Combination kyphoplasty and spinal radiosurgery: a new treatment paradigm for pathological fractures

PETER C. GERSZTEN, M.D., M.P.H., ANAND GERMANWALA, M.D., STEVEN A. BURTON, M.D., WILLIAM C. WELCH, M.D., CIHAT OZHASOGLU, PH.D., AND WILLIAM J. VOGEL, R.T.(T)

Departments of Neurological Surgery and Radiation Oncology, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania

Object. Patients with symptomatic pathological compression fractures require a stabilization procedure for mechanical control of back pain as well as radiation therapy for the underlying malignant process. In this study the authors evaluated a treatment paradigm of closed fracture reduction and fixation in which kyphoplasty was used, followed by single-fraction spinal radiosurgery performed with the CyberKnife.

Methods. Twenty-six patients (six men and 20 women, mean age 72 years) with histologically confirmed pathological compression fractures (16 thoracic, 10 lumbar) were prospectively evaluated. For inclusion in the study, the patients' presenting symptoms were limited to pain without neurological deficits. Histological findings included 11 lung, nine breast, and four renal carcinomas, one cholangiocarcinoma, and one ocular melanoma. All patients underwent kyphoplasty of the affected vertebral body, for which a percutaneous transpedicular procedure was used. Fiducial markers that allow image guidance for CyberKnife radiosurgery were placed into the pedicles at the adjacent levels at the time of the kyphoplasty procedure. Patients then underwent single-fraction radiosurgery (at a mean of 12 days after kyphoplasty) in an outpatient setting. The tumor dose was maintained at 16 to 20 Gy to the 80% isodose line (mean 18 Gy). Treated tumor volume ranged from 12.7 to 37.1 cm³. Axial pain improved in 24 (92%) of 26 patients during the follow-up period of 7 to 20 months.

Conclusions. A combined kyphoplasty and spinal radiosurgery treatment paradigm was found to be safe and clinically effective for patients with pathological fractures without significant spinal canal compromise. This technique combines two minimally invasive surgical procedures, thereby avoiding the morbidity associated with open surgery while providing immediate fracture fixation as well as a single-fraction tumoricidal radiation dose.

KEY WORDS • vertebral compression fracture • spinal metastases • image-guided surgery • kyphoplasty • robotic surgery • stereotactic radiosurgery

Metastatic spinal tumors affect a large number of patients each year, resulting in significant pain, destruction of the spinal column causing mechanical instability, and neurological deficits.^{8,54,55} It is estimated that in the US more than 20,000 cancer patients per year experience spinal cord or nerve root compression as a manifestation of metastatic disease. In approximately 30% of patients with cancer, symptomatic spinal metastases may develop during the course of the illness, and pain is the presenting symptom in most cases.^{13,21,52,53} The goal of the treatment of metastatic lesions involves stabilization of the spine as well as treatment of the tumor within the VB. Patients with painful pathological compression fractures require a stabilization procedure for mechanical pain control as well as radiation therapy for tumor control.

The percutaneous injection of acrylic materials into a fractured VB, called vertebroplasty, was developed in France and was first described in 1987.²³ For this proce-

dure the surgeon uses a large-bore needle to access a fractured VB percutaneously, inject bone cement, and thereby stabilize and reinforce the remaining bone structure. The procedure was first used to treat vertebral hemangiomas and was later applied to both osteolytic metastases and osteoporotic compression fractures.^{2,4,15,18,39,51} Although this method is used to treat both osteoporotic and pathological compression fractures, the majority of experience in the US so far has been with osteoporotic bone disease. Multiple observational cohort studies have been published in which the safety and efficacy of vertebroplasty has been documented.^{4,14,18,32,42,53} The primary outcomes measure for these studies has been pain reduction; in most series a greater than 90% success rate has been reported based on this outcomes measure.

The percutaneous balloon kyphoplasty procedure differs from vertebroplasty in that it attempts to address the limitation of little or no restoration of VB height with stabilization. This procedure involves the insertion of a balloon within the collapsed VB in an attempt to restore height and reduce kyphotic deformity prior to stabilization with polymethyl methacrylate.^{19,22,24,35,36,50,53} The inflatable

Abbreviations used in this paper: CT = computerized tomography; MMA = methyl methacrylate; MR = magnetic resonance; VB = vertebral body.

KyphX balloon (Kyphon, Inc., Sunnyvale, CA) is inserted through a cannula into the VB and inflated with a balloon-plasty technique, not only to create a focal cavity to fill with cement, but also to attempt reexpansion of the VB and thus regain height.²⁹ Multiple studies conducted using validated outcomes instruments support the use of kyphoplasty as both safe and effective.^{1,6,16,19,29,31,34–36,43,44} Kyphoplasty has become a safe and highly effective method for the treatment of osteolytic vertebral compression fractures that is associated with early clinical improvement of pain and function as well as some restoration of VB height.¹⁹

There has been a rapid increase in the use of radiosurgery as a treatment alternative for malignant tumors involving the spine.^{5,7,17,27,46} Recent technological developments, including imaging advancements for three-dimensional localization and pretreatment planning, the advent of intensity-modulated radiation therapy, and a higher degree of accuracy in achieving target dose conformation while sparing normal surrounding tissue have allowed clinicians to expand radiosurgery applications to treat malignant VB lesions close to the spinal cord and cauda equina. Radiosurgery delivers a large, single, highly conformal radiation dose to a localized tumor via a stereotactic approach.⁵⁴ This modality has been shown to be very effective for controlling intracranial malignancies.^{3,11,20,33,37,38,49} Stereotactic radiosurgery for tumors of the spine has been demonstrated more recently to be accurate, safe, and efficacious.^{5,7,10,17,27,30,40,41,45–47,54}

In patients with pain caused by pathological compression fractures associated with minimal spinal canal compromise, combining a kyphoplasty fracture fixation procedure followed by spinal radiosurgery would allow for the immediate stabilization of the fracture as well as for the delivery of a tumoricidal dose to control local disease progression. Both procedures are intended to help relieve the underlying pain associated with this condition, thereby improving the patient's quality of life. Our objective in this study was to assess the safety and efficacy of a combined kyphoplasty and spinal radiosurgery procedure for the treatment of painful VB compression fractures in patients with cancer.

CLINICAL MATERIAL AND METHODS

Study Protocol

This study was a prospective evaluation of 26 consecutive patients in whom pain caused by pathological compression fractures from metastatic disease was treated with closed fracture reduction by using the KyphX balloon (Kyphon, Inc., Sunnyvale, CA) to perform the kyphoplasty technique. This treatment was followed by spinal radiosurgery delivered by the CyberKnife Image-Guided Radiosurgery System with the aid of Dynamic Tracking System 3.0 software (Accuray, Inc., Sunnyvale, CA). All patients were treated at the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania, and the protocol was approved by the University of Pittsburgh's institutional review board. The study was designed to test the hypothesis that kyphoplasty followed by spinal radiosurgery is safe, feasible, and clinically effective for the treatment of pathological compression fractures.

Patient Population

The study cohort included 20 women and six men whose ages ranged from 47 to 83 years (mean 72 years). The primary cancer diagnoses included 11 lung, nine breast, and four renal carcinomas, one ocular melanoma, and one cholangiocarcinoma. Sixteen lesions were in the thoracic and 10 were in the lumbar spine. Seven lesions had previously undergone external-beam radiation treatment, with spinal cord tolerance doses that precluded any further conventional radiation therapy. Primary disease had been identified in all patients prior to the procedure. Therefore, the spinal radiosurgery was planned before the kyphoplasty procedure in all cases. Patients gave consent for the kyphoplasty procedure as well as for implantation of fiducial markers that would allow for subsequent image guidance during the radiosurgery procedure. Kyphoplasty was performed in all cases after induction of general anesthesia, as described elsewhere.^{19,21,29,35,53} There were no complications associated with the kyphoplasty procedure. After the kyphoplasty portion of the operation was completed, four to five 0.62 × 5-mm gold fiducial markers (Alpha/Omega Services, Bellflower, CA) were implanted into the adjacent pedicles both rostral and caudal to the lesion by using the same bilateral stab incisions. This technique is described elsewhere.²⁵

All patients subsequently underwent a treatment planning CT scan. The patients were placed supine in a conformal alpha cradle (Smither Products Inc., North Canton, OH) during CT scanning as well as during treatment. The CT scans were acquired using 1.25-mm-thick slices to include the lesion of interest as well as all fiducial markers.²⁸ The entire VB and any adjacent tumor extension were included within the radiosurgical treatment plan as the target volume. The patients then underwent radiosurgical treatment of the lesion. All treatments were performed using a single-fraction procedure in an outpatient setting.

RESULTS

The two procedures were successfully completed in all patients. The mean time interval between the kyphoplasty and radiosurgery procedures was 12 days. The tumor dose was maintained at 16 to 20 Gy to the 80% isodose line contoured at the edge of the target volume. The maximum intratumoral dose ranged from 20 to 25 Gy. The tumor volume ranged from 12.7 to 37.1 cm³ (mean 28.3 cm³). Follow-up duration for this patient cohort ranged from 7 to 20 months. For evaluation of pain relief, a 10-point verbal visual analog scale with intensity description was administered prior to kyphoplasty, at 1 month after radiosurgery, and at the last follow-up visit. Improvement in back pain occurred in 24 (92%) of 26 patients (Fig. 1). During a maximum follow-up period of 20 months, there were no clinically detectable neurological signs that could be attributable to acute or subacute radiation-induced spinal cord damage. Postoperative MR imaging revealed no changes indicative of radiation-induced spinal cord injury. The barium-impregnated MMA injected at the level of the treated tumor did not interfere with tracking of the fiducial markers during the radiosurgery treatment.

Sixteen of the 26 patients were found to have some

Fig. 1. Bar graph demonstrating the mean 10-point visual analog scale (VAS) pain scores in 26 patients at three time points: prior to kyphoplasty, at 1 month after radiosurgery, and at the last follow-up visit.

degree of correction of their kyphotic deformity based on plain x-ray films and the CT simulation reconstruction after the treatment. There were two patients in whom no documented pain improvement occurred. In one of the treatment failures, a 71-year-old woman with a T-12 metastasis from an ocular melanoma continued to suffer progressive kyphosis, for which she ultimately required a posterior decompressive laminectomy for progressive spinal cord compression. (The tumor had been treated with a 20-Gy dose.) In the second treatment failure, the patient was a 62-year-old woman who had a metastatic cholangiocarcinoma of the L-2 VB. Soon after treatment, the patient suffered a significant pathological fracture of her left hip. The complexity of the hip fracture precluded orthopedic surgical intervention. It was not possible for her to state whether she attained any significant relief after the kyphoplasty and radiosurgery because of poor pain control from her other fracture. Her treatment was considered to have failed.

ILLUSTRATIVE CASE

This 57-year-old woman with metastatic renal cell carcinoma (Fig. 2) reported severe axial pain through the midthoracic spine. An MR image revealed destruction of the T-6 VB with a compression fracture associated with kyphosis but without significant spinal canal compromise. She underwent a T-6 kyphoplasty procedure with a 5-cm³ injection of MMA. The patient noted significant pain relief immediately after the kyphoplasty procedure. On postoperative Day 1 she underwent a planning CT scan for the CyberKnife treatment. On postoperative Day 7 she underwent focused stereotactic radiosurgery, by which the tumor was treated with 22.5 Gy in a single fraction (18 Gy at the 80% isodose line). The lesion volume was 17.9 cm³. The maximum dose to the spinal cord was 9 Gy, and 0.02 cm³ of the spinal cord received more than 8 Gy. The patient had never undergone external-beam radiation therapy for this lesion.

DISCUSSION

The current nonsurgical treatment options for malignant spinal disease include analgesic medication, radiation therapy, hormone therapy, cytotoxic drugs, embolization, and bisphosphonates.⁴⁸ Open surgical intervention is usually reserved for patients in whom nonsurgical treatment has failed. Open surgery can be associated with significant morbidity and limited local tumor control. Conversely, radiation therapy may provide less than optimal pain relief and tumor control because the total dose is limited by the tolerance of adjacent tissues, namely the spinal cord. It often happens that pathological compression of the VB progresses after external-beam radiation therapy. Further radiation treatment will not improve the patient's pain related to mechanical instability. In recent series investigators have demonstrated a significant improvement in pain associated with cancer-related compression fractures by using percutaneous injection of MMA in VBs, using either the vertebroplasty^{15,21,51} or kyphoplasty^{19,21} procedure.

Injection of MMA into the involved VB allows for immediate stabilization of the fracture. Nevertheless, there remains the issue of treatment of the underlying tumor cells within the affected VB. The presence of these cells inhibits normal bone regrowth and subsequent fracture healing. The emerging technique of spinal radiosurgery represents a logical extension of the current state of the art in radiation therapy.^{5,7,10,17,27,30,40,41,45–47,54} It has the potential to improve local control of spinal tumors significantly. Spinal radiosurgery might also offer improved pain control and a longer duration of pain control by delivering larger radiobiological doses. Furthermore, this technique allows for the treatment of lesions that have been previously irradiated using external-beam radiation therapy. Another advantage to the patient is that radiation therapy can be completed in a single day rather than over the course of several weeks.²⁷

In this series, a combined kyphoplasty and spinal radiosurgery treatment paradigm was found to be feasible, safe, and clinically effective in patients with pathological fractures. This combination of two minimally invasive surgical procedures avoids the morbidity associated with open surgical therapy while allowing for a single-fraction tumoricidal radiation dose. Pathological fractures with significant spinal cord compromise would require open surgery and would preclude the kyphoplasty procedure. Nevertheless, at the time of open surgery, fiducial markers may be still be implanted so that a radiosurgical treatment can be delivered to the affected VB in the postoperative period.

Performing this procedure earlier in the course of the patient's disease, before there is significant VB collapse, might prevent further collapse and subsequent spinal canal compromise that would necessitate a larger open surgical intervention. Such surgeries often require instrumentation to be implanted to accomplish spinal stabilization. Open surgeries for spinal metastases are associated with significant morbidity and a high complication rate in these already debilitated patients.^{21,26} Furthermore, open surgery necessitates a postoperative recovery period that is not inconsequential for a patient with an already limited life expectancy.

Fig. 2. A: Gadolinium-enhanced axial MR image obtained in a 57-year-old woman with metastatic renal cell carcinoma, revealing a T-6 pathological compression fracture. B and C: Anteroposterior and lateral plain x-ray films showing the MMA implant following kyphoplasty. The four gold fiducial markers can be seen in the pedicles of T-5 and T-7. D and E: Axial and sagittal projections of the isodose lines of the treatment plan. The 80% isodose line represents the prescribed dose of 18 Gy, the tumor volume is 17.9 cm³, and 0.02 cm³ of the spinal cord received more than 8 Gy.

In spinal radiosurgery, the spinal cord is relatively spared from irradiation, while the tumor receives a higher dose than is possible with conventional radiation therapy.¹⁷ This approach avoids the need to irradiate large segments of the spinal cord as well as the bone marrow within adjacent VBs. It may also avoid the need to irradiate large segments of the spinal column, a procedure that is known to have a deleterious effect on bone marrow reserves in these patients. This would facilitate continuous chemotherapy for this vulnerable patient population. Ryu, et al.,⁴⁶ found a relatively rare occurrence of failure at the treated as well as at adjacent spinal segments, thereby lending support for radiosurgery targeting only to the involved single spinal segment. These authors also found that progressive pathological fracture of the treated VB was a major cause of treatment failure after radiosurgery. The placement of MMA within the VB prior to radiosurgery might very well prevent this pattern of failure.

The optimal treatment doses for spinal radiosurgery have not been determined.^{5,7,9,25,45–47} Experience with single-fraction radiation therapy of brain metastases has shown that lesions typically resistant to conventional fractionation regimens can be controlled and even obliterated when applying a large single dose of radiation.^{12,17} Similar

to their effect in the brain, doses greater than 18 Gy may be required to achieve long-term control of metastatic spinal lesions. Our experience with more than 400 single-fraction spinal radiosurgery cases has yielded encouraging results in relation to long-term control when maximum doses of 20 to 25 Gy are used.

CONCLUSIONS

In this study we have demonstrated that closed fracture reduction and fixation with MMA by using the kyphoplasty technique, followed by single-fraction CyberKnife radiosurgery, was a safe, feasible, and clinically effective treatment modality for patients with pain caused by pathological compression fractures. Our goal in using this technique is to provide good palliative effects at the specific location of disease that is causing pain and associated disability. Despite systemic therapy and even adequate local tumor control, in these patients with metastatic cancer the disease often progresses and becomes symptomatic at areas both within and outside of the spine, as seen in the two treatment failures in our series. This new paradigm plays an important role in the minimally invasive treatment of patients with symptomatic spinal metastases.

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Address reprint requests to: Peter C. Gerszten, M.D., M.P.H., Department of Neurological Surgery, Presbyterian University Hospital, Suite B-400, 200 Lothrop Street, Pittsburgh, Pennsylvania 15213. email: gersztenpc@upmc.edu.