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Yttrium-90 Radioembolization as Salvage Therapy for Colorectal Cancer With Liver Metastases

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Abstract

Yttrium-90 (⁹⁰Y) radioembolization is a treatment option for patients with metastatic colorectal cancer with unresectable liver metastases. We conducted a retrospective analysis to evaluate outcomes in 24 such patients who underwent ⁹⁰Y radioembolization. We concluded that ⁹⁰Y radioembolization is reasonable for select patients with unresectable hepatic metastases in the absence of other metastatic sites.

Background—Few patients with metastatic colorectal cancer (mCRC) are candidates for resection of their hepatic disease. Yttrium-90 (⁹⁰Y) radioembolization has promise in the treatment of unresectable mCRC. We conducted retrospective study to assess the efficacy in patients with refractory mCRC who underwent ⁹⁰Y radioembolization.

Materials and methods—Patients with unresectable mCRC with liver metastases treated at The Ohio State University were included in this analysis. Demographic data, carcinoembryonic antigen (CEA) values, observed toxicities, and information on prior therapies were collected. Response was assessed by RECIST (Response Evaluation Criteria in Solid Tumors) 1.1 criteria. Overall survival (OS) and progression-free survival (PFS) were estimated by the Kaplan-Meier method.

Results—Twenty-four patients (median age, 63 years) were included. Of the patients, 54% had extrahepatic disease; 67% had bilobar involvement. The patients had received a median of 3 prior therapies. No objective responses were observed. Five patients had a CEA response. Median PFS and OS were 3.9 months (95% CI, 2.4–4.8 months) and 8.9 months (95% CI, 4.2–16.7 months),

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Disclosure

The authors have stated that they have no conflicts of interest.

respectively. Patients older than 65 years had improved PFS (4.6 vs. 2.4 months) and OS (14 vs. 5.5 months) vs. younger patients, likely due to receipt of ^{90}Y treatment earlier in their disease course. The presence of extrahepatic disease and the absence of CEA response appeared negatively predictive of efficacy. Toxicities were expected and manageable.

Conclusion— ^{90}Y radioembolization is active in select patients with refractory mCRC and with liver metastases, and is safe and well tolerated in the elderly. In patients with extensive extrahepatic disease, ^{90}Y should be used in combination with chemotherapy. CEA may be a predictor of efficacy.

Keywords

Hepatic; Locoregional; Colorectal cancer; Y-90; Radioembolization

Introduction

Colorectal cancer is the third leading cause of cancer-related deaths in the United States.¹ The liver is the most common site of metastatic disease, with 25% of patients having detectable hepatic involvement at the time of first diagnosis.² Liver failure secondary to hepatic tumor burden is responsible for more than 90% of deaths in patients with mCRC.^{3,4} When feasible, surgical resection is the standard of care for patients with isolated hepatic metastases, with a 10-year survival rate reaching up to 17% and a median overall survival (OS) of 44 months.⁵ Unfortunately, only 10%–15% of patients with hepatic metastatic disease are candidates for surgical resection.⁶ With recent advances in chemotherapy and the development of new biologic agents that augment response rates, more patients are able to achieve sufficient reduction in tumor burden to render them potential surgical candidates after preoperative treatment. However, these patients remain in the minority, and the majority of patients will never achieve a resectable disease state despite multiple lines of systemic therapy. Thus, investigation into additional approaches to control liver metastatic disease is needed in this patient population.

Yttrium-90 (^{90}Y) radioembolization is a liver-directed therapy that has been used for more than 2 decades. The procedure is a form of brachytherapy that takes advantage of the physiologic imbalance between the blood supply to normal liver parenchyma and malignant tumor tissue. Normal liver parenchymal cells derive the majority of their nutrition from the portal venous system, whereas malignant cells, whether primary or metastatic, receive their blood supply from the hepatic artery. ^{90}Y radioembolization most commonly involves the fluoroscopic-guided injection of millions of radioactive microspheres within a lobar division of the hepatic artery. Once injected, these microspheres travel upstream and subsequently lodge within a vascular plexus that lies adjacent to a tumor. This anatomical “selectivity” allows for therapeutic doses of radiation to malignant cells, while largely sparing nearby liver parenchyma.⁷ Radioembolization for metastatic colorectal cancer (mCRC) is first given in the lobe of the liver that contains the largest tumor burden.

The role of ^{90}Y radioembolization is currently under investigation, both in the first-line setting in combination with chemotherapy and as salvage therapy. We conducted a retrospective study to evaluate the efficacy of ^{90}Y radioembolization in the salvage treatment of refractory mCRC that involves the liver.

Methods and Materials

Design

This study was a single-institution retrospective analysis of patients with mCRC treated with ^{90}Y radioembolization. The patients evaluated in this study had known refractory mCRC with liver metastases and had received ^{90}Y radioembolization at our institution between the years 2005 and 2009. All the patients had previously progressed on or were not candidates for any further standard chemotherapy and were referred to undergo radioembolization as salvage therapy, were found to be candidates for treatment, received treatment as planned, and had sufficient follow-up. ^{90}Y radioembolization was delivered via a hepatic artery catheter infusion. For patients who require treatment of both hepatic lobes, and, as per our institutional standard, this was performed sequentially for each lobe rather than simultaneously for both. Patient demographics, number and type of treatments, survival data, and follow-up were obtained from our institution's database. This study was approved by The Ohio State University Institutional Review Board.

Evaluation of Response

RECIST (Response Evaluation Criteria in Solid Tumors) 1.1⁸ was used to evaluate treatment response as assessed by computed tomography. Serial biomarkers (carcinoembryonic antigen [CEA]) were collected before and after treatment when available. The biochemical response to treatment was assessed via percentage change of CEA from baseline (the measured value before treatment). All images and biomarkers were obtained via our electronic database.

Statistical Analysis

The primary endpoint of this study was progression-free survival (PFS). Secondary endpoints included OS, radiographic response rate as defined by RECIST 1.1, and biochemical response as measured by change in CEA. PFS was defined as the time from first ^{90}Y therapy to disease progression or death, whichever occurred first. OS was defined as the time from ^{90}Y treatment to death of any cause. The patients who had not died or progressed or who were lost to follow-up were censored at the date of last visit. Median time to survival was estimated by using the Kaplan-Meier method. Confidence interval (95% CI) for survival was calculated by the Brookmeyer-Crowley method. Associations between the survival and categorical clinical outcomes were explored by the log-rank test. The Cox-regression model was used to explore any association between time to treatment and PFS (or OS). Descriptive statistics (such as mean, SD, range for continuous variables, and frequency for categorical variables) were provided to describe the patient population.

Results

Demographics

Patient demographics are summarized in Table 1. A total of 24 patients (16 men, 8 women), with a median age of 63 years (range, 35–83 years), received ^{90}Y radioembolization at our institution between February 2005 and February 2008. All of the patients had liver metastases. Thirteen (54%) patients had documented extrahepatic involvement by imaging before initiating ^{90}Y radioembolization, and 16 (67%) patients had bilobar liver disease. The median number of lines of chemotherapy before radioembolization was 3 (range, 0–7) for all patients. One patient (age, >65 years) had received no prior chemotherapy due to poor performance status. Patients age 66 years and older had received a median of 2 lines of prior systemic therapy (range, 0–7), whereas patients age 65 years and younger had received a median of 4 lines of prior systemic therapy (range, 1–5). Twenty (83%) patients received a single treatment of ^{90}Y radioembolization, whereas 4 (17%) patients received 2 sequential

treatments. All ^{90}Y radioembolization was delivered via hepatic artery catheter infusion, and the patients received doses that ranged from 11.9 to 51.4 mCi of radiation (median, 46.5 mCi).

Efficacy

There were no objective responses per RECIST 1.1. Five (21%) patients had a CEA response (Figure 1). Kaplan-Meier estimations of progression-free and overall survival are provided in Figure 2. The estimated median PFS was 3.9 months (95% CI, 2.4–4.8 months). The estimated median OS was 8.9 months (95% CI, 4.2–16.7 months).

Preliminary Predictive Factors for OS: Univariate Analysis

Preliminary predictive factors for OS by using univariate analysis are shown in Table 2. For patients aged >65 years, median OS was 14 months (95% CI, 4.8–25.1 months) vs. 5.5 months (95% CI, 2.4–NA [not available] months) for patients aged ≤65 years. There was no difference in survival for patients with CEA response vs. no CEA response (9.2 and 8.9 months, respectively). For patients with extrahepatic disease, mOS was 8.9 months (95% CI, 3.9–25.1 months) vs. 11.9 months (95% CI, 4.1–25.7 months) for patients without extrahepatic disease.

Preliminary Predictive Factors for PFS: Univariate Analysis

Preliminary predictive factors for PFS by univariate analysis are shown in Table 3. There was an association between PFS and age, with a median PFS for older patients (age, >65 years) trending better than for younger patients than 65 years of 4.6 (95% CI, 2.4–5.9 months) vs. 2.4 months (95% CI, 0.7–4.2 months). There also was a trend toward improved median PFS for patients who had a CEA response (4.8 months [95% CI, 2.4–5.9 months]) compared with CEA nonresponders (2.7 months [95% CI, 1.2–4.3 months]). The presence of extrahepatic disease resulted in shorter PFS (2.9 months [95% CI, 1.4–4.3 months] vs. 5.1 months [95% CI, 2.4–5.9 months]). There was no association between time to initiation of treatment and PFS.

Toxicity

Treatment overall was well tolerated. Toxicities were consistent with previously published data and were generally mild, easily managed with supportive care, and reversible. Two patients had gastric ulcers that required proton pump inhibitor therapy. Toxicity resolved in both patients with supportive measures without additional complications.

Discussion

Colon cancer continues to be a major therapeutic challenge despite recent breakthroughs in both our understanding of the disease and newer chemotherapy agents. Today, the 5-year OS of mCRC is <10%, with a median survival of <1 year for patients who receive standard second-line therapy.⁹ There is significant improvement in outcomes for patients who are able to undergo successful resection of limited hepatic metastases, with 5-year OS approaching 40%.¹⁰ Unfortunately, the majority of patients will never have resectable metastatic disease, and efforts to improve response rates and thereby increase resectability rates and prolong survival in this patient population are ongoing.

The addition of irinotecan¹¹ or oxaliplatin^{12,13} to 5-fluorouracil-based chemotherapy improves PFS and OS as well as response rates in patients with untreated mCRC. The addition of the anti-VEGF (vascular endothelial growth factor), monoclonal antibody bevacizumab to 5-fluorouracil plus irinotecan^{14,15} in the first-line setting and 5-fluorouracil plus oxaliplatin¹⁶ in the second-line setting provides additional OS and response benefit

(mOS, 28 months in untreated patients¹⁷ and 12.9 months in the second-line setting). For patients with KRAS wild-type tumors, targeted therapy directed against EGFR (epidermal growth factor receptor) is an additional therapeutic option. EGFR-targeted therapy with panitumumab or cetuximab improves PFS and response rates in the first-line^{18–20} and second-line settings when combined with chemotherapy.²¹ Cetuximab also improves response rate and time to progression when combined with irinotecan in patients with irinotecan-refractory mCRC.²² ⁹⁰Y radioembolization is being increasingly used in the treatment of mCRC. Although this technology is widely available, its role in mCRC still needs to be defined.

Our study is a retrospective analysis of a small number of patients treated with ⁹⁰Y radioembolization in the salvage setting. Patients in our study were heavily pretreated, with half of the patients receiving 3 or more chemotherapy regimens, and more than half of patients had extrahepatic disease, a poor prognostic factor, as shown above. There were no objective responses observed in our small patient population. This may relate to the inadequacy of RECIST to accurately assess responses in this setting. Tumor-size reduction is not expected to occur with ⁹⁰Y treatment in most instances, which makes response a difficult measure of treatment effect. The current standard for assessment of response to therapy in solid tumors, the RECIST, requires response to be assessed by using cross-sectional imaging. Various peri- and endotumoral processes can occur after ⁹⁰Y treatment, including edema, hemorrhage, and ring enhancement,²⁴ which can confound interpretation of response and may even appear consistent with progression. Adjunctive functional imaging, such as fluorine-18 fluorodeoxyglucose positron emission tomography or diffusion-weighted magnetic resonance imaging, can be used for additional clarification of response. The EASL (The European Association for the Study of Liver) response criteria^{25–27} account for tumor necrosis, which is often observed in liver tumors after local therapy and may be a more appropriate measure for response than RECIST. Future studies with this treatment modality should include both RECIST and EASL for measurement of response.

Despite a lack of objective responses, we observed survival outcomes similar to previously published studies of ⁹⁰Y radioembolization^{6,23,28} and to historic controls for second-line or higher chemotherapy.^{21,22,29} In our study population, although 67% of patients had bilobar disease, only 17% of the patients received separate treatments directed at both hepatic lobes. This observation is somewhat unexpected given that the median PFS in our patient population was sufficient to allow for treatment of both lobes in most patients. Potential explanations for this finding may include a lack of visible response by computed tomography observed in the treated lobe, which may have deterred clinicians from proceeding with a second treatment, which again highlights the limitations of conventional response criteria in the determination of efficacy of this treatment modality. It is unclear whether the lack of complete treatment in some patients with bilobar disease may have impacted the PFS observed in our patients, and interpretation is limited by the retrospective nature of this study. We did observe a trend toward improved PFS and OS in older patients, which is perhaps, in part, because older patients had ⁹⁰Y therapy earlier in their disease course, with a median of 2 prior lines of therapy compared with 4 lines for younger patients. There also was a trend toward improved PFS and OS in patients who had a treatment response in CEA and/or those who had an absence of documented extrahepatic disease. The observed relative ineffectiveness of radioembolization in patients with unresectable mCRC with liver metastases in the presence of extrahepatic disease is consistent with previously published data⁶ and argues that the use of ⁹⁰Y in this setting should be reserved for select patients with no or limited extrahepatic disease. Consideration can be given to using this modality in combination with systemic chemotherapy in patients with unresectable mCRC with liver metastases and extensive extrahepatic disease.

The interpretation of our results is limited by the retrospective nature of this study, which allows for potential biases, including selection and recall bias. Although no treated patients were excluded, no data were available on patients who were referred for ^{90}Y radioembolization but were found not to be candidates. In addition, a retrospective design raises the potential limitation of accurately and completely collecting toxicities. However, we believe that this is a minor limitation, given the large body of previously published safety data available for ^{90}Y radioembolization. Additional limitations to our study include small sample size and lack of a control population. Future studies should validate these and other results through randomized controlled trials.

Conclusion

^{90}Y radioembolization has shown evidence of activity in select patients with refractory mCRC. Analysis of our results suggest that ^{90}Y is safe and tolerable in patients >65 years of age and with limited hepatic metastatic disease. This is an important finding for a patient population that often does not tolerate systemic chemotherapy well. ^{90}Y also can be used safely in younger patients with limited hepatic metastases, particularly those who do not tolerate systemic chemotherapy. ^{90}Y therapy is appropriate single-modality therapy for patients with liver-only or liver-dominant disease. In patients with significant extrahepatic involvement, ^{90}Y therapy should be used in combination with systemic chemotherapy. Finally, CEA appears to be a useful predictor for efficacy, even in the absence of objective response by RECIST. Large randomized studies are needed to further investigate this finding.

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Clinical Practice Points

- The majority of patients with mCRC will never be candidates for hepatic metastasectomy. For these patients, ⁹⁰Y radioembolization can potentially improve outcomes, and this treatment modality is being increasingly used in mCRC.
- ⁹⁰Y radioembolization is safe and tolerable in the elderly, a patient population in which the utility of systemic chemotherapy is often limited by toxicities.
- ⁹⁰Y radioembolization is best used in patients with liver-only or liver-dominant metastatic disease. For patients with extensive extrahepatic disease, ⁹⁰Y can be used in combination with systemic chemotherapy.
- CEA response seemed to predict for efficacy of ⁹⁰Y radioembolization and could be considered as a predictive biomarker in this setting.
- There are limitations of RECIST in evaluating response to ⁹⁰Y therapy. Further studies of this treatment modality should use both RECIST and EASL criteria to assess response.

Figure 1.
Waterfall Plot of Carcinoembryonic Antigen (CEA) Response

Figure 2.
Kaplan-Meier Estimation of Progression-Free Survival and Overall Survival

Table 1

Patient Demographics

Age, No. Patients (%)	
65 y	11 (46)
>65 y	13 (54)
Age, Median (Range)	63 (35–83)
Sex, No. Patients (%)	
Men	16 (67)
Women	8 (33)
Race, No. Patients (%)	
White	22 (92)
Black	2 (8)
Extrahepatic Disease, No. Patients (%)	
Yes	13 (54)
No	11 (46)
Median No. Prior Therapies by Age Range	
65 y	4 (1–5)
>65 y	2 (0–7)
All	3 (0–7)
Liver Involvement, No. Patients (%)	
Bilobar	16 (67)
Single lobe	8 (33)

Table 2

Predictive Factors for OS

	n	Median OS (mo)	95% CI	P Value
Age				.28
65 y	11	5.5	2.4-NA	
>65 y	13	14	4.8–25.1	
CEA				.64
Elevated	12	8.9	3.5-NA	
Normal	12	9.2	4.1–18.3	
Extrahepatic Disease				.86
Yes	13	8.9	3.9–25.1	
No	11	11.9	4.1–25.7	

Abbreviations: CEA = carcinoembryonic antigen; NA = not available; OS = overall survival.

Table 3

Predictive Factors for PFS

	n	Median PFS (mo)	95% CI	P Value
Age				.052
65 y	11	2.4	0.7–4.2	
>65 y	13	4.6	2.4–5.9	
CEA				.088
Elevated	12	2.7	1.2–4.3	
Normal	12	4.8	2.4–5.9	
Extrahepatic Disease				.076
Yes	13	2.9	1.4–4.3	
No	11	5.1	2.4–5.9	

Abbreviations: CEA = carcinoembryonic antigen; PFS = progression-free survival.