Augmentation Therapy for Vertebral Compression Fractures

- Conservative treatment of vertebral compression fractures (bed rest, pain medications, and back bracing) is not risk free
- Augmentation therapy, including kyphoplasty or vertebroplasty, in which cement is placed percutaneously into a fractured vertebral body, results in a marked improvement in pain within 24 hours in 80-90% of those treated, shortening hospital stays
- Augmentation is increasingly being used for treatment of metastatic disease and multiple myeloma of the spine
- A prospective randomized trial has shown that quality-of-life and disability scores are significantly better after augmentation therapy, compared to conservative therapy, for at least 12 months post therapy

Each year, over 750,000 Americans sustain vertebral compression fractures (Figure 1). The vast majority of these are associated with osteoporosis but a substantial number result from metastatic disease, hematopoietic neoplasms, or trauma. Osteoporotic vertebral fractures may be caused by normal activity, such as stepping down stairs or opening a window, and have an incidence of 25% in women over age 50. Before the development of augmentation techniques, these fractures, which are associated with severe pain, were treated with a combination of bed rest, pain medications, and back bracing. Many patients will respond to this treatment and report a gradual reduction in pain over 2-12 weeks. Although this treatment is regarded as conservative, it is not without risk. Prolonged immobilization is associated with accelerated bone loss, muscle weakening, loss of cardiac function, and increased risk of developing pressure sores, pneumonia, gastrointestinal irritation due to medications, and deep vein thrombosis.

The augmentation therapies, primarily vertebroplasty (Figure 2) and kyphoplasty (Figure 3), are procedures in which spinal needles are placed percutaneously into a fractured vertebral body, typically through one or both pedicles. Polymethyl methacrylate (PMMA) cement is then injected into the vertebral body under careful fluoroscopic or CT guidance. Kyphoplasty differs from vertebroplasty in that a balloon is used to create a cavity in the vertebral body before injection of cement.

Efficacy of Augmentation Therapies

Even though many clinical trials have demonstrated rapid pain relief within 24 hours after vertebroplasty or kyphoplasty, the selection of augmentation therapy over conservative treatment has been controversial because patients will often recover from pain symptoms over time. However, in the opinion of many experts, equality in long-term pain relief does not negate the early positive effects of augmentation therapy because of the adverse effects of prolonged immobilization on overall health and physical function. Moreover, augmentation therapy is likely to be cost effective because it lessens the time patients are hospitalized, as has been demonstrated in a randomized prospective trial of vertebroplasty.
Recently, longer-term benefits of augmentation therapy have been demonstrated in an international prospective randomized controlled trial of kyphoplasty versus conservative therapy, published in *The Lancet*. The primary endpoint of this study was the difference in the short-form (SF-36) physical component summary (PCS) scale between the kyphoplasty and control groups from baseline to one month. Secondary outcome measures at 1, 3, 6, and 12 months after randomization were SF-36 scores as well as scores from a quality-of-life questionnaire, self-rated back pain, back function, and restricted activity days and bed rest because of back pain. The study demonstrated statistically significant higher scores for all of these endpoints in the group treated with kyphoplasty (p = 0.0009 on the quality-of-life questionnaire and p < 0.0001 for all other measures). In this study, the overall number of adverse events in the two groups did not differ significantly and there were two serious adverse events attributed to kyphoplasty (a soft-tissue hematoma and a urinary infection).

In terms of pain relief, mobility, and complication rates, there appears to be little difference between kyphoplasty and vertebroplasty. Both procedures were considered to be highly effective in a multi-society position statement on vertebral augmentation. Kyphoplasty is intended to reduce kyphosis and, therefore, factors that might affect choice of procedure include the degree of compression deformity, age of fracture, and presence of neoplastic involvement.

Partial symptomatic relief usually occurs immediately and continues to improve over several days or weeks. In the recently published Mass General patient series, one of the largest series in the literature, 40% of patients experience pain resolution and 49% experience improvement in their symptoms and decreased requirement for pain medications. Augmentation therapy stabilizes the fracture and helps to prevent further collapse of the vertebral body. To minimize the likelihood of additional compression fractures, patients should continue with treatment of osteoporosis, modify their activities, and strengthen their back muscles through physical or occupational therapy.
**Selection of Candidates for Treatment**

Patient selection is the critical factor in achieving treatment success. Incidental compression fractures are common in elderly patients with back pain due to other problems, such as disk disease and spinal stenosis. The diagnostic radiologist plays a major role in correlating symptoms with imaging findings, and excluding patients who are unlikely to obtain pain relief from augmentation therapy. Appropriate candidates for the vertebral augmentation can present with a variety of pain syndromes. Often, they have axial pain that gets worse over the course of the day and/or with activities. The pain level is likely to correspond to the site of the fracture. There are many variants of this and often patients present with band-like distributions of pain ("a tight belt") emanating from the site of the fracture. On physical examination, point tenderness over the appropriate level can be diagnostic.

Conventional radiography can be used to identify a new compression fracture, but advanced imaging is typically needed to determine whether a fracture is healed or not healed in patients with multiple vertebral compressions. Healed fractures do not necessarily benefit from augmentation therapy. Advanced imaging also helps to distinguish osteoporotic fracture from metastasis or infection, and is necessary to ensure that vertebroplasty can be performed safely. MRI is generally the best single test in assessing for the likelihood of benefit from augmentation.

**Contraindications**

Contraindications can vary based on the comfort of the practitioner in combination with the needs of the patient. Active infection is an absolute contraindication. Anticoagulation must be reversed. Vertebrae that have lost more than 80% of height pose technical challenges and may not respond to augmentation if displaced or if retropulsed bone fragments are compressing the spinal cord or other neural structures. Fractures caused by tumor infiltration may not be amenable to augmentation if there is cortical destruction and epidural soft tissue mass. The patient must be able to lie prone or prone oblique for the duration of the procedure. Most patients can tolerate this position with conscious sedation.

**Potential Complications**

The risk of procedural complications is low. During injection, leakage of cement into the spinal canal can cause compression of neural structures and may, potentially, require surgical removal. Most leakages are asymptomatic. Rib fracture or pedicle fracture can occur during needle placement and there is a theoretical risk of precipitating an adjacent vertebral fracture, though this remains controversial. Bleeding and infection are rare.
Alternate Applications of Augmentation Therapy

Augmentation therapy may also be beneficial to patients with debilitating pain from non-healing fractures, typically associated with metastatic lesions, at other sites in the body. In fact, this notion of local disease efforts to combat systemic disease has been gaining momentum. Neurointerventionalists at Mass General have begun offering off-label augmentation therapy for non-healing fractures of the non-vertebral bones including the acetabulum (Figure 5) and the calcaneous bone associated with metastatic disease. In addition, the neurointerventionalists have been working with radiation oncologists and radiation physicists on the potential use of cement containing radioisotopes for the treatment of bone metastases. While this combination of PMMA with radioisotope therapy remains theoretical, it offers exciting potential as a novel treatment for patients with cancer.

Scheduling

A consultation or office visit can be scheduled by contacting Interventional Neuroradiology / Endovascular Neurosurgery (617-726-1767).

Further Information

Vertebral augmentation therapy is covered by Medicare as well as most private insurance plans. For further questions about augmentation therapy, contact Joshua A. Hirsch, M.D., Director of Interventional Neuroradiology / Endovascular Neurosurgery at 617-726-1767.

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References


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