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Conditional Survival Analysis of Metastatic Colorectal Cancer Patients Living 24 Months: A Single Institutional Study

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Abstract

Objectives—The survival of patients with metastatic colorectal cancer (CRC) has been increasing over recent decades due to improvements in chemotherapy and surgery. There is a need to refine prognostic information to more accurately predict survival as patients survive for any given length of time to assist multi-disciplinary cancer management teams in treatment decisions.

Methods—We performed a single center retrospective analysis of patients treated with metastatic CRC (unresectable and resectable) who survived >24 months between 2005 and 2015 (N = 155). Patient tumor and treatment related variables were collected. Overall survival (OS) estimates conditional on surviving >24 months were compared with actuarial survival estimates of a cohort of patients (33,104 resected, 39,382 unresected) from the National Cancer Database (NCDB).

Results—With a median follow up of 44.2 months, the median OS of resected patients (n=86) was not reached. The median OS of unresected patients was 75.9 months. The conditional survival probabilities of living 1, 2 or 3 years longer after 24 months of survival are 92%, 72% and 52% respectively in unresectable patients and 98%, 92% and 89% in patients who were resected. The corresponding NCDB 1,2 and 3 year actuarial survival was 38%, 20%, and 11% for unresected patients and 68%, 46%, and 32% for resected.

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Conclusions—These results indicate that CRC patients who survive 24 months with metastatic colorectal cancer have an excellent prognosis and surgery may be appropriate in a subset of patients initially deemed unresectable.

INTRODUCTION

Colorectal cancer (CRC) remains a significant public health burden in the United States as it is the second and third most common cause of cancer related death for men and women respectively¹. There are approximately 95,520 new cases of CRC in the US annually and over half of these go on to develop metastatic disease¹. The management of metastatic CRC has evolved rapidly over the past several decades from single agent 5-fluorouracil in the 1980's to multimodality therapy. This improvement in CRC management is due to advancements in systemic and liver directed therapies in addition to the appropriate/well-timed/well-placed employment of metastasectomy. For example, in the unresectable setting, we have observed median survivals in the single agent floupyrimidine setting increase from 12 to 30 months with multi-agent therapy^{5,6}. Another factor that is driving these changes is a greater appreciation for the large heterogeneity in biology across these patients³. It has even been suggested that a new staging system is needed for patients with metastatic CRC⁴.

As these management changes have evolved so have patient outcomes. Overall survival rates for patients with both unresectable and resectable metastatic disease have been steadily increasing. In the resectable setting, the 5-year survival rates have increased from 22–35% during the 1980s and 1990s to as high as 58% in more modern series^{7–10}. Surgical interventions have improved outcomes for metastatic CRC, and surgical resection is now a standard of care for patients with hepatic-limited metastases. The criteria for metastasectomy continue to broaden, and now can include carefully selected patients with hepatic and extrahepatic disease, including pulmonary and peritoneal disease². As such, the role for resection continues to expand to include patients with multi-focal, bilobar hepatic metastases as well as patients with extrahepatic metastases. Moreover, patients with metastatic disease limited to the peritoneal cavity are now undergoing cytoreductive surgery with hyperthermic intraperitoneal chemotherapy with improved outcomes^{11,12}. Multidisciplinary management of these cases is central to extending survival rates for these patients.

Despite the increased overall survival, the cure rates for metastatic CRC have not improved indicating that more patients are living longer with, but not being cured of, their disease, which leads to significant management challenges for clinicians in multi-disciplinary teams. It is difficult for most patients to remain on systemic chemotherapy long-term, and if a patient has stable disease over a significant period of time, the question of whether they would benefit from metastasectomy becomes more salient. As such, there is an ongoing need to better refine prognostic information in this subset of patients to assist with treatment recommendations. Conditional survival is the probability that a patient will survive X years given that he/she has survived Y years¹³. These analyses have been reported for a number of solid organ cancers including breast, colon and ovarian cancer as a means of providing a more clinically relevant estimate of risk over time^{14–16}. Here we sought to perform a

conditional survival analysis using a cohort of patients with metastatic (resected and unresected) CRC to better understand features common to long term survivors treated at a single, National Cancer Institute Comprehensive Cancer Center where multidisciplinary care is pivotal to optimal patient care.

MATERIALS and METHODS

We included all patients seen at Rutgers Cancer Institute of New Jersey with an ICD-9 code for colon or rectal cancer from January 1, 2005 until March 10, 2015, the date of IRB approval (Figure 1). We reviewed 1046 charts to find 318 patients with metastatic CRC. This was further narrowed to 155 patients with metastatic disease and documented 24 months of survival. We focused on patients who had already survived 2 years in order to make our conditional survival analysis as clinically useful as possible, as this is the median survival routinely reported for metastatic CRC patients with unresectable liver disease¹⁷. Patients were considered to have resectable disease if surgery was able to be performed to remove all clinically identifiable sites of disease seen on imaging and during surgery. In resectable patients the majority of recurrences occur in the first two years following surgery. Moreover, a previous conditional survival analysis of a large cohort of patients undergoing hepatic surgery for metastatic CRC revealed that conditional survival in the first two years goes down before going up in years 3–5 indicating that in year 3–5 after resection conditional survival has greater prognostic impact^{18,19}. Synchronous disease was defined as metastatic disease present at diagnosis, which includes patients whose metastatic disease was discovered intraoperatively. To clarify, patients were considered synchronous if there was no prior treatment for stage 1–3 disease.

We defined resected with curative intent as removal or treatment of all identifiable tumor sites. Curative surgeries included removal of the primary, metastasectomies, and cytoreduction with hyperthermic intraperitoneal chemotherapy. Index surgery was defined as the surgery performed at the time the patient presented with metastatic disease. Liver-directed therapies without surgery were not considered curative, and patients who only received liver-directed therapy for hepatic metastases were not considered as resected with curative intent. Difficult-to-classify patient charts were reviewed with all the medical authors and categorized based on these definitions.

Comparisons of proportions of events were carried out using a standard statistical test of proportions. Survival curves were computed using the Kaplan-Meier method. Median follow-up was accomplished using the reverse Kaplan-Meier method²⁰. Conditional survival curves were estimated as described in¹³. The effects of multiple covariates on overall survival was ascertained using the Cox proportional hazards survival model.

National Cancer Database Data

A retrospective review of patients with metastatic (Stage IV) colorectal cancer using the National Cancer Database (NCDB) from 2004–2015 was performed to collect survival data on resected and unresected patients. We selected colorectal cancer patients with clinical stage 4 (stage at initial diagnosis; synchronous metastases) and subgrouped them into:

1. patients who underwent resection (definitive surgery, not palliative care), n=33,104
2. patients who were not resected who may have had palliative care, n=39,382

All patients were ensured of having a single malignant primary, with the possibility of subsequent malignant or in-situ primary tumor. The NCDB is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society.

RESULTS

We collected data on patients seen at Rutgers Cancer Institute of New Jersey between 2005 and 2015 with mCRC who had survived a minimum of 24 months with documented metastatic disease (Figure 1A). The primary reason that patients were unable to undergo potentially curative surgery was the presence of unresectable disease, noted in 83% of the non-resected patients, 57/69 (Figure 1B). The remaining non-resected seventeen patients with liver-only metastatic disease either had disease that was not amenable to surgery or were elderly and/or with multiple comorbidities and were considered poor candidates for surgery. Sixteen out of these seventeen patients had liver-directed therapy. Liver-directed therapy without resection was not considered curative. There was one patient who was not resected for cure without a clearly identifiable reason. She was referred to our institution only after her disease became widespread. Liver-directed therapies included intra-operative ablation by both radiofrequency ablation and microwave ablation, selective internal radiation therapy (SIRT), transcatheter chemoembolization (TACE) and stereotactic body radiation therapy (SBRT), Table 2. A total of 21 (24%) patients in the resected group and 16 (23%) patients in the not resected group underwent liver-directed therapy.

Resection vs Non-resection

Several patient demographic, tumor and clinical variables of the unresected and resected patients are listed in Table 1. There was no difference in age between the two groups; however, there was an increased frequency of KRAS mutant patients in the non-resected group. There were slightly more men than women who were resected at 52% vs. 42%, although this was not significant ($p = 0.20$). There were similar rates of synchronous and metachronous disease in both groups.

Thirty-three patients of the total had no reported KRAS mutational status. Of the remainder, there were significantly more KRAS mutant tumors in the patients who were not resected with curative intent than in the group that was resected with curative intent (55% vs 36%, $p = 0.033$). Finally, all synchronous patients who were able to be resected with curative intent underwent primary resection except for one patient with metastatic rectal cancer who was treated with curative intent with extended right hepatectomy with plans for primary resection of the rectum by abdominal-perineal resection after chemoradiation. However, definitive surgery could not be performed secondary to ascites resulting from hepatic insufficiency. There were ten patients included with appendiceal adenocarcinoma and nine of the ten were able to be resected for cure while one was unresectable, $p = 0.0433$.

Site of Metastatic Disease

We also collected data on the initial sites of metastatic disease (Table 1 and Figure 2). We categorized patients into three groups, patients with metastatic disease to the liver only, patients with liver and extra-hepatic disease, and extra-hepatic disease only. In the patients able to be resected for cure, there were 53% with liver only disease, 1% with liver and extra-hepatic disease and 45% with extra-hepatic only disease. Additionally, Figure 2 includes biopsy proven metastatic sites that were present in one patient each; these sites include bladder, diaphragm, retroperitoneal adenopathy, umbilical adenopathy, right iliac fossa, gelatinous peritoneal material, and kidney.

In the patients who were not resected for cure, there were 27 patients (39%) with liver only disease, 13 patients (19%) with liver and extra-hepatic disease and 29 patients (42%) with extra-hepatic only disease. Lymphadenopathy, lung and peritoneal spread were the predominant types of extrahepatic disease. As expected, there were more patients with hepatic only metastatic disease who were able to be resected with curative intent.

Curative surgical, palliative chemotherapy treatment regimens and liver directed therapies are listed in Table 2. Of the 86 patients who underwent surgery, 18 patients had their metastatic disease resected simultaneously with their primary, this included patients with liver only metastases and their primary (6 patients), extrahepatic metastases and their primary (10 patients) and liver plus extrahepatic metastasis plus their primary (2 patients). Thirty-one patients had liver resection only as their index surgery. Additionally there were six patients whom underwent hepatic resection and ablation intraoperatively. Only six patients underwent HIPEC; all were categorized as resected for cure.

Chemotherapy Regimens

All patients received multiple chemotherapy regimens. The number of treatment regimens that the patients not resected for curative intent received are summarized in Table 2. Information on specific adjuvant chemotherapy regimens was not collected. Both resected and not resected patients had a median of 4 lines of chemotherapy with a range of 1 to 7 lines of treatment. We summarized the chemotherapy regimens into nine main categories. The most common chemotherapy regimen in the unresectable patients was FOLOX or CAPOX closely followed by FOLFIRI with or without biological agents including bevacizumab, cetuximab or panitumumab. 23 patients (33%) participated in clinical trials (3 participated in 2 clinical trials each).

Survival Outcomes for Resection vs Non-Resection—Figure 3 shows the Kaplan Meier overall survival estimates for the resected vs non-resected groups with 95% confidence intervals. The median follow-up time for the resected group was 47.9 months, and for the group not resected for curative intent was 40.4 months. The median overall survival (OS) for the group that was resected for cure was not reached. The median OS for the patients not resected for cure was 75.9 months (CI 95% 51.6 - undefined). Univariate and multivariate analysis for the resected and non-resected groups did not demonstrate any statistically significant covariates beyond surgical resectability (Supplemental Table S1, Supplemental Digital Content 1, <http://links.lww.com/AJCO/A253>), .

We calculated conditional survival probabilities for 1, 2 and 3 years for these patients that had survived at least two years. These results are listed in Table 3 and graphed visually in Supplemental Figure S1, Supplemental Digital Content 1, <http://links.lww.com/AJCO/A253>. We found that for resected patients the probabilities of surviving 1, 2 and 3-years (given the patient survived 24 months) were 98.1%, 92.2% and 88.8% respectively. For unresected patients the probabilities were 91.7%, 71.6 and 54.6% respectively.

National Cancer Database Comparison—To compare these conditional survival percentages to actuarial survival we turned to the National Cancer Database. We obtained overall survival on 33,104 resected and 39,382 unresected patients. The 1, 2 and 3-year actuarial survival rates for the resected patients was 68%, 46% and 32% respectively, while that of the unresected patients was 38%, 20% and 11% respectively. Figure 4 depicts the comparison between these conditional and actuarial survival data and demonstrates several important points. 1) At all three time points, the conditional survival probability is significantly greater than the actuarial survival and 2) that conditional survival diminishes rather minimally over time while that of the actuarial survival diminishes over time consistently and to a much greater extent. We also calculated the probability of surviving an additional 1 or 2 years more after surviving 36 months and found the 1 and 2 year survival for the resected group was 94% and 91%, while that of the group not resected for cure was 78% and 62%, Table 3.

DISCUSSION

The treatment of metastatic colorectal has evolved rapidly in the 21st century. Concomitant with these changes, the survival of patients has been increasing in both the resectable and unresectable settings. This is generally thought to be due to advancements in therapies such as chemotherapy and liver-directed therapies, as well as the expansive use of surgery due to broader criteria used when considering metastasectomy. Although the survival has been increasing, we are still not able to cure these patients, suggesting metastatic colorectal cancer is becoming perhaps better considered and treated as a chronic disease. As patients live longer, their probability of surviving changes, and it is no longer useful to discuss their prognosis in terms of actuarial survival from the time of diagnosis. Conditional survival analyses have, in instances like these, become more useful in determining prognosis, which in turn guides a step-wise management of patients over time.

Our conditional survival analysis of patients with metastatic CRC who have survived at least two years reveals that patients in both the resected and unresected settings have a substantially better probability of surviving 1, 2 and 3 more years when compared to their actuarial survival at the time of diagnosis. Furthermore, we found that the actuarial survival continuously decreases with each year, while the conditional survival stays relatively constant (or diminishes slightly). This is consistent with other conditional survival analyses for metastatic colorectal cancer. For example, Nathan et. al. examined a cohort of 949 patients that underwent resection of liver-only metastases and found that their actuarial survival was highest at year one and continuously decreased by year 5 with years 3–5 being 26, 24, and 22%¹⁹. Contrast this with our 1, 2 and 3-year probabilities of surviving after resection (having survived two years) of 98%, 92% and 88%. Similarly, Chang et. al.

examined CRC survival data from the Surveillance Epidemiology and End Results (SEER) database across all stages and found that for stage IV patients actuarial survival at years 3–5 from the time of diagnosis ranged between 15–5%¹⁴. Contrast this with our 1, 2 and 3-year probability of surviving without being resected given (given already survived two years) of 91%, 71.6% and 54.6%.

Our study's main limitation is that the data were from a single center and thus perhaps may not be generalizable to a larger population of patients. Our conditional survival probabilities are considerably higher for both the resected and unresected patients in comparison to those published in the studies by Nathan and Chang. Furthermore, our actuarial survival data from the NCDB is limited by patients who presented with stage IV disease at initial diagnosis. The NCDB does not collect data on performance status, chemotherapy, or recurrences and thus we could not include patients who had a metachronous presentation of metastatic disease.

These data suggest that the two-year mark is a critical threshold of selection for metastatic patients after which if they have survived, it is highly likely they will continue to live at least three more years. In support of this, the study by Nathan et. al. in resected patients reported conditional survival for patients having survived 1–5 years after surgery¹⁹ and found that for patients having survived 1 and 2 years after surgery conditional survival actually decreases, but it begins increasing for 3, 4 and 5 years indicating that patients once surviving two years begin to have increasing conditional survivals.

How these results might impact clinical management of patients remains an interesting question. Clearly more patients are alive longer with disease, and more disease management teams need to make decisions about how to manage these patients over increasing periods of time. It is tempting to speculate that an analysis like this might be used to indicate that a patient who was initially unresectable and has survived two years might benefit from metastasectomy because they have declared themselves to have a “good” disease biology. Could local therapies (such as surgery or ablation) to any remaining active disease sites extend their survival?

For example, consider a patient with liver and lung metastases at the time of diagnosis who is unresectable and undergoes 6 months of systemic chemotherapy and after this has only 2 remaining disease sites in the liver detectable on imaging. If this patient were presented at multidisciplinary meeting for suggestion of metastasectomy, the argument against this would be that this person's two year actuarial survival is 19% and so it is highly likely this patient will develop progression at other disease sites negating the benefit of removing these two remaining disease sites. On the other hand, if this same person has now survived two years, their likelihood of surviving an additional two years would be 72%, which means it is much less likely that they will progress in other sites, and the argument that they may benefit from a surgery to remove these two remaining sites is strengthened.

Alternatively, consider a patient who has undergone a resection of their liver metastatic disease and has been rendered with no evidence of disease (NED) by that operation and recurs in the liver and lung 6 months later. This patient's two year survival according to the

actuarial data in Figure 4 would be 46%, which is low enough that putting this patient through the risk of another major operation (or operations) would not be logical given the risk of recurrence. However, take that same patient who recurs 30 months later, and their two year survival is now 92%, which would argue that they are less likely to develop progression at other sites of disease and local treatment of the clinically detectable sites would make more sense. At this time this is unknown but theoretically could be investigated with a clinical trial. This is the same rationale that is used in patients undergoing surgery at the time of diagnosis who have hepatic and extrahepatic metastases where the rationale for surgery is life extending rather than potentially curative.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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(A)

(B)

Figure 1. Flow diagram of the study population (A) and rationale of patients were unable to receive surgery with curative intent (B).

Resected Patients

Not Resected Patients

Figure 2.
Initial sites of metastatic disease in 155 patients with metastatic colorectal cancer.

Figure 3.
Overall survival of 155 patients with metastatic colorectal cancer in both resected and unresected settings.

A)

B)

Figure 4:

A) Actuarial vs conditional probability of survival at 1, 2 and 3 years in resected metastatic colorectal cancer. B) Actuarial vs conditional probability of survival at 1, 2 and 3 years in unresected metastatic colorectal cancer.

Table 1.

Demographics of 155 patients with metastatic colorectal cancer.

	Resected N=86	Not Resected N=72	P value
Median Age (range)	58 years (22–77)	61 years (21–92)	0.4211
Male	46/86 (52%)	29/69 (42%)	0.2021
KRAS mutated	23/64 (36%)	33/60 (55%)	0.0330 [^]
Primary resected	85/86 (99%) [*]	59/69 (85%)	0.0026 [^]
Colon	60/86 (70%)	57/69 (83%)	0.0543
Rectal	17/86 (20%)	11/69 (16%)	0.4671
Appendiceal	9/86 (10%)	1/69 (1.4%)	0.0433 [^]
Synchronous	53/86 (62%)	39/69 (57%)	0.7534
Metachronous	33/86 (38%)	30/69 (43%)	0.6442
Median disease-free interval of metachronous patients (range)	14 months (1–72)	22 months(1–79)	N/A

[^] statistically significant by Pearson chi-square

^{*} One patient with synchronous rectal cancer was treated with curative intent with extended right hepatectomy. However definitive APR was delayed secondary to ascites related to hepatic insufficiency. ID 108

Table 2.

Curative and palliative treatment regimens for 155 metastatic colorectal cancer patients.

Index Surgeries of Patients Resected with Curative Intent (N = 86)		
Liver Resection Only	31 (36%)	
	Lobectomy	9 (10%)
	Extended hepatectomy	2 (2.3%)
	Segmentectomy	8 (9.3%)
	Wedge Resection	12 (14%)
Liver Resection + Ablation	6 (7.0%)	
Liver Resection + Extrahepatic	2 (2.3%)	
Liver Resection + Primary	6 (7.0%)	
Extrahepatic Only	29 (34%)	
	Lung	6 (7.0%)
	Intra-abdominal	23 (27%)
Extrahepatic + Primary	10 (12%)	
Liver + Extrahepatic + Primary	2 (2.3%)	
Chemotherapy Regimens in Patients Not Resected with Curative Intent (N=69)		
FOLFOX(CAPOX) based regimens +/- Biological agents	69/69 (100%)	
FOLFIRI(CAPRI) based regimens +/- Biological agents	67/69 (97%)	
5FU/LV only based regimens	6/69 (8.7%)	
Capecitabine only based regimens	32/69 (46%)	
cetuximab/ panitumumab monotherapy	20/69 (29%)	
Regorafenib	10/69 (15%)	
Irinotecan only based regimens	14/69 (20%)	
Bevacizumab combined regimens	56/69 (81%)	
Clinical trial	23/69 (33%)	

Table 3.

Conditional survival probabilities for patients with metastatic colorectal cancer.

Given survived 24 months			
Probability of an additional:	1 year	2 years	3 years
Resected	98.1	92.2	88.8
Unresectable	91.7	71.6	54.6
Given survived 36 months			
Resected	94	90.5 *	
Unresectable	78.1	61.5	
Given survived 48 months			
Resected	96.3 ^		
Unresectable	78.8		

*
1 year and 8 months^
8 months