

Clinical Investigation

# Assessment of National Practice for Palliative Radiation Therapy for Bone Metastases Suggests Marked Underutilization of Single-Fraction Regimens in the United States



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## Summary

Single-fraction radiation therapy is an effective, cost-conscious means for palliating bone metastases. This study assessed trends in single-fraction treatment using the National Cancer Data Base. The analyses demonstrated that single-fraction palliative radiation therapy is significantly underutilized in the United States, identifying an area for future improvement in clinical practice.

**Purpose:** To characterize temporal trends in the application of various bone metastasis fractionations within the United States during the past decade, using the National Cancer Data Base; the primary aim was to determine whether clinical practice in the United States has changed over time to reflect the published randomized evidence and the growing movement for value-based treatment decisions.

**Patients and Methods:** The National Cancer Data Base was used to identify patients treated to osseous metastases from breast, prostate, and lung cancer. Utilization of single-fraction versus multiple-fraction radiation therapy was compared according to demographic, disease-related, and health care system details.

**Results:** We included 24,992 patients treated during the period 2005–2011 for bone metastases. Among patients treated to non-spinal/vertebral sites ( $n=9011$ ), 4.7% received 8 Gy in 1 fraction, whereas 95.3% received multiple-fraction treatment. Over time the proportion of patients receiving a single fraction of 8 Gy increased (from 3.4% in 2005 to 7.5% in 2011). Numerous independent predictors of single-fraction treatment were identified, including older age, farther travel distance for treatment, academic treatment facility, and non-private health insurance ( $P<.05$ ).

**Conclusions:** Single-fraction palliative radiation therapy regimens are significantly underutilized in current practice in the United States. Further efforts are needed to address this issue, such that evidence-based and cost-conscious care becomes more commonplace. © 2015 Elsevier Inc.

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## Introduction

Bone metastases are a common manifestation of advanced cancer, leading to pain, immobility, diminished performance status, and a decrement in quality of life in patients living with metastatic disease. The annual incidence of bone metastases cases in the United States has been estimated at more than a quarter of a million cases per year (1). The economic burden imposed by osseous metastases is therefore immense, both to the medical system from direct costs of treatment, as well as the indirect expense borne by patients and their families (2). Given the ongoing push for cost containment in health care, the treatment of metastatic bone disease has the divergent potential to yield either impressive savings if practiced in a value-conscious fashion, or a marked cost excess if it is not.

Radiation therapy is a highly effective standard therapy for painful bone metastases, with pain response rates approximating 60% to 80% (3-7). Additionally, radiation therapy may help prevent complications of osseous metastases, including fracture and injury to surrounding critical organs, such as the spinal cord. Numerous fractionation schedules exist, including 8 Gy in a single fraction, 20 Gy in 5 fractions, and 30 Gy in 10 fractions, with randomized evidence indicating equivalent effectiveness in terms of pain response (3-10). Single-fraction treatment represents the most convenient and least costly method for palliating pain from metastatic disease with radiation therapy (11, 12). Nonetheless, this approach is applied in the minority of cases worldwide, most notably in the United States, where estimates of its use remain below 10% (13-15).

Prior estimates of the frequency of application of various fractionation regimens in the United States have relied upon either institutional retrospective reports or analyses with a limited study period or population (13-15). Thus, we sought to characterize temporal trends in the application of various bone metastasis fractionations within the United States during the past decade using the National Cancer Data Base (NCDB). The primary aim was to determine whether clinical practice in the United States has changed over time to reflect the published randomized evidence and the growing movement for value-based treatment decisions. Our hypothesis was that utilization of single-fraction radiation therapy would be low, with application influenced significantly by demographic and health care system details.

## Patients and Methods

### Study design and data source

We performed a retrospective study of US national practice using the NCDB. The NCDB is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society. It contains deidentified information from approximately 70% of newly diagnosed cancers in the United States. The NCDB

contains information that is unavailable in the Surveillance, Epidemiology, and End Results database, including treatment details pertaining to radiation therapy dose, technique, and target (16). The data used in this study are derived from a deidentified NCDB file. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology used or the conclusions drawn from these data by the investigators.

### Study sample

We selected patients diagnosed with breast, prostate, or lung cancer between 2005 and 2011. Further inclusion criteria included age >18 years, receipt of photon-based external beam radiation therapy to an osseous site (ie skull, spine, ribs, pelvic bones, hip, and extremity bones), and known total dose and number of fractions. Patients treated with stereotactic body radiation therapy were excluded.

Additionally, we excluded patients with spinal/vertebral metastases in the primary analysis. This was because we could not exclude the possibility that a meaningful proportion of patients treated to a spinal/vertebral site had evidence of spinal cord compression, an exclusion criteria in Radiation Therapy Oncology Group protocol 9714, based on the data available in the NCDB (4). We anticipated that this factor could significantly impact the choice of fractionation and thereby confound the analyses. Sensitivity analyses including patients with spinal/vertebral metastases were performed.

Several additional exclusion criteria relating to details of radiation therapy were used to reduce the potential for misclassification due to miscoding during data submission to the NCDB. For this reason, patients reported to have received  $\leq 4$  Gy,  $\geq 50$  Gy, and/or  $\geq 30$  fractions were excluded. Additionally, patients receiving dose fractionations that were delivered to fewer than 200 patients were excluded, given that this could represent either miscoding or incomplete radiation therapy courses without a proper record of the intended dose prescription.

The NCDB only records the first course of radiation therapy related to a patient's specific cancer diagnosis. Thus, patients with prior radiation therapy preceding treatment of a bone metastasis from the same cancer diagnosis (eg whole-breast radiation therapy with subsequent bone metastasis treatment) are not captured in this sample. Similarly, patients' subsequent radiation therapy courses are not recorded in the NCDB.

### Construction of variables

Radiation therapy dose fractionation was defined by total dose, number of fractions, and dose per fraction. The latter was defined by dividing total dose by the number of fractions received. Fractionation was classified as single-fraction radiation therapy (SF-RT) versus multiple-

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