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*Master of Medicine in Surgery*  
Research Report

Submitted to  
**University of Cape Town**  
Faculty of Health Sciences

**Management of left-sided malignant colonic obstruction:  
an audit of a stent based protocol**

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## Abbreviations used in this document

AXR:	Abdominal X-ray
CT:	Computed Tomography
RCT:	Randomized Controlled Trial
SEMS:	Self-Expanding Metallic Stent
USA:	United States of America
UK:	United Kingdom

## Definitions of terms used in this document

<b>Bridge to surgery:</b>	colonic stent is used as an interim measure for decompression and definitive surgery is undertaken electively at a later stage
<b>Decompression tubes:</b>	hollow tubes placed via the anus to allow decompression of the obstructed bowel and evacuation of faecal material
<b>Left-sided colonic obstruction:</b>	colonic obstruction distal to the hepatic flexure
<b>Level 1 evidence:</b>	evidence obtained from at least one properly designed randomized controlled trial
<b>Perforation:</b>	rupture of a hollow organ, in this case the large bowel, which manifests with an acute abdomen
<b>REFWORKS®:</b>	online bibliographic management programme that allows users to create a personal database of references

<b>Right-sided colonic obstruction:</b>	obstruction proximal to and including the hepatic flexure
<b>Single stage surgery:</b>	tumour is resected and primary anastomosis performed at the first operation
<b>Stage the patient:</b>	conduct screening investigations (i.e x-ray, ultrasound, computed tomography scans) to confirm or refute evidence of metastatic disease
<b>Stent:</b>	self-expanding colonic metallic stent
<b>Stoma:</b>	surgically created opening in the intestine that allows the removal faecal material to drain into a collection device
<b>Two stage surgery:</b>	tumour is resected at first operation, proximal colon brought out as a stoma, and the rectal stump oversewn (Hartmann's procedure). Stoma can be closed at a later stage
<b>Three stage surgery:</b>	
First operation:	defunctioning loop colostomy;
Second operation:	tumour resection and primary anastomosis done;
Third operation:	stoma closure

## Declaration

I, Dr C Warden, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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## **PART A**

### **Protocol**



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## **Title**

Management of left-sided colonic obstruction: an audit of a stent based protocol

## **Investigators**

C Warden, D Stupart, P Goldberg

## **Introduction**

Despite improvements in medical and surgical care, patients presenting with colonic obstruction secondary to adenocarcinoma have mortality rates for emergency surgery of 15-20%.<sup>1</sup> The immediate treatment priorities for these patients are fluid resuscitation and relief of the obstruction. Up until 1991, surgery was the only means of relieving colonic obstruction. Three forms of surgery have been used to relieve the obstruction including: single stage, two stage and three stage procedures\*. It can be difficult to choose between simpler two or three staged operations that leave the patient with a stoma and single staged procedures that are technically demanding even for experienced colorectal surgeons. Colonic stenting offers a means of relieving the obstruction while avoiding the risks of surgery.

In 1991 Dohmoto<sup>2</sup> placed the first colonic stent and thus opened up a new avenue of treatment. Colonic stents have provided a way of decompressing the obstruction while avoiding the mortality related to surgery and the

morbidity of a stoma. A review of the literature by Khot<sup>4</sup> et al found that stents are successful at decompressing 92% of patients, 95% avoid stoma with a 1% mortality. Since 2004, the colorectal unit at Groote Schuur Hospital has treated left-sided obstructing colon cancers by endoscopic decompression using self-expanding metal stents.

## Aim

To determine the safety and efficacy of the colonic stent management protocol at Groote Schuur Hospital. (appendix A)

## Patients and Methods

This is a retrospective audit of all patients who presented with left-sided colonic obstruction due to adenocarcinoma to the Colorectal Surgery Unit at Groote Schuur Hospital, Cape Town between January 2004 and June 2009. Patients with colonic obstruction due to other causes (eg volvulus, diverticular disease) are excluded from this study. Patients with signs of perforation will not form part of this study as they progress directly to surgery according to our current management protocol. Data will be collected from hospital folders for: patient gender, age, level of obstruction, stent success/failure, indication for stent (palliative or bridge to surgery), length of hospital stay, complications, stoma rate and mortality. Data will be entered into an excel spreadsheet for analysis. Sample size is estimated at 70-90 patients.

## Definitions

**Left-sided colonic obstruction:** colonic obstruction distal to the hepatic flexure

**Stent:** self-expanding colonic metal stent

**Bridge to surgery:** colonic stent is used as an interim measure for decompression and definitive surgery is undertaken electively at a later stage

**Perforation:** rupture of a hollow organ, in this case the large bowel, which manifests with an acute abdomen

**\*Single stage surgery:** tumour is resected and primary anastomosis performed at the first operation

**\*Two-stage surgery:** tumour is resected at first operation, proximal colon brought out as a stoma, and the rectal stump over sewn (Hartmann's procedure). Stoma can be closed at a later stage

**\*Three-stage surgery:**

*First operation:* defunctioning loop colostomy;

*Second operation:* tumour resection and primary anastomosis done;

*Third operation:* stoma closure

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## Appendix A

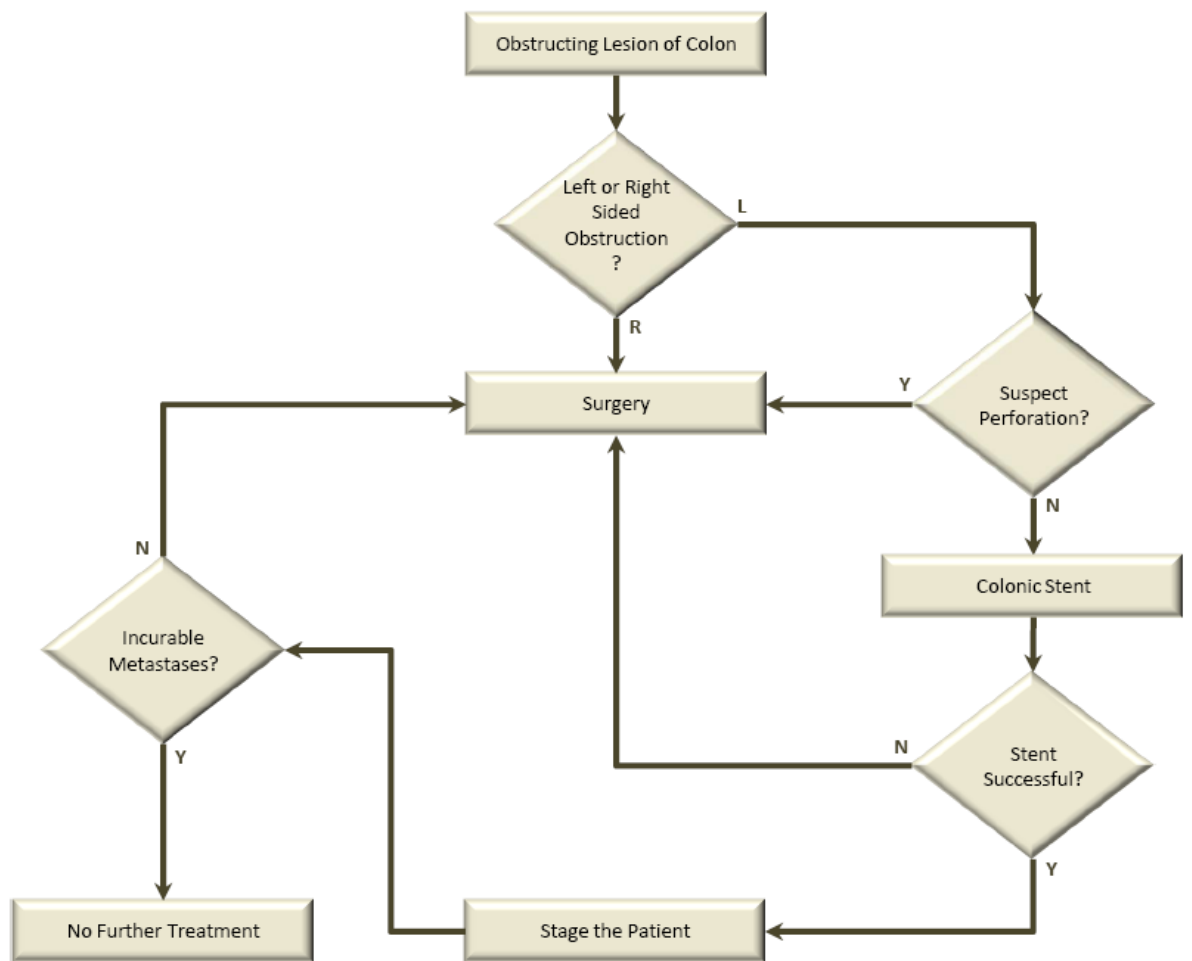


Figure 1: The GSH Colonic Stent Protocol

## **PART B**

### **Literature Review**

## 1 Introduction and Objectives

The management of obstructing left-sided colorectal cancer presents a significant challenge to the surgeon. Emergency surgery for acute malignant colonic obstruction is the current standard of care but is associated with significant morbidity and mortality. The concept of a non-operative form of management is appealing. Self-expanding metallic stents (SEMS) are an example of a relatively new technology that may allow surgery to be delayed or avoided completely in patients with obstructing colorectal cancer.

This literature review serves to gather further information on the safety profile and efficacy of SEMS and their use in left-sided malignant colonic obstruction. The evidence found will be used to analyze the indications for the use of colonic SEMS. The information gathered from the international literature, will be used as a benchmark against which to measure our Groote Schuur Hospital experience with colonic SEMS (see Part C).

## 2 Literature search method

The literature search strategy involved a database search using Pubmed<sup>®</sup> (National Center for Biotechnology Information at the National Library of medicine located at the United States National Institutes of Health). The terms 'colonic stent' and 'colonic obstruction stent' were used in this search. This database includes MEDLINE<sup>®</sup> (Compiled by the United States National Library of Medicine). The references used by the review articles located by this search were further investigated.

The search was limited to English language journal articles, human and adult articles that were found on the database. The initial Pubmed<sup>®</sup> search revealed 376 journal articles. Journal articles that focused on SEMS placed for benign disease, SEMS placed in other areas of the gastrointestinal tract, radiographical features of SEMS and those comparing differing manufacturer's SEMS types were excluded from the search. The time period for the search was limited from 1990 to 2009 as the first colonic SEMS was placed in 1991. Further important and randomized controlled trial articles were included in the review as they became available (until June 2011).

The journal articles found were stored in REFWORKS® for analysis. A total of 97 articles underwent further abstract analysis. Eight review articles were among the 97 and their reference lists were analyzed and further relevant journal articles added for analysis. A total of 115 journal articles were assessed by abstract review. Some journal articles were disregarded if they were considered to be a repeat of information pertaining to a particular patient group at a particular hospital. The latest published article containing data from that hospital unit was included for analysis (7 studies). The table below (table 1) outlines the types and number of articles included in the study.

**Table 1:** Types and number of articles included

Type of article	Number
Retrospective case series	57
Prospective studies	21
Review articles	15
Case reports	11
Letter to the editor	1
Randomized controlled trials (RCT)	6

Studies that included greater than 30 patients were included for more extensive article review. This amounted to 23 studies, both retrospective and prospective and 15 review articles. All of the six randomized controlled trials (RCT) were included in the final analysis.

### 3 Background: Extent of the colon cancer burden

Colon cancer is the fourth most common type of cancer in the United States of America (USA)<sup>1</sup>. Colorectal cancer is the second commonest cause of cancer related death in the western world and there are over 30 000 new cases per year in the United Kingdom (UK)<sup>2</sup>. Annually, more than 945 000 people develop colorectal cancer worldwide, and around half a million patients die as a result<sup>3</sup>. Malignancies of the colon develop sporadically in the majority of cases, although less commonly their aetiology may be linked to inflammatory bowel disease or due to an inherited cancer syndrome.



The majority of colorectal malignancies will present with non-specific symptoms such as anaemia, change in bowel habit, bleeding per rectum and abdominal discomfort. If appropriately screened with sigmoidoscopy or colonoscopy, the majority of patients with colorectal carcinoma should be detected early and referred for elective surgery as required. However, despite the introduction of colorectal cancer screening programmes, up to 20% of colorectal malignancies may still present as acute colonic obstruction<sup>4</sup>. Thus patients presenting with obstructing colorectal cancer remain a significant number and burden.

According to Baron et al as much as 85% of emergency surgery for colonic obstruction may be ascribed to malignancy<sup>5</sup>. The remainder involves benign conditions (e.g. volvulus, diverticular disease) or other forms of malignancy (e.g. genitourinary cancers).

South Africa currently has no national screening programme for colorectal cancer. Although the incidence of colorectal cancer is lower in Africa than in U.K or USA, there are certain population groups within South Africa that have a higher incidence. It is assumed that without a screening programme in South Africa there may be a higher number of patients that present with late stage or obstructing colorectal carcinoma.

## 4 Management options for obstructing colon cancer

### 4.1 Surgery for left-sided obstructing colorectal cancer

Until the early 1990's surgery was the only method of relieving colonic obstruction. Right-sided colonic obstruction (obstruction proximal to the hepatic flexure) is dealt with straightforwardly by a right hemicolectomy with a primary ileal to distal non-dilated colon anastomosis. In contrast, surgery for left-sided colonic obstruction is more complicated. Surgery for left-sided colonic obstruction is fraught with more difficulty and has a greater risk of anastomotic breakdown due to the dilated friable colon proximal to the obstruction that provides poor tissue for anastomoses<sup>6</sup>. In addition, electrolyte imbalances, nutritional compromise and faecal loading all contribute to an increased risk of anastomotic failure. Patients with malignant large bowel obstruction are clearly poor surgical candidates and mortality rates can reach up to 30%<sup>4,7,8</sup>.

Due to the above difficulties encountered with surgery for left-sided colonic obstruction and the risk of anastomotic leaks, initial surgery aimed to avoid an intra-abdominal anastomosis. Historically a "three-stage" operation was described. This encompasses three separate visits to theatre. The first operation is a decompressive stoma while the primary cancer is left in situ. The second surgery involves resection of primary tumour. Finally, the patient returns to theatre for closure of the stoma. The five-year survival for those patients completing all three operations was 19-38%<sup>4</sup>.

The morbidity of the three-stage surgery motivated surgeons to attempt "two-stage" procedures<sup>4</sup>. A "two-stage" procedure includes a resection of the obstructing lesion with closure of the distal colon/rectum and an end colostomy proximal to the lesion. Re-establishment of bowel continuity is performed electively. This has led to shorter hospital stays than with three-stage surgery although up to 60% of patients never have their stomas reversed<sup>7</sup>.

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

stage surgery in terms of morbidity and mortality<sup>9</sup> but studies in this area are non-randomized and thus open to bias of patient choice and procedure choice.

On-table colonic lavage is contentious. A prospective randomized study of elective colonic resection comparing bowel preparation to no bowel preparation failed to show a decrease in the risk of leakage or infection<sup>10</sup>, however it is difficult to extrapolate these results to the emergency surgery setting.

Emergency surgery has high morbidity (40-50%<sup>7</sup>) and mortality rates<sup>11</sup>. These rates are significantly higher than the 5% mortality in the elective situation<sup>11</sup> and emergency surgery often results in stoma creation.

Stoma formation has a negative impact on quality of life<sup>12</sup>. Colostomy formation has a morbidity rate of up to 34%<sup>13</sup>. Many patients are unable to undergo reversal of colostomy on basis of advanced age and co-morbidities and thus remain with a permanent stoma<sup>4</sup>. Some studies quote that 60% of these patients never go on to have stoma reversal<sup>4,14</sup>. The concept of a non-operative management that avoids stoma formation is certainly attractive.

Innovative non-surgical techniques

#### 4.1.1 Decompression tubes

Along the historical timeline between surgery and colonic stents, decompression tubes were developed. These were and still are used by some centres to relieve colonic obstruction while avoiding emergency surgery. Endoscopically placed decompression tubes have been employed as a temporizing measure to relieve large bowel malignant obstruction<sup>15</sup>. The tubes are used to decompress the colon thereby decreasing the risk of perforation and allow for preoperative bowel preparation. It is relatively inexpensive. Decompression tubes are placed by manual advancement over an endoscopically or fluoroscopically placed guide wire. The disadvantages are that it can be time consuming to place, is only a temporary measure and is not without the risks of perforation or bleeding<sup>16</sup>.

#### 4.1.2 Laser therapy

Another technological advancement has been the use of laser. It has been used mostly for palliation of rectosigmoid cancers. The largest published series of 272 patients documented the 14-year experience from France of patients undergoing palliative therapy for rectosigmoid cancers<sup>17</sup>. There was a high immediate success rate in treating obstructive symptoms (85%) and a low major complication rate (2%)<sup>17</sup>. These figures likely reflect on the large experience of the reporting treating endoscopists. Laser is effective for distal lesions but technically difficult for tumours proximal to the sigmoid colon. Disadvantages of laser therapy include: the requirement of specialized treatment rooms with special precautions to protect the operator and the assistants and the fact that multiple treatment sessions are often required. The smoke generated during the ablation procedure also limits the visibility thus increasing the possibility of perforation<sup>18</sup>.

#### 4.1.3 Balloon dilatation

Balloon dilatation has been used, particularly in conjunction with SEMS placement, but appears to be associated with a higher risk of perforation than with just SEMS placement alone<sup>19</sup>.

#### 4.1.4 Self-expanding metal stents for the colon

Over the last two decades, great advances have been made in the ability to palliate malignant obstruction throughout the gastrointestinal tract. SEMS are in routine use for malignant oesophageal, gastroduodenal and biliary obstruction. The first report of the successful placement of a rectal stent was published by Dohmoto in 1991<sup>20</sup>.

The appeal of endoscopic management rather than surgery is that high risk patients avoid surgery and the risks associated with anaesthesia. Another advantage of colonic stent placement done preoperatively is to allow for a preoperative colonoscopy to exclude synchronous lesions<sup>21</sup>. In Vitale's series, a synchronous cancer was detected in three patients (9.6% of his series) hence changing the initial surgical plan<sup>21</sup>.

SEMS have been used in two separate groups of patients. The first is the 'bridge to surgery' group. The term 'bridge to surgery' was described in 1994

by Tejero et al<sup>22</sup> to describe a group of patients who underwent successful decompression following colonic stent placement allowing time for a thorough clinical evaluation and for the patient to be staged before surgery<sup>23</sup>. SEMS placement in the colon has also been used in a second group of patients as effective palliation. In incurable patients with metastatic disease SEMS have been used as definite treatment. The risks of surgery are thus avoided. SEMS have been shown to provide durable palliation and improved quality of life over their counterparts undergoing emergency surgery and stoma creation<sup>24,25</sup>.

A meta-analysis comparing colonic SEMS and open surgery showed that colonic stenting was effective palliation for malignant colonic obstruction<sup>26</sup>. SEMS were associated with a lower length of hospital stay and low rate of stoma formation; however there was no difference in overall survival between those patients with stents who undergo subsequent resection and those undergoing emergency surgery<sup>26</sup>.

A few studies advocate that colonic stent placement need not be limited to tertiary centres. A study analyzing stent placement in a community hospital (Oshawa, Ontario Canada) showed that all meaningful parameters were comparable to those from tertiary centres<sup>27</sup>. Baerlocher and colleagues had a stent success rate of 91.3% and a complications rate of 18%. A study from the Countess of Chester Hospital in the U.K. showed a success rate of 78% and a complication rate of 16%<sup>28</sup>.

## 4.2 Self-expanding metallic stents: further discussion

### 4.2.1 Technique of SEMS placement

SEMS can be placed in the colonoscopy suite. Minimal sedation, as is given during routine screening colonoscopy, is all that is required for stent placement. Colonic SEMS can be placed under fluoroscopic or endoscopic/fluoroscopic guidance. There are no randomized clinical data formally comparing the two methods<sup>29</sup>. The endoscopic/fluoroscopic method of stent placement involves visualizing the obstructing tumour through a colonoscope. A guide wire is passed down the scope and across the bowel tumour and a catheter passed over the wire. This is all done under radiological screening. Contrast is injected through the catheter in order to confirm the position within the lumen of the bowel to ensure no perforation and to identify the upper limit of tumour. The stent is then railroaded over the guide wire and across the lesion. It is deployed using a specialised delivery system. It slowly expands creating a 1-2cm lumen. In contrast to decompression tubes, stents have potential to dilate obstructed colon to near-normal luminal diameter<sup>30</sup>. Colonic SEMS can be placed across lesions longer than the length of a single stent. Decompression is achieved by placing more than one stent and allowing the ends of the stents to overlap<sup>6</sup>.

### 4.2.2 Complications of colonic self-expanding metallic stents

Colonic SEMS are not without complications. Stool in large bowel is often solid and there is thus greater potential for SEMS to block compared to biliary tree or oesophageal stents. Obstruction rates vary and are often divided into early (<30 days) or late (>30days) obstruction. Colonic stents may become impacted with stool, particularly if long stents or multiple devices are used<sup>56</sup>. SEMS can also kink or fracture. Tumour ingrowth and overgrowth can cause obstruction of SEMS. Covered SEMS have been developed to counter tumour ingrowth but cannot prevent overgrowth.

Stent migration either during deployment or later can be problematic. Self-expanding metallic stents may migrate and lodge in the rectum, causing tenesmus and require removal<sup>64</sup>. Stents have also been placed for benign disease but appear more likely to migrate. This is attributed to the treatment of

the benign condition, which when started allows the inflammation causing the obstruction to settle<sup>64</sup>. Migration can also occur after tumour regression following radiation therapy<sup>65</sup>. This however, is not always clinically significant if the patient remains unobstructed.

Perforation of the colon may be due to the guide wire used for placement or due to stent expansion. Procedure related perforation is most likely to occur when dilatation of the tumour lumen is performed prior to stent insertion and this practice is not advised<sup>43</sup>. Pre-deployment dilatation has shown to increase the risk of perforation and tumour fracture<sup>5</sup>.

Experience is limited but patients with SEMS tolerate subsequent radiation and chemotherapy without increased incidence of complications<sup>66</sup>. Prior radiation therapy, however, increases the risk of bleeding and perforation because of inherent tissue weakness and poor vascularity. The evidence for this is largely extrapolated from the experience gained with oesophageal stents<sup>67,68</sup> but it is still important to consider when using colonic SEMS.

Post procedure pain, bleeding and tenesmus are most commonly seen with rectal lesions. The device has to be removed if the symptoms are intractable.

Stents are expensive although not as costly as surgery. Self-expanding metallic stents range from R5800-R8000 each (Wallstent<sup>®</sup> Boston Scientific) and can only be placed by medical professionals with specialized training<sup>29</sup>. If surgery is avoided and a stoma is not required then the use of colonic SEMS become a cost-effective measure.

There is one retrospective study<sup>32</sup> that found that the insertion of SEMS as a bridge to surgery in left-sided colonic obstruction had an adverse effect on the overall 5-year survival rate. The SEMS group was matched with patients who underwent elective surgery for non-obstructing tumours. It is unclear whether this adverse effect is thus related to the emergency presentation of obstruction rather than the SEMS.

#### 4.2.3 Existing evidence for colonic stents

The ideal results would be that placement of SEMS can be shown to reduce immediate mortality and morbidity without compromising long-term survival. Thus far, however, data to comprehensively answer these questions has been lacking. Further analysis of the available data was undertaken in an attempt to provide clarity on the safety and efficacy of SEMS used for colonic obstruction. A total of 23 prospective and retrospective case series that had patient numbers over 30 were included for assessment (table 2). The data captured included: year of study, whether retrospective or prospective, country of origin, total number of patients included in the study, stent success rate, reason for stent placement (palliative or bridge to surgery) and complications.

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**Table 2:** Colonic Stent Study Data

Reference	Year	Study	Country	Number	Palliative	Bridge to Surgery	Technical Success	Mortality	Perforation	Migration	Blocked
Athreya <sup>19</sup>	2006	Retrospective	UK	102	90	12	87	0	4	5	2
Baraza <sup>31</sup>	2008	Prospective	UK	63	56	7	57	0	0	6	8
Kim <sup>32</sup>	2009	Retrospective	Korea	35	7	28	35	-	-	-	-
Garcia-Cano <sup>33</sup>	2006	Retrospective	Spain	175	66	72	162	2	7	7	3
Li <sup>34</sup>	2009	Prospective	China	52	0	50	50	0	0	4	1
Soto <sup>35</sup>	2006	Retrospective	Spain	62	40	22	58	0	3	7	0
Shrivastava <sup>36</sup>	2008	Retrospective	UK	91	-	-	81	0	10	7	3
Stenhouse <sup>37</sup>	2008	Prospective	UK	72	56	16	68	1	2	14	-
Suzuki <sup>38</sup>	2004	Retrospective	UK	42	34	2	36	0	2	7	5
Repici <sup>39</sup>	2008	Prospective	Italy	42	23	19	39	0	1	1	7
Ptok <sup>40</sup>	2006	Prospective	Germany	48	48	0	44	0	0	7	3
Mucci- Hennekinne <sup>41</sup>	2007	Retrospective	France	67	55	12	62	0	2	3	8
Martinez- Santos <sup>14</sup>	2002	Prospective	Spain	43	17	24	41	0	0	0	2
Im <sup>42</sup>	2008	Prospective	Korea	49	49	0	49	0	2	3	9
Alcantara <sup>43</sup>	2007	Prospective	Spain	95	28	67	90	0	4	4	4
Vemulapalli <sup>44</sup>	2009	Retrospective	USA	53	53	0	50	0	6	4	4
Meisner <sup>45</sup>	2004	Prospective	Denmark	96	51	37	88	0	0	8	6
Law <sup>46</sup>	2003	Retrospective	China	30	30	0	29	0	1	3	0
Watson <sup>47</sup>	2005	Retrospective	UK	103	83	10	93	3	2	4	3
Camunez <sup>48</sup>	2000	Retrospective	Spain	80	42	38	67	1	4	3	2
Mainar <sup>49</sup>	1999	Retrospective	Spain	71	0	71	64	0	1	0	0
Fregonese <sup>50</sup>	2008	Retrospective	Europe	36	1	34	35	0	3	1	2
Jost <sup>51</sup>	2007	Retrospective	Switzerland	67	22	45	59	1	3	6	14
<b>TOTAL</b>				<b>1615</b>			<b>1482</b>	<b>8</b>	<b>57</b>	<b>104</b>	<b>86</b>

\*The Spanish survey (33) may overlap patient data with some of the other Spanish studies.

A combined total of 1615 patients were enrolled in the 23 studies reviewed. All studies were undertaken in northern hemisphere countries and the majority of studies were retrospective (60%). The studies were published between 2002 and 2009. The technical combined success of colonic stent placement was 92% (range 83-100%). This series review had a mortality of 0.5% and a perforation rate of 3.8%. The overall complication rate of SEMS placement or attempted placement was 16%.

Endoscopic stenting tends to produce lower mortality rates than urgent surgical intervention<sup>9</sup> and analysis of the data presented in table 2 would support this statement.

Published review articles of colonic SEMS usage show similar positive results. Khot et al<sup>52</sup> and Sebastian et al<sup>53</sup> reviewed results in patients treated with SEMS. See table 3 for a summary of results of these two aforementioned reviews.

**Table 3:** Results of review articles by Khot and Sebastian

	Khot et al <sup>53</sup>	Sebastian et al <sup>54</sup>
Technical success	88%	91%
Mortality	1%	0.6%
Perforation rate	4%	3.8%

The perforations in these two series were noted to be associated with balloon pre-dilatation of the strictures.

SEMS have been shown to reduce morbidity and mortality as well as the need for a permanent colostomy<sup>29</sup>. SEMS used to relieve colonic obstruction have been shown to be cost effective<sup>54</sup>. Cost saving is due in part to shorter hospital stays, fewer surgical procedures, reduced operating room time and fewer days in intensive care. The cost of stoma care and disposable stoma bags is a significant cost saving in the stented group<sup>55,56</sup>.

Stipa et al<sup>57</sup> reported that after successful SEMS placement and colonic decompression, open or laparoscopic surgery was possible. The presence of a stent did not adversely affect laparoscopic resection.

#### *4.2.3.1 Randomized controlled trial data*

In conflict to the above data on colonic stent placement is the data emerging from attempted randomized controlled trials. Three attempts (two from one centre) at randomized controlled trials have had to be terminated early due to concern over complications in the patient groups receiving colonic stents<sup>58,59,60</sup>. Van Hooft and colleagues have attempted two separate trials aiming to assess whether colonic SEMS were superior to surgical treatment. Both trials were terminated early by the safety monitoring committee due to a high number of unexpected adverse events (particularly stent related perforations) in the non-surgical/SEMS arm. The reasons offered for the high unexpected perforation rate were that perhaps the unexpected adverse events were specifically related to the type of stent or type of chemotherapy used.

Pirlet and colleagues<sup>58</sup> attempted a RCT where patients were randomized to emergency surgery or to the use of SEMS as a bridge to surgery. The trial was also terminated early due to a high number of complications and a high stoma rate in the patient group receiving stents.

Cheung and colleagues<sup>61</sup>, however, report conflicting results in their RCT. This RCT from China concludes that colonic SEMS can be safely placed in bridge to surgery patients and allows these patients to avoid the morbidity of a stoma.

Another RCT<sup>62</sup> found enrolled only 22 patients for palliative treatment of malignant rectosigmoid obstruction. They concluded there were no statistically significant differences between the surgery and stent group in terms of morbidity and mortality.

See table 4 for a summary of results from the six RCTs identified.

**Table 4:** Summary of Randomized Controlled Trial Data

Reference	Year	Country	Number	Stent	Surgery	Technical Success	Mortality	Perforation	Migration	Blocked
Van Hooft <sup>59*</sup>	2011	Netherlands	98	47	51	33	9	6	-	-
Van Hooft <sup>60*</sup>	2006	Netherlands	21	11	10	-	3	4	-	-
Cheung <sup>61</sup>	2009	China	48	24	24	20	0	0	0	0
Pirlet <sup>58*</sup>	2011	France	67	35	32	14	0	3	0	0
Fiori <sup>62</sup>	2004	Italy	22	11	11	11	0	0	0	0
Xinopoulos <sup>63</sup>	2004	Greece	30	15	15	14	0	0	1	6

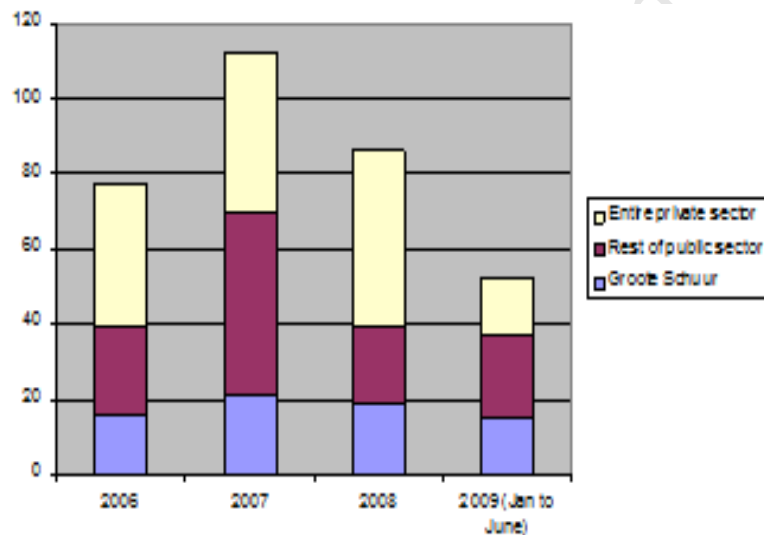
\* terminated early due to adverse events in stent group

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### 4.3 South African experience of colon stent usage

The National Cancer Registry of South Africa reported in 2003 that the cumulative lifetime incidence risk (0-74 years) of colorectal cancer was 1.07 making colorectal cancer the fifth commonest malignancy encountered in South Africa.

Although there are no South African studies available, data on colonic stent usage was obtainable from Boston Scientific, a company, which had the largest market share for colonic stents in South Africa during the time period 2006–2009 (figure 2).



**Figure 2:** Numbers of Boston Scientific Colonic Stents used per year in South Africa

The majority of SEMS are currently being utilized in the public sector in South Africa. Other than 2007, Groote Schuur Hospital, SEMS usage comprised roughly half of the stents supplied to the public sector.

## 5 Conclusion

Research conducted in the area of SEMS in the colon is rapidly evolving and in time it is likely that there will be enough data to conclusively make recommendations and draw up comprehensive guidelines for the usage of colonic SEMS. At this stage further well-structured randomized controlled trials are needed. Of concern is that three of the RCT's attempted have been terminated early due to complications in the SEMS group. This casts a shadow over the pooled data extracted from prospective and retrospective reviews that overwhelmingly seems to favour SEMS placement over emergency surgery in terms of morbidity and mortality. More studies focusing on the long term impact and complications of colonic stents are required. The impact and safety of SEMS placed in patients undergoing chemotherapy and radiotherapy needs to be further investigated. There is still concern that tumour perforation by stents may worsen patient prognosis but there appears to be no good evidence available to confirm or refute this.

There is at present no truly robust level I evidence in the realm of colonic SEMS. There appears to be no published South African literature or literature from elsewhere in Africa covering colonic SEMS. A South African cost effectiveness study would be beneficial as it is difficult to apply data extracted from elsewhere to our situation.

Colonic self-expanding metallic stents are a promising management tool in the battle against obstructing colon cancer. It would be unwise to encourage the widespread use of SEMS without, as with any new technology, careful prospective audit of outcomes.

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**Management of left-sided malignant colonic obstruction:  
an audit of a stent based protocol**

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## JOURNAL ARTICLE

### Abstract

#### Aim

Colonic self-expanding metallic stents (SEMS) are proven to be safe and effective in the management of selected cases of malignant colonic obstruction. Since 2005, we have used endoscopic decompression with SEMS as the primary treatment of all patients with left-sided obstructing colorectal cancer, in the absence of perforation. The purpose of the study was to assess the safety and efficacy of this management protocol.

#### Method

This is a study of consecutive patients who presented to our unit with left-sided obstructing colorectal cancer between January 2005 and June 2009. Patients were excluded if there was clinical or radiological suspicion of bowel perforation. Emergency surgery was offered to those patients in whom colonic stent placement failed. After successful decompression, surgery was offered to those patients who were found to have potentially curable disease.

#### Results

Seventy-eight patients presented to the unit during the study period. Protocol was not followed in one patient. SEMS were successfully placed in 60/77 patients (78%). In 35 patients, SEMS served as their definitive palliative treatment while in 25 patients, SEMS were placed as a bridge to surgery. Overall, 32/35 (91%) of patients in whom stents were successfully placed for palliation avoided surgery. Fifteen out of 17 patients, in whom SEMS placement failed, underwent emergency surgery. Stomas were fashioned in 5/60 patients who were successfully stented, and 12/17 (71%) patients in whom stenting failed ( $p=0.0001$ ). Five of the 60 successfully stented patients (8%) and 3/17 (18%) in the failed stent group died ( $p=0.3644$ ). All deaths in the successfully stented group were due to advanced metastatic disease. Eight patients had complications related to SEMS. No patients died from complications related to SEMS.

## **Conclusion**

In our unit, SEMS placement for left-sided malignant colonic obstruction could be performed safely, with a low mortality and complication rate, and allowed most patients to avoid a stoma.

## What is New in this Paper?

The patients that underwent attempt stent placement included all patients presenting with left-sided obstructing colorectal cancer that presented to one colorectal unit. The study is not limited to selected patients that may be considered easier to stent i.e. lower sigmoid cancers or shorter duration of obstructive symptoms.

## Introduction

Left-sided obstructing colorectal cancer has traditionally been managed with emergency surgery although not without significant accompanying morbidity and mortality<sup>1</sup>. Patients presenting with malignant large bowel obstruction are more likely to present with metastatic disease and have a poorer 5 year survival<sup>2</sup>.

Colonic self-expanding metallic stents (SEMS) have been advocated as an alternative method of achieving decompression of colonic obstruction whilst avoiding the physiological strain associated with emergency surgery. SEMS have been used as both definitive palliative treatment<sup>3</sup> of malignant obstruction and as a temporizing form of decompression prior to definitive surgery ('bridge to surgery')<sup>4</sup>.

In case series of selected patients with left-sided malignant colonic obstruction, SEMS have been shown to be effective in achieving decompression with good technical and clinical success rates<sup>5,6</sup>. These series also report low complication rates suggesting that SEMS can be considered a safe alternative to surgery.

As colonic SEMS become more widely used it is important to consider whether SEMS should be applicable to all patients with left-sided obstructing colorectal cancer or only to select patients. Since 2005, our colorectal unit adopted a protocol (figure 1) of endoscopic decompression with SEMS as the primary treatment of all patients presenting with left-sided obstructing colorectal cancer, without evidence of perforation. The purpose of the study was to assess the safety and efficacy of this management protocol.



## Method

This is a study of consecutive patients with left-sided obstructing colon carcinoma. All patients who presented to the Colorectal Surgery Unit at Groote Schuur Hospital (a university referral hospital in Cape Town, South Africa) with left-sided large bowel obstruction due to primary colorectal cancer between January 2005 and June 2009 were considered for enrollment in the study. Only patients with obstructing lesions from the hepatic flexure proximally to the upper third of the rectum distally were included. Patients with more proximal lesions were offered emergency surgery. All lesions were biopsied and confirmed to be adenocarcinoma on histology.

All patients had clinical and radiologic evidence of large bowel distension, and in all cases the lumen at the site of obstruction was too narrow to pass a colonoscope through it. Patients were included regardless of whether there was evidence of metastatic disease at the time of presentation.

In accordance the unit protocol (figure 1), patients were excluded if there was clinical (signs of peritonitis or sepsis) or radiological evidence (single contrast water soluble enema or abdominal computed tomography scan) of bowel perforation or peritonitis. These patients were offered emergency surgery.

Eligible patients were offered decompression of the colon using SEMS as the primary procedure. The procedure was performed in the endoscopy suite under conscious sedation or with the patient awake, depending on the level of discomfort during the procedure. The stents were placed by endoscopists with experience at placing colonic SEMS. No anaesthetist or radiologist was involved at the time of stent placement.

In all cases a guide wire was passed through the obstructing lesion via an endoscope, a catheter was passed over the guide wire, and water soluble contrast was introduced through the catheter to confirm its position to be intraluminal. The guide wire was then re-introduced, the SEMS was passed over the guide wire across the lesion, and deployed under radiological and endoscopic control. Boston Scientific® colonic stents were used in all cases.

Post procedure, abdominal and erect chest x-rays were performed to confirm decompression of the colon, and to detect any free intra-peritoneal gas.

SEMS insertion was considered to be successful if the stent was correctly deployed across the lesion, and if the bowel was decompressed both clinically and radiologically. If the stent was not successfully deployed, emergency surgery was offered. Emergency surgery was also offered for complications of SEMS placement where appropriate.

After successful decompression by SEMS and radiological staging of the malignancy, patients with potentially curable disease who were fit for surgery were offered elective resection ('bridge to surgery'). In patients with incurable disease, the stent was the definitive palliative procedure, and resection was not routinely offered ('palliative group'). The patients were described as being in the 'palliative' or 'bridge to surgery group' after staging. For example, a patient who was found to have unsuspected peritoneal metastases at the elective operation would still be considered to be in the 'bridge to surgery group'.

### **Statistical analysis**

Actuarial survival was calculated using the Kaplan-Meier technique. Continuous data were compared using Student's t-test, and ordinal data using the chi-square test. A P-value of  $\leq 0.05$  was regarded as significant.

### **Ethical approval**

All patients gave informed consent for the procedures undertaken. The study was approved by the Research Ethics Committee of the University of Cape Town.

## Results

### Demographics

During the four and a half year study period, 78 patients presented with left-sided colonic obstruction due to colorectal adenocarcinoma. In one case, protocol could not be followed and SEMS was not attempted, as there was no endoscopist capable of inserting SEMS available on that day. This patient was excluded from the study, leaving 77 patients in whom SEMS insertion was attempted. The ages, gender ratio and site of the tumour are presented in table five.

### Reasons for stent, technical success and immediate complications

SEMS was successfully placed in 60/77 (78%) of cases. Of the cases where SEMS were successfully placed, 25/60 (42%) were placed as a 'bridge to surgery', and 35/60 (58%) were placed for palliation. Perforation of the bowel during SEMS insertion occurred in one case (1.3%). This was recognized immediately, and the patient underwent an emergency Hartmann's procedure and had an uneventful post-operative course. There was one guide wire perforation that was detected immediately. The patient still had a stent successfully placed with no adverse outcome. There were no other immediate complications of SEMS placement. Five of 60 (8%) patients died within 30 days of successful SEMS insertion. All of these patients died of extensive metastatic disease, and there were no deaths due to complications of stent placement.

### Bridge to surgery group

Of the 25 patients who had SEMS placed as 'bridge to surgery', ten underwent attempted laparoscopic resections (with three conversions to open procedures), and 14 had open operations. The decision on the type of surgery offered was left to the discretion of the operating surgeon. There were no peri-operative deaths.

One patient declined surgery despite being fit for the procedure and having no evidence of metastatic disease at that time. She died eighteen months later of metastatic disease. One patient had extensive peritoneal metastases (that had not been detected on pre-operative staging) discovered at laparotomy. His

planned resection was abandoned, and the stent left in situ for palliation. Three of the 25 (12%) patients in this group had stomas. These were temporary loop ileostomies in patients who underwent low anterior resections for upper third rectal lesions.

### **Palliative group**

SEMS were placed for palliation in 35 patients (34 had incurable metastatic disease, and one was unfit for surgery). The median survival after SEMS for palliation was four months. The longest survivor was still alive at his most recent follow up after 22 months. Six patients developed long-term complications after SEMS. Stent migration occurred in two patients. One of these developed recurrent obstruction, and was successfully re-stented. The other passed the stent per rectum and then remained unobstructed until his death from metastatic disease. One patient with a rectal tumour developed tenesmus, and underwent a Hartmann's resection of the tumour. Three patients developed obstruction at the site of stent due to tumour ingrowth or kinking of the stent. One of these patients was successfully re-stented, one had a loop colostomy fashioned, and the other patient who presented with stent blockage developed nosocomial pneumonia and died before any surgical intervention. Overall, 32/35 (91%) of patients in whom stents were successfully placed for palliation avoided surgery.

### **Failed stents**

Attempted stent placement failed in seventeen patients. Reasons for the failures included inability to visualise the lumen, inability to pass the guide wire across the lesion, excessive angulation of the colon, fixity of the colon and inability to visualise the tumour. Two patients were considered unfit for surgery due to advanced malignancy and severe comorbidities, and died within a week after the procedure was attempted. The other 15 patients all underwent emergency surgery. The operations performed are summarized in table 6. One of these patients had extensive peritoneal carcinomatosis. It was not technically possible to mobilize the bowel sufficiently to give her a colostomy, and she died one week post surgery. There were no other peri-operative deaths in the failed SEMS group, so in total 3/17 (18%) died in this group. There was no significant difference in 30 day mortality between the patients

who were successfully stented and those in whom stenting failed (5/60 [8%] vs. 3/17[18%],  $p=0.51$ ).

### **Stomas**

Stomas were fashioned in 2/35 (6%) patients in the palliative group (both permanent), and 3/25 (9%) patients (temporary) in the bridge to surgery group. Among the patients who underwent surgery due to failed stenting, 12/17 (71%) had stomas created (10 were permanent, and two temporary). Successful SEMS placement was associated with a lower rate of stoma formation in both the palliative ( $P<0.0001$ ) and bridge to surgery ( $P=0.0001$ ) groups when compared with the failed SEMS group.

### **Discussion**

In this series of consecutive patients with left-sided colonic obstruction due to colorectal cancer, SEMS could be placed with a high success rate (78%) in relieving obstruction and with an acceptably low complication rate. The results of this study compare satisfactorily with other non-randomized prospective studies of selected patients that find colonic SEMS to be safe and effective<sup>7</sup> with a low morbidity and mortality<sup>6,8</sup>. These studies, however, have a higher clinical stent success rate (90-94%). Our lower success rate (78%) can be attributed to the adherence to the protocol of attempting to primarily stent all patients with left-sided colonic obstruction. No attempts were made before the procedure to identify whether the patients were good candidates for stents or whether the patients has favourable tumour morphology for stenting.

Successful SEMS placement allowed the majority of patients in our series to avoid the morbidity of a stoma. These results compare favorably with other small single centre randomized controlled trials showing SEMS to be safe and to have a lower stoma rate than in patients undergoing emergency surgery<sup>9,10</sup>.

Colonic stents have allowed patients undergoing palliative treatment to avoid surgical intervention<sup>11</sup>. In the palliative setting, our results showed that SEMS allowed the majority of patients in this group (91%) to avoid any surgery.

Although safety concerns have been raised by the preliminary results and early termination of recent multicenter randomized controlled trials<sup>12,13</sup>, the low complication rate in this series is in keeping with other published series<sup>4,14,15</sup>.

Although our data is not randomized, which limits our study, our patient group was not a select group of patients considered suitable for colonic SEMS but rather attempted placement of stents was done in all patients that fulfilled the unit protocol criteria. Another consideration is that the majority of our patients due to cost constraints received systemic 5-fluorouracil and leucovorin as the primary chemotherapeutic regime. It is unsure whether more aggressive chemotherapeutic regimes (e.g. addition of oxaliplatin or irinotecan) may incur a higher stent-related perforation rate.

We conclude that in our unit, stents are an effective and safe method of managing left-sided obstructing colorectal cancer in palliative as well as bridge to surgery patients.

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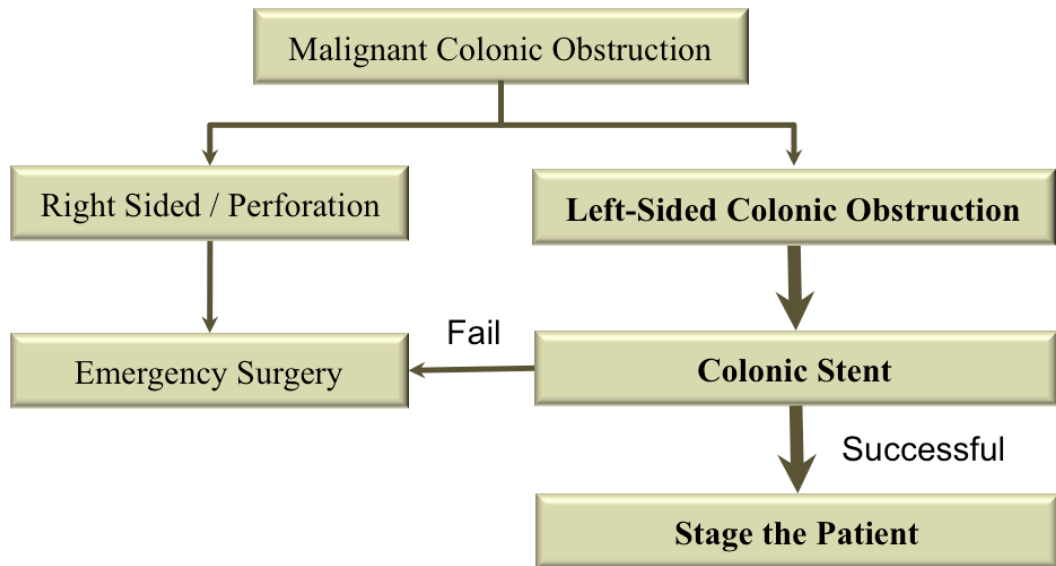


Figure 3: Colorectal Unit Protocol

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	<b>Failed Stent</b>	<b>Bridge to Surgery</b>	<b>Palliative Stent</b>
	(n= 17)	(n=25)	(n=35)
Gender ratio (M:F)	7:10	14:11	19:16
Median (range) age (years)	60 (31-81)	62 (26-84)	69 (36-95)
Site of tumour			
Splenic flexure	2	1	3
Descending colon	4	4	1
Sigmoid colon	8	13	16
Rectosigmoid	3	7	14
Rectum	0	0	1

**Table 5:** Demographics and Tumour Site



Operation	Failed stent (n= 17)	Bridge to surgery (n=25)	Palliative stent (n=35)
Defunctioning stoma resection)	8 (47%)	0	1 (3%)
Resection and temporary stoma	2 (12%)	3 (2%)	0
Resection and permanent stoma	2 (12%)	0	2 (6%)
Resection and primary anastomosis (no stoma)	2 (12%)	20 (80%)	0
Laparotomy only	1 (6%)	1 (4%)	0
No surgery	2 (12%)	1 (4%)	32 (91%)

**Table 6:** Operations Performed

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## Appendix C

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