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Kyphoplasty for Vertebral Augmentation in the Elderly With Osteoporotic Vertebral Compression Fractures: Scenarios and Review of Recent Studies

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Abstract

Background—Vertebral compression fractures caused by osteoporosis are among the most common fractures in the elderly. The treatment focuses on pain control, maintenance of independence, and management of the osteoporosis. Elderly patients often encounter adverse effects to pain medications, do not tolerate bed rest, and are not ideal candidates for invasive spinal reconstructive surgery. Percutaneous vertebral augmentation (vertebroplasty or kyphoplasty) has become popular as a less-invasive alternative. However, studies have questioned the effectiveness of these procedures.

Methods—The authors conducted a MEDLINE search using relevant search terms including osteoporosis, osteoporotic vertebral compression fracture, elderly, kyphoplasty and vertebroplasty.

Case summary/Results—Two elderly patients presented with a fracture of their third and first lumbar vertebral body, respectively. One patient progressed well with conservative treatment, whereas the other patient was hospitalized secondary to pain after conservative measures failed to offer improvement. The hospitalized patient subsequently opted for a kyphoplasty and was able to resume his normal daily activities after the procedure.

Conclusions—Selecting patients on an individual case-by-case basis can optimize the effectiveness and outcomes of a vertebral augmentation. This process includes the documentation of an osteoporotic vertebral compression fracture with the aide of imaging studies, including the acuity of the fracture as well as the correlation with the physical examination findings. Patients

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CONFLICTS OF INTEREST

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who are functional and improving under a conservative regimen are not candidates for kyphoplasty. However, if the conservative management is not successful after 4 to 6 weeks and the patient is at risk to become bedridden, an augmentation should be considered. A kyphoplasty procedure may be preferred over vertebroplasty, given the lower risk profile and better outcomes regarding spinal alignment.

Keywords

elderly; kyphoplasty; osteoporosis; vertebral augmentation; vertebral compression fracture; vertebroplasty

INTRODUCTION

The World Health Organization found that vertebral compression fractures were the most common type of osteoporotic fractures, mostly affecting the elderly.¹ In addition to pain, compression fractures also lead to additional morbidities, including an increased rate of having an additional vertebral compression fracture, height loss, kyphosis, loss of mobility, depression, and even pulmonary dysfunction.² Recent studies have shown an increased rate of mortality in the population with vertebral compression fractures. Both 4- and 5-year mortality rates in patients with compression fractures in their thoracic or lumbar spine exceeded those of patients suffering from hip fractures.³ The treatment of osteoporotic vertebral compression fractures in the elderly focuses on pain control, prevention of progression and deformity, and treatment of the underlying osteoporosis. The overall goal in this vulnerable patient population is to maintain their independence and functional status while avoiding prolonged hospitalizations and bed rest.² Several treatment options are available to achieve these goals, ranging from conservative treatment (including pain control) to invasive, reconstructive surgery (including dorsal and ventral instrumentation of the spine). Vertebral augmentation procedures, namely vertebroplasty and kyphoplasty, offer far less invasive alternatives to open-spine surgery.³ Although initial reports were very promising, recent studies have raised concerns about the effectiveness of vertebroplasty or kyphoplasty, including recommendations by some medical societies against certain types of vertebral augmentation.⁴

The objective of the present article was to discuss the controversy regarding vertebral augmentation in the context of 2 case presentations and to provide guidance to physicians about when to consider a patient for referral to be evaluated for vertebroplasty or kyphoplasty for an osteoporotic vertebral compression fracture. This article does not review or discuss the use of vertebral augmentation for metastatic disease of the spine.

METHODS

The authors conducted a MEDLINE search using relevant search terms including osteoporosis, osteoporotic vertebral compression fracture, elderly, kyphoplasty and vertebroplasty.

CASE DESCRIPTIONS

The first patient is a 74-year-old woman presenting with lower back pain without radiation and with no neurologic deficits. She has a history of chronic lower back pain. The current back pain has progressively increased in intensity, and she does not recall a trauma. The increased pain has been present for the past 3 months. Additional medical history includes breast cancer. Lumbar magnetic resonance imaging (MRI) with and without contrast revealed an acute/subacute fracture of her third lumbar vertebral body with fracture line and edema. The patient initially was prescribed hydrocodone/acetaminophen and tramadol for the ongoing pain; however, she did not have significant improvement and experienced intolerable adverse effects such as increased sedation. The patient's other medications included ibuprofen as needed (<2000 mg/d), a proton pump inhibitor, and Vitamin D. The patient was functional and able to perform her normal daily activities. Overall, her pain was improving slowly, and she decided not to escalate her oral pain medications or to proceed with a surgical intervention given her progress. At her 6-month follow-up, her lower back pain had receded to baseline levels.

The second patient is a 64-year-old man who presented with severely limited activities of daily living caused by thoracolumbar back pain present for >4 weeks after a "rough sit-down" on a chair. No neurologic deficits were noted on examination. He had a history of chronic lower back pain and successful placement of an interspinous process spacer 3 years ago to distract and open the corresponding neural foramen to decompress the spinal nerve and relieve associated leg pain. The patient's imaging studies demonstrated an acute fracture of his first lumbar vertebral body seen on plain radiographs. His pain did not improve, and the MRI obtained 5 weeks after the trauma demonstrated persisting edema and a fracture line (Figure 1). He was treated with opioids, including morphine and hydrocodone/acetaminophen and various NSAID medications, without adequate pain control. Eventually, he had to be hospitalized secondary to this persistent pain. After discussing his options and the risks, the patient decided to proceed with kyphoplasty under local anesthesia. The procedure was uneventful (Figure 2), and he was able to ambulate without braces on the day of the procedure and be discharged home. The patient's follow-up after 8 months was unremarkable.

Treatment of the underlying osteoporosis was continued by the primary care physicians of both patients.

Permission was granted by the institutional review board of the University of Texas Medical Branch (IRB 12-159). This protocol allows the retrospective review of patients treated in the Pain Clinic including publications. Patient information has to be de-identified.

DISCUSSION

Various treatment options have been described in the literature for osteoporotic vertebral compression fractures.

Conservative Treatment

Conservative treatment of vertebral compression fractures includes bed rest (along with other activity modifications), bracing, and analgesics. Patients are commonly prescribed a regimen of calcium, Vitamin D, calcitonin, and bisphosphonates with an evaluation for osteoporosis and, if warranted, possible malignancy. In the elderly population, inactivity and immobility has its own morbidities associated with increased rates of pneumonia, decubitus ulcers, venous thromboembolism, and death.² In addition, analgesics are not well tolerated in certain elderly patients, and the application of braces can be extremely troublesome due to compliance. Unfortunately, nonsurgical management commonly results in slow resolution of pain or no relief.⁵ A relatively slow resolution of pain was observed in our first patient; however, she was functional and wished to continue with conservative therapy despite experiencing adverse effects. Therefore, it was reasonable to continue with a conservative management in this patient. The second patient did not improve after several weeks of conservative management; therefore, it was appropriate to offer the patient kyphoplasty as an alternative treatment option.

Vertebral Augmentation

Historically, surgical treatment of vertebral compression fractures was very limited, with the patient having to undergo aggressive open stabilization procedures.³ This option was not acceptable for many elderly patients with multiple medical comorbidities, and these procedures have high failure rates in osteoporotic bone.³ Recently, the introduction of 2 percutaneous procedures, vertebroplasty and kyphoplasty, have provided additional modalities for treating vertebral compression fractures in the elderly population. Vertebroplasty was first described in 1987 by Galibert³ as a procedure involving the percutaneous injection of viscous polymethylmethacrylate into the fractured vertebrae. Needles are inserted through the pedicles into the body of the vertebral body under fluoroscopic guidance with the patient in the prone position. The procedure was originally attempted as a treatment for an aggressive hemangioma.

Kyphoplasty, introduced in 2001, involves the percutaneous insertion of a balloon (via the pedicles) into the fractured vertebrae; the balloon is subsequently inflated to provide a cavity in which the polymethylmethacrylate can be injected.^{3,6}

Benefits to these procedures include the ability to treat multiple fractured vertebral bodies at the same time; the procedure can be completed under sedation, thus avoiding general anesthesia; and the short operative times allow the procedure to be performed in an ambulatory setting. Patients are usually permitted to resume normal daily activities immediately after a vertebral augmentation without the need for any braces or bed rest as described in our second patient. Various risks to vertebral augmentation have also been described in the literature. Of the 2 procedures, kyphoplasty might be slightly superior to vertebroplasty in having a lower incidence of cement leakage. Cement leakages were only symptomatic in 0.01%. Spinal cord compression occurred in 0.16% of all kyphoplasties, with the overall perioperative mortality being 0.13%.^{3,6}

Comparing both techniques, it seems that kyphoplasty provides a better height restoration of the fractured vertebra and a lower risk of severe complications, including particulate embolism. Other outcome parameters (eg, improvement in pain) are negligible between techniques. The costs for kyphoplasty are higher compared with a standard vertebroplasty.^{3,6}

The majority of the current literature focuses on evaluating safety and outcomes in the elderly. Independent of the type of vertebral augmentation performed, it is generally recommended that treatment of the underlying condition (eg, osteoporosis) be established or continued.²

Vertebral Augmentation: Efficacy and Controversy

Results of studies assessing vertebroplasty and kyphoplasty compared with conservative, nonsurgical treatment without sham surgery as a control were first published in the last decade, and results were promising, demonstrating improved pain control after vertebroplasty and kyphoplasty for osteoporotic vertebral compression fractures.³ A key study supporting vertebroplasty was published in *Lancet*, which evaluated vertebroplasty versus conservative methods.⁷ The study, performed by Klazen et al, was coined the VERTOS II (Vertebroplasty Versus Conservative Treatment in Osteoporotic Vertebral Compression Fractures) trial and offered evidence that percutaneous vertebroplasty was an effective and safe treatment for osteoporotic vertebral compression fractures. They showed that not only did vertebroplasty provide immediate pain relief, but there was also a significant improvement in outcomes up to 1 year after the procedure compared with the conservative group at an acceptable cost.

Balloon kyphoplasty was compared with nonsurgical care in 2009 by Wardlaw et al⁸ in the FREE (Fracture Reduction and Evaluation Trial) study. This multicountry study evaluated the effectiveness and safety of balloon kyphoplasty and followed up patients up to 1 year postoperatively. The authors found that kyphoplasty was effective and safe in treating acute vertebral fractures. They also found improved patient outcomes at 12 months in those treated, with no significant adverse outcomes. However, given the fact that neither of the studies by Wardlaw et al or Klazen et al⁷ included a sham procedure for comparison, a placebo effect cannot be excluded in these studies.

In 2009, two papers were published in the *New England Journal of Medicine* discussing the findings from 2 separate randomized trials evaluating vertebroplasty as a treatment for vertebral fractures compared with a sham procedure. The multicenter, randomized, double-blind trial by Buchbinder et al⁹ in Australia assessed vertebroplasty versus a sham procedure in 71 participants. The patients were evaluated throughout a 6-month follow-up, and the investigators found no benefit to vertebroplasty for the treatment of osteoporotic vertebral fractures. Another trial performed by Kallmes et al¹⁰ at the Mayo Clinic evaluated 131 patients undergoing either vertebroplasty or a sham procedure. At a 3-month follow-up, the trial showed no significant improvement in pain or pain-related disability in treating osteoporotic compression fractures with vertebroplasty.

The studies by Buchbinder et al⁹ and Kallmes et al¹⁰ present a higher level of evidence, but they are not without controversy. Several issues have surfaced, including debate regarding

the imaging studies used and the correlation with the clinical examination as well as the acuity of the fractures as the sole cause of back pain. Another important critique is the amount of cement injected, which was considerably less compared with other studies, potentially rendering the vertebroplasty ineffective.^{3,6} Finally, Kallmes et al was forced to alter the inclusion criteria early in the study and lowered the visual analog scale pain rating to 3. Lower pain levels have been correlated to less improvement after vertebroplasty.¹¹

Retrospective studies using medical billing information have also added to the controversy. Edidin et al¹² compared vertebral augmentation versus conservative treatment by using Medicare data. Of note, their study was industry sponsored by a manufacturer of vertebral augmentation devices. Mortality up to 4 years was analyzed in a 100% Medicare data set (2005–2008) for patients with vertebral compression fractures. They found that survival was improved in the group undergoing a vertebral augmentation (60%) versus the nonoperated group (50%). There was no difference in comorbidities between groups. A subgroup analysis further demonstrated better survival after a kyphoplasty procedure compared with a vertebroplasty procedure (62.8% and 57.3%, respectively). The study by Edidin et al was criticized for possible selection bias. McCullough et al¹³ performed a retrospective analysis using a 20% sample of the Medicare and Medicaid billing claims data set comparing vertebral augmentation (vertebroplasty/kyphoplasty) with conservative management. Initially, they found that patients in the augmentation group had a significantly lower mortality rate, as described by Edidin et al. However, after performing a preprocedure analysis as well as a propensity analysis, mortality rates no longer differed between patients undergoing conservative management or augmentation. Furthermore, McCullough et al demonstrated that patients undergoing vertebral augmentation had a significantly higher rate of health care utilization and a higher rate of skilled nursing home admission compared with patients treated conservatively. Their group suggested that decreased mortality in patients undergoing vertebral augmentation was the result of a selection bias, with the physician selecting healthier patients for the procedure. Unfortunately, retrospective studies of billing claims, as the 2 studies discussed here, cannot provide any information about changes in pain or disability.

Recommendation for Selecting Patients

When evaluating an elderly patient with a vertebral compression fracture, several considerations should be made before proceeding with either medical management or undergoing a percutaneous intervention. The selection process is paramount, and special attention should be given to the patient's neurologic and functional status and the length of time the patient has been experiencing pain from the disease. An open surgical decompression and fixation should be emergently considered if the patient experiences neurologic deficits and/or gross deformities or instability of the spine. If there is no instability and no neurologic deficits, a conservative regimen can be suggested if tolerated by the patient and the fracture-related pain is improving. Conversely, if the fracture(s) will render the patient immobile secondary to pain, causing additional complications and loss of independence, vertebral augmentation such as a kyphoplasty early in the disease process should be considered.

The patient selection should be based both on clinical and radiologic signs. Clinical symptoms include axial back pain that can be localized to the level of the vertebral fracture seen with imaging. This method helps to ensure that the treatment is not for radicular or low back pain or in patients in whom the vertebral injury was found incidentally in an evaluation for other pain etiologies. When multiple fractures exist, it is important to identify the level most likely responsible for the symptoms the patient is experiencing. The identification of active osteoporotic vertebral compression fractures with advanced radiologic studies such as bone scans and magnetic resonance imaging (MRI) can also support the consideration of a percutaneous intervention.^{3,6} High uptake on technetium-99m hydroxydimethylpyrimidine bone scan, hyperintensity on short-time inversion recovery MRI and hypointensity on T1-weighted MRI, fracture opening on dynamic radiography, and the presence of vacuum clefts in the vertebral body on computed tomography scan implying vertebral osteonecrosis can support the choice in considering more invasive treatment of a vertebral body fracture by using 1 of these percutaneous methods.

Insurance plans, such as Medicare, provide reimbursement if there is documentation that a radiographically identified fracture exists, that the pain is caused by the fracture, and that more conservative treatment options were attempted. It is further suggested that the procedure not be performed in the emergency department, and a 12-month follow-up evaluation should be implemented.¹⁴

CONCLUSIONS

These controversial results of the current literature should be discussed with the patient, including the fact that vertebroplasty is no longer recommended by major medical societies such as the American Academy of Orthopedic Surgeons.⁵ In our experience, kyphoplasty procedures can be performed in an ambulatory setting without the need for general anesthesia and may benefit selected patients. When used early in the disease process with active fractures, kyphoplasty may help to improve patient functionality and quality of life while also relieving pain.

Kyphoplasty should be considered if a course of 4 to 6 weeks of conservative medical treatment, including medications and physical therapy, has failed to offer improvement and the patient is at risk of losing his or her independence and function.

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Figure 1.

Osteoporotic compression fracture of the first lumbar vertebral body. (A) Anterior–posterior view. (B) Lateral view. (C) Magnetic resonance imaging obtained 5 weeks after the trauma demonstrating a fracture line as well as persistent edema of the corresponding vertebral body. The lumbar interspinous process spacer is visible between the fourth and fifth lumbar spinous process and is not related to the patient’s acute compression fracture and treatment.

Figure 2.
(A, B) Before discharge and (C, D) at 8-month follow-up after a bilateral transpedicular kyphoplasty of the first lumbar vertebral body.