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Original Research Article

Oligo Metastatic Disease Management with SBRT: A Prospective Observational Study

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Conflict of interest: Nil

Abstract

Objective: For patients with few metastases, including those in difficult-to-reach body locations, stereotactic ablative body radiation (SABR) emerges as a safe and successful treatment. Because it delivers a high dosage to the target tissue and a low dose to the surrounding tissue, stereotactic body radiation therapy (SBRT) is a promising treatment for oligometastatic illness in bone. This study aims to evaluate the treatment's effectiveness and toxicity in individuals with oligometastatic bone disease who have not previously received radiation therapy.

Methods: Patients with oligometastatic bone disease—defined as ≤3 active sites of disease—were treated with SBRT. The fractionation schedule and SBRT dose were not required per protocol. There were reports on overall survival, prostate specific antigen progression, local progression-free survival, and progression-free survival. There have also been reports of treatment-related toxicity.

Results: This study includes 126 lesions from different tumor histologies and 98 patients in total. Patients were 80.6% male and 19.4% female, with a median age of 72.8 years. 26.7 months was the median follow-up. Prostate cancer was the most prevalent histology (68.4%, 67/98). 27/30 Gy in 3 parts (27.0%, 34/126), 30 Gy in 5 fractions (16.7%, 21/126), or 30/35 Gy in 5 fractions (16.7%, 21/126) were the most often prescribed doses. Dose painting, which uses a greater dose to the gross tumor volume and a lower dose to the clinical target volume, is reflected in multiple doses each treatment regimen. For every patient (3.2%, 4/126), four patients (4.1%, 4/98) had local progression at one site. 2-year local progression-free survival (includes death without local progression) for the complete cohort Patients were 80.6% male and 19.4% female, with a median age of 72.8 years. 26.7 months was the median follow-up. Prostate cancer was the most prevalent histology (68.4%, 67/98). 27/30 Gy in 3 parts (27.0%, 34/126), 30 Gy in 5 fractions (16.7%, 21/126), or 30/35 Gy in 5 fractions (16.7%, 21/126) were the most often prescribed doses. Dose painting, which uses a greater dose to the gross tumor volume and a lower dose to the clinical target volume, is reflected in multiple doses each treatment regimen. For every patient (3.2%, 4/126), four patients (4.1%, 4/98) had local progression at one site. This study includes 126 lesions from different tumor histologies and 98 patients in total.

Conclusion: Our research demonstrates that SBRT is both efficacious and tolerable in patients with oligometastatic bone disease, which is consistent with previous research. To ascertain long-term efficacy and toxicity, larger trials are both reasonable and necessary.

Keywords: Stereotactic Ablative Body Radiation; Oligometastatic Disease; Treatment's Effectiveness; Toxicity.

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Introduction

One of the most frequent causes of referrals to radiation oncology and one of the most frequent locations of metastatic illness is bone metastases [1,2]. Historically, 2- and 3-dimensional external beam radiation treatment (RT) has been the mainstay of local therapy choices for bone metastases. However, during the past few decades, there have been significant changes to the RT technique options for managing patients with metastatic disease. In particular, bone metastases

are increasingly being treated with stereotactic body radiation therapy (SBRT) [3, 4]. The use of SBRT for oligometastatic disease (bone and nonbone) in non-small cell lung cancer [5-7], prostate cancer [8,9], and patient populations with multiple histologies has been investigated in a number of phase I/II trials over the last ten years; improvements in progression-free survival and overall survival have been reported. Additionally, the use of SBRT for spine [10–12] and nonspine metastases [13] is now supported by results from randomized trials, including recent data from the SC24 trial for painful spine metastases. This has led to its increased adoption in clinical practice for both oligometastatic and more widely metastatic disease.

Prospective data on patients with bone metastases treated with SBRT is required because SBRT has been shown to be effective in treating bone metastases. In general, patients with bone-only metastases may fare better than those with bone and visceral or central nervous system metastases [14]. However, skeletal metastatic illness is still a diverse condition, with different results depending on factors such as histology [15–17], spine versus non-spine bone site, radiation dose, oligometastatic disease category, if applicable [18], and systemic therapy regimens. Long-term prospective data from patients treated with SBRT for nonspine bone metastases are scarce, with few prospective clinical studies described, despite the rising use of SBRT for both spine and nonspine bone metastases [13,19].

Long-term results of patients treated with spine SBRT are still required because there is a documented risk of spinal compression fracture following SBRT [20, 21]. Therefore, more prospective data are required to better address long-term disease control outcomes and toxicities of bone SBRT and to provide specific outcomes based on pertinent disease characteristics and treatment details, given the common use and guideline recommendations supporting use of SBRT for spine and nonspine metastatic disease [22,23]. In this work, we provide the findings from a prospective trial of oligometastatic patients receiving SBRT for spine and nonspine bone metastases.

Materials and Methods

Patients with oligometastatic bone disease (defined as ≤3 active sites of illness, including the original disease site) who were at least 18 years old and had an Eastern Cooperative Oncology Group performance status of ≤2 were enrolled in this prospective study. Additionally, according to the agreement of the TEACHH [25] and Chow et al [24] prognostication models, patients had to have a life expectancy of more than three months. If oligometastatic lesions were found in the spine, they were to be ≤6 cm in maximal dimension and evaluable on a computed tomography (CT) or magnetic resonance imaging (MRI) scan that covered ≤3 contiguous vertebral bodies. Although each metastatic lesion did not need to be biopsied, metastatic illness had to be biopsy-proven. This study did not include patients who had previously received radiation therapy for oligometastatic lesions. Between December 2016 and May 2019, patients received care at Beth Israel Deaconess Medical Center and Brigham and Women's Hospital/Dana Farber Cancer Center. The institutional review board of Beth Israel Deaconess Medical Center and Brigham and Women's Hospital/Dana Farber Cancer Center approved this study, and all patients gave their informed permission.

All known diseases identified by the planning CT and any other diagnostic imaging were included in the gross tumor volume (GTV). The clinical target volume (CTV) for spine lesions was established in accordance with international consensus recommendations.26. The CTV for nonspine bone lesions was decided by the treating radiation oncologist and usually ranged from 5 to 20 mm. It was defined as the GTV plus areas thought to contain microscopic illness. For spine lesions, the planned target volume (PTV) was specified as a margin of 0 to 2 mm around the CTV to account for internal organ motion and treatment setup variability. According to institutional practice, the PTV in nonspine bone lesions varied between 2 and 5 mm [27–29].

According to protocol, follow-up intervals were determined. Three months after therapy, patients were first assessed using imaging (CT or MRI, depending on the treating physician). Following treatment, patients were scanned every six months for two years using imaging modalities chosen by the treating physicians. After therapy, patients were scanned every year for three to five years. It was not necessary for the imaging modality used for follow-ups to be the same as the imaging modality used for baseline imaging; however, each time point's diagnostic modality was employed for follow-up.

Radiographic advancement at treated locations was used to identify local failure. The main outcomes were progression-free survival (PFS), which included deaths as well as local, distant, and prostatic specific antigen (PSA) progression, and local progression-free survival (LPFS), which included deaths without local progression. Overall survival (OS) and PSA PFS were secondary goals. According to Prostate Cancer Clinical Trials Working Group 3 recommendations [30], PSA progression was defined as nadir plus 2 ng/mL, where nadir was the lowest reported PSA after

SBRT treatment was finished.31. A single patient may have more than one lesion. The earliest progression was used for a single patient if there were several progressions. Cox regression analysis was used for both univariate and multivariable studies.

Result

The study included 98 patients (80.6% male, 19.4% female) with 126 lesions; Table 1 summarizes the demographic data for these patients. There were 65 spine locations and 61 nonspine sites among the 126 lesions. Due to illness progression before to the start of planned SBRT, two patients withdrew soon after enrollment. The time between the initial diagnosis and the diagnosis of oligometa-static disorders is known as the "disease-free interval," and the median was 35.8 (range: 0-352.3 months). The majority of patients (75.0%; 72/96) had SBRT treatment for a single metastatic bone location, whereas 25.0% (24/96) received treatment for two to three lesions (Table 1). Prostate (69.8%; 67/96) was the most often treated main histology (Table 1). ADT was administered to most prostate cancer patients (89.6%; 60/67) along with their SBRT (defined as within 90 days of SBRT). the most typical dosage recommendations. 27/30 Gy in 3 parts (27.0%, 34/126), 30 Gy in 5 fractions (16.7%, 21/126), or 30/35 Gy in 5 fractions (16.7%, 21/126) were the most often prescribed doses. The GTV had an average BED of 55.8 Gy10, while the CTV received an average of 49.4 Gy10. All lesions had mean and median GTV volumes of 13.6 cc and 6.5 cc, respectively (range, 0.2-120.3 cc). The PTV volumes ranged from 4.1 to 338.6 cc, with a mean of 61.2 cc and a median of 49.6 cc. A second PTV (PTV2) given to a greater dose was also used for individuals treated using a dose painted method. The mean and median PTV2 volumes for these lesions were 10.6 cc and 18.2 cc, respectively (range: 0.3-174.7 cc). The mean and median GTV volumes for spine-only lesions were 12.9 cc and 6.3 cc (range, 0.2-116.3 cc), the mean and median PTV volumes were 56.5 cc and 49.7 cc (range, 6-189.7 cc), and the mean and median PTV2 volumes were 13.8 cc and 8.7 cc (range, 0.3-55.2 cc), respectively. 26.9 months was the median follow-up.

Table 1: Demographic characters of patients at baseline

Variables	**N (%)**
Gender	
Female	19 (19.4%)
Male	79 (80.6%)
Age (Years)	72.0±10.4
Number of metastatic bone sites treated with SBRT (N = 98)	
1	72 (73.4%)
2	18 (18.4%)
3	6 (6.1%)
Withdrawn	2 (2.0%)
ECOG (N = 98)	
0	65 (66.3%)
1	31 (31.6%)
2	2 (2.1%)
Diagnosis (N = 98)	
Breast Cancer	6 (6.2%)
Lung cancer	7 (7.1%)
Prostate Cancer	67 (68.4%)
Kidney Cancer	7 (7.1%)
Melanoma	2 (2.0%)
Sarcoma	1 (1.0%)
Other	8 (8.2%)
ESTRO/EORTC classification (N = 98)	
Synchronous oligometastatic disease	22 (22.4%)
Metachronous oligoprogression	11 (11.2%)
Metachronous oligorecurrence	46 (46.9%)
Induced oligoprogression	3 (3.1%)
Induced oligorecurrence	6 (6.1%)
Induced oligopersistence	2 (2.0%)
Repeat oligoprogression	4 (4.1%)
Repeat oligorecurrence	1 (1.0%)
Repeat oligopersistence	1 (1.0%)

NA	2 (2.0%)
Bone Sites Treated (N = 126)	
C-spine	5 (4.0%)
T-spine	34 (27%)
L-spine	19 (15.1%)
Sacrum	8 (6.3%)
Hip/lower limb	37 (29.4%)
Pelvis	1 (0.8%)
Rib	10 (7.9%)
Shoulder	4 (3.2%)
Skull	2 (1.6%)
Sternum	5 (4%)
Clavicle	1 (0.8%)

Table 2: Parameters at the baseline related to SBRT

Parameters	**N(%)**
Symptomatic lesion (N = 126)	
Yes	46 (36.5%)
No	80 (63.5%)
Soft tissue/paraspinal extension (N = 126)	
Yes	16 (12.6%)
No	110 (87.3%)
Epidural disease (N = 126)	
Yes	10 (7.9%)
No	116 (92.1%)
Baseline evaluation imaging (N = 126)[y]	
CT	57 (45.2%)
MRI	70 (55.6%)
PET/CT	2 (1.6%)
PSMA PET	1 (0.8%)
Dose (BED10 Gy) (N = 126)	
1 fraction	
16 (41.6)	1 (0.8%)
16/18 (41.6/50.4)	3 (2.4%)
18(50.4)	5 (4%)
18/20 (50.4/60.0)	19 (15.1%)
20 (60.0)	2 (1.6%)
3 fractions	
27 (51.3)	12 (9.5%)
27/30 (51.3/60.0)	34 (27%)
30 (60.0)	2 (1.6)
5 fractions	
22.5/30 (32.6/48.0)	2 (1.6%)
25/28.5 (37.5/44.8)	1 (0.8%)
25/30 (37.5/48.0)	2 (1.6%)
30 (48.0)	21 (16.7%)
30/33 (48.0/54.8)	1 (0.8%)
30/35 (48.0/59.5)	21(16.7%)

49 participants in the cohort of patients receiving SBRT according to protocol experienced progression, including distant, local, or PSA progression. Four of these patients (4.2%, 4/96) had local failure (Table 2). Every patient who had a local failure also had a systemic failure. 2-year OS was 87.3% (95% CI, 77.5%-93.0%), 2-year PFS (including fatalities as well as local, distant, and PSA progression) was 47.5% (95% CI, 36.2%-57.9%), and 2-year LPFS (containing death without local progression) was 84.8% (95% CI, 74.7%-91.1%).

Table 3: Summary of patients who developed local progression following stereotactic body radiation therapy

Variable	Patient A*	Patient B	Patient C	Patient D[y]
Primary cancer diagnosis	Non-small cell lung cancer	Carcinoma of the renal cells	Prostate	Prostate
Site treated on protocol	L5	L1	Left coracoid	Right acetabulum
Dose fractionation	30 Gy in 5 fractions	30 Gy in 5 fractions	30 Gy in 5 fractions	30/35 Gy in 5 fractions
Planned target volume (cm^3)	152.3	43.4	29.0	93.3/14.8
Time to local progression (mo)	20.5	7.6	30.9	30.3
*This patient was also treated to the left ilium and left acetabulum on this protocol. This patient was also treated to a sacral lesion on this protocol.				

Fatigue (10/96; 10.4%), pain or soreness (7/96; 7.3%), and nausea (5/96; 5.2%) were the most frequent treatment-related toxicities across the entire population (Table 4). Grade 3 was the highest level of toxicity encountered. Grade 3 vertebral fractures occurred in three patients, all of whom were treated with an interventional treatment. For a total of 4 fractures in 66 spine sites (6.1%), one more patient had a grade 1 fracture. With a range of 13.7 to 39.2 months, the median duration to fractures was 23.6 months.

Table 4: Postbaseline treatment-related toxicities

Toxicity	Grade 1	Grade 2	Grade 3
Patients with only nonspine lesions			
Back pain	1 (1%)		
Decreased appetite	1 (1%)		
Dermatitis	1 (1%)		
Diarrhea	1 (1%)		
Fatigue	3 (3%)		
Hoarseness/hypophonia	1 (1%)		
R sciatica pain		1 (1%)	
Rib pain		1 (1%)	
Patients with only spine lesions			
Abdominal bloating	1 (1%)		
Back pain	2 (2%)		
Diarrhea	1 (1%)		
Dry mouth	1 (1%)		
Esophagitis	2 (2%)		
Fatigue	5 (5%)		
Gastritis		1 (1%)	
Radiculitis	1 (1%)		
Vertebral fracture	1 (1%)		3 (3%)
Patients with both spine and nonspine lesions			
Back crepitus	1 (1%)		
L hip soreness	1 (1%)		
Skin induration	1 (1%)		
Skin hyperpigmentation	1 (1%)		

Some patients had multiple toxicities. The maximum-grade instance of the toxicity is noted if a patient experienced the same toxicity more than once.

Discussion

The use of SBRT in clinical practice, especially for oligometastatic disease where ablative local treatments may be carried out with curative purpose, has been demonstrated by the growing data on SBRT for spine and nonspine bone metastases. Long-term toxicities (such spinal compression fracture after spine SBRT) and the results of SBRT-treated nonspine bone metastases—of which there are few published studies—are crucial. At the sites receiving SBRT, we observed acceptable toxicity profiles and generally high rates of local control. During the study's follow-up period, only four of the 126 metastatic bone lesions treated with SBRT showed local progression. With a median of 20.4 months, PFS was likewise good in this investigation. Our findings add to the expanding corpus of research on the course of oligometastatic illness after SBRT

treatment. The effectiveness of using SBRT to treat oligometastatic (bone and nonbone) lesions in a variety of histologies has been evaluated in numerous prospective trials [4-6, 15, 17]. Although the OS benefit of adding SBRT to oligometastatic lesions was first demonstrated by the SABR-COMET study, which covered both bone and non-bone lesions and enrolled a variety of histologies, subsequent trials indicate that the therapeutic effect may differ depending on clinical parameters including histology [5, 6, 14–16]. Our study offers important disease outcome data on the more focused subset of patients with oligometastatic bone-only disease treated with various clinical (histology, location, size) and treatment factors (dose/fractionation, coverage) that differ greatly in the metastatic patient population.The effectiveness of using SBRT to treat oligometastatic (bone and nonbone) lesions in a variety of histologies has been evaluated in numerous prospective trials [4-6, 15, 17]. More prospective data on patient subpopulations with metastatic cancer will be crucial when SBRT is included into conventional therapy options for individuals with metastatic disease.

While post-SBRT spinal compression fracture is a known concern, numerous studies have shown that SBRT [10, 28, 32-34] to the spine is safe and beneficial in this regard [20, 21, 35]. About half of the lesions in our analysis were spine metastases, while the other half were nonspine bone metastases. There are very few prospective clinical studies in the literature, but several retrospective studies [36,37] reflect the latter [13, 38]. Patients with mostly non-spine painful bone metastases were randomly assigned to either single-fraction SBRT or conventional palliative RT in a recent MD Anderson randomized phase II trial, which showed a higher rate of pain response than multifraction conventional RT [13].However, due to the substantial disparities in the enrolled patient population in our study (≤3 active sites of illness, the majority of which were asymptomatic) and the primary objective of pain relief in the MD Anderson research, direct comparisons of efficacy are not feasible.

Our findings add to the expanding corpus of research describing toxicity and long-term illness outcomes among subsets of individuals treated for metastatic disease. Using SBRT. We do point out a few restrictions on our research, though. Although our inclusion of all histologies makes the results more broadly applicable, it makes it more difficult to draw firm conclusions about disease-specific outcomes, particularly for nonprostatehistologies, which were underrepresented in this group. Furthermore, a variety of systemic medication regimens that were employed in this investigation are implied by the diversity in histology. Additionally, systemic therapy regimens and the date of their initiation were not standardized because they were decided upon independently by the patients' treating physicians.

As a result, it is challenging to determine how SBRT and systemic therapy selection affect clinical results and progression. In a similar vein, a variety of radiation doses were employed in this trial, and the treating radiation oncologist made the decision on the radiation dose. Finally, we point out that the study's toxicities were recorded by doctors; the trial's patient-reported quality-of-life results will be presented separately.

Lastly, we point out that there is ongoing research on the definition of oligometastatic disease and who can benefit from ablative local therapy. Although it's uncertain how many metastatic sites can still benefit from ablative treatment, our trial included individuals with ≤3 oligometastatic bone lesions. The complexity of these clinical choices increases when one takes into account the organ systems implicated, the size of the lesions, the rate of progression, and the time it takes for metastases to develop.

Conclusion

When combined, the findings from our prospective trial offer more evidence in favor of using SBRT for patients with ≤3 lesions who had oligometastatic bone disease. Our findings showed minimal levels of physician-reported toxicity and excellent disease outcomes. More research is necessary to determine the ideal dosage, the number of lesions treated, and the factors that predict local failure in this patient population.

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