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RTOG 0631 Phase II/III Study of Image-Guided Stereotactic Radiosurgery for Localized (1-3) Spine Metastases: Phase II Results

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Abstract

Purpose—The phase II component of RTOG 0631 assessed the feasibility and safety of spine radiosurgery (SRS) for localized spine metastases in a cooperative group setting.

Materials and Methods—Patients with 1-3 spine metastasis with a Numerical Rating Pain Scale (NRPS) score ≥ 5 received 16 Gy single fraction SRS. The primary endpoint was SRS feasibility: image-guidance RT (IGRT) targeting accuracy ≤ 2mm, target volume coverage > 90% of prescription dose, maintaining spinal cord dose constraints (10 Gy to ≤ 10% of the cord volume from 5-6mm above to 5-6mm below the target or absolute spinal cord volume < 0.35cc) and other normal tissue dose constraints. A feasibility success rate < 70% was considered unacceptable for continuation of the phase III component. Based on the one-sample exact binomial test with α=0.10

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(1-sided), 41 patients were required. Acute toxicity was assessed using the National Cancer Institute Common Toxicity Criteria for Adverse Events, version 3.0.

Results—Sixty-five institutions were credentialed with spine phantom dosimetry and IGRT compliance. Forty-six patients were accrued, and 44 were eligible. There were 4 cervical, 21 thoracic and 19 lumbar sites. Median NRPS was 7 at presentation. Final pre-treatment rapid review was approved in 100%. Accuracy of image-guided SRS targeting was in compliance with the protocol in 95%. The target coverage and spinal cord dose constraint were in accordance with the protocol requirements in 100% and 97%. Overall compliance for other normal tissue constraints was per protocol in 74%. There were no cases of grade 4-5 acute treatment-related toxicity.

Conclusion—The phase II results demonstrate the feasibility and accurate use of SRS to treat spinal metastases, with rigorous quality control, in a cooperative group setting. The planned RTOG 0631 phase III component will proceed to compare pain relief and quality of life between SRS and external beam radiotherapy.

INTRODUCTION

Spine metastases are a common manifestation of cancer. The primary treatment for spine metastases has been conventional external beam radiotherapy (EBRT) with the palliative goal of pain relief. It has been demonstrated that low-dose short course fractionated radiotherapy, including a single dose of 8-10 Gy, is as effective as a high-dose protracted regimen for palliation of painful bone metastases, with about one-third of patients achieving complete pain relief (1-5). However, the radiation dose-pain response has not been well established. In a subset analysis of patients with spine metastases on RTOG 9714, which randomized between 8 Gy in a single fraction and 30 Gy in 10 fractions, the pain response rate was only 51% at 3 months in both arms (3). These findings raise the question as to whether an increase in the radiation dose may improve pain control. The difficulty is that radiation dose intensification is not achievable with conventional EBRT techniques due to the dose-limiting spinal cord, which is close to the vertebral body and sometimes encased by epidural tumor.

Stereotactic radiosurgery (SRS) has emerged as a treatment option for spine metastases, precisely targeting the tumor to deliver high radiation doses but sparing the spinal cord. Clinical experience with single high dose SRS for spinal metastases demonstrated both safety and efficacy (6-10). Median time to pain relief was within 2 weeks, and there was durable pain contorl in 80-90%. Recurrence at the immediately adjacent vertebrae was less than 5% (11). As patients with oligometastasis may experience a longer survival with more effective local treatment, a prospective study of SRS for spine metastases is further warranted.

The RTOG 0631 phase II/III study was thus initiated to determine whether a more intensive radiation dose delivered by image-guided single fraction SRS could improve pain control and quality of life as compared to conventional EBRT in patients with localized spine metastases. The phase II component was performed to determine the feasibility of delivering a single 16 Gy SRS dose in the RTOG cooperative group setting.

METHOD and MATERIALS

Eligibility criteria

All patients gave written informed consent in accordance with each center's institutional review board guidelines. The eligible patients were at least 18 years old, had a Zubrod performance status of 0–2, and a proven diagnosis of primary malignancy with localized spine metastasis (a solitary spine metastasis; 2 contiguous spine levels; or up to 3 separate sites) per screening imaging study (PET, CT or MRI). Each of the separate sites may have involvement of two contiguous vertebral bodies. The pain score ≥ 5 on the Numerical Rating Pain Scale (NRPS) within one week prior to treatment was documented, as was data on pain medication use. Neurologic examination was required one week prior to registration. MRI of the involved spine was required within 4 weeks prior to trial registration. Ineligibility criteria included spine instability due to a compression fracture, > 50% loss of vertebral body height, bony retropulsion, and frank spinal cord compression causing significant neurological deficit.

Spine radiosurgery procedure

Patients were immobilized in a stable supine position that would ensure reproducibility from simulation to treatment while meeting the protocol directed image-guidence requirement. While any available image-guided radiosurgery device was permitted, the accuracy of SRS localization had to be less than 2 mm from simulation/planning to the end of treatment. With the proper immobilization, CT simulation was performed with slice thickness of ≤ 2.5-3 mm. Image fusion between MRI (gadolinium contrast T1-weighted and T2-weighted images) and simulation CT was required for delineation of both the soft tissue tumor component and the spinal cord. MRI simulation could be used. The radiosurgery target volume included the involved vertebral body, both left and right pedicles, and the gross paraspinal or epidural lesions. An epidural lesion was included in the target volume provided that there was a ≥ 3 mm gap between the spinal cord and the epidural lesion. A paraspinal mass ≤ 5 cm in the greatest dimension contiguous with spine metastasis was included. The target was not enlarged (i.e., no "margin" for presumed microscopic extension). This target volume, with no expansion, ultimately became the radiosurgery planning target volume. The prescription dose was a single dose of 16 Gy to the margin of the target volume. The treatment plan was optimal when ≥ 90% of the target volume was covered by the prescribed dose.

Partial spinal cord volume was defined from 5-6 mm above the target spine to 5-6 mm below the target spine, based on the image fusion with T2- and T1-weighted MRI with contrast. The partial spinal cord volume was adopted based on the reported clinical tolerance dose by Ryu et al (12). This relative percent volume-tolerance dose was determined by the nature of rapid dose fall-off and interpersonal variation of spinal cord diameter and position. A conventional spinal cord volume and other organs at risk were delineated according to RTOG guidelines, which required delineation of the normal tissues within 10 cm of the target volume. The spinal cord dose constraints were 1) the spine cord dose 10 Gy to no more than 10% of the partial spinal cord volume, or 2) the spinal cord dose 10 Gy to the absolute spinal cord volume less than 0.35 cc (12, 13). These constraints were applied to

each treated spine level. Radiosurgery was not recommended for any cases that did not meet the spinal cord constraints.

Quality assurance and protocol compliance criteria

In order to achieve the highest standard of spine SRS, four core methods of quality assurance were adopted with institutional credentialing of image-guided radiation therapy (IGRT) and intensity-modulated radiation therapy (IMRT), spine phantom irradiation, rapid review of the cases, and central dosimetric analysis.

Image-guidance criteria: To check the alignment of coordinate systems between imaging system and delivery system, data of pre-treatment, post-shift imaging (if applicable), and post-treatment images, including a completed IGRT spreadsheet of the shifts, were obtained by the Image-Guided Therapy Center (ITC). Setup images were compared to corresponding reference images to identify potential deviation. Optimal (per protocol) IGRT had to demonstrate a < 2 mm difference between simulation/planning and treatment, and at the end of treatment. A difference of 2-3 mm was considered acceptable (minor variation). A difference > 3 mm was considered unacceptable (major deviation).

Spine phantom study: The spine phantom was designed by the Radiological Physics Center (RPC) in accordance with the protocol. The phantom contained 4 thermoluminescent dosimeters (TLDs) in the target volume, one TLD in the heart, and radiochromic film in the sagittal and axial planes through the center of the target. Each institution had to image the phantom, develop a treatment plan, reposition the phantom and deliver treatment as if it were an actual patient. The institution submitted their treatment planning data and dose distribution electronically to the RPC, where the measured dose distributions and the institution's calculated doses were compared. TLDs were read using the RPC's standard phantom reading method (14). The film was read with a densitometer. RPC in-house software was used to convert the optical density to dose, and the film was then normalized to the TLD results. A gamma analysis was performed for an area encompassing 1 cm beyond the target volume. The credential criteria for spine phantom study were dosimetric discrepancy within 5% and targeting accuracy within 3 mm.

Rapid review—A pre-treatment rapid review of the treatment plan, contouring of the target volume, spinal cord and other normal tissues, and dosimetric information was performed prior to delivering radiosurgery. When treatment plans were not satisfactory, descriptive suggestion was provided for improvement. This review was performed by the study PI within 24 hours of planning data submission to the ITC.

Dosimetric criteria—Treatment planning images and dosimetry information were collected by the ITC. The optimal (per protocol) treatment plan was at least 90% of the target volume was covered by the prescription dose. Coverage of 80-90% was acceptable (minor variation). Coverage < 80% was unacceptable (major deviation). Exceeding dose volume limits for normal tissues by more than 2.5-5 % was a minor variation and exceeding them by more than 5 % was a major deviation. Any deviation of the spinal cord dose constraint was unacceptable.

Statistical considerations

The primary endpoint was the successful delivery of image-guided spine SRS. Successful treatment was defined as per protocol and acceptable (minor variation) according to the criteria of quality assurance and protocol compliance. Based on the results of RTOG 0236, in which 85% were successfully treated with SBRT for lung cancer, we expected a similar success rate for the spine radiosurgery. A success rate below 70% was considered unacceptable to continue the phase III component. Based on the one-sample exact binomial test with alpha 0.10 (one-sided), 41 patients was required to detect 18% relative reduction in the success rate (from 85% to 70%) with a statistical power of 0.85. Adjusting 5% to allow for patients that were found retrospectively ineligible or not evaluable, the target sample size for the phase II component was 43 patients. Radiosurgery would be deemed feasible if at least 32 evaluable patients successfully completed SRS. Acute adverse events were reported using the National Cancer Institute Common Toxicity Criteria for Adverse Events (CTCAE), version 3.0.

RESULTS

Study population

A total of 46 patients entered the study from August 2009 to March 2011. Two patients were not eligible for analysis as one did not receive the protocol treatment and the other did not complete the required IGRT images. The characteristics of the 44 eligible patients are shown in Table 1. Complete data sets of image-guidance and dosimetric data for the primary endpoint were available in 39 patients. Therefore, primary endpoint analysis was performed on these 39 patients.

Quality assurance and SRS delivery

A total of 8 spine phantoms were made available for institutional credentialing use on this trial. During the study period, 65 institutions were fully credentialed (passed the irradiated phantom dosimetry and IGRT components). The main difficulty in passing the phantom credentialing was because of the robust criteria of dosimetric discrepancy within 5% and targeting accuracy within 3 mm (± 5%/3 mm). Other causes of credentialing failure were inadequate inclusion of the treatment table in the plan calculation, and the heterogeneity correction of bone and lung.

For SRS delivery in patients, complete data sets of pre- and post-treatment image-guidance were compared. The records of two patients were not evaluable because the post-treatment imaging information was not recorded. IGRT was per protocol in 35 patients (90%), and two patients (5%) had acceptable images with minor variation. The compliance of image-guidance is summarized in Table 2.

The final approval rate for pre-treatment rapid review was 100%. At first submission, 56% of the cases were approved for SRS. For the cases that needed assistance, an additional 33% were approved at second submission. Eleven percent required further revision and was approved at the third submission. The most common cause for disapproval was high dose spillage outside of the target volume.

Central dosimetric analysis was performed by reviewing the target coverage and normal tissue constraints. Target coverage was per protocol in 74% with minor variation in 26%. The spinal cord dose constraints were per protocol in 100%. Overall compliance for other normal tissue constraints (except the spinal cord) was per protocol in 74%. The main causes were non-compliance of contouring the required nornal tissues (70%), and a small area of high dose spillage outside the target volume (30%) with minor variation. With respect to the primary endpoint, 39 patients were successfully treated with image-guided spine SRS, resulting in a success rate greater than the hypothesized rate of 80%. The quality assurance and compliance results of dosimetric evaluation are summarized in Table 2.

Safety

Acute adverse event (AE) information was reported for 33 patients. Grade 1-2 definitely, probably or possibly SRS-related AEs were reported in only 11 patients. The reported symptoms were headache, cough and palpitations (1 patient); pruritus and bone pain (1 patient); increase in back pain (4 patients); nausea (1 patient); dysphagia (1 patient); pharyngolaryngeal pain and neuropathy (1 patient); pain in extremity, motor and sensory neuropathy and dyspepsia (1 patient); and dysphagia, pain in extremity, neck and back pain (1 patient). The majority of these events were considered not directly related to spine SRS. One grade 3 possible radiosurgery-related AE (neck pain) was experienced. There were no grade 4-5 radiosurgery-related AEs.

DISCUSSION

RTOG 0631 is the first clinical trial of image-guided spine radiosurgery performed in a cooperative group setting. There are several advantages of using spine radiosurgery for painful spine metastases. First, more bone marrow may be preserved by reducing the radiation target volume compared to the large external beam radiation fields, which generally include 4 uninvolved vertebral bodies. This may help facilitate the tolerability to chemotherapy. Second, SRS is a single treatment offering convenience to the patient, and does not interfere with the ongoing chemotherapy schedules. Third, SRS is a non-invasive procedure. Finally, spine SRS has the potential to be used for non-surgical decompression in selected patients with metastatic epidural spinal cord compression (15).

The phase II component of RTOG 0631 was performed with rigorous quality assurance including institutional credentialing with spine phantom irradiation, rapid pre-treatment review of SRS cases, and central review of dosimetry and image-guidance. Overall, 66% of the phantom irradiations analyzed by the RPC passed all credentialing criteria on their first attempt (16). One of the main reasons for this moderate pass rate is that the spine phantom was assigned more stringent dosimetric and targeting accuracy (±5%/3mm) than the RPC's other IMRT phantoms (±7%/4mm for head and neck and prostate, ±5%/5mm for lung), (14). Ultimately, the strict criteria of the credentialing phantom study provided institutions with an opportunity to become familiar with the protocol prescription, image-guidance and planning procedures, likely contributing to the success of the primary feasibility endpoint, despite the complexity of spine SRS.

The process of real-time rapid review provided review of the target volumes, spinal cord and other normal tissue contouring, and the SRS plan. Through this process, investigators received SRS education as well as a higher level of confidence when performing the procedure. The only issue identified on rapid review concerned the required contouring of the other organs-at-risk, which was corrected prior to treatment. Due to the use of high-dose intensity-modulated beams, it was advised to identify all organs at risk in order to diligently monitor for any unexpected radiation distribution. Safety, although not the primary endpoint, was also addressed through review of acute toxicity (NCI CTCAE, v3). Patients tolerated SRS very well with minimal morbidity.

The results of this phase II study have paved the way to proceed with the phase III randomized clinical trial, which will compare a single dose of external beam radiation (8 Gy), building off the results of RTOG 9714, versus a single dose of SRS (16 Gy or 18 Gy), with the primary endpoint of pain control for painful spine metastases as measured by the NRPS at 3 months post-study entry (Figure 1). A radiation dose-response relationship for pain control has not been established in patients with bone metastases. There have been several randomized trials comparing the effectiveness of pain control with various regimens of fractionated external beam radiotherapy including single dose 8 Gy. Pain control rates in these trials were essentially the same regardless of the fractionation pattern (1-4). However, higher doses of radiation could not be administered for spine metastases given the risk of radiation-induced spinal cord toxicity. Thus, it is not known whether higher radiation doses may achieve better pain control from bone metastases. With the use of the advanced technology of spine SRS, much higher radiation doses may be delivered to the spinal tumor target while sparing the normal spinal cord. As such, this phase III clinical trial may provide additional biological evidence of a radiation dose response for pain control. Recent experience of single high dose spine SRS demonstrated a high pain response in patients with spine metastases; radioresistant tumors were equally responsive to a large fraction of radiosurgical dose (10, 17-19). Of note, the phase III component has been revised to allow the choice of two SRS doses, 16 Gy or 18 Gy, and to include radioresistant tumors such as melanoma, renal cell carcinoma, colon cancer and soft tissue tumors. Important secondary endpoints will include patient-reported outcomes, as measured by the Functional Assessment of Cancer Therapy-General (FACT-G); pain as measured by the Brief Pain Inventory (BPI); and health utilities as measured by the EuroQol (EQ-5D).

While our study represents the first cooperative group analysis of SRS for the treatment of painful spinal metastases, this report has rather limited information on the long-term outcome of spine radiosurgery. This phase II trial was designed to evaluate feasibility and early safety before proceeding to a large phase III effort. As such, it will also be important to analyze the long-term effects on the spinal cord and vertebral body with this approach. Of note, the spinal cord dose constraint adopted in the current study has been reported to be safe in patients who survived > 1 year after spine SRS (12). However, this will be closely monitored as will the rate of new vertebral compression fractures, which have been reported with the use of high radiosurgical doses (20). The phase III trial includes MRI follow-up studies to analyze the long-term effects of high dose radiation to the spinal cord and vertebral body.

CONCLUSION

The RTOG 0631 phase II results demonstrate the feasibility and early safety of performing single fraction image-guided SRS with rigorous QA in a cooperative group setting, and support proceeding with the planned phase III component to compare pain relief and quality of life between 16 Gy or 18 Gy single fraction SRS and 8 Gy single fraction external beam radiotherapy. In the future, image-guided SRS may become a standard of care for the management of localized spine metastases with or without spinal cord compression. As such, this ongoing clinical trial is critical to assess the utility of this emerging radiation delivery technique.

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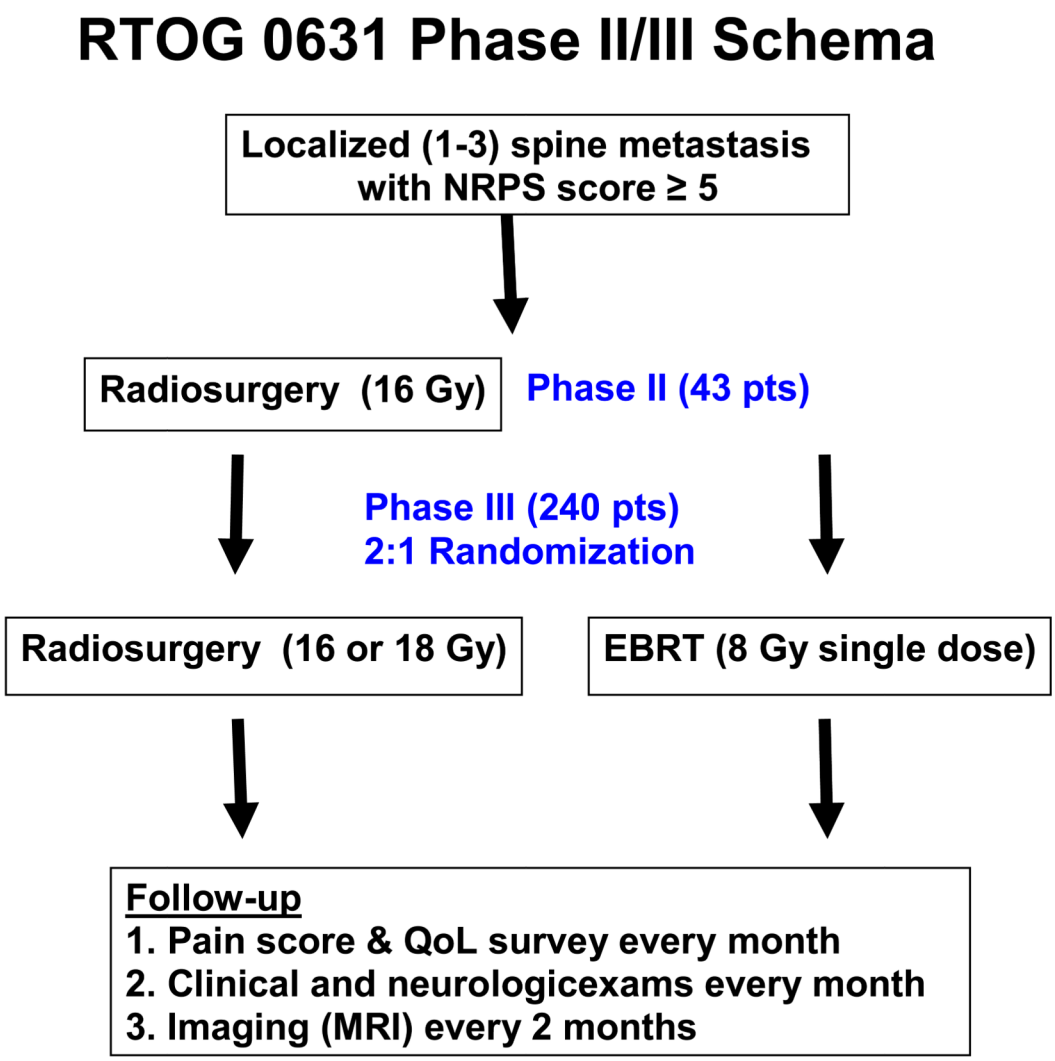

Figure 1.

Schematic illustration of the phase II/III designed RTOG 0631 study of spine radiosurgery for painful, localized spine metastasis. Abbreviations include NRPS = Numerical Rating Pain Scale; pts = patients; EBRT = external beam radiation therapy; QoL=Quality of life.

Table 1

Patient Characteristics (n=44)

Median Age: 63 Years (range 25-89)	
Gender: Male 26 (59%), Female 8 (41%)	
Median Baseline Pain Score:* 7 / 10	
Without pain medication	2 pts (5%)
With pain medication	42 pts (95%)
Zubrod Performance Status	
0	13 pts (29%)
1	25 pts (57%)
2	6 pts (14%)
Number of Spine Metastasis	
1	36 pts (82%)
2	8 pts (18%)
Location of Index Spine Metastasis	
C1 - C7	4 pts (9%)
T1 – T12	21 pts (48%)
L1 - L5	19 pts (43%)

*Pain assessed using the Numerical Rating Pain Scale (NRPS); n, number of patients; pts, patients

Table 2
Compliance to Quality Assurance (Primary Endpoint)

Image-guidance compliance (n=39)	
Per protocol	35 (90%)
Acceptable variation	2 (5%)
Not evaluable	2 (5%)
Dosimetric evaluation (n=39)	
Target coverage	
Per protocol	29 (74%)
Variation acceptable	10 (26%)
Deviation unacceptable	0 (0%)
Spinal cord constraint	
Per protocol	39 (100%)
Deviation unacceptable	0 (0%)
Other normal tissue constraints	
Per protocol	29 (74%)
Unacceptable	10 (26%)