results of this study, albeit of limited quality, did not show any additional benefit for SEMS placement over surgical resection with respect to patient quality of life after treatment.

Technical success of SEMS placement was generally defined as successful deployment of a stent, and assessed accordingly. However, clinical success after SEMS placement was variously defined across studies and in a small number of these was not provided. Definitions included successful colonic decompression, relief from obstructive symptoms, improvement of obstructive symptoms within 48 hours, and resumption of bowel function and oral intake. Definitive time periods for determining clinical success were generally not reported, but were presumed to be short term in nature. Definitions

of clinical success after surgery also varied, and in a number of studies were not provided. Definitions included relief from obstructive symptoms, and resumption of bowel function and oral intake. While the lack of universal definitions and direct statistical comparisons made evaluation of the relative procedural success between two groups difficult, the majority of comparative studies reported equivalent or slightly higher rates of clinical success in patients who underwent surgical resection than those receiving SEMS placement. Studies showed that stents did not always remain patent during a patient's lifespan, and in a number of cases required retreatment for re-obstruction. In patients who received SEMS placement for palliative purposes, the rate of retreatment generally varied from zero to 10 per cent. No study reported on the need for re-intervention after surgery.

For post-procedural hospital and ICU stay, patients who received SEMS placement commonly experienced significantly better outcomes than those who underwent surgical resection. As stenting is a minimally-invasive endoscopic procedure compared to open surgical resection or colostomy, this is to be expected. However, it is important to remember that readmission is often necessary if an adverse event, such as stent migration, occurs. Long-term follow-up after SEMS placement, needed in order to identify the reasons for re-admission, was not reported in the available evidence.

With regards to length of survival in patients who received treatment for palliative purposes, three comparative studies found no significant differences between patients receiving SEMS and those receiving surgical resection. However, patient survival would have been largely dependent on pre-intervention health status. It may be worth noting that in one of those studies, SEMS patients had a significantly worse baseline health status, and could have been anticipated to experience worse survival outcomes than patients who underwent surgery.

The evidence showed some tentative support for the use of SEMS as a bridge to surgery. One study showed patients who received SEMS placement were able to undergo planned surgery significantly sooner and required a shorter duration of hospital stay after planned surgery than those who initially underwent surgery with temporary stoma. While it was implied across the included studies that the majority of patients who received a SEMS avoided multi-stage resection, the proportion of patients could not be definitively determined as details of subsequent surgeries were not reported in detail.

With respect to relative effectiveness, SEMS placement appeared to be non-inferior to multi-stage surgical resection. However, this conclusion was based on a small number of studies with considerable methodological deficiencies, and should be accepted with caution.

What are the economic considerations?

A major limitation in determining the cost-effectiveness of SEMS insertion was the lack of randomised comparative studies, as discussed above. For example, the cost-effectiveness model comparing SEMS with colostomy for palliation was applied using effectiveness data extracted from two small European RCTs ($n<60$). These data were used to model the median survival of patients. However, the applicability of these results to the Australian setting is questionable and the results should be interpreted with caution. Due to the limited information provided in the RCTs, additional data were extracted from case series studies to populate the models in terms of clinical and technical success of SEMS. The probability of a technical and clinical success of SEMS

was derived from one large study (n>500). However, there may have been differences in the baseline risk of these patients and consequently the results may be biased if there are any systematic differences in these patients compared to patients in the Australian population. Accurate estimates of technical and clinical success are required, because these variables are key drivers of the economic model. In both the palliation model and bridge to surgery model, if the technical success is less than 67 per cent or 86 per cent respectively, SEMS is no longer a cost savings procedure.

The results of the cost-effectiveness analyses demonstrate that the majority of the cost savings associated with SEMS was due to the reduction in hospital stay. It is worth noting that this did not represent a significant saving to the MBS, as the major beneficiaries of these savings were patients (through lower out-of-pocket expenses) and insurers (through lower hospital costs). SEMS was associated with higher consumables costs, mainly the stent device; these costs were likely to be borne by the medical insurer.

The cost of the stent procedure was also a main driver in the model. In the bridge to surgery model, if the patient co-payment was greater than $761 (in additional to the MBS benefit), SEMS would no longer result in cost-savings. However, given that SEMS was associated with additional benefits, the additional cost would still be considered cost-effective at commonly used willingness-to-pay thresholds.

A further limitation was the appropriateness of best supportive care as the only treatment for patients requiring palliation. In many of these cases, colostomy may have been an appropriate alternative. However, no data were available that identified what proportion of palliative patients would be suitable for colostomy or best supportive care only. This had financial implications because SEMS was cost saving relative to colostomy but more costly than best supportive care.

The overall financial impact was uncertain due to difficulty in estimating the number of patients who would be suitable for SEMS insertion and additionally, the number of patients who would elect to have a SEMS in the private setting. The incidence of bowel obstruction has been quoted in the literature to range from 8 per cent to 30 per cent, resulting in a large range in the estimated number of patients. Also, there was a lack of evidence regarding the proportion of patients who would receive SEMS as a bridge to surgery versus receiving a SEMS in lieu of a colostomy for palliative purposes, which also impacted the final patient estimates.

Conclusions

Safety

From the available evidence, it was difficult to make a definitive determination of the relative safety of SEMS placement compared to multi-stage surgery. Based on this evidence, which was largely low-level and of questionable methodological quality, SEMS placement appeared to be approximately equivalent to multi-stage surgical resection in terms of safety, albeit with the prospect of severe medical consequences arising from issues such as bowel perforation and tumour growth-related events.

Effectiveness

Based on comparative evidence that was generally of low methodological quality and potentially subject to considerable bias, this assessment has found no benefit to patients receiving SEMS placement over multi-stage surgical resection with regards to clinical outcomes or quality of life. Limited evidence suggested that patients receiving SEMS as a bridge to surgery may have been more likely to avoid multi-stage resection; however, the quantity and quality of available evidence was insufficient to verify this conclusively.

Economic considerations

Patients fit for multi-stage surgery

A decision tree was developed to estimate the cost-effectiveness given differences in length of hospital stay and complications between the two treatments.

For patients requiring palliation

- SEMS for malignant bowel obstruction for palliation was a cost savings ($2,707) when compared to palliative colostomy.
- The SEMS group was estimated to gain an additional 0.01 QALYs when compared to the colostomy group.

For patients requiring a bridge to surgery

- SEMS for malignant bowel obstruction followed by multi-stage surgery was cost saving when compared to colostomy or Hartmann's procedure ($440).
- The SEMS group was estimated to gain an additional 0.52 QALYs when compared to the colostomy group.

The financial analyses suggested that SEMS insertion was a cost savings versus the comparators for both palliation and bridge to surgery. An estimated cost savings ranged from $363,981 to $1,319,430 in the palliation group and $138,045 to $500,412 in the bridge to surgery group based on the lowest and highest estimate of the number of patients eligible to be treated with SEMS for malignant bowel obstruction.

Patients unfit for multi-stage surgery

For patients who were unfit for surgery, where SEMS would have replaced best supportive care, the cost of providing the stent procedure rather than palliation alone was estimated to be $9,659.

The financial analyses suggested that if all patients received SEMS rather than best supportive care, the overall additional cost would be between $1,294,105 (lower limit) and $4,703,201 (upper limit).

Appendix A Health Expert Standing Panel and Assessment Group

Health Expert Standing Panel – MSAC application 1150

Member	Nomination/expertise or affiliation
Dr Chip Farmer	Colorectal surgeon

Assessment Group

Name	Organisation
Dr Yasoba Atukorale	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)
Mr Ben Hoggan	ASERNIP-S
Ms Robyn Lambert	ASERNIP-S
Ms Stefanie Gurgacz	ASERNIP-S
Ms Jody Church (CHERE)	Centre for Health Economics Research and Evaluation
Dr Stephen Goodall	CHERE

Appendix B Search strategies

MeSH search

1 - Stents
2 - Intestinal obstruction
3 - Constriction, pathologic
4 - Intestine, Large
5 - #3 and #4
6 - #2 or #5
7 - #1 and #6

Text-word search

8 - stent*
9 – Ultraflex
10 – Wallstent
11 – Wallflex
12 - Z-stent
13 - Z stent
14 – Zstent
15 – SEMS
16 - #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15
17 - stricture*
18 - stenos*
19 - obstruct*
20 - narrow*
21 - #17 or #18 or #19 or #20
22 - intestin*
23 – bowel
24 – colorectal
25 - colon*
26 – rectal
27 – rectum
28 - #22 or #23 or #24 or #25 or #26 or #27
29 - #16 and #21 and #28
30 - #7 or #29

Appendix C Databases searched

Table 77 Electronic databases searched

Databases	Period covered
Cochrane Library – including Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, the Cochrane Central Register of Controlled Trials, the Health Technology Assessment Database, and the NHS Economic Evaluation Database	Inception – 09/2011
PubMed (incorporating Medline)	Inception – 09/2011
CINAHL	Inception – 09/2011
EMBASE	Inception – 09/2011
The University of York Centre for Reviews and Dissemination	Inception – 09/2011
CINAHL: Cumulative Index to Nursing and Allied Health Literature	

Table 78 Electronic internet databases searched

Database	Internet location
National Health and Medical Research Council (NHMRC) (Australia)	http://www.nhmrc.gov.au
Australian Department of Health and Ageing	http://www.health.gov.au/
Scirus – for Scientific Information Only	http://www.scirus.com
TRIP database	http://www.tripdatabase.com
National Health Service (NHS) Evidence	http://www.evidence.nhs.uk/
Current Controlled Trials metaRegister	http://controlled-trials.com/
Australian New Zealand Clinical Trials Registry	http://www.anzctr.org.au/
ClinicalTrials.gov	http://clinicaltrials.gov/
World Health Organization International Clinical Trials Registry Platform	http://apps.who.int/trialsearch/
National Library of Medicine Health Services/Technology Assessment Texts	http://text.nlm.nih.gov/
National Library of Medicine Locator Plus database	http://locatorplus.gov
New York Academy of Medicine Grey Literature Report	http://www.nyam.org/library/pages/grey_literature_report

Table 79 Health technology assessment internet sites searched

Internet sites	Results
Argentina	
Institute for Clinical Effectiveness and Health Policy (IECS) http://www.iecs.org.ar	Nil
Australia	
Adelaide Health Technology Assessment (AHTA) http://www.adelaide.edu.au/ahta	Nil
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) http://www.surgeons.org/asernip-s	Watt et al 2007
Centre for Clinical Effectiveness, Monash University http://www.southernhealth.org.au/page/Health_Professionals/CCE/ /	Nil
Health Economics Unit, Monash University http://www.buseco.monash.edu.au/centres/che/	Nil
Medical Services Advisory Committee (MSAC) http://www.msac.gov.au	Nil
Austria	
Institute of Technology Assessment (ITA) http://www.oeaw.ac.at/ita/e1-3.htm	Nil
Brazil	
Departamento de Ciência e Tecnologia (DECIT) http://portal.saude.gov.br/portal/saude/area.cfm?id_area=1088	Nil
Canada	
Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé (AETMIS) http://www.aetmis.gouv.qc.ca/site/index.php?home	Nil
Alberta Heritage Foundation for Medical Research (AHFMR) http://www.ahfmr.ab.ca/publications/	Nil
Canadian Agency for Drugs and Technologies in Health (CADTH) http://www.cadth.ca	Nil
Centre for Health Economics and Policy Analysis (CHEPA), McMaster University http://www.chepa.org	Nil
Centre for Health Services and Policy Research (CHSPR), University of British Columbia http://www.chspr.ubc.ca	Nil
Health Utilities Index (HUI) http://www.fhs.mcmaster.ca/hug/index.htm	Nil
Institute for Clinical and Evaluative Studies (ICES) http://www.ices.on.ca	Nil
Institute of Health Economics (IHE) http://www.ihe.ca/	Nil
Ministry of Health and Long-Term Care – Medical Advisory Secretariat http://www.health.gov.on.ca/english/providers/program/mas/mas_mn.html	Nil
Saskatchewan Health Quality Council http://www.hqc.sk.ca	Nil
Denmark	
Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) http://www.sst.dk/English/DACEHTA.aspx	Nil
Danish Institute for Health Services Research (DSI) http://dsi.dk/english/	Nil
Finland	
Finnish Office for Health Technology Assessment (FinOHTA) http://finohta.stakes.fi/EN/index.htm	Nil
France	
Committee for Evaluation and Diffusion of Innovative Techniques (CEDIT) http://cedit.aphp.fr/-Pays-.html?rubrique&lang=en&dir=ltr	
French National Authority for Health (HAS) http://www.has-sante.fr/portail/jcms/c_5443/english?cid=c_5443	Nil
Germany	

Internet sites	Results
German Agency for Health Technology Assessment (DAHTA) http://www.dimdi.de/dynamic/en/hta/db/index.htm	Nil
Hungary	
Unit of Health Economics and Technology Research Assessment (HunHTA) http://hecon.uni-corvinus.hu/corvinus.php?lng=en	Nil
The Netherlands	
Health Council of the Netherlands Gezondheidsraad http://www.gezondheidsraad.nl/en/	Nil
Institute for Medical Technology Assessment http://www.imta.nl/	Nil
Netherlands Organisation for Health Research and Development (ZonMw) http://www.zonmw.nl/en/	Nil
New Zealand	
New Zealand Health Technology Assessment (NZHTA) http://nzhta.chmeds.ac.nz/	Nil
Norway	
Norwegian Knowledge Centre for the Health Services http://www.kunnskapssenteret.no/home	Nil
Spain	
Agencia de Evaluación de Tecnologias Sanitarias, Instituto de Salud Carlos III/Health Technology Assessment Agency (AETS) http://www.isciii.es/htdocs/en/investigacion/Agencia_quees.jsp	Nil
Andalusian Agency for Health Technology Assessment (AETSA) http://www.juntadeandalucia.es/salud/servicios/aetsa/	Nil
Catalan Agency for Health Technology Assessment (CAHTA) http://www.gencat.cat/salut/depsan/units/aatrm/html/en/Du8/index.html	
Sweden	
Swedish Council on Technology Assessment in Health Care (SBU) http://www.sbu.se/en/	Nil
Center for Medical Health Technology Assessment http://www.cmt.liu.se/english/publications	Nil
Switzerland	
Swiss Network on Health Technology Assessment (SNHTA) http://www.snhta.ch/	Nil
United Kingdom	
Health Technology Board for Scotland http://www.htbs.co.uk/	Nil
National Health Service Health Technology Assessment (UK)/National Coordinating Centre for Health Technology Assessment (NCCHTA) http://www.ncchta.org/	Nil
NHS Quality Improvement Scotland http://www.nhshealthquality.org/	Nil
The European Information Network on New and Changing Health Technologies http://www.euroscan.bham.ac.uk/	Nil
National Institute for Clinical Excellence (NICE) http://www.nice.org.uk/	Stent placement in colon: not in remit.[a] Colorectal cancer: the diagnosis and management of colorectal cancer. Evidence review 9 Nov 2011. Includes section on stents.
United States	
Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov/clinic/techix.htm	Nil
Harvard School of Public Health – Cost-Utility Analysis Registry http://www.tufts-nemc.org/cearegistry/	Nil
Institute for Clinical Systems Improvement (ICSI) http://www.icsi.org	Nil

Internet sites	Results
Minnesota Department of Health (US) http://www.health.state.mn.us/htac/index.htm	Nil
National Information Centre of Health Services Research and Health Care Technology (US) http://www.nlm.nih.gov/hsrph.html	Nil
Oregon Health Resources Commission (US) http://www.oregon.gov/OHA/OHPR/HRC/index.shtml l	Nil
Office of Health Technology Assessment Archive (US) http://fas.org/ota/	Nil
US Blue Cross/Blue Shield Association Technology Evaluation Centre (TEC) http://www.bcbs.com/blueresources/tec/	Nil
Veterans' Affairs Technology Assessment Program (VATAP) http://www.va.gov/VATAP/site_search.asp	Nil

a Date notified to NICE:01 April 2002; Topic area: Digestive system; Reason: Established procedure.
Explanation: Established procedure - Procedures do not fall within the program's remit if they are considered standard clinical practice with an efficacy and safety profile that is sufficiently well known.
This page last updated: 30 March 2010.

Appendix D Studies included in the review

Patients with colorectal obstruction, stricture or stenosis medically fit for surgery

Comparative studies

Level II studies

Fiori, E., Lamazza, A. et al 2004. 'Palliative management of malignant rectosigmoidal obstruction. Colostomy vs. endoscopic stenting. A randomized prospective trial', *Anticancer Research*, 24 (1), 265-268.

Xinopoulos, D., Dimitroulopoulos, D. et al 2004. 'Stenting or stoma creation for patients with inoperable malignant colonic obstructions? Results of a study and cost-effectiveness analysis', *Surgical Endoscopy*, 18 (3), 421-426.

Level III studies

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Johnson, R., Marsh, R. et al 2004. 'A comparison of two methods of palliation of large bowel obstruction due to irremovable colon cancer', *Annals of the Royal College of Surgeons England*, 86 (2), 99-103.

Nagula, S., Ishill, N. et al 2010. 'Quality of life and symptom control after stent placement or surgical palliation of malignant colorectal obstruction', *Journal of the American College of Surgeons*, 210 (1), 45-53.

Osman, H. S., Rashid, H. I. et al 2000. 'The cost effectiveness of self-expanding metal stents in the management of malignant left-sided large bowel obstruction', *Colorectal Disease*, 2 (4), 233-237.

Varadarajulu, S., Roy, A. et al 2011. 'Endoscopic stenting versus surgical colostomy for the management of malignant colonic obstruction: comparison of hospital costs and clinical outcomes', *Surgical Endoscopy*, 25 (7), 2203-2209.

Non-comparative evidence

Level IV studies

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Athreya, S., Moss, J. et al 2006. 'Colorectal stenting for colonic obstruction: the indications, complications, effectiveness and outcome--5 year review', *European Journal of Radiology*, 60 (1), 91-94.

Baraza, W., Lee, F. et al 2008. 'Combination endo-radiological colorectal stenting: a prospective 5-year clinical evaluation', *Colorectal Disease*, 10 (9), 901-906.

Branger, F., Thibaudeau, E. et al 2010. 'Management of acute malignant large-bowel obstruction with self-expanding metal stent', *International Journal of Colorectal Disease*, 25 (12), 1481-1485.

Cho, Y. K., Kim, S. W. et al 2011. 'Clinical outcome of self-expandable metal stent placement in the management of malignant proximal colon obstruction', *Gut and Liver*, 5 (2), 165-170.

De Gregorio, M. A., Laborda, A. et al 2011. 'Ten-year retrospective study of treatment of malignant colonic obstructions with self-expandable stents', *Journal of Vascular and Interventional Radiology*, 22 (6), 870-878.

Demarquay, J.-F., Dumas, R. et al 2008. 'Twelve years of colorectal stenting: Results and follow-up in 204 patients. [French, English]', *Acta Endoscopica*, 38 (4), 339-347.

Garcia-Cano, J., Gonzalez-Huix, F. et al 2006. 'Use of self-expanding metal stents to treat malignant colorectal obstruction in general endoscopic practice (with videos)', *Gastrointestinal Endoscopy*, 64 (6), 914-920.

Jost, R., Schoch, E. et al 2007. 'Colorectal stenting: an effective therapy for preoperative and palliative treatment', *Cardiovascular and Interventional Radiology*, 30 (3), 433-440.

Keränen, I., Lepisto, A. et al 2011. 'Stenting for malignant colorectal obstruction: a single-center experience with 101 patients', *Surgical Endoscopy*, 26 (2), 423-430.

Kim, J. H., Song, H. Y. et al 2009. 'Dual-design expandable colorectal stent for malignant colorectal obstruction: comparison of flared ends and bent ends', *American Journal of Roentgenology*, 193 (1), 248-254.

Kim, S. Y., Kwon, S. H. and Oh, J. H. 2010. 'Radiologic placement of uncovered stents for the treatment of malignant colorectal obstruction', *Journal of Vascular and Interventional Radiology*, 21 (8), 1244-1249.

Lee, H. J., Hong, S. P. et al 2011. 'Long-term outcome of palliative therapy for malignant colorectal obstruction in patients with unresectable metastatic colorectal cancers: endoscopic stenting versus surgery', *Gastrointestinal Endoscopy*, 73 (3), 535-542.

Lee, K. M., Shin, S. J. et al 2007. 'Comparison of uncovered stent with covered stent for treatment of malignant colorectal obstruction', *Gastrointestinal Endoscopy*, 66 (5), 931-936.

Lepsenyi, M., Santen, S. et al 2011. 'Self-expanding metal stents in malignant colonic obstruction: experiences from Sweden', *BMC Research Notes*, 4 (1), 274-278.

Li, Y. D., Cheng, Y. S. et al 2010. 'Management of acute malignant colorectal obstruction with a novel self-expanding metallic stent as a bridge to surgery', *European Journal of Radiology*, 73 (3), 566-571.

Mackay, C. D., Craig, W. et al 2011. 'Self-expanding metallic stents for large bowel obstruction', The *British Journal of Surgery*, 98 (11), 1625-1629.

Mainar, A., Gregorio Ariza, M. A. et al 1999. 'Acute colorectal obstruction: treatment with self-expandable metallic stents before scheduled surgery--results of a multicenter study', *Radiology*, 210 (1), 65-69.

Masci, E., Viale, E. et al 2008. 'Enteral self-expandable metal stent for malignant luminal obstruction of the upper and lower gastrointestinal tract: a prospective multicentric study', *Journal of Clinical Gastroenterology*, 42 (4), 389-394.

Meisner, S., Gonzalez-Huix, F. et al 2011. 'Self-expandable metal stents for relieving malignant colorectal obstruction: short-term safety and efficacy within 30 days of stent procedure in 447 patients', *Gastrointestinal Endoscopy*, 74 (4), 876-884.

Moon, C. M., Kim, T. I. et al 2010. 'Comparison of a newly designed double-layered combination covered stent and D-weave uncovered stent for decompression of obstructive colorectal cancer: a prospective multicenter study', *Diseases of the Colon and Rectum*, 53 (8), 1190-1196.

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Park, S., Cheon, J. H. et al 2010. 'Comparison of efficacies between stents for malignant colorectal obstruction: a randomized, prospective study', *Gastrointestinal Endoscopy*, 72 (2), 304-310.

Park, J. K., Lee, M. S. et al 2011. 'Outcome of palliative self-expanding metal stent placement in malignant colorectal obstruction according to stent type and manufacturer', *Surgical Endoscopy*, 25 (4), 1293-1299.

Selinger, C. P., Ramesh, J. and Martin, D. F. 2011. 'Long-term success of colonic stent insertion is influenced by indication but not by length of stent or site of obstruction', *International Journal of Colorectal Disease*, 26 (2), 215-218.

Shrivastava, V., Tariq, O. et al 2008. 'Palliation of obstructing malignant colonic lesions using self-expanding metal stents: a single-center experience', *Cardiovascular and Interventional Radiology*, 31 (5), 931-936.

Small, A. J. and Baron, T. H. 2008. 'Comparison of Wallstent and Ultraflex stents for palliation of malignant left-sided colon obstruction: a retrospective, case-matched analysis', *Gastrointestinal Endoscopy*, 67 (3), 478-488.

Small, A. J., Coelho-Prabhu, N. and Baron, T. H. 2010. 'Endoscopic placement of self-expandable metal stents for malignant colonic obstruction: long-term outcomes and complication factors', *Gastrointestinal Endoscopy*, 71 (3), 560-572.

Stenhouse, A., Page, B. et al 2009. 'Self expanding wall stents in malignant colorectal cancer: is complete obstruction a contraindication to stent placement?', *Colorectal Disease*, 11 (8), 854-858.

Suh, J. P., Kim, S. W. et al 2010. 'Effectiveness of stent placement for palliative treatment in malignant colorectal obstruction and predictive factors for stent occlusion', *Surgical Endoscopy*, 24 (2), 400-406.

Vitale, M. A., Villotti, G. et al 2006. 'Preoperative colonoscopy after self-expandable metallic stent placement in patients with acute neoplastic colon obstruction', *Gastrointestinal Endoscopy*, 63 (6), 814-819.

Yoon, J. Y., Jung, Y. S. et al 2011. 'Clinical outcomes and risk factors for technical and clinical failures of self-expandable metal stent insertion for malignant colorectal obstruction', *Gastrointestinal Endoscopy,* 74 (4), 858-868.

Young, C. J., Suen, M. K. et al 2011. 'Stenting Large Bowel Obstruction Avoids a Stoma: Consecutive Series of 100 Patients', *Colorectal Disease*, 13 (10), 1138-1141.

Patients with colorectal obstruction, stricture or stenosis medically unfit for surgery

No evidence found.

Appendix E Current clinical trials for colonic stents

Completed

Gerdes, H. (Principal Investigator), Memorial Sloan-Kettering Cancer Center, New York, United States. 'Outcome of Palliative Management of Malignant Large Bowel Obstruction With Colorectal Stents or Surgery.' Reported completion October 2006. Location: Memorial Sloan-Kettering Cancer Center, New York. See ClinicalTrials.gov for more information, identifier NCT00140868.

Ho, K. (Responsible Party), Department of Colorectal Surgery, Singapore General Hospital, Singapore. 'Endoscopic Stenting and Elective Surgery versus Emergency Surgery for Left-Sided Malignant Colonic Obstruction: A Prospective Randomized Trial.' Reported completion June 2008. Location: Singapore General Hospital, Singapore. See ClinicalTrials.gov for more information, identifier NCT00758186.

Julie, K. (Responsible Party), Comprehensive Cancer Center, Northwestern University, Illinois, United States. 'A Pilot Phase I/II Trial of Enteral Wallstents for Colonic Obstruction in the Setting of Malignancy.' Reported completion February 2003. Location: Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago, Illinois. See ClinicalTrials.gov for more information, identifier NCT00004911.

Hauge, T. (Study Director), Multiple centres from Norway. 'Palliative Endoscopic Treatment of Malignant GI-strictures With Self Expanding Metal Stents(SEMS)-a Prospective Multicenter Study.' Reported Completion April 2010. Location: seven health care institutions in Norway. See ClinicalTrials.gov for more information, identifier NCT00422409.

Wah, L.K. (Study Director), Pamela Youde Nethersole Eastern Hosptial, Hong Kong. 'Endo-Laparoscopic Approach versus Conventional Open Surgery in the Management of Obstructing Left-Sided Colon Cancer: A Randomized Trial'. Reported completion date December 2007. Location: Pamela Youde Nethersole Eastern Hosptial, Hong Kong. See ClinicalTrials.gov for more information, identifier NCT00654212.

Ongoing/recruiting

Morino, M. and Targarona, E.M. (Principal Investigator), Multiple centers from Italy and Spain. 'Prospective, Randomised European Multicentric Study, Comparing Enteral Stent Followed by Elective Surgery versus Emergency Surgical Treatment in Malignant Colonic Obstruction.' Estimated primary completion December 2012. Location: University of Torino, Italy and Hospital de la Santa Creu i Sant Pau, Barcelona (Spain). See ClinicalTrials.gov for more information, identifier NCT00591695.

Not yet recruiting

Cook (Responsible Party), Multiple centers from Canada, Denmark, France, Italy, Netherlands, Spain, United Kingdom. 'Treatment of Colonic Obstruction with Cook Evolution® Colonic Stent System.' Study first received March 29, 2010. Location:

Canada, Denmark, France, Italy, Netherland, Spain, UK. See ClinicalTrials.gov for more information, identifier NCT01102283.

Unknown

Lau, J.Y.M. (Principal Investigator), Endoscopy Centre, Prince of Wales Hospital, Hong Kong, China. 'Endolaparoscopic versus Immediate Surgery for Obstructing Colorectal Cancers: A Randomised Trial.' Study first received September 12, 2005. Location: Prince of Wales Hospital, Hong Kong. See ClinicalTrials.gov for more information, identifier NCT00164879.

Peute, I. (Contact name), Academic Medical Center, Department of Gastroenterology, Amsterdam, Netherlands. 'Colonic stenting as bridge to surgery versus emergency surgery for management of acute left-sided malignant colonic obstruction: a multicentre randomised trial.' Anticipated end January 2010. Location: Academic Medical Center, Amsterdam (Netherland). See controlled-trials.com for more information, identifier ISRCTN46462267.

Terminated

http://clinicaltrials.gov/show/NCT01196494

http://clinicaltrials.gov/ct2/show/NCT00514332

Search date: 22/11/2011

Appendix F Included studies – randomised controlled trials

Authors (year), location	N	Male/ female	Age (mean)	Population	Intervention (manufacturer)	Inclusion/exclusion criteria
Fiori et al (2004), Italy	Total: 22 SEMS: 11 Surgery: 11	Total: 13/9 SEMS: 6/5 Surgery: 7/4	Total: 77.2 ± 3.3 years SEMS: 77.2 ± 3.3 years Surgery: 76 ± 4.6 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction Rectum: 14 (63.6%); Sigmoid colon: 8 (36.4%) Length of stenosis (mean): NR Diagnosis Benign: 0; Malignant: 22 (100%) Site of metastases: Liver: 18; Lung: 4 Advanced local diseases: 9	SEMS (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 9 cm (n=8) or 12 cm (n=3); Diameter: NR Guidance: endoscopic and fluoroscopic Anaesthesia: conscious sedation (Midazolam) Use of balloon dilation: NR	Inclusion criteria: Patients with malignant recto-sigmoidal obstruction; patients informed consent Exclusion criteria: NR Patients excluded: NR
Xinopoulos et al (2004), Greece	Total: 30 SEMS: 15 Surgery: 15	Total: 16/14 SEMS: 9/6 Surgery: 7/8	Total: 72.4 years SEMS: NR Surgery: NR	Type of obstruction Partial:30[a] (100%); Complete: 0 Location of obstruction Rectosigmoid: 18 (60%); Sigmoid colon: 12 (40%) Length of stenosis (mean): 4.2 cm (range 3-6) Diagnosis Benign: 0; Malignant: 30 (100%) Site of metastases Liver, lungs, bones and/or brain: 16	Wallstent (Boston Scientific) Type of SEMS: uncovered Size of SEMS Length: 8cm; Diameter: 20-22 mm Guidance: endoscopic and fluoroscopic Anaesthesia: IV Midazolam and Pethidine. No general anaesthesia used Use of balloon dilation: 20 mm dilation with Savary-Gillard dilators was performed (n=30)	Inclusion criteria: Patients with inoperable (metastases, haemodynamic or pulmonary instability) malignant partial obstruction in the left colon due to colorectal or ovarian cancer; patients informed consent Exclusion criteria: NR Patients excluded: One patient with obstruction of a tortuous rectosigmoid flexure was excluded from the SEMS group, as colon stenting was not possible

a All patients had greater than 70% of colonic narrowing

N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NR: Not reported; SEMS: Self-expanding metallic stent.

Appendix G Included studies – non-randomised comparative studies

Authors (year), location	N	Male/female	Age (mean)	Population	Intervention (manufacturer)	Inclusion/exclusion criteria
Baik et al (2006), South Korea	Total: 37 SEMS: 18 Surgery: 19	Total: 22/15 SEMS: 10/8 Surgery: 12/7	Total: NR SEMS: 58.4±13.9 years Surgery: 57.2 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 17 (45.9%); Sigmoid colon: 17 (45.9%); Descending colon: 3 (8.1%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 37 (100%) Site of metastases: Nil, patients with distant metastasis were excluded	Choo stent (Soho Medi-Tech, Korea) Type of SEMS: Covered and uncovered Size of SEMS Length: 8 to 14 cm; Diameter: 22 mm Guidance: Endoscopic or fluoroscopic Anaesthesia use: IV sedation Use of balloon dilation: not performed	Inclusion criteria: patients with symptoms of vomiting, nausea, abdominal fullness, pain, no passage of flatus and stool; abdominal distension or tympanic, increased mechanical bowel sounds; typical plain radiographs on intestinal obstruction Exclusion criteria: signs of peritonitis and exhibited volvulus of a bowel segment, obstruction that was proximal to the splenic flexure; patients with distant metastasis Patients excluded: NR
Johnson et al (2004), UK	Total: 38 SEMS: 20 Surgery: 18	Total: 21/17 SEMS: 11/9 Surgery: 10/8	Total: NR. SEMS: median 81 years (range 60-93) Surgery: median 70 years (range 36-90)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: NR Length of stenosis: NR Diagnosis Benign: NR; Malignant: NR Site of metastases: NR	Memotherm and Wallstent Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: NR Anaesthesia use: NR Use of balloon dilation: NR	Inclusion criteria: Patients medically unfit for major surgery (ASA 4 or 5) with irreversible disease or have incurable malignancy due either to radiologically confirmed metastatic disease or locally advanced fixed pelvic tumours Exclusion criteria: NR Patients excluded: NR

Nagula et al (2010), USA	Total: 44 SEMS: 30 Surgery: 14	Total: 13/31 SEMS: 8/22 Surgery: 5/9	Total: 57 years SEMS: 59 years Surgery: 54 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 4 (9.1%); Rectosigmoid: 15 (34.1%); Sigmoid: 16 (36.4%); Descending: 2 (4.5%); Splenic flexure: 2 (4.5%); Transverse: 2 (4.5%); Hepatic flexure: 3 (6.8%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 44 (100%) Site of metastases: NR	Wallstent or Ultraflex (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: endoscopic or fluoroscopic, or both Anaesthesia use: IV conscious sedation or general anaesthesia. Use of balloon dilation: NR	Inclusion criteria: Patients >18 years old with unresectable-for-cure malignancies presenting with symptoms of large bowel obstruction Exclusion criteria: Patient unwilling to provide informed consent, evidence of perforation, previous palliation for malignant bowel obstruction, multifocal obstruction, or obstruction located within 2 cm of the dentate line or proximal to the hepatic flexure, recent myocardial infarction or cerebrovascular accident or un-correctable coagulopathy. After enrolment patients were excluded if any palliative procedures for obstruction were performed at an outside institution Patients excluded: 7 (withdrew consent (1), lost to follow-up before first survey (2), protocol violation, as a surgical procedure performed at an outside institution (1), no endoscopic evidence of colonic obstruction (1), died before first follow-up from non-procedural complication (2))
Osman et al (2000), UK	Total: 26 SEMS: 16 Surgery: 10	Total: 12/14 SEMS: 8/8 Surgery: 4/6	Total: NR SEMS: 72 years (range 42-91) Surgery: 73 years (range 53-95)	Type of obstruction Partial: NR; Complete: NR Location of obstruction (expressed as the distance from anus for SEMS group only): <5 cm: 1 (6.2%); 5-10 cm: 1 (6.2%); 11-15 cm: 3 (18.8%); 16-20 cm: 3 (18.8%); 21-25 cm: 4 (25%); 26-30 cm: 1 (6.2%); >30 cm: 3 (18.8%)	Wallstent (Schneider Inc.) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 6-9 cm; Diameter: 20-22 mm Guidance: Endoscopic or fluoroscopic Anaesthesia use: Minimal sedation and	Inclusion criteria: Patients with malignant acute left-sided large-bowel obstruction Exclusion criteria: NR Patients excluded: NR

				analgesia Length of stenosis (SEMS group only): <5 cm: 9 (56.2%); ≥5 cm: 7 (43.8%) Use of balloon dilation: NR Diagnosis Benign: 0; Malignant: 26 (100%) Site of metastases: NR	
Varadarajulu et al (2011), USA	Total: 36 SEMS: 12 Surgery: 24	Total: 17/19 SEMS: 6/6 Surgery: 11/13	Total: NR SEMS: 67.08 years Surgery: 58.25 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 6 (16.7%); Sigmoid: 27 (75%); Transverse: 3 (8.3%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 36 (100%) Site of metastases: NR	Ultraflex (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 6, 9 or 12 cm; Diameter: 25 mm Guidance: Fluoroscopic Anaesthesia use: IV midazolam and meperidine Use of balloon dilation: NR	Inclusion criteria: > 19 years of age, underlying diagnosis of colorectal cancer, who underwent procedures for relief of acute obstruction Exclusion criteria: Patients who had undergone colostomy for perforated colon cancer; stenting for benign disease Patients excluded: 2 SEMS patients were excluded because they returned to the referring facility for further care after stent placement; none of them had experienced any intra-procedural complications

N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NR: Not reported; SEMS: Self-expanding metallic stent.

Appendix H Included studies – level IV evidence

Authors (year), location	N	Male/female	Age (mean)	Population (%)	Intervention (manufacturer)	Inclusion/exclusion criteria
Alcantara et al (2007), Spain	95	42/53	68 years (48-94 years)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 20 (21%); Recto-sigmoid junction: 28 (29%); Sigmoid colon: 24 (25%); Descending colon: 16 (17%); Splenic flexure: 5 (6%); Left transverse colon: 2 (2%) Length of stenosis: NR Diagnosis Benign: 3 (3.2%); Malignant: 92 (96.8%) Site of metastases: NR	Wallstents (Boston Scientific-Microinvasive); Esophacoil (Medtronic); Hanaro colorectal (MI Tech). Later, these were replaced by a modified form of Enteral Wallflex (Boston Scientific-Microinvasive) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: Fluoroscopic Anaesthesia use: 'In the early treatment sessions, IV sedation was used in a few patients. Later, IV sedation was given only if patients preferred' Use of balloon dilation: NR	Inclusion criteria: NR Exclusion criteria: Patients with clinical and radiological suspicion of perforation or necrosis, haemodynamic instability (hypotension and tachycardia), sepsis or acute peritonitis Patients excluded: NR
Athreya et al (2006), United Kingdom	102	53/49	Median 75 years (46-102)	Type of obstruction Partial: 0; Complete: 102 (100%) Location of obstruction: Rectum, recto-sigmoid and sigmoid colon: 75 (79.8%); Descending colon: 15 (16%); Splenic flexure: 3 (3.2%); Transverse colon:1 (1.1%); Proximal to the mid-transverse colon: 0	Memotherms (Bard UK), Wallsstents (Boston scientific), Ultraflex (Boston scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS	Inclusion criteria: NR Exclusion criteria: NR Patients excluded: 16 patient records were Not available

				Length of stenosis: NR Diagnosis Benign: 3 (2.9%); Malignant: 99 (97.1%) Site of metastases: NR	Length: NR; Diameter: NR Guidance: Fluoroscopy alone, or fluoroscopy and endoscopy Anaesthesia use: Conscious sedation (IV midozolam and diamorphine), antispasmodics Use of balloon dilation: Not routinely ballooned. 1 patient required	
Baraza et al (2008), United Kingdom	63 patients (71 procedures)	39/32	78 years (range 38-93)	Type of obstruction Partial: 47 (66.2%); Complete: 24/71 (33.8%) Location of obstruction: Rectum: 5 (7%); Rectosigmoid: 20 (28%); Sigmoid colon: 30 (42%); Descending colon: 8 (11.3%); Transverse colon/splenic flexure: 5 (7%); Ascending colon/hepatic flexure: 1 (1.4%); Multiple strictures-proximal sigmoid/rectosigmoid: 2 (2.8%) Length of stenosis: NR Diagnosis Benign: NR; Malignant: NR Site of metastases: NR	Niti-S stents (Taewoong Medical), Bard Memotherm (Angiomed) Type of SEMS: Covered and uncovered Size of SEMS Length: NR; Diameter: NR Guidance: Direct endoscopic visualisation and radio-opaque markers on either end of the stent Anaesthesia use: Conscious sedation (IV midazolam) Use of balloon dilation: None used	Inclusion criteria: NR Exclusion criteria: NR Patients excluded: NR
Branger et al (2010), France	93	57/36	Median 76 years (range 34-97)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 14 (15.1%); Recto-sigmoid junction: 25 (26.9%); Sigmoid: 31 (33.3%); Descending: 16 (17.2%); Splenic	Hanarostent (MI Tech) and Wallstent (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS	Inclusion criteria: Patients who underwent the insertion of a SEMS for an obstructing neoplastic lesion in the left sided colon or rectum Exclusion criteria: Patients with features of peritonitis

				flexure: 6 (6.5%) Length of stenosis: 5.5 cm (2-15). Diagnosis Benign: 0; Malignant: 93 (100%) Site of metastases: NR	Length: NR; Diameter: NR Guidance: Endoscopic and fluoroscopic Anaesthesia use: Conscious sedation Use of balloon dilation: NR	Patients excluded: NR
Cho et al (2011), South Korea	136	69/67	NR	Type of obstruction Partial: 38[a] (27.9%); Complete: 98[b] (72.1%) Location of obstruction: Rectum: 39 (28.7%), Sigmoid: 49 (36%), Descending: 9 (6.6%); Splenic flexure: 2 (1.5%); Transverse: 14 (10.3%); Hepatic flexure: 11 (8.1%); Ascending: 12 (8.8%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 136 (100%) Site of metastases: NR	Hanaro® stents (n=84) (M.I. Tech Co.) Bona® stents (n=52) (Standard Sci-Tech Inc.) Type of SEMS Covered: NR; Uncovered: 124 Size of SEMS Length: 6-16 cm; Diameter: 22-24 mm Guidance: Endoscopic and fluoroscopic Anaesthesia use: NR Use of balloon dilation: in ≥ 1 patient	Inclusion criteria: NR Exclusion criteria: Colon obstruction not caused by colorectal malignancies Patients excluded: NR
De Gregorio et al (2011), Spain	467	289/178	Median 68.9 ± 9.5 years (range, 38-96)	Type of obstruction Partial: 155 (33.2%); Complete: 312 (66.8%) Location of obstruction: rectum: 15 (3.2%); Recto-sigmoid junction: 134 (28.7%); Sigmoid: 95 (20.3%); Distal location: 244 (52.2%); Left colon: 178 (38.1%); Transverse colon: 29 (6.2%); Hepatic flexure: 16 (3.4%); Proximal location: 223 (47.8%)	Wallstent (Boston Scientific) SX-ELLA colorectal stent (Ella) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 5-9 cm (Wallstent), 8.2-11.2 cm (SX-ELLA); Diameter: 16-25 mm (Wallstent), 22-30 mm (SX-ELLA)	Inclusion criteria: Eligibility was predicted on the presence of total or partial large-bowel obstruction secondary to malignancy Exclusion criteria: Patients with a terminal condition (life-expectancy < 1 month), American Society of Anaesthesiologists classification greater than 4, suspected perforated colon, and severe colonic neoplastic bleeding

				Length of stenosis: NR Diagnosis Benign: 0; Malignant: 467 (100%) Site of metastases: NR	Guidance: Fluoroscopic alone or combined with endoscopic Anaesthesia use: Not routinely used; conscious sedation and analgesia was administered if the patient was uncooperative Use of balloon dilation: NR	Patients excluded: NR
Demarquy et al (2008), France	204	86/118	73.2 years (range 49-97)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: NR Length of stenosis: NR Diagnosis Benign:19; Malignant:185 Site of metastases (n=185): Colorectal adenocarcinoma: 175 (94.6%); Pancreatic cancer: 3 (1.6%); Gastric cancer: 1 (0.5%); Uterine cancer: 3 (1.6%); Ovarian cancer: 1 (0.5%); Gallbladder cancer: 2 (1.1%)	Wallstent and Wallflex (Boston Scientific), Colonic Z-stent (Wilson-Cook), Ultraflex (Microinvasive Co.), Choo stent (M.I Tech) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 6, 7, 9, 10, 11, 12 cm; Diameter: 20, 22, 23, 35 mm Guidance: Endoscopic and fluoroscopic Anaesthesia use: Propofol-induced anaesthesia Use of balloon dilation: NR	Inclusion criteria: NR Exclusion criteria: Patients with a low rectal tumour (below 5 cm) in whom it was felt that a stent would impinge on the anal sphincter Patients excluded: NR
Garcia-Cano et al (2006), Spain	175	112/63	73.8 (33-97, 12 years)	Type of obstruction Partial: 94 (53.7%); Complete: 73 (41.7%); Prophylactically: 8 (4.6%) Location of obstruction: Rectosigmoid: 129 (73.7%); Descending colon: 27 (15.4%); Splenic flexure: 4 (2.3%);	Wallstent (Boston Scientific Corp), Hanarostent (M.I. Tech), Ultraflex Precision (Microvasive) Type of SEMS Covered: NR; Uncovered: NR	Inclusion criteria: Patients were included if they were suffering from malignant colorectal obstruction Exclusion criteria: NR Patients excluded: NR

				Transverse colon: 8 (4.6%); Hepatic flexure: 5 (2.9%); Ascending colon: 2 (1.1%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 175 (100%) Site of metastases: NR	Size of SEMS Length: NR; Diameter: NR Guidance: All endoscopic with or without Fluoroscopic monitoring Anaesthesia use: without sedation (26.3%), general anaesthesia (7.4%), deep sedation (14.3%), conscious sedation (52%) therefore any type of sedation was used in 129 of 175 patients (73.7%) Use of balloon dilation: No dilation	
Jost et al (2007), Switzerland	67	35/32	67.3 years (range 25-93)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum/recto-sigmoid junction: 20 (30%); Sigmoid: 27 (40%); Descending colon, left colonic flexure: 14 (21%) Length of stenosis: mean 4.65 cm (2-12 cm, SD 2.21) Diagnosis Benign: 8 (11.9%); Malignant: 59 (88.1%) Site of metastases: NR	Wallstents (Boston Scientific) Type of SEMS: Uncovered Size of SEMS Length: 48-91 mm; Diameter Guidance: Endoscopic and fluoroscopic Anaesthesia use: Conscious sedation (midazolam,Dormicum; Roche, Switzerland) and analgesia (pethidine) Use of balloon dilation: Generally not used, but in 10 cases additional balloon dilatation was necessary immediately after stent placement	Inclusion criteria: NR Exclusion criteria: Clinical or radiological evidence of bowel perforation Patients excluded: NR
Karanen et al (2011), Finland	101	58/43	66 years (range, 36-98)	Type of obstruction Partial: 42 (41.6%); Complete: 55 (54.4%); Data not provided: 4 (4%)	Ultraflex, Ultraflex Precision, Wallflex, and Wallstent (Boston Scientific). Memotherm (Bard), Choo	Inclusion criteria: Patients who had undergone SEMS placement for malignant colorectal obstruction at Helsinki University Central

				Location of obstruction: Rectum: 42 (41.6%); Sigmoid colon: 45 (44.6%); Descending colon: 6 (5.9%); Transverse colon: 7 (6.9%); Hepatic flexure: 1 (1%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 101 (100%) Site of metastases: NR	(M.I.Technical), Instent and Bard (Olympus Corporation). Ultraflex Precision and Wallflex were used in the majority of procedures Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: Endoscopic and fluoroscopic Anaesthesia use: IV sedation Use of balloon dilation: in one patient	Hospital Exclusion criteria: NR Patients excluded: NR
Kim et al (2009), South Korea	122	75/47	58.84 ± 18.81 years (range 17-88)	Type of obstruction Partial: 74 (60.7%); Complete: 48 (39.3%) Location of obstruction: Rectum: 35 (28.7%); Recto-sigmoid: 16 (13.1%); Sigmoid: 40 (32.8%); Descending colon: 9 (7.4%); Transverse colon: 21 (17.2%); Ascending colon 1 (0.8%) Length of stenosis (mean): 63.19 ± 29.74 mm (range 20-200 mm) Diagnosis Benign: 0; Malignant: 122 (100%) Site of metastases: NR	Dual-design SEMS Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: 24 mm Guidance: Fluoroscopic Anaesthesia use: NR Use of balloon dilation: n=55. Dilation was carried out using a 15-mm (n=32) or 20-mm (n=23) balloon catheter	Inclusion criteria: Documented malignant disease and colorectal obstruction and had undergone placement of SEMS Exclusion criteria: If the patient had no symptoms, clinical evidence of perforation or peritonitis combined with multiple small-bowel obstructions, or had extension of rectal cancer to the anal sphincter Patients excluded: 3 lost to follow-up
Kim et al (2010), South Korea	116 attempts	59/40	65 years (range 28-99)	Type of obstruction	Hanaro (Solco Intermed) and EGIS (S & G Biotech)	Inclusion criteria: Documented malignancy, symptoms and signs of colorectal obstruction

	(99 patients)			Partial: NR; Complete: NR Location of obstruction (technical success, n=110): Rectum: 24 (21.8%); Sigmoid colon: 55 (50%); Descending colon: 20 (18.2%); Transverse colon: 10 (9.1%); Ascending colon: 1 (0.9%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 99 (100%) Site of metastases: NR	Type of SEMS: Uncovered Size of SEMS Length: 6, 8, 10, 12, 14 or 16 cm; Diameter: 22 mm Guidance: Fluoroscopic Anaesthesia use: None Use of balloon dilation: Not used	and uncovered stent placement Exclusion criteria: Patients who had bowel necrosis, perforation, cancer extending to < 5 cm from the anal verge, or cancer located near the ileocecal valve were excluded from stent placement Patients excluded: NR
Lee et al (2007), South Korea	80	45/35	63.3 years (range 34-87)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 38 (47.5%); Sigmoid colon: 28 (35%); Descending: 10 (12.5%); Transverse: 3 (3.8%); Ascending: 1 (1.2%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 80 (100%) Site of metastases: NR	Niti-S (Taewong Inc.) Type of SEMS: Covered and uncovered Size of SEMS Length: 6,8 and 10 cm; Diameter: 18 mm Guidance: Endoscopic and fluoroscopic. Anaesthesia use: Conscious sedation, meperidine and midazolam Use of balloon dilation: NR	Inclusion criteria: Patients with malignant colorectal obstruction Exclusion criteria: Patients were excluded from the study if they showed evidence of bowel perforation or peritonitis, free intra-peritoneal air on an abdominal radiograph, significant coagulopathy, or either hemodynamic or pulmonary instability; patients who had chemotherapy or radiotherapy after stent insertion were excluded Patients excluded: NR
Lee et al (2011), South Korea	71	47/24	64.14 ± 14.38 years (26-87)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 13 (18.3%); Sigmoid: 35 (49.3%); Descending: 7 (9.9%); Transverse: 9 (12.7%); Ascending colon: 6 (8.5%); Caecum: 1 (1.4%)	Wallflex (Boston Scientific), Comvi (Boston Scientific), Niti-S D-type (Taewoonf Medical Co.) Type of SEMS Covered: Comvi; Uncovered: Wallflex and Niti-S	Inclusion criteria: Incurable obstructive colorectal cancer; informed consent Exclusion criteria: evidence of bowel perforation, peritonitis and recurrent tumour; patients who underwent surgery after successful stenting

				Length of stenosis: NR Diagnosis Benign: 0; Malignant: 71 (100%) Site of metastases: Liver : 44 (62%); Lung: 4 (5.6%); Liver & Lung: 8 (11.3%); Carcinomatosis: 15 (21.1%)	Size of SEMS Length: Diameter: 25 mm (Wallflex), 20 mm (Comvi) Guidance: Endoscopic and fluoroscopic Anaesthesia use: NR Use of balloon dilation: Not used	Patients excluded: 25, due to tumour recurrence (13), undergoing palliative surgery after successful stenting (12)
Lepsenyi et al (2011), Sweden	75 attempts	47/24	74 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 5 (7%); Recto-sigmoid: 15 (21.1%); Sigmoid: 31 (43.7%); Splenic flexure: 9 (12.7%); Proximal to splenic flexure: 11 (15.5%) Length of stenosis: Median 4 cm (range 2-10 cm) Diagnosis Benign: NR; Malignant: NR Site of metastases: NR	Wallstent and Wallflex stents (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 6 cm, 9 cm, 12 cm; Diameter: NR Guidance: Endoscopic and radiological Anaesthesia use: Conscious sedation by midazolam hydrochloride and ketobemidon chloride Use of balloon dilation: NR	Inclusion criteria: NR Exclusion criteria: NR Patients excluded: NR
Li et al (2010), China	52	28/24	67.52 ± 9.32 years (range 35-91)	Type of obstruction Partial: 34 (65.4%); Complete: 18[c] (34.6%) Location of obstruction: Rectum: 18 (34.6%); Sigmoid colon: 24 (46.2%); Left colon: 7 (13.5%); Splenic flexure: 3 (5.8%) (Distance of the lesion from the anus, mean 20.2 cm (range, 4–75 cm))	SEMS (Micro-Tech) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 7-10 mm; Diameter: 25-30 mm	Inclusion criteria: Clinical signs and symptoms of acute colorectal obstruction, need for bridge to surgery, SEMS placement, documented malignancy and life expectancy > 6 months Exclusion criteria: Low risk associated with emergency surgery, known or suspected colonic ischemia or perforation or multiple

				Length of stenosis: 46.2 mm (range 34-65 mm) Diagnosis Benign: 0; Malignant: 52 (100%) Site of metastases: NR	Guidance: Endoscopic and fluoroscopic Anaesthesia use: None used Use of balloon dilation: Not performed	sites of obstruction, right sided location of obstruction and extension of rectal cancer to the anal sphincter Patients excluded: NR
Mackay et al (2011), United Kingdom	82	44/38	75 years	Type of obstruction Partial: 60 (73.2%); Complete: 22 (26.8%) Location of obstruction Malignant obstruction (n=67) Rectum: 16 (19.5%); Sigmoid colon: 43 (52.4%); Descending colon: 7 (8.5%); Proximal colon: 1 (1.2%) Benign obstruction (n=15) Rectum: 1 (1.2%); Descending colon: 1 (1.2%); Sigmoid colon: 13 (15.9%) Length of stenosis: NR Diagnosis Benign: 15 (18.3%); Malignant: 67 (81.7%) Site of metastases: NR	Memotherm (C.R. Bard); enteral Wallstent and Ultraflex stents (Boston Scientific); Niti-S (Taewoong Medical) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: radiological Anaesthesia use: NR Use of balloon dilation: NR	Inclusion criteria: NR Exclusion criteria: NR Patients excluded: NR
Mainar et al (1999), Spain	71	47/24	63 years (42-87)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectosigmoid: 48 (67.6%); Descending colon: 22 (31%); Transverse colon: 1 (1.4%) (Distance of the lesion from the anus,	Wallstents , Memotherm stent (Angiomed) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS	Inclusion criteria: Patients with large bowel carcinoma and clinical signs and symptoms of intestinal obstruction; informed consent Exclusion criteria: Clinical evidence of intestinal perforation

				mean: 20.l7 cm (range, 4–75 cm)) Length of stenosis (mean): 46.2 mm (range, 34–65 mm) Diagnosis Benign: 0; Malignant: 71 (100%) Site of metastases: NR	Length: 4-10 cm; Diameter: 20-25 mm Guidance: Fluoroscopic Anaesthesia use: None Use of balloon dilation: Not performed	Patients excluded: NR
Masci et al (2008), Italy	72	NR	NR	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum and/or recto-sigmoid junction: 49 (68.1%); Colon or colonical anastomosis: 23 (31.9%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 72 (100%) Site of metastases: NR	Wallstent (Microvasive Endoscopy, Boston Scientific Co.), Wallstent Precision (Microinvasive Endoscopy, Boston Scientific Co.), colonic Z stent (Wilson-Cook Medical Inc.) and Hanarostent (M.I. Tech Co.) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: Endoscopic and fluoroscopic Anaesthesia use: NR Use of balloon dilation: NR	Inclusion criteria: Documented malignant obstruction; obstruction-related clinical symptoms (abdominal tension, stool retention) and enteral stent placement Exclusion criteria: Patients with a documented benignant stenosis Patients excluded: NR
Meisner et al (2011)	463 (6 hours post-procedural safety data available on 447 patients, and 30-	277/186	72.1 ± 12.4 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction (n=447): Rectum 15.8%; Left-sided colon (rectosigmoid junction, sigmoid and descending colon, splenic flexure) 77.8%; Proximal colon (transverse colon, hepatic flexure, and ascending colon) 7.8%.	WallFlex (Boston Scientific Co.) Type of SEMS: Uncovered Size of SEMS Length: 9 cm, 12 cm; Diameter (body/flare): 25/30 mm	Inclusion criteria: NR Exclusion criteria: Placement of a previous colonic stent, enteral ischemia, suspected or impending perforation, intra-abdominal abscess/perforation, contraindication to endoscopic treatment, and any use of the stent other than those specifically outlined under indications of use

	day cumulative safety data available on 382 patients only)			Length of stenosis: NR Diagnosis Benign: 0; Malignant: 447 (100%) Site of metastases: Liver metastasis: 57.2%; Lung metastasis: 21.7%; Peritoneal carcinosis: 28.1%; Multiple metastasis: 38%	Guidance: Endoscopic and radiological Anaesthesia use: sedation was used during the majority of procedures (333 (75.7%), general anaesthesia in 16 patients and no sedation used in 91 Use of balloon dilation: 14 strictures were dilated using either a balloon or bougie dilator	Patients excluded: 16 patients were excluded from safety analysis data due to inability to place stent; 101 patients were excluded from the clinical success analysis
Moon et al (2010), South Korea	68	39/29	65.8 ± 14.8 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 14 (20.6%); Sigmoid colon: 27 (40%); Descending colon: 11 (16.2%); Splenic flexure: 5 (7.4%); Transverse colon: 9 (13.2%); Ascending colon: 2 (3%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 68 (100%) Site of metastases: NR	D-Weave (uncovered) and D-Weave double-layered combination (covered) Type of SEMS: Covered and uncovered Size of SEMS Length: 6 or 8 cm; Diameter: 20 mm Guidance: Endoscopic and fluoroscopic Anaesthesia use: Pethidine (25mg) Use of balloon dilation: NR	Inclusion criteria: large-bowel obstruction due to documented primary colorectal cancer from the upper rectum to the ascending colon, confirmed by plain abdominal radiography and CT Exclusion criteria: Any contraindications for colonoscopy (bowel perforation, hemodynamic, or respiratory instability), benign stricture, non-colorectal extrinsic compressive tumour, colorectal obstruction combined with small-bowel obstructions Patients excluded: NR
Mucci-Hennekinne et al (2007), France	67	42/25	73.5 years (range, 47–97)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectosigmoid junction: 28 (41.8%); sigmoid colon: 24 (35.8%); Descending colon: 12 (18%); splenic flexure: 2 (3%); At the anastomotic site, following surgery for recurrent sigmoid colon cancer: 1 (1.5%) Length of stenosis: 6 cm (range 2-11)	Hanarostent (MI Tech) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: Endoscopic and fluoroscopic	Inclusion criteria: Patients with resectable and non-resectable malignant colorectal obstructions Exclusion criteria: NR Patients excluded: NR

				Diagnosis Benign: 0; Malignant: 67 (100%) Site of metastases: NR	Anaesthesia use: Conscious sedation in all patients Use of balloon dilation: NR	
Park et al (2010), South Korea	151	86/65	61.4 ±13.0 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 27 (17.9%); Sigmoid colon: 78 (51.7%); Descending colon: 14 (9.3%); Splenic flexure: 13 (8.6%); Transverse Colon: 7 (4.6%); Hepatic flexure: 3 (2%); Ascending colon: 9 (6%) Length of stenosis: NR. Diagnosis Benign: 0; Malignant: 151 (100%) Site of metastases: NR	WallFlex (Boston Scientific Co.), Comvi (Taewoong Medical Co) Type of SEMS Covered (Comvi) and Uncovered (Wallflex) Size of SEMS Length: 6,8, 9, 10 and 12 cm; Diameter: 11, 20, 22 or 25 mm Guidance: Endoscopic and fluoroscopic Anaesthesia use: NR Use of balloon dilation: 1	Inclusion criteria: Acute colorectal malignant obstruction (upper rectum to ascending colon) confirmed with clinical obstructive symptoms and a radiological examination; written informed consent Exclusion criteria: Patients with suspected bowel perforation, concomitant multiple sites of small-bowel or colonic obstruction because of peritoneal carcinomatosis, other synchronous colonic obstruction, far distal rectal cancer, or causes of obstruction other than malignancy, such as bowel adhesion or benign stricture Patients excluded: NR
Park et al (2011), South Korea	103	54/49	67.3 ± 13.6 years	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 25 (24.3%); Sigmoid colon: 39 (37.9%); Descending colon: 22 (21.4%); Transverse colon: 9 (8.7%); Ascending colon: 8 (7.8%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 103 (100%)	Wallstent (Boston Scientific), Niti-S (Taewoon Inc.) Type of SEMS: Covered and uncovered Size of SEMS Length: 6 or 9 cm (Wallstent), 10 cm (Niti-S); Diameter: 18, 20 or 22 mm (Wallstent) Guidance: Endoscopic and fluoroscopic	Inclusion criteria: Patients with malignant colorectal obstruction that underwent palliative SEMS placement Exclusion criteria: SEMS as a bridge to surgery Patients excluded: 20/123; no reasons provided for exclusion

				Site of metastases: Metastatic cancer from gastric cancer: 3 (2.9%); Metastatic cancer from pancreatic cancer: 1 (1%); Colon invasion of cervical cancer: 1 (1%)	Anaesthesia use: Conscious sedation with IV midazolam with/without propofol Use of balloon dilation: NR	
Selinger et al (2011), United Kingdom	96	45/51	72.3 years (range, 36–97)	Type of obstruction Partial: NR; Complete: NR Location of obstruction (n=96): Rectum: 17 (17.7%); Sigmoid colon: 60 (62.5%); Proximal to the sigmoid colon: 19 (19.8%) Length of stenosis: NR Diagnosis Benign: 5 (5.2%); Malignant: 91 (94.8%) Site of metastases: NR	Hanaro stent, Wallstent, CHOO, Niti-S and others Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: endoscopic and fluoroscopic Anaesthesia use: NR Use of balloon dilation: NR	Inclusion criteria: NR Exclusion criteria: NR Patients excluded: NR
Shrivastava et al (2008), United Kingdom	91	41/50	73.7 ± 11 years (median 1 73)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 25 (27.5%); Recto-sigmoid: 26 (28.6%); Sigmoid: 35 (38.5%); Descending: 3(3.3%); Transverse; 2 (2.2%) Length of stenosis: 30-50 mm Diagnosis Benign: 0; Malignant: 91 (100%) Site of metastases: NR	Memotherm (Bard), WallFlex (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 6 or 8 cm; Diameter: 22, 30 mm Guidance: Fluoroscopic Anaesthesia use: Not used Use of balloon dilation: 2	Inclusion criteria: Patients with advanced malignant colorectal lesions who required palliation for intestinal obstruction and in whom the risk of mortality from surgery was high Exclusion criteria: Patients who already had symptoms/signs of bowel perforation; patients who underwent SEMS as a bridge to surgery Patients excluded: NR

Small and Baron (2008), USA	85	50/35	NR (range 17-94)	Type of obstruction Partial: 64 (75.3%); Complete: 21 (24.7%) Location of obstruction: Rectosigmoid: 62 (73%); Descending colon: 13. (15.3%); Splenic flexure: 3 (3.5%); Distal transverse colon: 7 (8.2%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 85 (100%) Site of metastases: NR (Metastatic disease 19 (22.4%))	Wallstent, Ultraflex Type of SEMS: Uncovered Size of SEMS Length: 5.7, 6, 8.7, 9, 11.7 cm; Diameter: 20, 22, 25 mm Guidance: Fluoroscopic Anaesthesia use: NR Use of balloon dilation: In seven patients dilation was performed immediately before stent insertion up to 12 mm	Inclusion criteria: Palliative intent to treat, inoperable malignant tumour of the left colon, obstructive symptoms, evidence of colon stenosis by radiography, and complete medical record data with (1) follow-up longer than 7 days after insertion, (2) until the stent was removed, or (3) death; strictures located in the distal half of the transverse colon Exclusion criteria: NR Patients excluded: NR
Small et al (2010), USA	233	136/97	NR (range 17-94 years)	Type of obstruction Partial: 173 (74.2%); Complete: 60 (25.8%) Location of obstruction: Rectosigmoid colon: 143 (61.4%); Descending colon: 23 (9.9%); Splenic flexure: 9 (3.9%); Distal transverse colon: 11 (4.7%); Proximal transverse colon: 11 (4.7%); Hepatic flexure: 9 (3.9%); Ascending colon: 13 (5.6%); Anastomosis: 12 (5.2%); Ileocecal valve: 2 (0.9%) Length of stenosis: NR Diagnosis Benign: NR; Malignant: NR Site of metastases: NR	Wallstents, Ultraflex precision colonic stents, Wallflex (Boston Scientific) Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: NR Anaesthesia use: NR Use of balloon dilation: was performed using 8 or 10 mm balloons, or 9, 12 or 14- mm bougie dilators before stent placement when the stricture would not allow passage of the stent introducer system.	Inclusion criteria: Malignancy, obstructive symptoms, radiographic colon stenosis, attempted SEMS, and follow-up until stent removal or patient death Exclusion criteria: NR Patients excluded: NR

Stenhouse et al (2009), United Kingdom	72	49/23	71 years (range, 49-98)	Type of obstruction Partial: 36[d] (50%); Complete:32[e] (44.4%); NR: 4 (5.6%) Location of obstruction: Sigmoid colon in (48%) of patients Length of stenosis: NR Diagnosis Benign: 0; Malignant: 72 (100%) Site of metastases: NR	Enteral Wallstent (Boston Scientific), Memotherm (BARD) Type of SEMS: Uncovered Wallstent, Memotherm NR Size of SEMS Length: NR; Diameter: 22 mm (Wallstent) Guidance: Endoscopic and fluoroscopic Anaesthesia use: NR Use of balloon dilation: NR	Inclusion criteria: Patients were found to have metastatic colorectal cancer and surgery thought to be inappropriate, or they were deemed unfit for surgery at the time of initial presentation Exclusion criteria: NR Patients excluded: NR
Suh et al (2010), South Korea	55	23/32	65.5 years (34 – 90, SD 16)	Type of obstruction Partial: NR; Complete: NR Location of obstruction: Rectum: 23 (41.8%); Sigmoid colon: 15 (27.3%); Descending colon: 4 (7.3%); Transverse colon: 8 (14.5%); Hepatic flexure: 4 (7.3%); Ascending colon: 1 (1.8%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 55 (100%) Site of metastases: NR	Hanarostent® (M.I. Tech Co) Type of SEMS: Uncovered Size of SEMS Length: 6-16 cm; Diameter: 22 mm Guidance: endoscopic and fluoroscopic Anaesthesia use: conscious sedation with midazolam and pethidine Use of balloon dilation: not performed	Inclusion criteria: Extensive metastatic or locally advanced colorectal cancers that were surgically unresectable, or non-colorectal extrinsic tumours with colorectal invasion or compression Exclusion criteria: Patients with clinical and radiological suspicion of perforation or acute peritonitis and haemodynamic instability were excluded Patients excluded: NR
Vitale et al (2006), Italy	57	33/24	69 ± 18 years	Type of obstruction Partial: NR; Complete: NR	Wallstent, Ultraflex Precision Colonic Stent	Inclusion criteria: Patients with acute neoplastic bowel obstruction

				Location of obstruction: Rectosigmoid junction: 26 (45.6%); Sigmoid colon: 11 (19.3%); Sigmoid-descending colon junction: 5 (8.8%); Descending colon: 5 (8.8%); Splenic flexure: 4 (7%); Transverse colon: 5 (8.8%); Hepatic flexure: 1 (1.8%) Length of stenosis: NR Diagnosis Benign: 0; Malignant: 57 (100%) Site of metastases: NR	Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: 6 to 12 cm; Diameter: 22 to 30 mm Guidance: Endoscopic and fluoroscopic Anaesthesia use: Conscious sedation (IV midazolam) Use of balloon dilation: NR	Exclusion criteria: Suspicion of bowel perforation Patients excluded: 19 patients were excluded from the study after SEMS placement due to advanced cancer precluding further surgery; they did not undergo a complete colonoscopy
Yoon et al (2011), South Korea	412	250/162	60.8 ± 0.7 years (range 22-92)	Type of obstruction Partial: 111[b] (27%); Complete: 301[a] (73%) Location of obstruction: Left colon: 327 (79.4%); Right colon: 85 (20.6%) Length of stenosis: NR Diagnosis Benign: 0 (0%); Malignant: 412 (100%) Metastatic colorectal cancer: 114 (27.7%) Site of metastases (n=114): Gastric 82 (19.9%); Gynaecologic: 13 (3.2%); Pancreatobillary: 12 (2.9%); Urogenital: 6 (1.5%); Head and neck: 1 (0.2%)	Wallflex colonic (Boston Scientific), Niti-s colonic, Comvi stent, Niti-s colonic D type (Taewoong Medical) Type of SEMS: Covered and uncovered Size of SEMS Length: 6, 8, 9, 10, and 12 cm; Diameter: 18, 20, 22 or 25 mm Guidance: Fluoroscopic Anaesthesia use: NR Use of balloon dilation: Performed using 8 or 10 mm balloons where a stent did not expand (n=16)	Inclusion criteria: NR Exclusion criteria: NR Patients excluded: Because they did not undergo a SEMS procedure due to open lumina or multifocal strictures (n=109), as they had benign lesions (n=54) and due to previous SEMS placement at a separate hospital (n=5)
Young et al (2011), Australia	100	52/48	63.9 years (range 16–95)	Type of obstruction Partial: NR; Complete: NR	Wallstent (Boston Scientific), Ultraflex (Boston Scientific) and Wallflex (Boston Scientific)	Inclusion criteria: NR Exclusion criteria: Patients with curable malignant large bowel obstruction and who

Location of obstruction: Rectum: 32 (32%); Rectosigmoid: 16 (16%); Sigmoid colon: 26 (26%); Descending colon: 13 (13%); Splenic flexure: 2 (2%); Transverse colon: 8 (8%); Hepatic flexure: 2 (2%); Ascending colon: 1 (1%) Length of stenosis: NR Diagnosis Benign: 7 (7%); Malignant: 93 (93%) Site of metastases: NR	Type of SEMS Covered: NR; Uncovered: NR Size of SEMS Length: NR; Diameter: NR Guidance: Endoscopic and fluoroscopic Anaesthesia use: General anaesthesia Use of balloon dilation: used early in the study	were healthy enough to have an immediate operation Patients excluded: NR

a Symptoms such as nausea, vomiting, abdominal distension, decreased or absent bowel sounds, or the inability to pass any stool or gas per anus presented
b Symptoms such as bowel distension, difficulty in passing solid stool or presence of narrowed stool caliber, or the ability to only pass small amounts of liquid stool or gas presented
c No passage of contrast medium during contrast medium studies before or during stent placement
d Partially obstructing lesion with retrograde flow of gastrografin
e No retrograde flow of gastrografin or bowel dilatation proximal to a transition zone followed by distal bowel collapse on CT
N: Based on all patients for whom safety data are reported, regardless of the number of patients enrolled in a study, or their technical/clinical success. In some cases, the number of stenting attempts or procedures performed has been considered as the denominator instead of the number of patients; NR: Not reported; SD: Standard deviation; SEMS: Self-expanding metallic stent.

Appendix I Excluded studies

Health Technology Assessments and Systematic reviews

Inappropriate population and/or comparator

Breitenstein, S., Rickenbacher, A. et al 2007. 'Systematic evaluation of surgical strategies for acute malignant left-sided colonic obstruction', *The British Journal of Surgery*, 94 (12), 1451-1460.

Tilney, H. S., Lovegrove, R. E. et al 2007. 'Comparison of colonic stenting and open surgery for malignant large bowel obstruction', *Surgical Endoscopy*, 21 (2), 225-233.

Watt, A. M., Faragher, I. G. et al 2007. 'Self-expanding metallic stents for relieving malignant colorectal obstruction: a systematic review', *Annals of Surgery*, 246 (1), 24-30.

Zhang, Y., Shi, J. et al 2011. 'Self-expanding metallic stent as a bridge to surgery versus emergency surgery for obstructive colorectal cancer: a meta-analysis', *Surgical Endoscopy*, 26 (1), 110-119.

Did not meet criteria for systematic reviews

Ansaloni, L., Andersson, R. E. et al 2010. 'Guidelenines in the management of obstructing cancer of the left colon: consensus conference of the world society of emergency surgery (WSES) and peritoneum and surgery (PnS) society', *World Journal of Emergency Surgery*, 5, 29.

Baron, T. H. 2001. 'Expandable metal stents for the treatment of cancerous obstruction of the gastrointestinal tract', *The New England Journal of Medicine*, 344 (22), 1681-1687.

Baron, T. H. and Harewood, G. C. 2003. 'Enteral self-expandable stents', *Gastrointestinal Endoscopy*, 58 (3), 421-433.

Datye, A. and Hersh, J. 2011. 'Colonic perforation after stent placement for malignant colorectal obstruction--causes and contributing factors', *Minimally Invasive Therapy and Allied Technologies*, 20 (3), 133-140

De Salvo, G. L. and Pucciarelli, S. 2005. 'Insufficient evidence to compare clinical effectiveness and safety of self-expanding metal stents with other treatments for malignant colorectal obstruction', *Cancer Treatment Reviews*, 31 (3), 226-229.

Dionigi, G., Villa, F. et al 2007. 'Colonic stenting for malignant disease: review of literature', *Surgical Oncology*, 16 (Suppl. 1), S153-S155.

Finan, P. J., Campbell, S. et al 2007. 'The management of malignant large bowel obstruction: ACPGBI position statement', *Colorectal Disease*, 9 (Suppl. 4), 1-17.

Harris, G. J., Senagore, A. J. et al 2001. 'The management of neoplastic colorectal obstruction with colonic endolumenal stenting devices', *The American Journal of Surgery*, 181 (6), 499-506.

Khot, U. P., Lang, A. W. et al 2002. 'Systematic review of the efficacy and safety of colorectal stents', *The British Journal of Surgery*, 89 (9), 1096-1102.

McGregor, M. 2003. 'Should the MUHC approve the use of colorectal stents?', Technology Assessment Unit of the McGill University Health Centre (MUHC), Montreal, Canada.

Readding, L. A. 2004. 'Management of colorectal patients with self-expandable metal stent: information for nurses and patients', *World Council of Enterostomal Therapists Journal*, 24 (4), 12.

Saida, Y., Nagao, J. et al 2007. 'Self-expandable metallic stent for patients with non-resectable malignant colorectal stricture: Review of 102 cases in the Japanese literature', *Digestive Endoscopy*, 19 (2), 59-64.

Sebastian, S., Johnston, S. et al 2004. 'Pooled analysis of the efficacy and safety of self-expanding metal stenting in malignant colorectal obstruction', *The American Journal of Gastroenterology*, 99 (10), 2051-2057.

Tierney, W., Chuttani, R. et al 2006. 'Enteral stents', *Gastrointestinal Endoscopy*, 63 (7), 920-926.

Trompetas, V. 2008. 'Emergency management of malignant acute left-sided colonic obstruction', *Annals of the Royal College of Surgeons of England*, 90 (3), 181-186.

Varadarajulu, S., Banerjee, S. et al 2011. 'Enteral stents', *Gastrointestinal Endoscopy*, 74 (3), 455-464.

Comparative evidence

Duplicate Publication

Xinopoulos, D., Dimitroulopoulos, D. et al 2004. 'Palliation of inoperable malignant colonic obstruction. Comparison and cost effectiveness analysis between stent placement and stoma creation', *SO: Annals of Gastroenterology*, 17 (3), 294-299.

Foreign Language

Kim, H. H., Kim, H. K. et al 2009. 'Usefulness of self-expandable metallic stents for malignant colon obstruction', *Journal of the Korean Society of Coloproctology*, 25 (2), 113-116.

Inappropriate comparator (included single-stage resection)

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Inappropriate intervention

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Non-consecutive patient enrolment

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Non-comparative evidence (case series or level IV studies)

Inappropriate population (Benign obstruction only)

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Inappropriate or no clinical data

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Inappropriate study design

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Non-consecutive patient enrolment

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Inappropriate or wrong intervention

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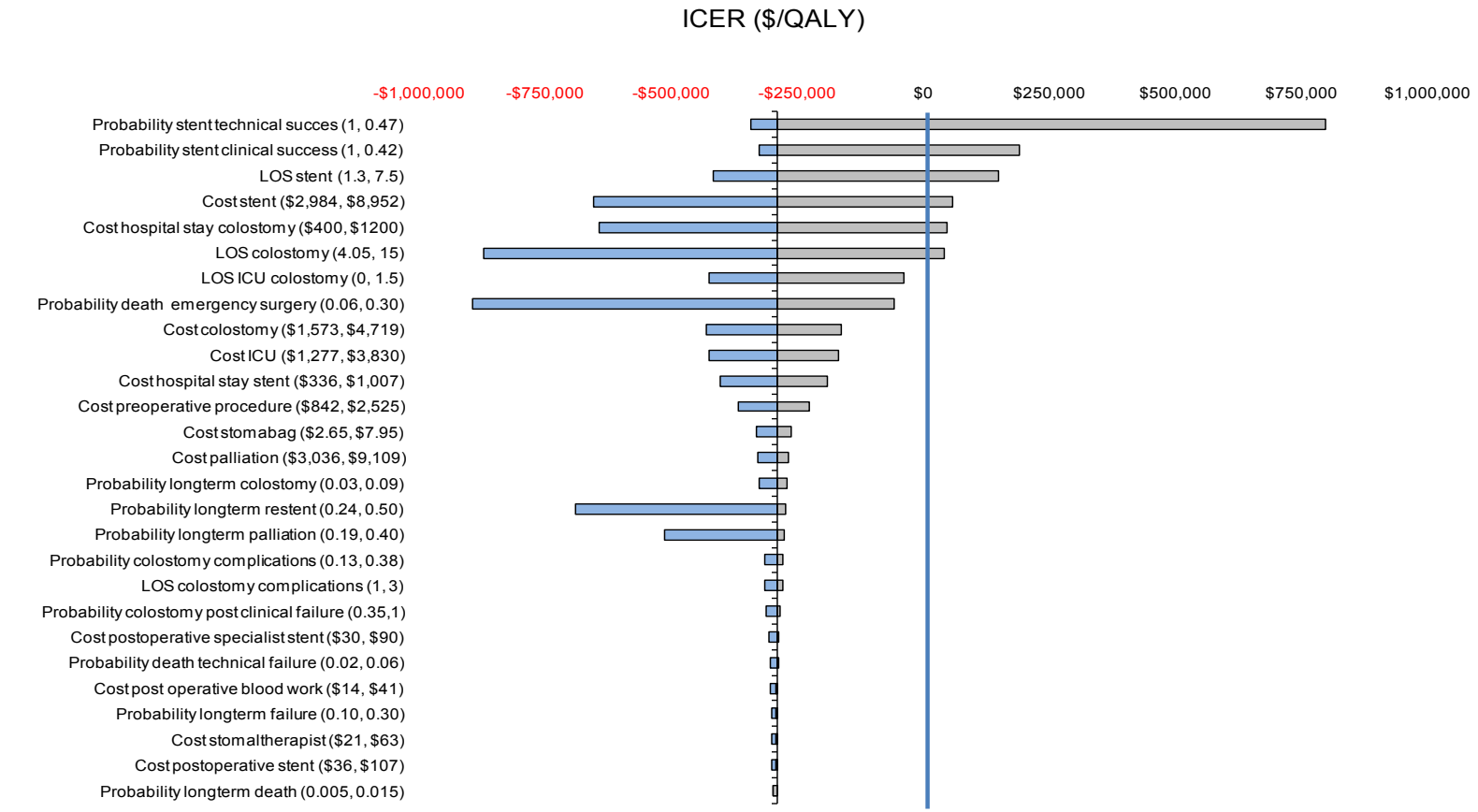
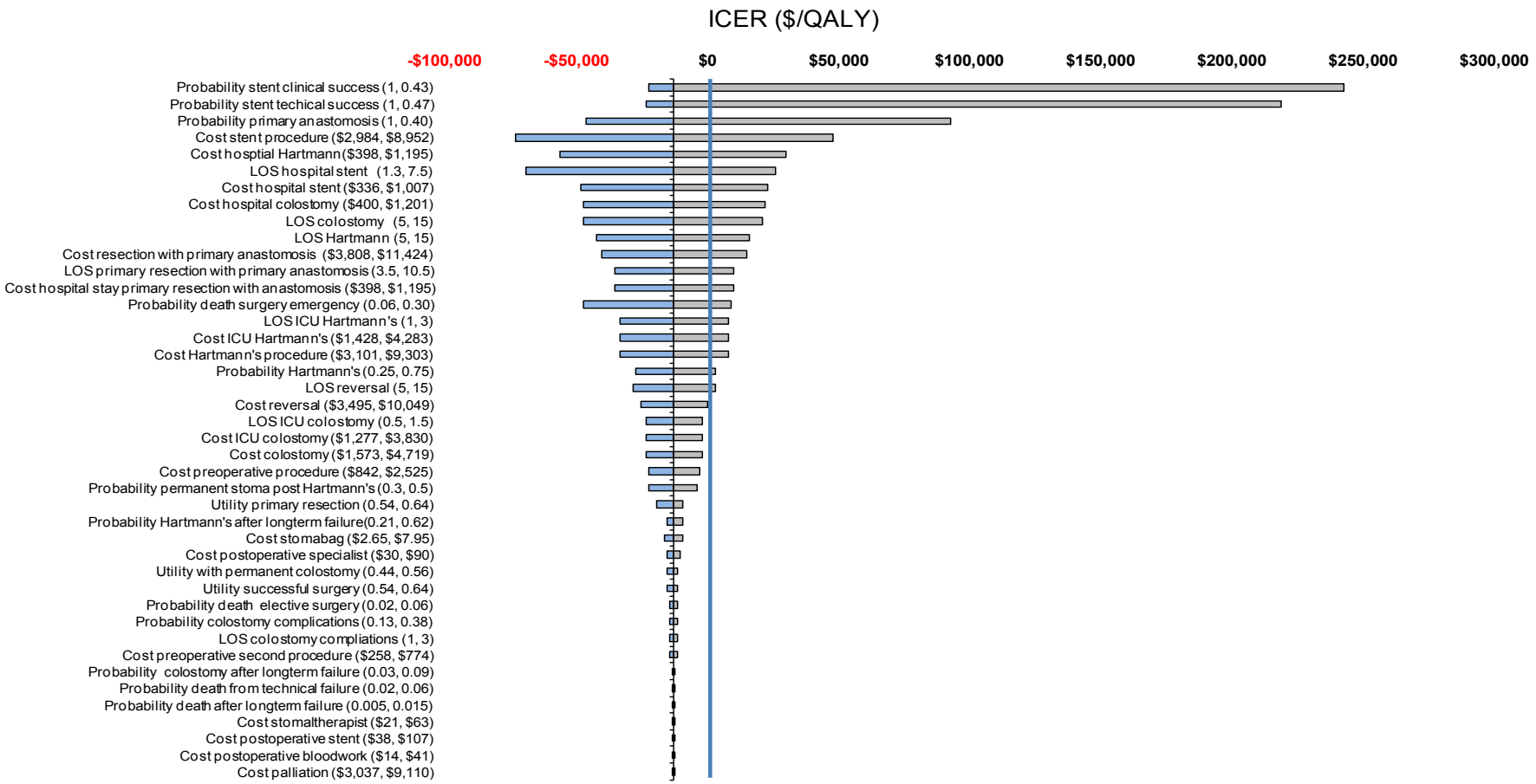
Appendix J Sensitivity analysis

One-way sensitivity analysis (SEMS vs Colostomy for palliative treatment)



ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year

One-way sensitivity analysis (SEMS vs Colostomy/Hartmann's procedure as a bridge to surgery)



ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life year

Glossary and abbreviations

AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
APC	argon plasma coagulation
AR-DRG	Australian Refined Diagnostic Related Group
ARTG	Australian Register of Therapeutic Goods
ASA	Australian Society of Anaesthetists
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
CHERE	Centre for Health Economics Research and Evaluation
CSSANZ	Colorectal Surgical Society of Australia and New Zealand
DRG	diagnosis related group
FACT-C	Functional Assessment of Cancer Therapy – Colorectal
HESP	Health Expert Standing Panel
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
ICU	intensive care unit
IQR	interquartile range
ITT	intention to treat
LOS	length of hospital stay
LYG	life year gained
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NHMRC	National Health and Medical Research Council
PASC	Protocol Advisory Sub-Committee
PRISMA	preferred reporting items for systematic reviews and meta-analyses
QALY	quality-adjusted life year

RCT	randomised controlled trial
SEMS	self-expanding metallic stent
SD	standard deviation
TGA	Therapeutic Goods Administration
UK	United Kingdom
USA	United States of America
WTP	willingness-to-pay

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