SBRS to Manage Painful Bone Metastases: The Challenges Ahead

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The authors have provided a concise review of stereotactic body radiosurgery (SBRS) in the treatment of mainly spinal/paraspinal metastases. This technique was primarily developed to treat spinal metastases in the reirradiation scenario given that treatment alternatives are limited for these patients and that—in the setting of advanced metastatic disease—surgical decompression is often not a suitable option.

SBRS for spinal metastases was first described in 1995 by Hamilton et al.[1] He developed an invasive stereotactic body frame to treat five previously irradiated patients with SBRS. This type of invasive frame is no longer required, given the capacity for image-guided radiotherapy, sophisticated noninvasive immobilization devices, and modern treatment planning software and equipment that allow for image-guided intensity-modulated radiation delivery. As a result of these technologic innovations, SBRS as a field within radiation oncology is emerging into the community as an acceptable and achievable practice.

SBRS for spinal metastases has now been extended to the treatment of unirradiated spinal metastases, and in the postoperative setting, with the aim of replacing conventional radiotherapy techniques and dose fractionation. However, as the authors point out, it is unknown whether this approach is of significant benefit as compared to conventional radiotherapy.

Literature Limitations

The current evidence for SBRS to spinal bone metastases is limited to retrospective reviews and a few phase I/II studies. No true dose-escalation phase I study has yet been conducted; much of the literature is limited to feasibility studies, and prospective/retrospective cohort studies. The published literature encompasses significant heterogeneity in terms of the prescribed dose and fractionation, contouring of the target volume (an anatomic margin beyond the gross tumor[2] vs the gross tumor volume alone[3]), and the reporting of dosimetric measures to describe the actual dose delivered (given that tumor at the spinal cord interface will be relatively underdosed in order to respect the cord radiation dose limits). Even with a uniform approach to treatment planning and doses delivered, identification and standardization of outcome measures is the major barrier to interpreting the spinal SBRS literature.

Based on the current SBRS literature, specific outcome measures for pain and local control have been inconsistently reported upon or unspecified.[1,2,4-13] Furthermore, the definition of local control has varied between imaging-based criteria alone, symptomatic benefit alone, or a combination of the two. This has also been the problem in the conventional external-beam radiotherapy literature evaluating potential clinical benefits for palliative radiotherapy, as different conclusions can arise when different endpoints are used. The International Bone Metastases Consensus Working Group identified key issues relating to palliative endpoints and published their recommendations[14] with the aim of standardizing the approach to the evaluation of pain outcomes to allow meaningful comparisons across radiotherapy trials. SBRS investigators should also standardize their outcome measures, especially as we are in the development phase of this technique with no multicenter trial yet conducted.
SBRS data indicate efficacy for pain relief with minimal toxicity, and much of the literature includes patients who have been previously irradiated. However, the same conclusion was claimed in the reported retreatment trials using conventional external-beam radiotherapy.[15-17] Only a randomized study will resolve whether the use of SBRS over conventional radiotherapy is warranted and justifies the risks associated with doses of 20–24 Gy in a single fraction to 24–35 Gy in three to five fractions, given the potential for spinal cord damage. Radiation-induced myelopathy has already been reported and represents an unacceptable complication, especially for patients in the palliative setting.[10, 18-20]

**Palliative Care Considerations**

Pain control and improved quality of life are paramount goals and suitable endpoints for clinical trials in the palliative care population given that the rate of progression to malignant epidural spinal cord compression with conventional fractionation is still approximately 6% based on reports from randomized data,[21] and for the most part these palliative patients cannot return for consecutive magnetic resonance imaging scans. Therefore, tumor response by imaging alone may not be the right measure on which to base efficacy. At best, imaging response can serve as a surrogate endpoint for efficacy but needs to be translated into corresponding improvement in symptoms and quality of life in order to justify this labor-intensive and costly treatment option when conventional radiotherapy is still an option.

A bone metastases-specific quality-of-life instrument should also be employed to document the benefits of such treatment from a patient perspective. A bone metastasis module developed with the European Organisation for Research and Treatment of Cancer (EORTC) is currently undergoing international validation (EORTC QLQ-BM22) as a new specific quality-of-life tool.[22] This tool may be useful in determining the true benefit of spinal SBRS, and should be used in the design of randomized studies as the measure of efficacy.

**Concluding Remarks**

As yet, no dose-response relationship has been demonstrated with conventional external-beam radiotherapy fractionation in the treatment of painful bone metastases, based on randomized data and meta-analysis.[21] It remains to be seen if the contrary is true for SBRS, as the delivered dose is significantly greater than doses previously tested. It remains controversial whether or not the biologic effectiveness is greater with high biologic equivalent dose hypofractionated radiotherapy. Only a phase III randomized study will answer this question.

SBRS has the theoretical advantage of utilizing the latest technologic advances, which may lead to less toxicity given the ability to conform radiotherapy away from organs at risk. However, the technique first needs to undergo vigorous clinical testing in the form of clinical trials with a standardized approach to outcomes before it can be considered a standard treatment option.

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The main article can be found here: [Stereotactic Body Radiotherapy in the Management of Painful Bone Metastases](http://www.physicianspractice.com)

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