Current Concepts of Vertebral Augmentation

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ABSTRACT

Vertebroplasty and kyphoplasty are relatively new minimally invasive methods to treat osteoporotic or pathologic vertebra fractures. Both technics are similar in principle whereas in kyphoplasty a balloon is introduced into the vertebra to restore the height loss. Currently there are several studies reporting the safety and efficacy of both methods and in this report technical nuances and evidence based outcomes and complications were discussed.

KEY WORDS: Kyphoplasty, Minimally invasive spine surgery, Vertebroplasty

INTRODUCTION

Vertebroplasty and Kyphoplasty are minimally invasive treatment options for pathological (osteoporosis or malignancy) compression fractures that are refractory to clinical management. Their excellent, almost immediate, results, and extremely low rate of complications have made them uncommonly popular among treating physicians and patients. Approximately 1/3 of osteoporotic compression fractures evolve to become chronically symptomatic and debilitating (38). Classically, due to elevated morbidity and high failure rate of performing spinal surgery on patients with osteoporosis, vertebral compression fractures were treated conservatively unless they presented with gross spine instability or neurological deficit. Both Vertebroplasty and Kyphoplasty consist of injecting a bone filler material (most commonly PMMA – poly methyl methacrylate) into the vertebral body to restore the stability and treat the pain associated with it in compression fractures. PMMA is a polymer also known as “bone cement”. It is extremely compatible with human tissues and has been safely used in hip and knee arthroplasty for over 40 years.

Vertebroplasty was developed first, in France, introduced by Galibert et al. (17) in 1987, and is the simple injection of the filler into the vertebral body. It is, of course, cheaper but requires the cement injection to be under pressure. Kyphoplasty was developed later, and has two main advantages over the first procedure, that, at least in theory, should bring a better overall outcome. In Kyphoplasty, before the injection of the PMMA, a balloon is inserted into the vertebra. The balloon is then filled with fluid, creating a cavity where the low pressure cement injection takes place. 1) Injecting the cement in a low pressure manner diminishes the risk of PMMA extravasation during the procedure. 2) Inflating the balloon also partially restores the vertebral height lost with the fracture, improving the overall sagittal balance and the patient’s kyphosis, hence its name. The mechanism of action of both procedures is believed to be due the immediate stabilization of the fracture by the hardened cement. Another less accepted theory is that the PMMA exothermic reaction when inserted, would kill the nerve endings at the fracture site promoting pain relief. This second theory does not explain how pain is also promptly relieved when other fillers that do not cause an exothermic reaction are injected into the vertebral body.

It is estimated that the worldwide prevalence of insufficiency vertebral compression fractures is around 1.4 million (24) while the US prevalence is 750,000 (7). The exact incidence and prevalence of vertebral osteoporotic compression fractures are difficult to obtain because of
the heterogeneity in how vertebral fractures are defined and the overall lack of diagnosis (2). From 2001 to 2006, the number of vertebroplasty procedures performed in the United States has doubled, from 4.3 to 8.9 per 1000 persons (54). There are multiple studies to date reporting the good outcomes and low complications of patients receiving vertebroplasty and kyphoplasty for osteoporotic compression fractures. Recent attention was directed to the subject when, in 2009, two prospective, randomized, placebo controlled studies published on the same issue of the New England Journal of Medicine (NEJM) basically showed no difference between vertebroplasty and a sham operation (4,25). These studies have generated significant controversy around the procedure and its indications having elicited letters and statements of clarification from field leaders and even national societies (3,27,32). These were on face well performed trials but had significant limitations. Despite the fact these articles found no difference between vertebroplasty and injecting anesthetic into the vertebral periosteum, vertebral augmentation (filling) procedures for the treatment of insufficiency fractures continue to be widely used with excellent results in pain control, return to function and minimal complications; at least within expert opinion, multiple case series and non blinded, non placebo controlled prospective studies.

Patient selection:

Identifying patients who would benefit from these procedures requires a thorough workup incorporating the findings of history, physical examination, and imaging studies (35). Physicians need to be extremely careful in correlating a patient's back pain with the compression fracture. The clinical history is usually a sudden onset of back pain that may or may not be associated with a traumatic event. High energy trauma is the exception in these cases. On physical examination, acute compression fractures tend to have tenderness directly over the fracture site. This finding is very important to differentiate them from old compression fractures, which usually do not hurt, are stable, and do not require treatment.

Posteroanterior and lateral radiographs will detect most vertebral compression fractures, the overall spinal column alignment, and any focal kyphosis associated; however, it is often difficult to differentiate whether the fracture is acute or chronic or whether it is associated with a tumor. MRI is an excellent imaging modality because not only can it detect the edema associated with acute fractures, but it can also show any tumorous lesions associated. The best sequences to observe the edema of the acute changes the sagittal T2-weighted and fat-suppressed T2-weighted or the short tau inversion recovery (STIR) images. These images show increased signal intensity at the fracture site in patients who have acute and subacute fractures and, thus, help select who will benefit the most from the intervention (33). Patients who demonstrate no increased signal intensity on the MRI are less likely to experience improvement after the procedure. For patients in whom MRI is contraindicated nuclear scintigraphy (bone scan) can be used to evaluate the acuity of the fracture (Figure 1).

**Indications for Vertebroplasty or Kyphoplasty:**

1) Acute painful pathologic compression fractures (osteoporotic or tumoral)
2) Painful lytic metastatic vertebral lesions.
3) Painful vertebral hemangioma.

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![Figure 1: A fat-suppressed T2-weighted MRI demonstrating a compression fracture (high signal) of a T12 vertebral body. Note that the patient has previous cement injection at both T11 and L1.](image-url)
4) Post-traumatic osteonecrosis of the vertebral body
   (Kummell's disease)

   **Contra-indications**

1) Fracture associated with a neurological injury.
2) Burst type fracture.
3) Fractures that extend to the spinal canal – relative.
4) Fractures in the presence of vertebral osteomyelitis.
5) Matrix producing metastatic vertebral lesions - relative.

   **Technical Considerations:**

   Both Vertebroplasty and Kyphoplasty are minimally invasive percutaneous procedures. Their indications are basically the same. The patient is positioned prone on the operating table. Insertion of the cement is done through a cannula placed trans or extrapedicular into the vertebral body. Anesthesia can be local or general and the procedure can be done in the hospital or at an outpatient surgery center, depending mostly on the general condition of the patient. Blood loss is minimal. An extremely import part of the procedure is obtaining a biopsy of the lesion before inserting the cement through the cannula. Biopsy should be considered for first time fractures and those with any history of malignancy. Good fluoroscopy imaging is fundamental as for all percutaneous procedures. Having biplanar (AP and lateral fluoroscopy at the same time) imaging is found to be very helpful during vertebral augmentation.

   **Evidence Based Outcomes:**

   **Vertebroplasty for osteoporotic fractures:**

   Voormolen et al. prospectively randomized 18 patients to vertebroplasty and 16 patients to optimal medical management. Vertebroplasty was associated with significantly greater pain reduction, less analgesic use, and greater mobility and physical function when compared to optimal medical management 1 day and 2 weeks after treatment.

   In another prospective, non-randomized study, Alvarez showed that Vertebroplasty was associated with a significantly greater reduction in pain 3 and 6 months after the intervention, when compared with optimal medical treatment. It was also associated with better functional scores and less pain medication use at 3 months. There was no difference between the 2 methods at 1 year follow up. Diamond, in a prospective non-randomized trial, concluded that vertebroplasty was superior to medical management in improving pain control and physical activity at 24 h post procedure. No difference was found at 1.5, 5 or 12 months. In a different study, the same author compared vertebroplasty and medical management and found that the vertebroplasty group had better pain scores and function at 6 weeks, but no difference at 1 or 2 year follow up. The incidence of adjacent vertebral fractures was the same for the 2 groups at 2 years.

   A recent study (Vertos II) prospectively randomized 202 patients with acute painful fractures confirmed by MRI into 2 groups as Vertebroplasty and conservative treatment. There was clear superiority in the treatment on the Vertebroplasty group. No complications were reported. Hockmuth et al published a meta-analysis on vertebroplasty where they analysed 30 studies (total of 2086 patients) concluding that a rapid and consistent relief of the pain was achieved on every study. Their complications were 0.9% major morbidity, 0.1% cement embolism, 0% mortality.

   Hulme had a meta-analysis (69 studies and over 4000 patients) comparing Kyphoplasty to Vertebroplasty and showed that both methods are efficacious for rapid pain control. The complications were: 3.9% symptomatic complications, 0.6% neurological decline, 0.6% pulmonary embolism for the vertebroplasty group and 2.2% symptomatic complications, 0.03% neurological decline and 0.01% pulmonary embolism for Kyphoplasties. Eck did a similar review on 136 studies with over 9500 patients comparing both methods (Kypho and Vertebroplasty). Pain improvement results were the same as in the previous cited articles. The complications were: 1.6% symptomatic cement leak, 0.9% pulmonary embolus, 0.3% hematoma, and 0.1% infection for Vertebroplasty and 0.3% symptomatic cement leak, 0.4% pulmonary embolus, 0.1% hematoma, and 0.3% infection for Kyphoplasty.

   Finally, multiple case series studies report a significant and rapid improvement in pain after vertebroplasty for osteoporotic compression fractures.

   **Kyphoplasty for osteoporotic fractures:**

   Kasperk compared kyphoplasty with optimal medical management in a prospective, controlled, non-randomized trial and found that patients who underwent kyphoplasty had better pain scores and returned to activity at 3 and
In a case series of 37 patients with tumor associated fractures, Weil had 94% of pain improvement and 8.1% of transient radiculopathy due to cement extravasation (53).

In his series on tumor associated fractures, Cortet had cement leakage in 72.5% of cases, with 6.9% requiring surgery for that complication (11). Other studies of kyphoplasty or vertebroplasty on tumor associated fractures report asymptomatic cement leakage from 4 to 26% (14,16,28,34,41).

Prospective randomized placebo controlled studies:

Buchbinder et al. (Australian New Zealand Clinical Trials Registry) measured pain, quality of life, and functional status at 1 week and at 1, 3, and 6 months after a sham procedure and vertebroplasty finding no significant between-group differences at any time point. Patients in the two study groups had improvement in pain (4).

Kallmes et al. (25) report that pain and disability outcomes at 1 month in a group of patients who underwent vertebroplasty were similar to those in a control group that underwent a sham procedure. In both studies, the sham procedure consisted in injecting a short acting anesthetic in the vertebral periosteum.

These studies, even though well designed, had numerous flaws. In both, the majority of invited patients (approximately 70%) refused to be randomized and opted to be able to choose their own treatment, therefore not being able to participate. Arguably, those could be the patients that were in a greater deal of pain and did not want to risk getting the sham treatment, creating a huge selection bias to start with. Another problem noted was that both studies were underpowered and had poor definition of inclusion criteria. Buchbinder had 80% of patients from one single center. Also, in both studies, patients with subacute fractures of up to 1 year were included, what could have also made the difference to the control sham group not so significant. MRI to assure the fractures had inflammatory changes at the time of treatment also was not a constant in these studies.

Finally, two prospective randomized trials with adequate power and more controlled inclusion criteria were published at The Lancet in 2009 and 2010 clearly favoring Vertebroplasty (Vertos II study)(27) and Kyphoplasty (FREE study)(52) when compared to optimal medical management. These two articles reproduce the great results of vertebral augmentation of...
innumerable case series and case control studies, as well as the anecdotal positive experience of an uncountable number of physicians worldwide.

**New filler materials:**

Although PMMA is extremely biocompatible and cheap, it has a few drawbacks. It hardens by means of an exothermic reaction that may theoretically be harmful to surrounding tissues (46) and does not reabsorb, not allowing bone remodeling to occur through it (osteocoduction).

Newer filling material like ceramic cements (especially calcium phosphate) and acrylic resin/ceramic composites show good mechanical properties, biocompatibility and allow for bone to remodel through it (animal studies data) (42,48,49).

These new fillers for Kyphoplasty and Vertebroplasty are expensive and clinical data in humans is still recent, small, and the results are at best comparable with when using PMMA (40).

The concept of osteocoduction is very appealing and the property of graft reabsorption and bone incorporation is definitely the ultimate goal when treating fractures with bone void fillers. However, this concept may be more relevant to fill and incorporate a graft used to treat a segmental tibial plateau fracture in a young patient that will need his knee for many years to come, and not so important in patients treated for osteoporotic vertebral fractures in whom the PMMA bone interface will most likely outlast them. One of our recent studies shows that at 5 year follow up, 57% of patients treated with Kyphoplasty were either deceased or unreachable and the other 43% were pleased with the treatment result using PMMA as a filler (their SF 36 was comparable the age matched controls) (44).

**CONCLUSION**

Although insufficiency vertebral compression fractures were classically treated nonoperatively due to open surgery morbidity, they can now be stabilized with reproducible good results and minimally invasive techniques. There are currently multiple studies reporting the good outcomes and low complication rates of patients receiving vertebroplasty and kyphoplasty for osteoporotic or tumoral compression fractures. Both procedures have been shown to be quite similar in regards to bringing excellent functional and pain improvement. Lastly, Kyphoplasty seems to have the advantage of fewer filler extravasation related complications and the ability to restore vertebral height after the fracture. Nevertheless, the exact relation of vertebral height correction after Kyphoplasty and clinical outcome is yet to be determined. Vertebral augmentation procedures are extremely relevant for the treatment of the patient's osteoporosis, especially when under immunosuppressant agents that not only will contribute to the causing of osteoporotic fractures but will also elevate the traditional surgery risks even more (45).

**ACKNOWLEDGEMENT**

Parts of the introduction, conclusion and basic concepts of vertebral augmentation on this chapter have been previously sent to publication on a book for Rheumatologists (45). This article, however, is a much larger and more complete version, containing the technical nuances and evidence based outcomes and complications of interest to the surgeon reader.

**REFERENCES**

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