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Impact of National Comprehensive Cancer Network Guidelines Inclusion of Level 1 Evidence on Insurance Denial for Randomized Controlled Trial Patients with Metastatic Spine Disease

Authors: Ulysses G. Gardner Jr, Melissa M. Brately, Raed Zuhour, Yilun Sun, Daniel E. Spratt, Shearwood McClelland III

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Impact of National Comprehensive Cancer Network Guidelines Inclusion of Level 1 Evidence on Insurance Denial for Randomized Controlled Trial Patients with Metastatic Spine Disease

Running title: NCCN Guidelines and Clinical Trial Insurance Approval

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Ulysses G. Gardner Jr¹, Melissa M. Brately², Raed J. Zuhour², Yilun Sun², Daniel E. Spratt², Shearwood McClelland III^{2,3}

¹*Department of Radiation Oncology and Molecular Radiation Sciences, The Johns Hopkins Hospital, Baltimore, United States*

²*Department of Radiation Oncology, University Hospitals Seidman Cancer Center, Case Western Reserve University School of Medicine, Cleveland, OH, United States*

³*Department of Neurological Surgery, University Hospitals Seidman Cancer Center, Case Western Reserve University School of Medicine, Cleveland, OH, United States*

Corresponding Author: Shearwood McClelland III, MD, 11100 Euclid Avenue, Cleveland, OH 44106, United States; e-mail: drwood@post.harvard.edu

Abstract

Background: The primary treatment of metastatic spine disease is radiation therapy (RT), traditionally conventional external beam RT (EBRT) or stereotactic body RT (SBRT). Until recently, there had been no Level 1 evidence supporting SBRT over EBRT, which has led to difficulties obtaining insurance approval. Publication of the first randomized controlled trial (RCT) comparing SBRT to EBRT for spine metastases [Canadian Cancer Trials Group (CCTG)] helped change this. The results showed superiority of SBRT in pain response; however, the results were not cited by The National Comprehensive Cancer Network (NCCN) until March 24,

2023. We present results from an ongoing RCT to assess the impact of this NCCN inclusion on insurance denials for trial-eligible patients.

Materials and methods: The ongoing SPORTSMEN RCT randomizes metastatic spine cancer patients to SBRT versus EBRT. Trial-eligible patients during the first six months were examined to assess if SBRT was denied by insurance before March 24, 2023, versus afterwards. Fisher's exact test was used to assess for statistical significance.

Results: Prior to CCTG NCCN inclusion, 25% of 12 trial-eligible patients experienced SBRT insurance denial. Following NCCN inclusion, of 8 patients, one (12.5%) has undergone insurance denial of SBRT. These differences were not statistically significant.

Conclusions: The inclusion of Level 1 evidence in the NCCN guidelines has resulted in a numerical halving of spine SBRT insurance denials on a RCT, with the small sample size likely the largest culprit of not meeting statistical significance. These findings illustrate the importance of generating high-quality evidence, followed by timely inclusion into the NCCN guidelines.

Key words: spine metastases; stereotactic body radiation therapy; NCCN; insurance; clinical trials

Introduction

The National Comprehensive Cancer Network (NCCN) produces broad clinical practice guidelines that are evidence-based to help inform clinicians in the best-practices for prevention, diagnosis, and management of benign and malignant neoplasms. These clinical guidelines are derived from the latest data available and are updated on a continual basis to provide optimal care and outcomes for patients. The published NCCN Guidelines and compendia are widely regarded in clinical practice as standard-of care recommendations and processes that provide algorithms and flow diagrams for standardized clinical decision making [1]. As such, many public and private payers [i.e. Centers for Medicare & Medicaid Services (CMS) and United Healthcare (UHC)] base their coverage determination of oncologic therapeutics and management on NCCN Guidelines [2]. The NCCN Radiation Therapy Compendium includes recommendations based on the clinical scenario and disease-specific etiology and is a reference for radiation oncology coverage [3], including payment authorization of radiation therapy in the treatment paradigm of primary and metastatic cancer.

The primary treatment of metastatic spine disease has involved radiation therapy, traditionally conventional external beam radiation therapy (EBRT) or, more recently, spine radiosurgery/stereotactic body radiation therapy (SBRT). However, until recently, there had been no Level 1 evidence supporting SBRT over EBRT for these patients, which has led to difficulties in obtaining insurance approval for SBRT over EBRT in some instances. Completion and publication of the first published phase 2/3 randomized controlled trial (RCT) comparing SBRT to EBRT for symptomatic spine metastases [Canadian Cancer Trials Group (CCTG) [4]] helped change this in June 2021. The results of this RCT showed superiority of SBRT over EBRT in complete pain response; however, the results of this trial were not cited in the NCCN Guidelines until March 24, 2023 [5]. We present results from an ongoing comparative spine radiation therapy RCT to assess the impact of this NCCN inclusion on insurance denials for trial-eligible patients. To our knowledge, we are the first to report on the reductions in insurance denials after inclusion of Level 1 evidence in NCCN guidelines.

Materials and methods

The ongoing Spine Patient Optimal Radiosurgery Treatment for Symptomatic MEtastatic Neoplasms (SPORTSMEN) phase II randomized clinical trial (NCT05617716 on clinicaltrials.gov) [6] began enrollment in January 2023 with randomization of symptomatic metastatic spine cancer patients to spine SBRT versus EBRT. Trial-eligible patients during the first six months of enrollment were examined to assess whether the option of SBRT was denied by their insurance. A six-month time interval was selected to provide an equivalent time period prior to and post NCCN update of guidelines. The rate of insurance denial before March 24, 2023, versus afterwards was assessed and compared to examine the impact of NCCN inclusion of the CCTG RCT on insurance denial. Fisher's exact test was used to assess for statistical significance, set at $p < 0.05$.

Results

Prior to CCTG NCCN inclusion, of 12 trial-eligible patients, three (25%) experienced SBRT insurance denial. Following NCCN inclusion, of 8 trial-eligible patients, one (12.5%) has undergone insurance denial of SBRT. These differences were not statistically significant.

Discussion

The NCCN guidelines are used to determine whether a particular treatment is medically necessary and appropriate for a patient's condition and the nation's largest health payer and largest private payer, CMS and UHC, respectively, base their coverage determination on NCCN recommendations.(7) (8) Other large payers and guarantors, such as Aetna, Blue Cross/Blue Shield, and Humana, also rely on NCCN for appropriateness of oncology treatments [9–11]. The NCCN provides independent recommendations for cancer treatments based on “real-time update with rapid advancements in cancer research [12]”, although in this instance there was an almost 2-year interval before the CCTG RCT data was included as supporting data in published NCCN Guidelines and compendia. The current recommendations for metastatic spine tumors include SBRT, with common fractionations now including 24 Gy in 2 fractions as per CCTG RCT with the included citation [5].

The results of this review of the SPORTSMEN RCT indicate the importance of inclusion of Level 1 evidence into NCCN Guidelines to inform clinical decision making and for the approval of insurance authorizations to ensure patients are getting the best care available. Prior authorization requests are often required for insurance approval for specialized radiotherapy techniques [i.e. intensity-modulated radiation therapy (IMRT), proton beam therapy (PBT), image-guided radiation therapy (IGRT) and SBRT] in the setting of comparable conventional treatment options to determine necessity and clinical benefit. Clinicians often reference high-level evidence in support of their clinical decision as rationale to obtain approval for the preferred treatment option. Insurance companies have their own policies and criteria for approving treatments; however, many of the largest companies reference the NCCN to determine if the cited references are supported by the network.

A limitation of this review is a small sample size of only 20 patients, which likely affects the power, statistical value and confidence level, playing a large role in our findings not reaching defined criteria for significance ($p < 0.05$). Future directions include an update to this review as more institutions open SPORTSMEN and accrual continues with patients randomized to the SBRT arm requiring insurance approval to determine the significance of NCCN guidelines on insurance approval.

Conclusions

The inclusion of Level 1 evidence in the NCCN guidelines for treatment of metastatic spine disease has resulted in a numerical halving of spine SBRT insurance denials (25% to 12.5%) on an ongoing RCT, with the small sample size likely the largest culprit of this difference not meeting statistical significance. These findings illustrate the importance of generating and publishing high-quality evidence, followed by timely inclusion of this evidence into the NCCN guidelines. Such timely inclusion optimizes the likelihood of patients receiving insurance approval for optimal care.

The SPORTSMEN trial was reviewed and approved by the University Hospitals Seidman Cancer Center Institutional Review Board; ethical approval was otherwise not necessary for the preparation of this article.

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Conflicts of interest

Dr. Gardner receives research funding from the National Institutes of Health (R01 CA237005-05S1). Dr. Spratt receives research funding from the National Institutes of Health and the Prostate Cancer Foundation and receives personal fees from Astellas, AstraZeneca, Bayer, BlueEarth, Boston Scientific, Elekta, GT Medical Technologies Inc., Myovant, Pfizer, Janssen, Novartis, and Varian. Dr. McClelland receives research funding from the National Institutes of Health (National Cancer for Advancing Translational Sciences), University Hospitals Minority Faculty Career Development Award, the Robert Winn Diversity in Clinical Trials Career Development Award (sponsored by the Bristol Myers Squibb Foundation), the Gilead Sciences Research Scholars Program in Solid Tumors Award, the Radiation Oncology Institute, and the Susan G Komen Career Catalyst Research Grant. No other author has any conflicts of interest.

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Author contributions

Conception and design: S.McC.; data collection: M.B., R.Z., Y.S., S.McC.; data analysis and interpretation: U.G.G., S.McC., D.E.S.; manuscript writing: U.G.G., S.McC.; final approval of manuscript: U.G.G., M.B., R.Z., Y.S., D.E.S., S.McC.

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