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Abstract

Background

The aim of colonic stenting with self-expandable metallic stents in neoplastic colon obstruction is to avoid emergency surgery and thus potentially reduce morbidity, mortality, and need for a stoma. Concern has been raised, however, about the effect of colonic stenting on short-term complications and long-term survival. We compared morbidity rates after colonic stenting as a bridge to surgery (SBTS) versus emergency surgery (ES) in the management of left-sided malignant large-bowel obstruction.

Methods

This multicentre randomised controlled trial was designed with the endorsement of the European Association for Endoscopic Surgery. The study population was consecutive patients with acute, symptomatic malignant left-sided large-bowel obstruction localised between the splenic flexure and 15 cm from the anal margin. The primary outcome was overall morbidity within 60 days after surgery.

Results

Between March 2008 and November 2015, 144 patients were randomly assigned to undergo either SBTS or ES; 29/144 (13.9%) were excluded post-randomisation mainly because of wrong diagnosis at computed tomography examination. The remaining 115 patients (SBTS $n = 56$, ES $n = 59$) were deemed eligible for analysis. The complications rate within 60 days was 51.8% in the SBTS group and 57.6% in the ES group ($p = 0.529$). Although long-term follow-up is still ongoing, no statistically significant difference in 3-year overall survival ($p = 0.998$) and progression-free survival rates between the groups has been observed ($p = 0.893$). Eleven patients in the SBTS group and 23 in the ES group received a stoma ($p = 0.031$), with a reversal rate of 30% so far.

Conclusions

Our findings indicate that the two treatment strategies are equivalent. No difference in oncologic outcome was found at a median follow-up of 36 months. The significantly lower stoma rate noted in the SBTS group argues in favour of the SBTS procedure when performed in expert hands.

Keywords

Large bowel obstruction Endoscopic stenting Bridge to surgery Emergency colorectal surgery Randomized controlled trial

Elective colonic surgery is considered a safe procedure, with a low risk of post-operative anastomosis leakage, whereas emergency colonic surgery is associated with consistent morbidity and mortality rates [1]. Emergency surgery patients are generally older and often present with multiple comorbidities and bowel distension [2]. An alternative to emergency surgery is stenting with self-expandable metallic stents (SEMSs). Clinical and technical successes of stenting with SEMS in various regions of the gastrointestinal tract, including the oesophagus, duodenum, and biliary tract, have been reported over the last 30 years. Endoscopic stent placement was extended to the treatment of neoplastic colonic obstruction initially with palliative intent [3], then later as preoperative decompression and as palliative final treatment with good preliminary results [4].

The aim of stenting with SEMS in an obstructed colon is to transform an emergency surgical case into an elective surgery case and restore bowel transit, thus reducing morbidity, mortality, and the need for an enterostomy. Several randomised controlled trials (RCTs) and case-matched studies have reported controversial results and expressed concern regarding the effect of colonic stenting on short-term complications long-term survival in patients with potentially curable disease, due to the potential risk of local advancement of the cancer and metastatic spread [5, 6]. With this study, we compared morbidity rates after colonic stenting as a bridge to surgery and after emergency surgery to evaluate the efficacy and safety of the two strategies in the management of malignant, left-sided large-bowel obstruction.

Methods

This multicentre RCT was designed with the endorsement of the European Association for Endoscopic Surgery (EAES). The project was approved by the Local Ethics Committee of the Città Della Salute e Della Scienza Di Torino, University of Torino, Italy, which served as the principle study centre. The project was registered with ClinicalTrials.gov, US International Clinical Trials Databank (US National Institutes of Health), ID-code NCT00591695, on behalf of the EAES. The study design conformed with CONSORT criteria.

Study population

The main inclusion criterion was acute, symptomatic malignant left-sided large-bowel obstruction localised between the splenic flexure and 15 cm from the anal margin, as diagnosed by computed tomography (CT) examination in the emergency room. The main clinical complaint was failure to pass gas and faeces. Exclusion criteria were bowel perforation as diagnosed by clinical exploration and complementary studies, associated conditions contraindicating general anaesthesia and/or haemodynamic instability, impossibility to obtain valid informed consent or refusal by the patient, distant metastases as diagnosed by CT scan at the time of diagnosis.

Patient recruitment

Consecutive eligible patients were recruited at the emergency room of the participating centres. Patients fulfilling the above-mentioned criteria were informed about the aim of the study by a clinician involved in the study. Patients granting informed consent were randomly assigned to one of the two study arms and treated according to the study protocol. Participating centres had to demonstrate that more than 25 SEMS placement procedures had been performed with a documented complications rate not higher than that reported in the literature.

Randomisation

Patient data were entered into a centralised web-based database and blind randomisation was done by means of an unchangeable number-generating software programme. Randomisation was stratified per single centre and according to tumour stage (T4 vs. others). Patients were randomly assigned to receive either stent bridge to surgery (SBTS) followed by elective surgery (if successful) or emergency surgery (ES). Treatments were planned within 24 h after diagnosis.

Operative technique

In the SBTS treatment arm, SEMS placement was performed using a colonoscope with a 4.2-mm operative channel. A hydrophilic guide contained in a five Fr catheter was advanced across the neoplastic stenosis under radiographic control. The catheter was inserted through the stenosis and water-soluble contrast liquid injected above the stenosis to evaluate the length of the stenosis under fluoroscopic vision. A super stiff guide wire was left in place while the five Fr catheter was retracted. Stents were positioned so as to exceed 1–2 cm from each side of the stenosis. No tumour or stent dilatation was performed. Technical success was defined as correct stent placement under radiographic and endoscopic vision. Clinical success was defined as resolution of occlusive symptoms by gas and faeces passage. Emergency surgery was indicated in case of technical or clinical failure. If symptom relief was achieved with stenting, elective surgery was scheduled depending on the patient's clinical conditions and included laparoscopic or laparotomic bowel resection, with or without creation of a protective stoma, according to surgeons' preferences and intra-operative findings.

In the ES treatment arm, surgeons could decide between simple enterostomy and bowel resection based on their experience, the patient's clinical condition, and intra-operative findings. Bowel resection could be performed using Hartmann's procedure, on table irrigation, and primary anastomosis or subtotal colectomy.

Preoperative, intra-operative, and post-operative care, including adjuvant therapy protocols and follow-up, were carried out in accordance with the standards of care at each centre and were the same for all patients at each centre.

Primary end point

Overall morbidity was defined as any surgery-related morbidity diagnosed within 60 days after surgery. Morbidity was defined as the occurrence of any complication directly or indirectly related to endoscopy and/or surgery. Complications were classified according to Dindo [7].

Secondary end points

Technical success and clinical success of SEMS placement were defined as correct stent placement under both radioscopic and endoscopic inspection and as resolution of occlusive symptoms by passage of gas and faeces, respectively. Operative time was defined as the length of time in minutes

between skin incision and end of skin closure. Hospital stay was defined as the length of hospital stay in days between admission to and discharge from hospital.

Post-operative complications during hospital stay were defined as any local or systemic complications observed during hospital stay. Complications at 60 days were defined as any local or systemic complications still observed at 60 days after initial treatment.

Oncologic outcome *was* defined as the comparison of the log-rank overall and progressive disease curves of the two groups for a minimum of 3 years unless censored. Quality of life was measured using the 36-item Short Form Health Survey (SF-36) at 60 days after surgery.

Sample size and power calculation

Assuming a baseline overall morbidity within 60 days of 15% after SBTS and of 35% after ES (average morbidity based on the literature), a total of 144 patients was needed to prove superiority of SBTS over ES, with a β-error of 0.2 and an α-error of 0.05.

Data analysis

Intra- and post-operative data were entered by the recruiting clinician in a web-based database at any time during the study. Patients' personal data were protected against unauthorised or accidental access. All analyses were carried out primarily on an intention-to-treat basis.

Data monitoring

An expert in colorectal surgery and endoscopy was designated as data monitor. He had access to the data during the entire course of the study and could recommend cessation of the trial if one arm was providing manifestly inferior results.

Statistical analysis

Categorical variables are described as frequencies and percentages, while median and interquartile ranges (IQR) (in brackets) report continuous variables. Fisher's exact test was performed to evaluate the association between any categorical variable and the treatment arm (SBTS/ES), while the Mann–Whitney test was used for continuous variables. The primary end points for survival analyses were overall survival (OS) and progression-free survival (PFS). OS was defined as the time from accrual to death from any cause, and PFS as the time from accrual to progression/relapse/death from any cause, whichever came first. In both cases, patients still alive were censored at the date of last contact. OS and PFS curves were estimated by the Kaplan–Meier method and compared using the log-rank test. All reported *p* values were obtained using a two-sided exact method at the conventional 5% significance level. Data were analysed as of June 2016 by R 3.2.3 (R Foundation for Statistical Computing, Vienna-A, http://www.R-project.org).

Results

Upon receipt of approval from the ethics committee, enrolment was started on 1 March 2008 and closed on 16 November 2015. Five centres were involved in the study (Table 1). Of the 144 initially randomised patients, 29 were excluded post-randomisation: 20 (13.9%) because of wrong diagnosis at CT, one patient because no endoscopist was free to attend, and eight patients withdrew consent

(Table 2). Table 3 presents the distribution of the remaining 115 patients at the various centres; the patients' characteristics are given in Table 4. Figure 1 illustrates the patients' flow chart.

Table 1

Distribution of patients initially randomised by study centre

Study centre	Patients (*N* = 144)
University of Torino, Torino, Italy	53
ASO Santa Croce e Carle, Cuneo, Italy	40
Hospital de la Sta Creu i St Pau, Barcelona, Spain	32
Hospital General Universitario de Elche, Alicante, Spain	12
Humanitas Gradenigo Hospital, Torino, Italy	7

Table 2

Causes of dropout from the study

	SBTS group	ES group	Total no. (%)
Diverticulitis	5	6	11 (7.6)
Faecaloma	1	1	2 (1.4)
Colonic pseudo-obstruction	2	0	2 (1.4)
CDAD	1	0	1 (0.7)
Ischaemic colitis	1	0	1 (0.7)
Synchronous neoplasm	1	0	1 (0.7)
No stenosis at endoscopy	1	1	2 (1.4)
Endoscopist unavailable	1	0	1 (0.7)
Consent withdrawn	5	3	8 (5.6)
Overall total	18	11	

SBTS stenting as a bridge to surgery, *ES* emergency surgery, *CDAD Clostridium difficile* associated diarrhoea

Table 3

Distribution of patients by study centre

Hospital participating in the study	SBTS (*N* = 56)	ES (*N* = 59)
Dept. of Surgical Sciences, University of Torino, Italy	21	22
ASO Santa Croce e Carle, Cuneo, Italy	16	16
Hospital de la Sta Creu i St Pau, Barcelona, Spain	12	15
Hospital General Universitario de Elche, Alicante, Spain	5	5
Humanitas Gradenigo Hospital, Torino, Italy	2	1

SBTS stenting as a bridge to surgery, *ES* emergency surgery

Table 4

Clinical characteristics of patients allocated to treatment with stenting as a bridge to surgery (SBTS) or emergency surgery (ES)

	SBTS group (*N* = 56)	**ES group (*N* = 59)**	***p* value**
Sex (M/F)	28/28	32/27	0.711
Mean age (years)	72 (range 43–90)	71 (range 44–94)	0.606
Age >70	29	30	0.920
BMI	24.8 (range 19.5–40.2)	24.5 (range 18–35)	0.608
ASA classification			0.775
ASA I	12	11	
ASA II	27	28	
ASA III	14	16	
ASA IV	3	4	

BMI body mass index (weight in kg divided by height in m squared)

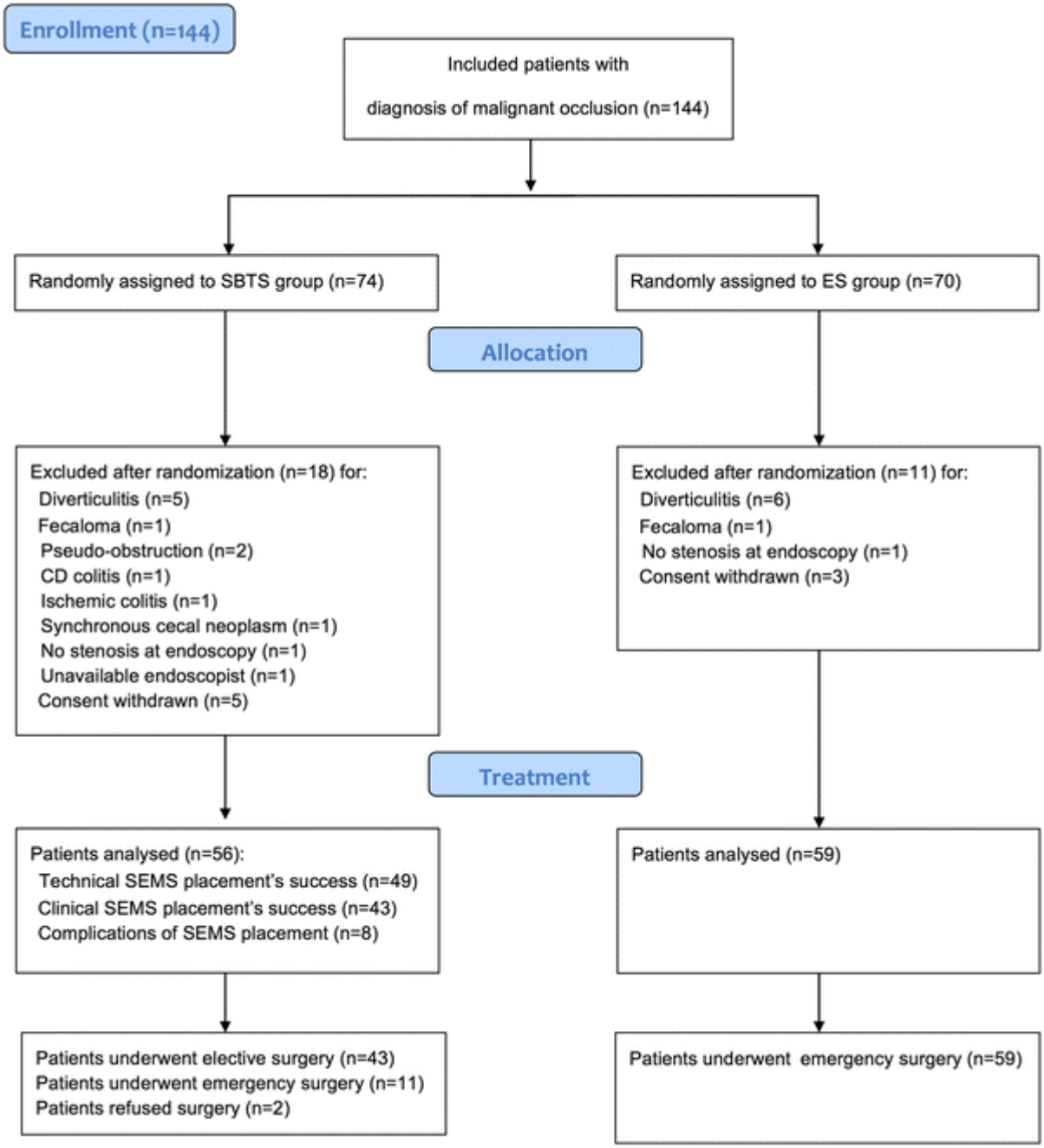

Fig. 1

CONSORT 2010 flow diagram

The occlusion site was the splenic flexure in 18 patients (5 in the SBTS and 13 in the ES group), the descending colon in 77 (43 in the SBTS and 34 in the ES group), and the sigmoid colon in 20 (8 in the SBTS and 12 in the ES group) ($p = 0.055$). Stents of four different diameters were used: 20 mm in four cases, 22 mm in 21, 24 mm in 2, 25 mm in 15, and 30 mm in 5; stent diameter was not reported in seven cases. Technical success was reported in 49 of the 56 stented patients. Eight cases of stent-related complications occurred: perforation in 5, bleeding in 1, relevant pain 1, and pulmonary infection due to aspiration in 1. All five cases of perforation occurred at the tumour site (the descending colon in three and the sigmoid tract in two). Six patients required emergency surgery. Clinical success was achieved in 44 (78.6%) patients.

The median time between SEMS placement and elective surgery was 5 days (range 3–8). Table 5 presents the type of surgery performed in the two groups ($p < 0.001$). Eleven patients (22.2%) in the SBTS group and 23 (39%) in the ES group ($p = 0.031$) received a stoma, which consisted of an end colostomy of the left colon in all cases, except one in which a lateral colostomy without bowel resection was performed due to peritoneal carcinomatosis. No association was observed between time to elective surgery after stenting and need for a stoma ($p = 0.845$).

Table 5

Type, number, and percentage (%) of surgical procedures

Surgery	**SBTS group (*N* = 54)**	**ES group (*N* = 59)**	***p* value**
Hartmann's procedure	11 (20.4)	20 (33.9)	
Subtotal colectomy	2 (3.6)	15 (25.4)	
Washout and anastomosis	1 (1.8)	10 (16.9)	
Colostomy	0	1 (1.7)	
Left colectomy	27 (50)	11 (18.6)	
Sigmoidectomy	11 (20.4)	2 (3.4)	
Anterior resection	2 (3.7)	0	
Overall total	54	59	<0.001

SBTS stenting as a bridge to surgery, *ED* emergency surgery

The median operative time was 165 min in the SBTS group (range 120–200) and 180 min in the ES group (range 150–210) ($p = 0.098$). A laparoscopic approach was used in 23 (41.1%) stented patients, in 17 (30.3%) of which resection was completed laparoscopically and by conversion to open surgery in 6.

Post-operative complications during hospital stay were classified as local or systemic and were multiple in some cases. Local complications developed in 9 (16.7%) patients in the SBTS group (anastomotic leakage in 3, intra-abdominal abscess in 1, ileus in 2, wound infection in 4, and wound haematoma in 1) and 12 (20.3%) in the ES group (anastomotic leakage in 2, ileus in 2, colostomy-related complication in 1, and wound infection in 7) ($p = 0.616$). Systemic complications developed in 14 (25.9%) patients in the SBTS group (pneumonia in 2, urinary complications in 3, acute pulmonary embolism in 1, sepsis in 4, anaemia in 2, heart failure in 2, and diarrhoea in 2) and in 21 (36.2%) in the ES group (pneumonia in 2, urinary complications in 5, multiorgan failure in 2, pulmonary thromboembolism in 1, sepsis in 3, anaemia in 3, heart failure in 3, diarrhoea in 5, hepatic failure in 1, respiratory failure in 1, and neurological complications in 2) ($p = 0.214$). One patient in the SBTS group died after stent placement due to perforation and 1 refused surgery after stent placement. One patient in the ES group received a colostomy without resection due to peritoneal carcinomatosis (Fig. 2).

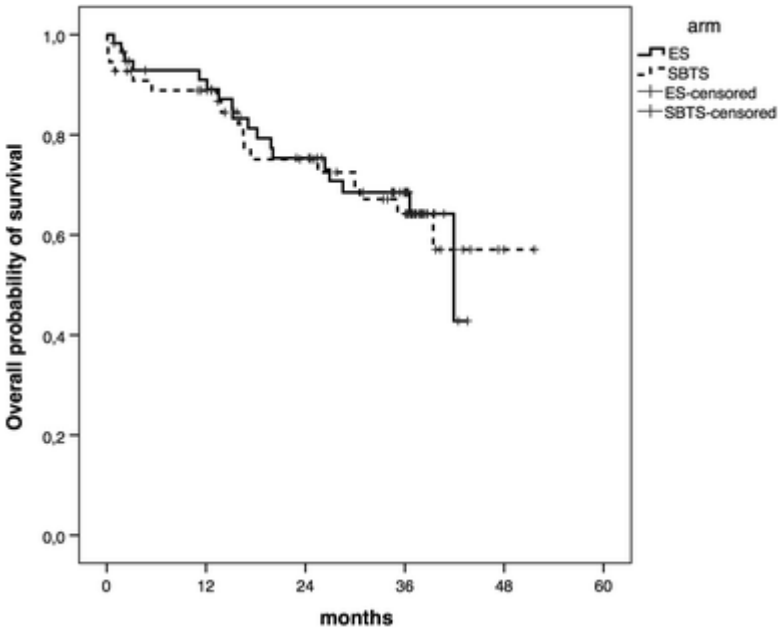

Fig. 2

Kaplan–Meier overall probability of survival

Parenteral nutrition was administered in 18 (32.1%) patients in the SBTS and in 27 (45.8%) in the ES group ($p = 0.135$). Blood transfusion was given in 7 (12.5%) patients in the SBTS and in 11 (18.6%) in the ES group ($p = 0.365$). The median length of hospital stay was 15 days in the SBTS group (range 12–20) and 11 days in the ES group (range 8–15) ($p < 0.001$). The median length of hospital stay after surgery was 10 days in the SBTS (range 7–13) and 11 days in the ES group (range 8–15) ($p = 0.039$).

Definitive histology of the surgical specimen showed pT2 adenocarcinoma in two patients, pT3 in 37, and pT4 in 15 in the SBTS group, and pT2 adenocarcinoma in one patient, pT3 in 36 patients, and pT4 in 21 in the ES group ($p = 0.547$). Infiltrated resection margins were noted in two patients in the ES group. Tumour grade was G1 in 14 patients, G2 in 35, and G3 in 5 in the SBTS group, and G1 in 12 patients, G2 in 34, and G3 in 12 in the ES group ($p = 0.233$). Lymph node status was pN0 in 27 patients, pN1 in 19, and pN2 8 in the SBTS group, and pN0 in 27 patients, pN1 in 20, and pN2 in 11 in the ES group ($p = 0.837$). The number of harvested lymph nodes was <12 in 9 (16.7%) patients in the SBTS group and 15 (25.9%) in the ES group ($p = 0.236$). The median number of lymph nodes harvested was 18 in the SBTS group (range 12–21) and 15 in the ES group (range 11–19) ($p = 0.098$). Liver metastases were discovered during surgery in four patients from each group ($p = 0.897$).

Local complications at 60 days after surgery were recorded in three patients in the SBTS group (wound infection in 1, parastomal hernia in 1, and ileus in 1) and in 2 in the ES group (wound infection in 1 and severe perianal dermatitis in 1) ($p = 0.605$), while systemic complications developed in five patients in the SBTS group (diarrhoea in 2, thrombocytopenia in 1, and constipation in 2) and in 2 in the ES group (diarrhoea in 1 and urinary tract infection in 1) ($p = 0.214$).

Post-surgical complications within 60 days after surgery were recorded in 29 patients (51.8%) in the SBTS group and in 34 (57.6%) in the ES group, demonstrating a substantial equivalence between the two groups in terms of morbidity ($p = 0.529$). Complications were classified according to Dindo [7] (Table 6). No substantial difference between the groups was observed ($p = 0.269$). Four patients

in the SBTS group died (2 from septic shock, 1 from pneumonia, and 1 from disease progression) and 3 in the ES group (1 from septic shock, 1 from pneumonia, and 1 from disease progression) ($p = 0.943$).
Table 6

Number and percentage (%) of patients presenting with complications after colonic stenting as a bridge to surgery (SBTS) or emergency surgery (ES) according to the Dindo classification

Complication	**SBTS group**	**ES group**	***p* value**
Grade I	10 (17.9)	11 (18.6)	
Grade II	8 (14.3)	12 (20.3)	
Grade IIIa	0	2 (3.4)	
Grade IIIb	7 (12.5)	3 (5.1)	
Grade IVa	0	3 (5.1)	
Grade IVb	0	0	
Grade V	4 (7.1)	3 (5.1)	
Overall total	29	34	0.269

At a median follow-up of 36 months (range 16–38), 17 relapses (30.3%) were observed in the SBTS group and 20 (33.9%) in the ES group ($p = 0.685$) (Table 7). Stoma reversal, which entailed reversal of a Hartmann's procedure in all cases, was performed in 2/11 patients (18.2%) in the SBTS group and in 8/23 (34.8%) in the ES group ($p = 0.320$), for a total stoma reversal rate of 29.4% (10/34 patients). Eight patients have not had their stoma reversed so far due to progressive disease (2 in the SBTS and 6 in the ES group) and 16 patients due to poor clinical conditions (7 in the SBTS and 9 in the ES group). Adjuvant therapy was planned in 48 patients in the SBTS group and 55 in the ES group; however, treatment could not be initiated due to persisting complications in 16/48 (33.3%) in the SBTS group and 17/55 (30.9%) in the ES group ($p = 0.793$). At follow-up 1 year after surgery, 34 (60.7%) patients in the SBTS group and 41 (69.4%) in the ES group presented with post-operative complications ($p = 0.323$).
Table 7

Number and percentage (%) of patients with disease recurrence

Recurrence	**SBTS group**	**ES group**	***p* value**
Locoregional	6 (10.7)	7 (11.9)	
Liver	7 (12.5)	4 (6.8)	
Lung	2 (3.6)	1 (1.7)	
Laparotomy wound	0	1 (1.7)	
Pelvic	1 (1.8)	3 (5.1)	
Carcinomatosis	1 (1.8)	2 (3.4)	
Uterus	0	1 (1.7)	
Bladder	0	1 (1.7)	
Overall total	17	20	0.685

SBTS stenting as a bridge to surgery, *ES* emergency surgery

Analysis of the data from 79.2% of patients who completed the minimum follow-up of 3 years or censored showed that overall survival and progression-free survival in the two groups were comparable ($p = 0.998$ and $p = 0.893$, respectively) (Tables 2, 3).

Unfortunately, the data about quality of life measured with the SF-36 were insufficient for inferential analysis.

Discussion

Bowel obstruction is a medical and surgical emergency. A key hypothesis driving surgeons' interest in the use of SEMS placement in colonic obstruction is that it could convert an emergency surgery into an elective one, thus potentially reducing preoperative morbidity, restore bowel function, and avoid the need for a stoma, which is more often permanent rather than temporary and significantly diminishes the patient's quality of life. Our findings are shared by those reported by Van Hooft et al. [8] and showed a fairly similar morbidity rate within 60 days after surgery and mortality rate in both treatment groups (Fig. 3).

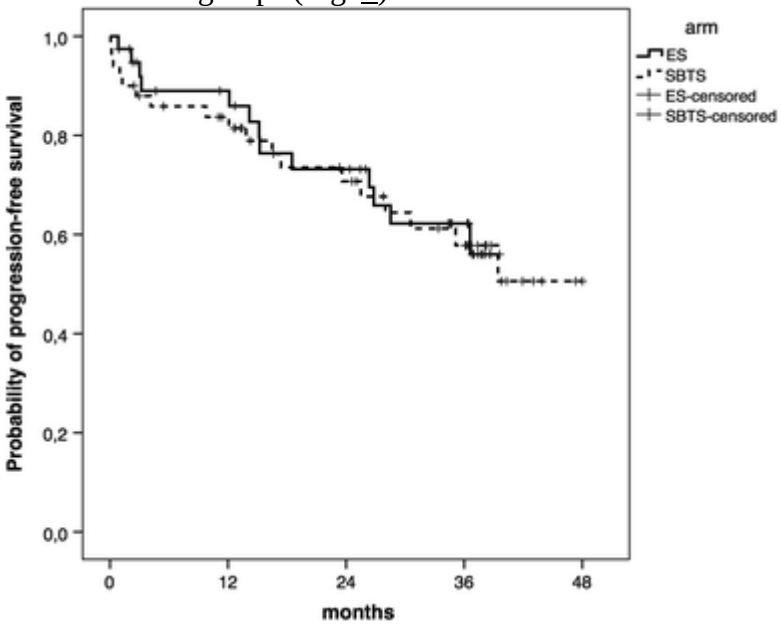

Fig. 3

Kaplan–Meier probability of progression-free survival

Extremely relevant in this context is the unexpectedly high rate of wrong diagnosis due to complicated diverticulitis in some cases and in others to a variety of clinical findings, which, if discovered intra-operatively, could severely burden clinical outcome. This is why it seemed questionable, whether stenting was indicated or not, if flexible colonoscopy should have been performed preoperatively in either all cases or none.

The sample size of our study was calculated based on the literature, essentially retrospective series, available at the time the protocol was conceived. We had initially calculated a 35 and a 15% overall complications rate after ES and SBTS, respectively. Contrary to our expectations, however, we observed rates of 57.6 and 51.8%, respectively, which are far higher than what we anticipated. This most probably stems from use of the Dindo classification, which defines complications as any sort of deviation from the normal post-operative course even without the need for pharmacological treatment or surgical, endoscopic or radiological interventions. These are classified as grade I complications and account for more than one-third of the complications reported in our study. A

similar finding was observed by Van Hooft et al. [8] who also classified complications according to Dindo and found that grade I complications accounted for 40% of all post-operative complications.

Major concern has been raised regarding oncologic outcome after SBTS and the increased risk of disease spread, particularly of liver metastases. Sabbagh reported significantly lower overall survival rates in the SBTS group (25 vs. 62%, $p = 0.0003$), even among those without perforation or metastasis at diagnosis [6]. These findings contrast with the prospective RCTs published by Alcantara et al. [9] and Cheung [10], however. Furthermore, Sloothaak reported that, although stent placement was associated with a higher risk of recurrence, the numbers were too small to draw a definitive conclusion from the long-term results of the Stent-In 2 trial. While subgroup analysis indeed showed a higher rate of recurrence among patients who experienced perforation during SEMS placement, we now know that one of the weaknesses of the study was the variation in operator experience with stenting in the participating centres, which could partly explain the high rate of perforations as compared with the published literature [11]. As a result, in order to minimise the risk of perforation, surgeons in the Netherlands must prove sufficient expertise before they can perform colonic stenting. The general consensus is that further larger trials are mandatory and that stent placement should be performed only in centres where experienced endoscopists are available [12, 13, 14, 15].

The overall survival and progression-free survival curves for our series show comparable results between the two groups. This might be related to the fact that the majority of patients were treated at three centres with proven expertise in operative endoscopy, as shown by a 78.6% clinical success rate with SEMS placement, which is consistent with previous RCTs.

Moreover, Kim recently reported a higher number of stented patients with at least 12 lymph nodes harvested [16]. In our series, the number of patients who had at least 12 lymph nodes harvested at surgery was similar in the two groups; however, while we observed that the median number of harvested lymph nodes was significantly higher in the SBTS group, it is not clear whether this difference is relevant in terms of oncologic outcome. Until further data become available, no relation can be established between oncologic outcome and number of harvested lymph nodes.

It might be argued that a limitation of our study is that, while clinicians skilled in colonic stent placement were included, because the surgical procedure/technique was not standardised across all centres, our conclusions regarding stoma formation are based completely on “surgeon’s preference”. The options for performing bowel resection included Hartmann’s procedure, on table irrigation, and primary anastomosis or subtotal colectomy, according to the protocol. We acknowledge that this led to sizeable variability in treatment; nevertheless, we felt that surgeons experienced in colorectal surgery would find standardisation stifling when on duty in the emergency room. Also, there is no clear evidence that one procedure may be better than another among those we included in the present study.

Unfortunately, we were unable to collect sufficient quality of life data. The need for stoma creation was significantly lower in the SBTS group and only about 30% of the patients have had their stoma reversed so far, which holds particular importance for patients’ perception of quality of life. Moreover, a consistently higher incidence of subtotal colectomy was recorded in the ES group ($p = 0.001$), which further burdens the quality of life of patients, as documented by the SCOTIA study [17]. Given the fairly similar morbidity rates and substantially equivalent oncologic outcomes, SBTS in the management of left-sided malignant colonic obstruction seems a reasonable strategy that can be adjusted when subgroup analyses identify preferable indications.

The current guidelines of the European Society of Gastrointestinal Endoscopy (ESGE) [18] explicitly state that colonic SEMS placement as a bridge to elective surgery is not recommended as a standard treatment of symptomatic left-sided malignant colonic obstruction (strong recommendation, high-quality evidence). The authors of the guidelines mention that some advantages of SEMS as a bridge to surgery are supported by a recent meta-analysis [19] of RCTs. However, the observation of a higher oncologic risk associated with perforation prompted the authors to recommend a more cautious use of stents. The motivation for this recommendation seems to have derived from the findings of a single RCT [11], where it did not translate into a worse overall survival. Nevertheless, the authors concluded that the oncological risks of SEMS should be balanced against the operative risks of emergency surgery. As there is no reduction in post-operative mortality and stenting seems to impact on oncological safety, the use of SEMS as a bridge to elective surgery is not recommended as a standard treatment for potentially curable patients with left-sided malignant colonic obstruction, except in patients at high surgical risk. We believe that, in the light of our findings, the current guidelines should be reconsidered regarding the use of SEMS in an SBTS strategy, at least in high-volume centres.

A final point is that the time to restoration of bowel function varies from individual to individual and that delayed return of normal bowel activity can prolong hospital stay after SBTS. While this is definitely true, especially in settings where an early discharge policy after stenting is not practiced, it is also true that in-hospital stay calculated as the time between surgery and discharge was significantly shorter in the SBTS group. A future area of focus should be to optimise and standardise protocols for post-stent care, including in-hospital stay and the need for proper bowel preparation.

Conclusions

This is the largest multicentre randomised controlled study to date that compared morbidity within 60 days after SBTS and ES for left-sided malignant colonic obstruction. Based on the literature available at the time the study was conceived, reduced morbidity was expected after SBTS. Our findings show that the two strategies are equivalent, that there were no differences in oncological outcomes at a median follow-up of 36 months, and that the stoma rate was markedly lower in the SBTS group. Furthermore, considering that up to 30% of temporary stomas are never reversed, the quality of life in these patients will be reduced. Taken together, the results of our study indicate that SBTS, when performed in expert hands, is a viable endoscopic approach to elective surgery for malignant colonic obstruction.

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