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Outcomes in the management of obstructive unresectable stage IV colorectal cancer

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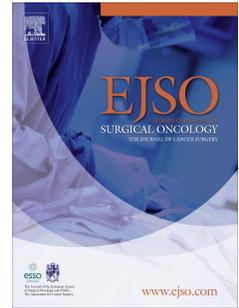
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cancer.

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Aim: To analyze short term results and to report survival rates in a series of patients after palliative emergency treatment for obstructive left-sided colorectal cancer (CRC) with unresectable synchronous metastases.

Patients and methods: From 2004 to 2008, 55 patients were included. Palliative management consisted of stenting to recover bowel patency and starting chemotherapy. Indications for surgery were perforation or failure of stenting. Early failure occurred when decompression after insertion was unsuccessful and late failure when obstruction occurred after successful decompression. Morbidity and mortality were analyzed for stenting and surgery and survival for resected and non resected patients.

Results: Stenting was scheduled in 49 patients. Morbidity and mortality occurred in 5 and 3 patients respectively. Early failure occurred in 4 patients and late failure in 11 patients. Surgery was indicated in 6 patients for peritonitis at diagnosis and in 11 patients for complications (1 case) or stenting failure (10 cases). Of the 17 operated patients, 12 cases were resected and 5 cases were not. Mortality occurred in 1 case. Resected patients received first-line (12 cases) and second-line (5 cases) systemic chemotherapy based on FOLFIRI or FOLFOX while stented and non resected patients were similarly treated in 37 cases and 12 cases respectively. Overall survival at 2 years was 39.3% in resected patients and 1% in stented and non resected patients ($p= 0.008$).

Conclusion: Stenting in palliative stage IV obstructive CRC patients may be less successful as previously thought. Prospective studies are needed to define the role of palliative resection.

INTRODUCTION

The most frequent cause of large bowel obstruction in western countries is colorectal adenocarcinoma (CRC). Despite improvement in early detection of CRC, patients presenting with obstruction at diagnosis range between 7% and 29%.¹ Tumors distal to the splenic flexure represent 78% of all cases.² Up to 19% of patients will already have distant metastases at diagnosis, and two thirds of those will be considered unresectable.^{2,3} Surgical resection of primary tumor and resectable metastasis combined with adjuvant or neoadjuvant therapy when indicated remains the potentially curative strategy for CRC.⁴ However, CRC with unresectable metastasis represents a heterogeneous group of patients ranging from isolated hepatic metastasis to diffuse intra and extra-abdominal metastatic disease whose treatment is based on chemotherapy and is prone to individualized management.

Therapeutic strategy for stage IV patients with unresectable metastasis presenting with obstruction is complex. On the one hand assuring patency of bowel lumen and recovering bowel transit is an absolute priority; on the other, prognosis of disease determines the aggressiveness of treatment. Both synchronous metastasis and bowel obstruction are considered poor prognosis factors as well as high preoperative levels of CA 19.9, histological grade, extension of liver metastasis or peritoneal metastases.^{2,5,6}

Resection of the primary tumour has been claimed to improve survival^{7,8} but it has also been suggested that adding a surgical aggression to palliative patients with high volume disease may lead to high morbidity and mortality. The American Society of Clinical Oncology (ASCO) does not recommend resection of stage IV CRC in asymptomatic patients unless an intention to cure strategy is planned or when at risk of obstruction.⁹

The use of colonic stents as a bridge to surgical resection or as a palliative treatment for CRC has provided some evidence of improvement in quality of life, with a decrease in stoma construction and hospital stay and low morbidity and mortality rates.¹⁰⁻¹² However, a high risk of

serious complications has recently been reported in patients undergoing chemotherapy with a colonic stent in place.¹³

Survival at 5 years of stage IV CRC patients ranges from 58 % after resection of colorectal liver metastasis with curative intent¹⁴ to 9.8 % for all patients under palliative treatment.¹⁵ In the last decades, the development of new oncological drugs has achieved an improvement in survival and quality of life in these patients.¹⁶

These achievements from the oncological point of view and the possibility to offer a less aggressive treatment for obstruction to patients with little time to live have lead to reconsider the most appropriate palliative treatment for stage IV CRC patients.

The aim of this study was to describe short term results and survival rates of palliative patients with obstructing left sided CRC managed at the emergency department after the introduction of colon stenting in the therapeutic armamentarium at a single institution. A secondary aim was to compare the clinical results of the patients treated with stenting with those that needed surgical resection of the primary tumour.

Type of study:

A retrospective observational study was designed to analyze results of palliative management of patients presenting as an emergency at the Bellvitge University Hospital with stage IV obstructing CRC from January 2004 to December 2008.

Data were obtained from a prospectively maintained data base of all patients treated for colorectal diseases at our institution.

Patients:

The study analyses patients with tumours distal to the splenic flexure excluding those with mid or low rectum tumours and those with resectable metastases. Cases of extrinsic compression of the colon lumen were not considered for study. Patients with WHO Performance Status worse than 2 and American Society of Anesthesiology (ASA) classification IV and V were excluded from the analysis.

Left sided CRC obstruction was diagnosed when total absence of flatus or bowel movements were present for the previous 24h accompanied by abdominal distension and dilated colon on plain radiologic films; confirmed either with gastrografin[®] enema or abdominal CT with oral and endovenous contrast with suspicion of cancer as the cause of obstruction and leading to emergency treatment of some kind.

Stage IV patients presented distant metastasis at any localization (liver, pulmonary, bone, peritoneum, retroperitoneal lymph nodes, adrenal glands) assessed by CT and were considered for palliative treatment in cases of unresectable hepatic or extra hepatic metastasis.

Liver metastasis were not suitable for resection when more than 70% of liver parenchyma was involved, in cases of multiple bilateral metastasis, portal involvement, venous bilateral infiltration, infiltration of three hepatic veins or if vascular pedicle node metastasis were identified. Extrahepatic disease was considered unresectable in cases of peritoneal carcinomatosis, bilateral pulmonary metastasis, retroperitoneal lymph nodes or bone metastasis.

Since 2004, our strategy for the palliative management of patients with obstructing left sided CRC and unresectable metastatic disease has been trying to recover bowel transit by means of a permanent colon stent and start palliative chemotherapy aiming to avoid surgery in these patients unless staging varies as a response to systemic therapy.

Palliative patients who presented with complete acute colon obstruction at diagnosis or during the course of palliative chemotherapy were prepared to receive colonic stenting in the emergency setting.

Indication for palliative emergency surgery in cases of unresectable distant metastasis was established when colonic perforation was suspected, when stenting did not resolve obstruction or after complications of colonic stenting.

When not contraindicated by comorbidities, chemotherapy was administered to patients who recovered oral intake and bowel movements and maintained a WHO performance status no worse than 2.

First-line systemic chemotherapy consisted on a combination of 5-fluorouracil (5-FU), leucovorin (LV) and irinotecan (FOLFIRI) or oxaliplatin (FOLFOX). The treatment was scheduled within 2 weeks after stent insertion or in less than 3 weeks after surgery. Response to systemic therapy was evaluated by CT every 3 months following RECIST Criteria (Response Evaluation Criteria in Solid Tumours).¹⁷ Second-line systemic chemotherapy was administered to those patients whose disease progressed or who did not respond after first-line chemotherapy. Depending on the previous regime, second-line treatment exchanged oxaliplatin for irinotecan and vice versa. Xeloda was used in elderly patients. More recently, monoclonal antibodies, cetuximab or bevacizumab were added to the chemotherapy regimes.

Surgical morbidity was defined as any complication occurring within the first 30 postoperative days. Morbidity after colonic stenting considered any complication associated with the insertion process (colon perforation, bleeding, and migration). Mortality was calculated within the first 30 days after surgery or stent placement.

Failure of stenting treatment included: inability to place the stent across the tumour (technical failure), lack of decompression after stent insertion leading to immediate obstruction needing endoscopic or surgical intervention (early failure) and obstruction after initial successful decompression due to tumour progression (late failure).

For the purpose of survival reporting we have observed two groups of patients: resected patients and patients managed without resection, either by stenting, palliative non resective surgery or a combination of both. Overall survival at 2 years was considered the crude survival including all causes of death. Patients who died in the postoperative period were included in the analysis. Cancer-related survival was calculated from the date of first treatment of obstruction to the date of death as consequence of cancer persistence.

Statistical analysis:

Continuous variables are expressed as the mean, median, and range between brackets. Categorical variables are presented as absolute numbers and by percentages. Comparative analyses of the quantitative data were performed using the Student t test or nonparametric test when needed (Mann-Whitney U test). The chi-square test for proportions or Fisher exact test was used in the analysis as appropriate. Survival analysis was performed using Kaplan-Meier actuarial method and survival curves were compared using the log-rank method. Statistical significance was determined a priori at $p < 0,05$. Stepwise logistic regression was performed using SAS V9.1 (SAS Institute, Cary, NC).

In the study period, 119 patients presented with left sided obstructing CRC. Of those, 69 patients (57.9%) presented synchronous metastasis.

Fourteen patients were excluded for the study. Causes of exclusion were: resectable metastasis subsequently treated (7 patients, two of those patients were considered resectable after stent placement), performance status higher than 2 (5 patients) and extrinsic compression from carcinomatosis implants in the pelvis (2 patients). Fifty five patients received palliative treatment for a stage IV obstructing CRC.

Localization of metastasis, demographic and general variables are described in *Table 1*. No differences were observed in sex, age, renal function, American Society of Anaesthesiologists' (ASA) classification, chemotherapy administration and localization of metastasis between resected patients and stented or non resected patients. Carcinomatosis in the surgical group presented as localized implants.

At diagnosis, emergency surgery was indicated in 6 patients and stent placement was decided in 49 patients. Subsequently, two groups were analyzed (flow diagram in figure 1).

Short term results:

Stent group

Stenting was scheduled in 49 patients achieving placement in 45 cases (91.8%). Technical failure of the procedure occurred in 4 cases (8.2 %) in which technical difficulty precluded stent placement. Of those, 2 patients needed an operation (1 colostomy and 1 by-pass), and 2 elderly patients who suffered from a widely disseminated disease underwent supportive care and died. Complications after stenting occurred in 5 patients (11.1 %). One patient bled needing endoscopic electrocoagulation. Perforation secondary to stenting occurred in 2 patients under chemotherapy at 27 and 74 days after stenting and re-stenting respectively. Migration of stent occurred in 2 patients at 24 days in 1 patient, and 3 months in the other patient. All two were treated by re-stenting. Medical events did not occur.

Early failure of the procedure occurred in 4 cases (8.8%) in which bowel transit after stent placement was not achieved needing resective surgery in 2 patients, colostomy in 1 patient and re-stenting in 1 patient.

Late failure after successful stenting and decompression occurred in 11 patients (26.1 %) presenting with further colon obstruction on follow up. Mean time to late stent obstruction was 144.5 days. Of those, 5 patients needed an operation (3 with primary tumour resection and 2 with colostomy) and 6 were re-stented. Of the 6 re-stented patients, one suffered a complication (peritonitis for perforation leading to surgical resection) and 5 were successfully controlled after re-stenting. Chronology of stenting morbidity and failure is shown in Figure 2.

Of the 49 patients scheduled for stenting, 35 patients (71.4%) were successfully treated with one or more stents in place in. Eleven patients intended to be treated by stenting were finally operated on (22.4%) and 9 patients needed re-stenting (20%). Successful decompression with a single stent occurred in 28 patients (57.1%) and in 27 patients (55.1%) stenting treatment was successful without any complication or need for re-stenting.

Mortality of 6,1% accounts for two patients who died after initial stenting failure and one patient who died after perforation during the first stenting procedure with no further treatment in none of the 3 cases.

The mean length of stay was 8.8 days (range: 2-29).

Surgical group

Of the 17 patients who were operated on in the series, 5 patients were not resected and have been described in the stent group. Twelve patients were operated on for resection. In 6 cases surgery was indicated at diagnosis for peritonitis. Six patients initially meant to be managed by stenting were finally operated on: 2 patients after early failure, 1 patient with perforation after re-stenting, and 3 patients after late failure.

Operations performed were 6 left colectomies, 3 subtotal colectomies with primary anastomosis and 3 Hartmann's procedures (two of those last ones had a stent in place).

Surgical postoperative mortality and morbidity were 8.3% and 41.6% (anastomotic leak in 1 patient, prolonged ileus in 1 patient, cardiac failure in 1 patient, urinary infection in 1 patient and 1 patient had both wound infection and incisional hernia) respectively.

The mean length of stay was 14.5 days (range: 9-24)

Survival observations:

Reporting survival compares 12 patients in the surgical group (resection surgery) and 43 patients in the stent group (including stented and non-resected operated patients). Chemotherapy is also described attending to these two groups.

FOLFOX or FOLFIRI regimes as first-line treatment were administered in 10 of the 12 patients in the surgical group, and in 33 of the 43 patients in the stent group. Alternative regimes were Xeloda and 1 patient in the surgical group and 2 patients in the stent group; xeloda and oxaliplatin in 1 patient in each group and capecitabin in 1 patient in the stent group. Second-line regimes were FOLFOX or FOLFIRI cross over in 5 patients in the surgical group and 12 patients in the stent group. Cetuximab or bevacizumab were added to the chemotherapy regimens in 4 and 6 cases respectively.

Overall, chemotherapy regimes were similar for both groups: no significant differences were observed in the proportion of patients who received chemotherapy ($p=0.321$), and the type of treatments was similar. No patient had complete remission of metastases. One resected patient could subsequently be rescued for radical treatment with hepatic surgery after chemotherapy.

Overall survival at 2 years after obstruction for CRC with unresectable metastasis was 39.3% in patients treated with resection of primary tumour and 1% in patients treated by stenting or non resective surgery. The median survival time to death in the surgical group was 23.7 (3.7-32.2) months and 4.4 (0.2-32.0) months in the stent group. Figure 3

DISCUSSION

It has been observed that complicated CRC operated on in emergency presents at a more advanced stage with distant metastasis being more common.⁷ In this study, left sided obstructed tumours presented with distant metastasis in 57.9% of patients. It is also well known that emergency surgical treatment of colorectal obstruction deals with a high morbidity and mortality on the range of 46% and 19% respectively.¹⁸⁻²⁰ Results from the surgical group in the series are in that context.

In 1991, Domocho describes the use of intraluminal stents as a means of treatment for colon obstruction.²¹ Other groups have tried to stent palliative patients as a definitive treatment of obstruction.²² This has been so far the idea of our group hoping to spare morbidity and mortality to patients to whom curative treatment is no longer possible.

Short term results.

High efficacy at a low morbidity and mortality risk has been claimed as an advantage of this technique. As a palliative treatment, success rates of up to 96.4% have been reported with early and late major morbidity rates of 24.4 % (including perforation, migration, bleeding) and 8.9 % re-obstruction rate.²² It has also recently been reported how a prospective randomized study, allocating stage IV patients under chemotherapy at risk of obstruction for either stenting or surgery has been closed due to a high incidence of severe complications in the stent group.¹³ In the present series, we report a successful insertion rate of 91.8 % with 11.1% morbidity rate. However, we also observed early and late failure rates of 8.8 % and 26.1 % respectively and mortality rate of 6.1 %. Furthermore, re-stenting rate was 18.3 %. If we consider 'success rate' the proportion of patients initially aimed to be treated by stenting that were finally controlled without major morbidity or need for re-stenting, we then report a lower 55,1%. It may be interpreted that success is not so achievable and aggressiveness is higher than it seems, although lower than that of emergency surgery.

Lowering hospital stay and therefore allowing earlier start of chemotherapy is another pretended benefit of stenting in the management of palliative obstructing CRC.²² In the present series, surgical resected patients stayed in hospital a mean of 14.5 days as opposed to with 8.8 days when managed by stenting. However, it should also be taken into consideration that with a re-stenting rate of 18.3 %, patients managed by stenting have a cumulative hospital stay due to repeated treatment that surgical patients do not face and that can interfere with chemotherapy already started.

Stenting has also been related to a lower rate of colostomy construction and an associated improvement in quality of life.²² The study we report does not analyze quality of life but neither supports the tight association between palliative surgery and colostomy construction. Of the 17 patients finally operated on, only 7 colostomies were constructed: four lateral colostomies and 3 Hartmann's operations. Avoiding anastomosis after resection in these patients was mainly explained by the technical difficulty of operating with a stent in place. Following our strategy for surgical treatment of colonic obstruction described elsewhere⁷, of the 12 patients who were resected an anastomosis was achieved in 9 patients (75%). Quality of life comparisons between stenting and palliative colostomy may not be as fair as between stenting and resection with primary anastomosis and remains an issue that needs further understanding.

Survival report.

Survival of stage IV CRC palliative patients depends mainly on systemic chemotherapy to treat systemic disease. Although treatment of non complicated patients has been definitively defined in multiple phase III trials,²³ the management of complicated patients has been less thoroughly evaluated. Currently, regimes based on FOLFOX or FOLFIRI are the standard of systemic chemotherapy with the eventual addition of monoclonal antibodies.^{24,25} In the present series, resected patients and patients managed by stenting or non respective surgery received equivalent systemic chemotherapy. Neither the proportion of patients treated nor the type of treatment received varied between the two groups.

Elias et al. have reported medium survival in selected patients treated for carcinomatosis with surgery, hyperthermic intraperitoneal chemotherapy and systemic chemotherapy of 23,9 months.²⁶

It has also been argued that resection of primary tumour improves survival of palliative patients.²⁷

Although the study we report on was not specifically designed to analyze survival and the number of patients in the groups is not enough to come to a conclusion, we have observed a difference in clinical behaviour of those two strategies (resection vs stenting or non respective surgery for emergency control of obstruction) that are based on posterior equivalent systemic therapy. We report a medium survival in resected patients of 23.7 months and of 4.4 months in non resected patients. Resected patients were not selected for better prognosis. On the contrary, more than half of these patients had bad prognosis from associated perforation. Even though, resected patients lived longer in this study.

Since the introduction of Folfox it has been observed that 16% of previously unresectable hepatic metastasis are rendered surgically resectable.²⁴ It has also been reported that systemic chemotherapy activity is not only of benefit to the metastatic disease but also affects the primary tumor.²⁸ Consequently, the use of systemic chemotherapy not only has improved patients survival but has also allowed a dynamic re-evaluation of the palliative situation of patients depending on response.²⁹ Thus, management of the primary tumour can change within follow up. Unfortunately, in the present series there was only one patient who fitted this re-evaluation of palliation. This patient, previously resected for obstruction control, could subsequently be treated with a radical intention and was operated on for hepatectomy.

Although the literature does not recommend surgery in patients with locally advanced disease and severe comorbidities² in the elective scenario, both the possibility of offering patients further treatment, in some cases, and the eventual gain in life time may encourage a reconsideration of the management of obstruction in this situation.

However difficult it can be to conclude from an heterogeneous group of clinical situations, we have observed how morbidity and failure of a less aggressive treatment, as stent has been claimed to be, is not negligible.

Prospective studies should help us defining the role of palliative surgery in relation to survival. Will stage IV patients with not locally advanced disease and good status benefit from palliative resection of primary obstructing tumours in the emergency? It may be wise to considered stenting as part of the therapeutic armamentarium available to treat some patients and some phases of disease after an individualized evaluation.

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Table 1. Patient Characteristics

	Surgery group (resected) (n= 12)	STENT group (Stented or nonresected) (n= 43)	p value
Gender			1,000 a
Male	9	32	
Female	3	11	
Age (year- range)	65,5 (50-77)	65,9 (19-84)	
Age (years)			0,660 b
< 70	7	22	
≥ 70	5	21	
Creatinine >120 Mmol/l			0,712 a
no	9	34	
yes	3	9	
Chemotherapy			0,321 a
no	0	6	
yes	12	37	
ASA score*			0,831 b*
I	1	2	
II	5	18	
III	6	23	
Metastatic lesion			
Liver	10	30	0,477 a
Peritoneal	+3	12	
Lung	2	12	0,709 a
Retroperitoneal lymph node	2	6	1,000 a
Other organs	0	4	0,566 a

a - Fisher Exact Test;

b - Pearson Chi-square;

* ASA score: I-II vs III;

+Localized

Figure 1. Flow diagram of treatment

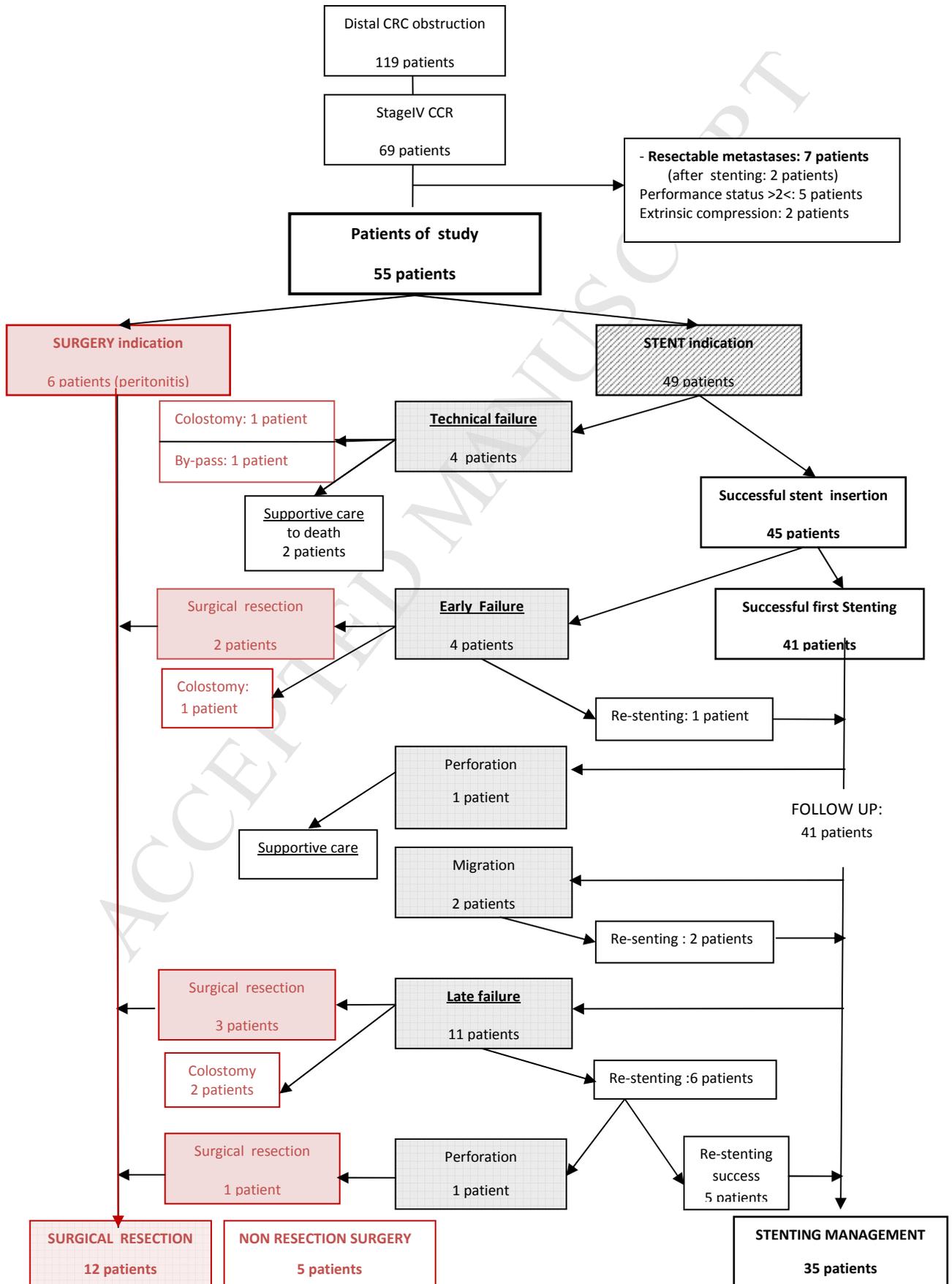
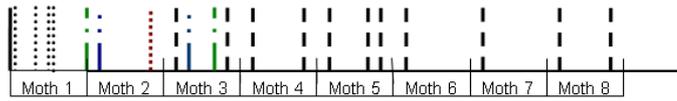
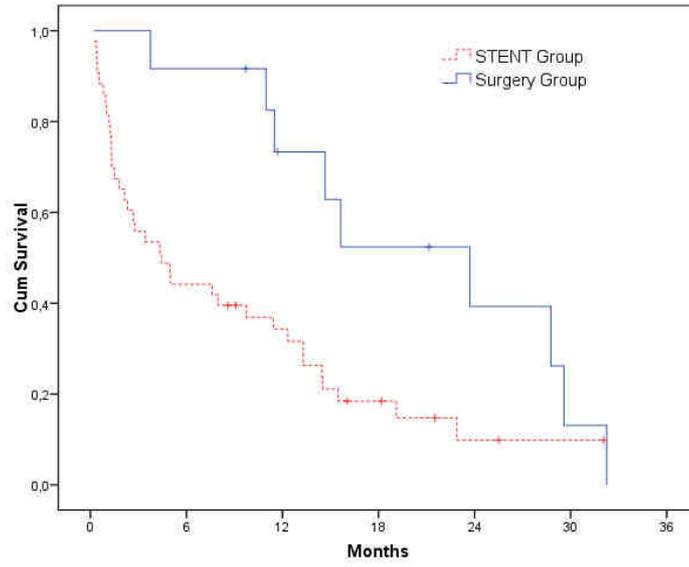


Figure 2. Chronology of stenting morbidity and failure

	Bleeding (n=1)
	Technical failure (n=4)
	Migration (n=2)
	Early failure (n=4)
	Late failure (n=11)
	Perforation (n=2)



ACCEPTED



ACCEPTED