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Safety and efficacy of self-expandable metal stents for obstructive proximal and distal large bowel cancer

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Abstract

Self-expandable metal stents are often used to treat obstructive large bowel cancers. This study assessed the safety and efficacy of colonic stent insertion carried out in a district general hospital.

Methods A retrospective review was carried out between 1 January 2007 and 28 February 2014 to identify patients who underwent stent insertion for malignant colorectal obstruction.

Results Seventy-five patients (median age 75.2 years, 70.6% male) with primary colorectal cancer underwent stent insertion – 53 underwent semi-elective self-expanded metal stent insertion (for subacute bowel obstruction) and 22 had emergency stent inserted (for acute bowel obstruction). The majority (88%) had self-expanded metal stents inserted for palliation. Technical and clinical success rates were 98.7% and 91.2%, respectively. One patient had stent-related perforation; there was no procedure-related mortality.

Conclusion This study shows that self-expanded metal stent insertion in malignant colorectal obstruction is safe and effective and can be successfully delivered in a district general hospital with high technical and clinical success rates.

Keywords acute bowel obstruction, colorectal cancer, district general hospital, self-expanded metal stent

Declaration of interests No conflicts of interest declared

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Introduction

Colorectal cancer (CRC) is the fourth most common cancer in the UK, accounting for 13% of all new cancer cases, and the second most common cause of cancer-related death in the UK (2011). Malignant bowel obstruction can be a late feature of advanced CRC. A significant proportion (8%–29%) of patients with CRC present with acute bowel obstruction (ABO) which is a surgical emergency.[1] Emergency decompression surgery with colostomy can be associated with significant morbidity and mortality (up to 25%).[2,3] Postoperative death in patients undergoing surgery for ABO might account for one-fifth of all postoperative deaths following surgery in CRC patients.[4] As a consequence, there has been a lot of debate in the literature regarding the optimal initial therapeutic approach of managing these patients who present with ABO.

Self-expandable metal stents (SEMS) provide a low-risk and successful therapeutic option for managing these patients.[5] Colorectal stents can be used in the setting of ABO as a palliative option in non-resectable CRC and as a bridge to surgery in resectable disease.[3,6] In recent years, lower costs, reduced hospital stay, fewer complications and short term mortality has led to increased acceptability of colonic stents in this setting compared to decompression surgery.[7]

The National Institute of Health and Care Excellence guidelines[8] recommend the establishment of facilities in acute surgical admission units to allow the placement of colonic stents for patients with large intestinal obstruction as an alternative to emergency surgery. Most of the published literature on colonic stents in ABO is from large tertiary centres. However, there is limited literature on the safety and efficacy of colonic stents in acute colorectal obstruction in the district general hospital setting.[1] We set out to evaluate the outcome of the use of SEMS in malignant ABO in a district general hospital.

Aim

The aim was to assess and compare the safety and efficacy of colonic stents for obstructive proximal and distal large

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bowel cancer in a district general hospital. We also compared the technical and clinical success rates of colonic stents in the setting of palliative CRC and as a bridge to surgery in resectable disease.

Materials and methods

University Hospital of North Tees is a district general hospital in the north-east of England with a catchment population of 340,000. The endoscopy unit is a Joint Advisory Group accredited national bowel cancer screening centre and approximately 6,000 colonoscopies are carried out in this unit annually. This study was carried out using routinely collected clinical data and, in accordance with the UK National Research Ethics Service guidelines, formal ethical approval was not required.

All colonic stents were discussed in the colorectal multidisciplinary team prior to insertion. After obtaining informed patient consent, procedures were undertaken, by three experienced consultant gastroenterologists (ADD, BKC and JH) who were not blinded to the results of any previous cross-sectional imaging or colonoscopic examination. All SEMS were placed endoscopically either by using a large channel (3.2 cm) colonoscope (Olympus). A twin channel therapeutic gastroscope (Olympus IT therapeutic gastroscope) was used in cases where visualisation was difficult due to severe bowel angulation. Uncovered SEMS (Wallflex stent, Boston Scientific and Wilson Cook) were inserted under fluoroscopic guidance. The stricture was delineated using a swing tip ERCP cannula with contrast and the length of the SEMS was based on the estimated length of the stenosis at the time of the procedure. Any information available from prior colonoscopy with regards to the estimated length of the stricture in previously passable strictures was taken into account while assessing the length of the stricture. Following the deployment of SEMS, no attempt was made to negotiate the stricture by passing the scope through the SEMS. No attempt at balloon dilatation was made following SEMS deployment in case of initial insufficient expansion. Patients were observed in the hospital for at least 72 hours following the procedure. Technical success was defined as successful insertion of SEMS across the entire length of the stricture. Clinical success was defined as the relief of obstructive symptoms within 72 hours of SEMS insertion. The overall clinical success was defined as the successful maintenance of stent function and the lack of need for further treatment at the site of obstruction during the follow-up period.

A retrospective review of our prospectively maintained endoscopy database was carried out between 1 January 2007 and 28 February 2014 to identify all patients who underwent colonic stent insertion during that period. Patients either presented with ABO and underwent emergency stent insertion or were stented semi-electively for subacute bowel obstruction in view of impassable CRC stricture in patients deemed inoperable on staging investigations. Patients identified from the endoscopy database were cross referenced with a prospectively maintained stent logbook maintained in the endoscopy unit. All CRC patients who underwent SEMS insertion initially presented with symptoms of ABO (nausea, vomiting, abdominal distension and absence of stool/flatus) or subacute obstruction confirmed on radiological imaging (CT scan). All SEMS were inserted within 24 hours of confirmed diagnosis. Data collected included patient demographics, site and histology of the lesion, treatment intent (palliative vs bridge to surgery), stent dimensions, technical success, clinical success, adverse events and time to death.

Table 1. Demographics, safety and efficacy of colorectal stent insertion in malignant CRC

Number of patients who underwent SEMS	75
Median age (yrs)	75.2
Male (%)	70.6
Left colon (%)	91
Palliative stenting (%)	88
Technical success (%)	98.7
Clinical success (%)	91.2
Complications (%)	17.3
Overall mortality (%) (none procedure related)	10.8

Statistical analysis

Categorical variables are expressed as percentages and compared among groups using the Fishers exact test. A two tailed p value of less than 0.05 was considered statistically significant.

Results

During the study period, a total of 79 patients had SEMS inserted for management of colorectal obstruction; 75 had primary colorectal cancer and four had extra-colonic malignancy with colonic metastasis or direct colonic invasion (two ovarian cancers, one renal cancer and one breast cancer).

For the purpose of our study, 75 patients with primary CRC were included. Table 1 shows the demographics, site of CRC, purpose of stenting (palliative vs curative), technical and clinical success rates, complications and 30-day mortality.

Of these 75 patients, 53 (70.5%) underwent semi-elective SEMS insertion (for subacute bowel obstruction) and 22 (28.5%) had emergency stents inserted (for ABO) (Table 2). In the semi-elective group, six (11.3%) patients subsequently underwent curative surgery at a later date while SEMS were inserted in the remaining 47 (88.7%) with palliative intent. In the emergency stent group, three (13.6%) patients subsequently underwent curative surgery and in 19 (84.4%) SEMS were inserted for palliation. Overall, nine (12.0 %) SEMS were inserted as a bridge to surgery while 66 (88%) were inserted for palliation. Of the patients who underwent palliative stent insertion, one 90 year old female patient chose to undergo palliative stent insertion although she had resectable CRC.

Table 2. Comparison of safety and efficacy of colonic stent insertion in proximal and distal colon

	Distal colon (n = 68)	Proximal colon (n = 7)	p value (Fisher's exact test)
Males	49	4	0.03
Palliative intent	60	6	1.00
Technical success rate	67	7	1.00
Clinical success rate	59	7	0.58
Adverse events	13	0	0.34
Emergency stenting	22	0	0.09

Sixty-eight (91%) patients had SEMS inserted in their left colon (see Table 3). The sites of CRCs in our stent population in decreasing order of frequency were: sigmoid colon (38(50.6%)), descending colon (14(18.6%)), rectum (7(9.3%)), recto-sigmoid (7(9.3%)), transverse colon (3(4%)), hepatic flexure (4(5.3%)) and anastomotic recurrence post left hemi-colectomy (2(2.6%)). In six patients, two colonic stents were inserted in series to cover the stricture. Stent sizes varied in length between 6 to 12 cm.

Technical success was achieved in 74 (98.7%) out of 75 cases with one patient proceeding to surgical decompression before undergoing curative resection. Of the 74 that were technically successful, 66 (91.2%) went on to be clinically successful (functional stent) in the post-procedure period. During subgroup analysis, we found that out of nine patients who had SEMS placed as a bridge to surgery, technical success rate was 89% (8/9) and clinical success rate was 87.5% (7/8). Technical success rate was 100% (66/66) and clinical success rate was 89.3% (59/66) in the subgroup of patients who had SEMS placed with palliative intent.

Of the eight patients who underwent successful SEMS insertion as a bridge to surgery, one patient had a recurrence of cancer at the anastomotic site two years after the initial curative surgery (Duke's C2 staging on resection histology), another patient presented with distal metastasis four months after the surgery (Duke's C2 staging on resection histology) and a third presented with distal metastasis 22 months following the initial surgery (Duke's C1 staging on resection histology).

Early adverse events (within 30 days of procedure) were as follows: one patient with recto-sigmoid cancer had a stent-related perforation (patient proceeded to palliative rescue Hartmann's procedure); three had blocked stents within five days of the procedure (one was unblocked during repeat endoscopy by flushing and enema leading to successful stent function, one underwent palliative Hartmann's procedure and another patient with advanced disease declined further endoscopy or Hartmann's and had supportive care); two patients had stents that failed to re-establish luminal patency

Table 3. Comparison of safety and efficacy of colonic stenting in emergency and semi-elective stent insertion groups

	Emergency stenting (n = 22)	Semi-elective stenting (n = 53)	p value (Fisher's exact test)
Males	12	41	0.05
Palliative stenting	19	47	0.71
Technical success rate	22	52	1.00
Clinical success rate	18	48	0.43
Adverse events	4	9	1.00
Left or distal colon SEMS insertion	22	46	0.09

despite successful deployment (one proceeded to palliative decompression surgery while the other had an additional stent placed successfully with no further complication); and in three patients the stent migrated (in one patient with descending colon cancer, the stent migrated partially but was functional and patent for two years, in the second patient with rectal cancer the stent migrated and was removed and in the third patient with recto-sigmoid cancer the stent migrated and self-extruded). One patient with rectal cancer experienced significant discomfort in the lower abdomen and perianal area following the procedure that settled with analgesia.

Late adverse events (after 30 days of SEMS insertion) were as follows: one patient with distal sigmoid cancer had a stent migration six months following his index procedure. He needed a further procedure after 14 months of his second procedure as his stent became blocked due to tumour overgrowth; another patient with descending colon cancer presented with a blocked stent due to tumour overgrowth about 15 months after the index procedure and underwent a successful second procedure.

Overall, adverse events were noted on 13 occasions (17.3%) in 12 patients of which there was one major complication (stent-related perforation – 1/75 or 1.3%). On subgroup analysis, four events occurred in the emergency colonic stent (4/22, 18%) group – one patient had stent-related perforation, two had blocked stents in the early post procedure period (within 30 days) and one had a blocked stent in the delayed post procedure period (after 30 days). Nine events occurred in the semi-elective stent group (9/53, 17%).

Discussion

Malignant large bowel obstruction is a common complication of colonic neoplasm. In the past, this was managed by surgical resection. However, over the past two decades there has been an increasing shift towards endoscopic management of this complication of CRC using SEMS placement.

A recent retrospective multicentre study by Manes et al.[9] carried out in five tertiary teaching hospitals reported a technical success rate of 91.5% and clinical success rate of 89.7% (in those who underwent successful stent insertion) following SEMS insertion in palliative CRC patients. Another prospective multicentre study by Repici et al.[10] in nine European study centres, involving tertiary teaching hospitals, reported a technical success rate of 95% and a clinical success rate of 81% following SEMS insertion in palliative CRC patients. In our single-centre retrospective study carried out in a district general hospital setting, the technical and clinical success rates were 100% and 89.3% in a similar group of patients.

Several studies have demonstrated a statistically significant reduction in length of hospitalisation, fewer medical complications, decreased frequency of the need for stoma formation and more prompt initiation of chemotherapy[11–14] in patients undergoing SEMS placement compared to surgery in palliative CRC patients. Moreover, a study by Xinopoulos et al.[7] showed that SEMS placement was more cost-effective compared to initial surgical colostomy in the palliative CRC group. Some studies have also reported a trend towards decreasing mortality.[15]

In patients with resectable CRC and colonic obstruction, SEMS placement allows decompression, adequate bowel preparation, optimisation of patients' comorbid status, thorough staging evaluation of the cancer and opportunity for neoadjuvant chemotherapy for rectal cancers before going for planned elective surgery. A meta-analysis by Watt et al.[16] showed a technical and clinical success rate following SEMS insertion of 96% and 92%, respectively, in the setting of resectable CRC and colonic obstruction. Another study showed a technical success rate varying between 85% and 92%.[17] Although the numbers of SEMS inserted in resectable CRC were small (n = 9) in our study, the technical and clinical success rates were 89% and 87.5%, respectively, and comparable with the published literature. Compared to emergency surgery in this setting, it results in significantly lower complication rates, reduced length of hospitalisation, lower rates of colostomy and a higher rate of primary anastomosis.[16,18] However, there is no difference in mortality between the SEMS group and the surgery group in this setting.[19]

Recently, the European Society of Gastrointestinal Endoscopy guidelines on colonic stent insertion in malignant colonic obstruction were published.[20] They state that SEMS placement as a bridge to surgery in resectable disease is not recommended as a standard of treatment for the management of malignant ABO. However, it may be considered in patients with greater risk of postoperative morbidity and mortality (age > 70 years and ASA grade > 3).These statements follow the findings of higher recurrence of cancer in the SEMS group as compared to the primary surgery group in some studies[21–23] – risks of recurrence outweighs the potential benefits. This may be related to complications of SEMS placement; mainly perforation. Data from the Stent-2 trial[24] corroborate with the findings of higher recurrence of cancer in the SEMS group as compared to the primary surgery group (42% vs 25%) with subgroup analysis showing a higher recurrence rate in the stent-related perforation group (83%). This possibly highlights the importance of experienced operators performing or supervising the procedure thereby reducing stent-related complications. Although our numbers for SEMS inserted as a bridge to surgery were small (n = 8), there were no cases of disease recurrence attributable to SEMS insertion. This could be related to the fact that all colonic stents were inserted by experienced operators (between 20–25 procedures each) at our hospital. All three patients, who had disease recurrence, had advanced Duke's staging on resection histology.

In our study, we also looked at the subgroup where SEMS inserted for proximal right colon obstruction (n = 7); six patients had SEMS inserted for palliative reasons and one had a stent inserted as a bridge to surgery. Although the numbers were small, both technical and clinical success rates in this group were 100%. Studies by Repici et al.[25] and Dronamraju et al.[26] involving 21 and 16 patients, respectively, showed that technical and clinical success rates of SEMS in proximal colonic obstruction were 95% and 87%, respectively. A larger study (n = 81) on SEMS in proximal colon obstruction[27] demonstrated a technical and clinical success rate of 96.3% (78/81) and 96.1% (75/78), respectively. These figures suggest that SEMS insertion in proximal colonic obstruction is equally effective when compared to distal colonic obstruction in experienced hands.

Stent-related adverse events can be classified as early (within 30 days of the procedure) or late (after 30 days of procedure). Early complications[28–30] include bleeding (0–5%), stent migration (0–5%), blocked stents (0–5%), stent non-function after successful insertion (0–11%), perforation (0–12%) and pain (0–7.4%). Late complications[29,31] include stent migration (1–12%), blocked stents (4–22%) and, rarely, perforation (0–4%). Procedure related 30-day mortality has been reported in up to 4% of patients. In our study, early stent-related adverse events were as follows: stent migration (2.66%), stent non-function (2.66%), pain (2.66%), blocked stents (4.0%), stent-related perforation (1.3%). Late stent-related adverse events were stent migration (1.3%) and blocked stents (2.6%). The rate of complications in our study population is comparable to the published literature. There was no procedure related 30-day mortality.

Our study had a few limitations. This was a retrospective, single centre study and there was no pre-defined study protocol – some patients had a SEMS inserted as a bridge to surgery while others proceeded to surgery directly. The choice of management was clinically driven and depended on clinician choice and multidisciplinary team recommendation rather than pre-defined criteria. Being a retrospective study, endoscopy reporting for the colorectal stents was not standardised. There was some missing data, such as procedure time, fluoroscopy time and ASA grade in some of the reports, hence we could not comment on these aspects.

The main strength of our study is the robust data collection. Although this was a retrospective study, all patients who underwent SEMS insertion during this period were identified from the electronic endoscopy database and cross-referenced with the colorectal multidisciplinary team database and the stent logbook. Any missing data with regards to the cause of death and follow up was obtained by directly contacting the patient's GP.

In conclusion, colonic stent insertion in malignant colorectal obstruction is safe and effective in both proximal and distal large bowel cancers and can be successfully delivered in a district general hospital. Careful patient selection and delivery of the service by experienced operators are key factors for successful outcomes. The service needs to be responsive and timely to manage ABO. All hospitals, that have acute surgical admissions units, should have rapid access to a colonic stenting service either locally or through a regional network. A colonic stent insertion service should be planned depending on the number of patients requiring SEM insertion in a given catchment hospital. This would help in service delivery and develop the expertise of a limited number of experienced operators who undertake colonic stent insertion.

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