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The long-term recurrence rate and survival of obstructive left-sided colon cancer patients: a stent as a bridge to surgery

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ABSTRACT

Background: a colonic stent as a bridge to elective surgery for left-sided malignant colonic obstruction is an alternative to the classical treatment. The aim of our study was to evaluate the recurrence rate as well as the morbidity and mortality of this treatment.

Patients and methods: patients admitted to the Emergency Department with left-sided malignant colonic obstruction between June 2006 and January 2014 were analyzed in a retrospective observational study. Patients who underwent self-expanding metallic stent placement via endoscopy as a bridge to surgery were included. The observation period was performed until May 2017.

Results: fifty-three patients were treated with a colonic stent as a bridge to surgery; nine patients died during the postoperative period. The deceased patients were more

frequently male (100% in the deceased *vs* 62% in the non-deceased, p = 0.02), with a more advanced age (81.4 ± 5.1 *vs* 71.6 ± 10.8, p < 0.001), lower hemoglobin levels on admission (12.9 *vs* 13.6 p < 0.001), a greater number of leukocytes (12,918 *vs* 9,437, p < 0.001) and greater coagulopathy (INR 1.6 *vs* 1, p < 0.001). Eight patients had a distant relapse with a median disease-free survival of 19.1 months. The variables were compared according to the appearance of distant disease and the mean age was lower in patients with a recurrence (65.9 ± 11.3 *vs* 74.9 ± 9.9, p < 0.001).

Conclusions: the results of the use of a stent as a bridge to curative surgery in patients with obstructive left colon cancer in our hospital is comparable to previous studies.

Key words: Cancer. Intestinal obstruction. Adenocarcinoma. Surgery. Stents. Treatment outcome.

INTRODUCTION

Up to 30% of colorectal cancers can present with a colonic obstruction, which is located in the left colon in 70% of cases (1). Emergency surgery has been the treatment of choice for many years with an associated high morbi-mortality, and a stoma needs to be performed in up to 40% of cases (2-4). In more than 50% of these patients, intestinal transit is not subsequently repaired (5). The use of the colonic stents as a bridge to elective surgery *versus* emergency surgery was compared in a systematic review of seven randomized studies (6). There was a lower incidence of permanent stomas and a greater number of primary anastomoses in the stent group, with no differences in mortality and a lower perioperative morbidity. However, articles published in recent years indicate a probable increase in recurrence rate (1,7-9), with no differences in overall survival in patients treated with decompressive stents prior to elective surgery compared to those treated with emergency surgery.

Due to the characteristics of our tertiary hospital (Hospital Ramón y Cajal), the long-term oncologic outcomes in our population were analysed and our daily clinical practice may also be modified based on this. The aim of the study was to estimate the outcome of the placement of a colonic stent as a brigde to elective surgery in terms of postoperative mortality, overall survival, disease-free survival and local or distant

recurrence. As secondary outcomes, morbidity related to the endoscopic technique, the number of primary anastomoses, the need for temporary or definitive stoma, the morbidity associated with surgery and hospital stay were also analysed.

PATIENTS AND METHODS

A retrospective observational and longitudinal study was performed of patients who attended the Emergency Department of the Hospital Ramón y Cajal with colonic obstruction due to left-sided colon cancer, who underwent treatment with a colonic stent as a bridge to curative elective surgery.

Consecutive patients were included in the study from June 2006 to January 2014. Cases with a primary tumour located at the splenic flexure of the colon, descending colon, sigmoid or rectum-sigmoid junction and criteria of curable disease by imaging tests were included. Patients who were treated as a palliative intention with a stent or those who were diagnosed with a colonic perforation in the Emergency Department (clinical or radiological) were excluded from the study.

Emergency endoscopy was performed in all cases with decompressive intention, using an Olympus flexible thin endoscope with a working channel. Once the stenosis was visualized, a 0.89 mm guide was introduced under fluoroscopic and endoscopic guidance. The Wallflex™ 25 x 90 mm or Wallflex™ 25 x 120 mm, uncovered (Boston Scientific Co., Natick, MA) self-expanding metallic stent was used. A technical success was considered when the stent was correctly placed, overcoming the stenosis, and stool evacuation was visualized through it. Clinical success was considered when there was a complete resolution of the obstructive symptoms. Elective surgery was performed by laparotomy in patients with a technical and clinical success, after colonic preparation with an evacuating solution. Patients who did not present technical or clinical success or those with any complications after treatment with the stent underwent emergency surgery. The observation period was from June 2006 to May 2017, in order to perform a minimum follow-up of three years in all patients, except in the case of death.

Variables studied

The following quantitative variables were collected: age, analytical parameters, length of stenosis tumor, radiological parameter (cecal size), time to elective surgery, time of surgery, tumour size, number of lymph nodes resected, number of lymph nodes affected, follow-up and time to local or distant recurrence.

The following qualitative variables were collected: sex, ASA anesthetic, comorbidity pre-treatment, previous pharmacological treatment, radiological parameters (presence of competent ileocecal valve, free fluid or pneumatosis), tumor location, technical success and clinical success of stent placement, stent complications (perforation, bleeding or migration), type of surgical intervention, post-surgical complications according to the Clavien-Dindo classification (10), presence of metastases at admission, adjuvant treatment, overall survival, disease-free survival, tumor progression and local or distant recurrence. A distant relapse was defined as the appearance of metastatic disease (peritoneal, pulmonary, hepatic or in other organs).

Statistical analysis

Quantitative variables are expressed as the mean ± standard deviation (SD) or median and interquartile range (IQR), depending on whether the variable followed a normal distribution. With regard to qualitative variables, these are expressed as absolute and relative frequencies. The Student's t-test or the Mann-Whitney test were used for comparisons of quantitative variables between the groups. The Chi-square test or Fisher's test were used to compare qualitative variables. A univariate analysis was performed in order to study the association between postoperative mortality and local or distant recurrence with the rest of the variables. Statistical significance was set at $p < 0.05$. Multivariate analysis could not be performed due to the low number of events. Survival analysis was estimated using the Kaplan-Meier method. The STATA 13.1 statistical package was uaed for the statistical analysis. Our study was presented and approved by the Ethics Committee of our hospital.

RESULTS

Fifty-three patients (17 female, 36 female) with an average age of 73.4 (± 10.6) years attended the Emergency Department in the Hospital Ramón y Cajal due to colonic

obstruction during the inclusion period from June 2006 to January 2014. A self-expanding stent was urgently placed. The demographic characteristics of the cohort are described in table 1. The diagnosis of colonic obstruction was clinical in all cases and the presence of a tumor was confirmed with an opaque enema in ten patients and computed axial tomography in 43 patients. Clinical or radiological data of a perforation were discarded in all cases and patients underwent endoscopy in the Endoscopy Service of our hospital. The lesion was more frequently located in the sigma (n = 29, 55%) and the median distance to the external anal margin was 30 cm (19-47.5). Technical success was obtained via the placement of the stent in 51 patients (96%) and an adequate clinical success was achieved in 46 (87%) cases.

There were three clinical complications of the stent placement (two perforations and one rectal bleeding). It was necessary to perform emergency surgery in eight patients (15%) with a mean time of 1.1 days ± 1.6 due to technical or clinical failure or stent complication. Patients with no complication and in whom the colonic obstruction was resolved underwent elective surgery (n = 44) with a median time of four days (3-5). Only one patient rejected surgical treatment. Radical surgery was performed in 51 patients, including partial or complete resection of the bladder or intestinal resection in some cases (Table 1); one of them was unresectable. Of the 51 patients who underwent curative surgery, two liver lesions of suspected metastases were resected in one case. In the remaining six patients with suspected liver metastases, two rejected any type of treatment for metastases and the rest underwent treatment specified in table 2. Primary anastomosis was performed in 39 patients (75%) and there were two postoperative anastomotic leaks that required surgery. A stoma was required in 14 patients (27%), six of whom were operated on urgently due to clinical failure or stent complication. One patient had an unresectable tumor, one patient had asymptomatic macroscopic perforation as an intraoperative finding and the remaining six patients underwent complex tumor resections that required a stoma. The intestinal transit could be reconstructed in only two cases during the evolution of the disease (Table 1).

Some complications occurred during the postoperative period in 22 patients (42%) according to the Clavien-Dindo classification. Eight were classified as grade II; four patients with wound infection, three patients with paralytic ileus and one patient with

pneumonia due to the need for treatment with antibiotic therapy or parenteral nutrition. Four patients were classified as grade IIIb as they required surgery; one patient with anastomotic leak, two patients with intra-abdominal abscess and one patient with hemoperitoneum. One patient was classified as grade IV due to the occurrence of heart failure that required intensive medical treatment. Nine patients (17%) were classified as grade V as they died during the postoperative period due to complications. A second surgery was required in six patients (12%); two patients with an anastomotic leak, two patients with intra-abdominal abscess, one patient with hemoperitoneum and one patient with a sunken colostomy. Of the nine patients who died during the postoperative period, three required emergency surgery after stenting due to bleeding (one) and clinical failure (two); two patients needed surgical reoperation (one for anastomotic leak and another for sunken colostomy) and four patients had multiorgan failure after the surgery (Table 1). The anatomopathological characteristics of the resected specimens are shown in table 2 as well as the presence of micro or macroscopic perforations (13 patients). Two patients presented clinical symptoms of acute abdomen due to perforation of the colon secondary to the stent, five patients had perforations identified during the surgical procedure and six had microscopic perforations. The location of the stent was in the splenic flexure in one of the cases.

Forty-eight per cent of the patients received adjuvant treatment. The median follow-up time was 32 months (4-69). None of the patients had local recurrence. However, there were eight cases of distant relapse (18%) with a median disease-free survival of 19.1 months (3.4-49.1) (Table 2). One of the patients had a microscopic perforation of the colon at the level of the stent. Thirty-four patients were alive at the date of the last follow-up, 24 patients were free of disease and ten patients had disease progression. Eighteen patients died during follow-up; nine patients died during the postoperative period, five due to disease progression and four died without disease due to other causes. The patient who refused surgical intervention after the placement of the stent did not maintain follow-up.

A univariate analysis was performed to identify the association between the independent variables studied and postoperative mortality. Significant differences

were found with regard to sex (more frequent in males), age (81.4 ± 5.1 *vs* 71.6 ± 10.8, p < 0.001), lower preoperative hemoglobin levels (12, 9 ± 2.2 *vs* 13.6 ± 2.3, p < 0.001), higher number of leukocytes on admission (12,918 ± 5,285 *vs* 9,437 ± 2,575, p < 0.001) and the presence of coagulopathy (INR: 1.6 ± 1.2 *vs* 1 ± 0.2, p < 0.001) in the group of deceased patients. Significant differences were also observed with regard to a lower number of anastomoses (44% *vs* 81%, p = 0.02) and a greater number of stomas in this group (67% *vs* 19%, p = 0.003). The patients who died during the postoperative period had a significantly higher number of postoperative complications; all deceased cases had at least one complication *vs* 30% of the other cases, p < 0.001. The percentage of clinical success of stent placement was lower but did not reach statistical significance (67% *vs* 91%, p = 0.05). The variables studied were compared according to the appearance of distant disease, with significant differences in terms of age, 65.87 ± 11.3 *vs* 74.86 ± 9.95 (p = 0.001) and analytical parameters upon arrival to the Emergency Department (hemoglobin, leukocyte count and INR) (Table 3). A Kaplan-Meier survival curve analysis was used to study the mortality of the cohort due to disease (Fig. 1). The 12-month survival estimate was 78% and 72% at 60 months, whereas the overall survival of the series for all-cause mortality was 77% and 61% at 12 and 60 months, respectively (Fig. 2). The Kaplan Meier survival curve analysis of distant recurrence that excluded patients diagnosed with metastatic disease (seven cases) estimated that the proportion of patients without recurrence at 12 months was 92% and 71% at 60 months (Fig. 3).

DISCUSSION

Colon cancer is a very common pathology in our environment and up to 30% of patients with colorectal cancer can present with a colonic obstruction, 70% in the left colon (1). The traditional treatment for this problem is an emergency surgery, with an associated morbidity of 40-50% and a mortality rate of 15-20%. Up to 40% of cases required a temporary or definitive stoma (2-4). In 1991, the use of an intratumoral stent for the treatment of unresectable or metastatic obstructive tumors was first described by Dohmoto (11). Subsequently, Tejero et al. published the first experience with the use of a stent as a bridge to elective surgery in obstructive colon tumors (12).

Since then, numerous retrospective studies have compared the use of stents in obstructive colon tumors in patients with potentially curative disease prior to elective surgery *versus* patients treated with a single emergency surgery (13,14).

Seven prospective randomized studies (7,8,15-19) and reviews with meta-analysis (20-26) have concluded that there is a greater number of primary anastomosis and minor stoma without apparent differences in short-term morbidity and mortality in the group of patients with a stent prior to elective surgery. In our study, a primary anastomosis rate of 75% and a stoma rate of 27% was obtained, which is similar to other series. However, three of the randomized prospective studies closed prematurely due to a higher than expected increase in complications in one of the two groups (8,15,16). Pirlet et al. and Van Hooft et al. closed the study due to an increase in the number of complications in the stent group (15,16). However, Alcantara et al. reported an increase in the global number of complications and anastomotic leaks in the emergency surgery group (8).

There are few studies at present that analyze the long-term results of this type of treatment and therefore, the survival and recurrence rate associated with each treatment (1,7-9). Therefore, this study tried to provide an insight and is one of the largest in the literature, with 53 stent cases as a bridge to surgery. Reports of long-term survival and tumor recurrence with this kind of stent as a bridge to surgery treatment is confusing, with inconclusive results, probably due to the small number of samples (1,7-9). A potential complication of the stent is tumor perforation that may result, according to some authors, in a dissemination of tumor cells, and therefore have long-term consequences with respect to oncological outcomes (27). In our study, two clinical perforations (2/53, 4%) were found and 13 perforations were identified by the Pathological Anatomy Service (13/51, 25%). Sloothaak et al. (9) analyzed the oncological results in terms of recurrence and survival of one of the prospective multicenter randomized studies (The Dutch Stent-In 2 study [16]) that closed prematurely due to an increased morbidity at 30 days in the stent group as a bridge to surgery during the intermediate analysis. There was a significantly higher recurrence in the stent group associated with tumor perforation and a poorer survival. However, they acknowledge a lack of evidence to reject this treatment due to the small number

of patients in the study. It has not been possible to establish this relationship in our study, as local recurrence was not identified in any of the cases of clinical and histological perforations. Only one case of distant recurrence was diagnosed in one of the patients with a microscopic perforation. Tung (7) et al. reported the long-term analysis of a randomized study in which they identified a greater tumor recurrence in the stent group. However, this did not significantly affect survival. Kavanagh et al. (28) showed a similar survival in 49 patients, as well as Knight et al. (29). Sabbagh et al. (14) performed a retrospective study of 87 patients, 48 in the stent group and 39 in the emergency surgery group. This study showed a significantly lower 5-year overall survival rate, 25% *vs* 62% (which was 50% at five years in this study), with a significantly higher rate of cancer mortality at five years in the stent group, 48% *vs* 21% (this was 25% at five years in our study). Gorissen et al. (1) reported a significantly greater local recurrence in the stent group, in patients younger than or equal to 75 years in a non-randomized prospective study. The incidence of clinical perforation of the stent is estimated according to a meta-analysis as 6.9% (23), which is associated with the location of the tumor, tumor stricture, type of stent and experience of the endoscopist.

There was a 4% clinical perforation rate in our study. Stent perforations associated with the use of some chemotherapeutic agents (antiangiogenic) have also been described (30), although there were no cases in our cohort. However, there are no conclusive data in the literature as studies report a worse oncological result in patients undergoing stent placement prior to elective surgery. Clinical practice guidelines recommend the use of stents in patients with a high mortality risk associated with emergency surgery (ASA ≥ III and age > 70 years old) (31).

In conclusion, this study aims to provide the experience of a third level hospital in the treatment of this disease as well as reporting the morbidity and mortality rate and local or distant recurrence in this setting. The results obtained in this study are better than those of other published series in the literature (14,23). The limitation of the study is that it is a non-comparative retrospective study. Additional prospective studies are required as well as a comparative analysis with emergency surgery.

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Table 1. Demographic, diagnostic and treatment characteristics of the sample

Variables	
1. Age (years old, X ± DS)	73.4 ± 10.6
2. Sex	17 (32%)
– Female	36 (68%)
– Male	
3. ASA category	6 (11%)
– I	30 (57%)
– II	15 (28%)
– III	2 (4%)
– IV	0 (0%)
– V	
4. Comorbidity	28 (53%)
– Hypertension	9 (17%)
– Diabetes	13 (25%)
– Hypercholesterolemia	11 (21%)
– Cardiovascular disease	14 (26%)
– Smoker/ex-smoker	
5. Blood test (X ± DS)	13.5 ± 2.2
– Hemoglobin (g/dl)	10,067 ± 3,415
– Leukocyte count/ul	1.1 ± 0.5
– INR	
6. Radiological parameters of CT	32 (74%)
– Competent ileocecal valve	2 (5%)
– Pneumatosis	20 (47%)
– Free fluid	8.8 (7.5-9)
– Cecal size cm (median, IQR)	

7. Endoscopic parameters	8 (15%)
– Tumor location	29 (55%)
• Rectosigmoid junction	12 (23%)
• Sigma	4 (7%)
• Descending colon	4 (3-4.5)
• Splenic flexure	51 (96%)
– Stricture length, cm (median, IQR)	46 (87%)
– Technical success	3 (6%)
– Clinical success	2
– Endoscopic complication	1
• Perforation	
• Bleeding	
8. Surgery treatment variables	52 (98%)
– Surgery treatment	8 (15%)
– Emergency surgery	51/52 (98%)
– Tumor resected	1/7 (14%)
– Metastases resected in the same	39 (75%)
surgery	14 (27%)
– Primary anastomosis	12
– Stoma	1
• Colostomy	1
• Ileostomy	160 (127.5-200)
• Protective ileostomy	22 (42%)
– Time of surgery (median, IQR)	0
– Surgical complications *Clavien-Dindo*	8
• Grade I	0
• Grade II	4
• Grade IIIa	1
• Grade IIIb	0
• Grade IVa	9
• Grade IVb	6 (12%)

• Grade V – Surgical reintervention	
9. Mortality variables – Mortality during hospital admission – Time to death, days (median, IQR)	9 (17%) 11 (7-34)

Table 2. Oncological and evolutionary characteristics of the sample

Variables	
1. Metastases at diagnosis	7 (13%)
2. Metastases treatment	2
– No treatment	1
– Surgery treatment in a while	1
– Deferred surgical treatment	1
– Embolization	2
– Chemotherapy	
2. Pathological results	13 (25%)
– Micro/macroscopic colon perforation by stent	42 (82%)
– pT	9 (18%)
• pT3	1 (0-3)
• pT4	17 (12-23)
– pN	24 (47%)
• Positive nodes (median, IQR)	13 (26%)
• Nodes resected (median, IQR)	14 (27%)
• pN0	
• pN1	
• pN2	
3. Adjuvant treatment	25 (48%)
4. Follow up	0 (0%)
– Local relapse	8 (18%)
– Distant recurrence	19.1 (3.4-49.1)
– Time to recurrence in months (median, IQR)	28 (54%)
– Evolution	24
• Disease-free	4
– Alive	15 (29%)
– Deceased for other causes	10

• Diseases progression	5
– Alive	9 (17%)
– Deceased	
• Mortality during the admission	
5. Follow-up time in months (median, IQR)	32 (4-69)

Table 3. Univariate analysis between variables and postoperative mortality/distant recurrence

	Postoperative mortality event			*Distant recurrence event*		
Variables	*Deceased*	*Survivors*	*p*	*Presence*	*Absence*	*p*
1. Age (years, X ± SD)	81.4 ± 5.1	71.6 ± 10.8	*< 0.001*	65.9 ± 11.3	74.9 ± 9.9	*< 0.001*
2. Sex	0	17	*0.02*	2	12	0.68
– Female	9	26		6	25	
– Male						
3. ASA Category	4	31	0.12	5	24	0.89
– I/II	5	12		3	13	
– ≥ III						
4. Comorbidity	7 (78%)	21 (48%)	0.11	3 (38%)	22 (59%)	0.25
– Hypertension	2 (22%)	6 (14%)	0.53	1 (13%)	7 (19%)	0.67
– Diabetes	4 (44%)	9 (21%)	0.14	2 (25%)	20 (27%)	0.91
– Hypercholesterolemia	3 (33%)	8 (19%)	0.33	1 (13%)	9 (24%)	0.47
– Cardiovascular disease	4 (44%)	10 (23%)	0.19	2 (25%)	11 (30%)	0.79
– Smoker/ex-smoker						

5. Blood test (X ± SD)	12.9 ± 2.2	13.6 ± 2.3	*< 0.001*	14.9 ± 1.2	13.4 ± 2.4	*< 0.001*
– Hemoglobin (g/dl)	12,918 ±	9,437 ±	*< 0.001*	9,014 ±	10,353 ±	*< 0.001*
– Leukocyte count/ul	5,285	2,575	*< 0.001*	2,287	3,767	*< 0.001*
– INR	1.6 ± 1.2	1 ± 0.2		1 ± 0.0	1.2 ± 0.6	
6. Radiological parameters of CT	5 (55%)	27 (63%)	0.39	5 (63%)	22 (59%)	0.55
– Competent ileocecal	0 (0%)	2 (5%)	0.49	0 (0%)	2 (5%)	0.45
valve	4 (44%)	16 (37%)	0.83	5 (63%)	14 (38%)	0.43
– Pneumatosis						
– Free fluid						
7. Endoscopic parameters	3.3 (2.5-4)	4 (3.3-4.5)	0.19	4 (3-4)	3.5 (3-4)	0.85
– Stricture length, cm	9 (100%)	41 (95%)	0.51	8 (100%)	36 (97%)	0.64
(median, IQR)	6 (67%)	39 (91%)	0.05	8 (100%)	31 (84%)	0.22
– Technical success	1 (11%)	2 (5%)	0.45	0 (0%)	3 (8%)	0.40
– Clinical success						
– Endoscopic complication						

8. Surgery treatment variables	4 (44%)	4 (9%)	*0.008*	0 (0%)	7 (19%)	0.18
– Emergency surgery	155 (125-170)	160 (130-205)	0.67	177.5 (150-192.5)	157.5 (127.5-207.5)	0.46
– Time of surgery minutes (median, IQR)	4 (44%)	35 (81%)	*0.02*	7 (88%)	26 (70%)	0.37
– Primary anastomosis	6 (67%)	8 (19%)	*0.003*	1 (13%)	11 (30%)	0.3
– Stoma	9 (100%)	13 (30%)	*< 0.001*	3 (38%)	18 (49%)	0.52
– Surgical complications	2 (22%)	4 (9%)	0.27	1 (13%)	5 (14%)	0.92
– Surgical reintervention						
9. Colon perforation by stent	4 (44%)	9 (21%)	0.15	1 (13%)	11 (30%)	0.28

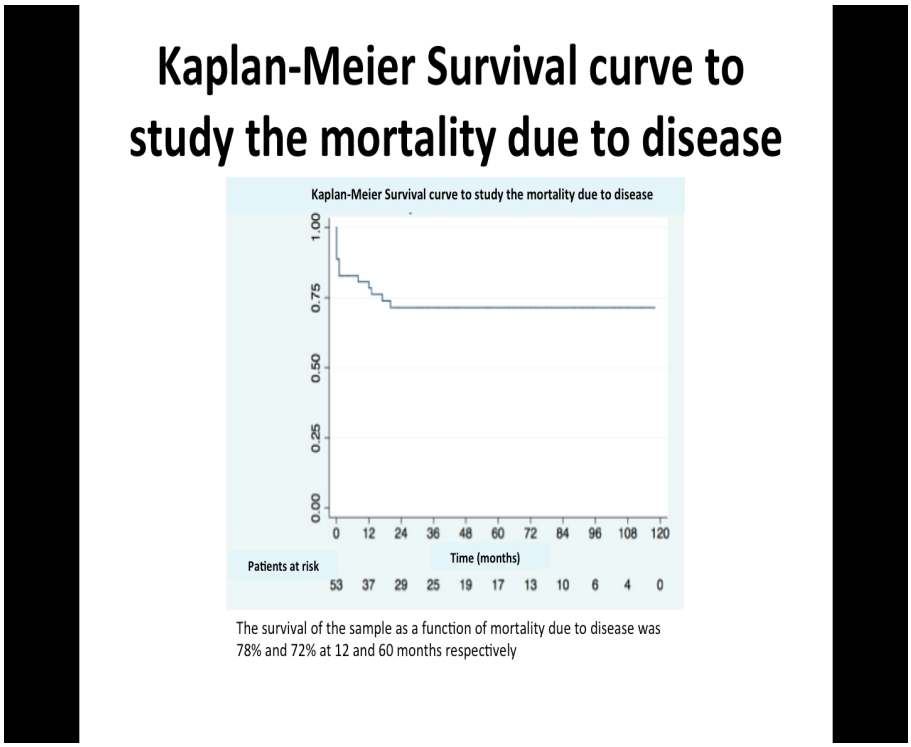
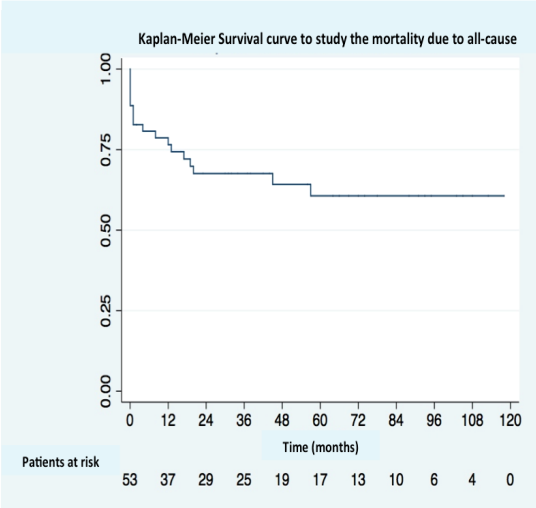
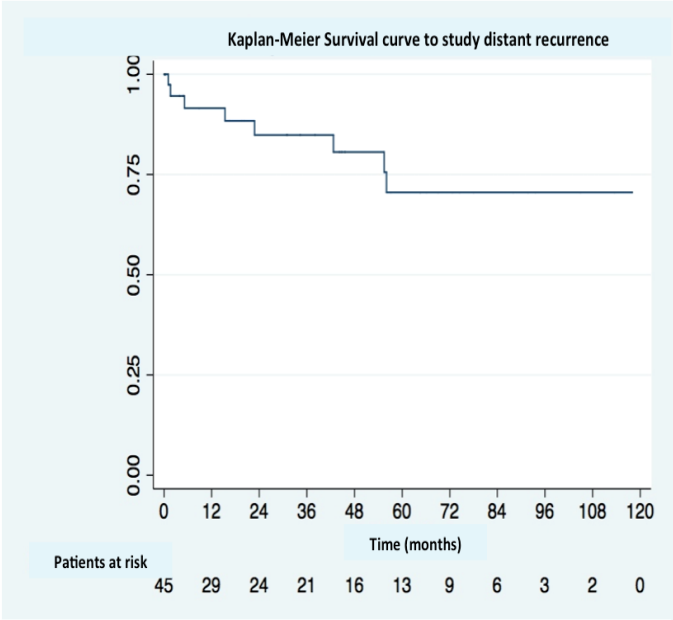


Fig. 1. Kaplan-Meier survival curve analysis of mortality due to disease.



The overall survival of the sample for all-cause mortality was 77% and 61% at 12 and 60 months respectively.

Fig. 2. Kaplan-Meier survival curve analysis of mortality due to all-causes.



The stimate of the probability without distant recurrence was 92% and 71% at 12 and 60 months respectively

Fig. 3. Kaplan-Meier survival curve analysis of distant recurrence.