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The vertebroplasty controversy

Introduction

Two recent articles published in the *New England Journal of Medicine* have put the proverbial cat among the pigeons in the spinal community. Both the articles report results of investigation into vertebroplasty. Vertebroplasty entails the percutaneous injection of polymethylmethacrylate (PMMA) into the affected vertebral body and has been advocated as a treatment for painful osteoporotic vertebral fractures. Many previous studies have shown that there is an immediate and sustained reduction in pain after this procedure is performed. Randomised trials have been done that have confirmed the efficacy of this procedure. None of the previous studies have been randomised double-blind controlled studies with a sham control group. The procedure has become very popular in treating these fractures and has been very positively received by treating physicians. I have found this procedure to be very successful in treating my patients with vertebral compression fractures, as have many of my colleagues. For this reason, the results of the articles below have been met with surprise and disbelief.

A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures

Buchbinder R, Osborne RH, Ebeling PR, Wark JD, Mitchell P, Wriedt C, *et al.*
***N Engl J Med.* 2009; 361(6): 557-68**

In this article, 71 patients with back pain and osteoporotic vertebral fractures were randomised into two groups. The patients from both groups were taken to theatre and prepared in the same way. They were then randomised to a sham group or a cement group. Both groups would have the needles inserted according to the standard vertebroplasty technique. Cement would be mixed in both groups so the patient would smell it, but in only the one group of patients would the cement be injected into the vertebra. The patient would not know whether they had received the cement or not.

The patient would then be followed up at 1 week, 1 month, 3 months and 6 months, and be assessed for their pain relief and functional outcome according to internationally accepted outcome scores.

There was no statistically significant difference found in the outcomes between the two groups at the follow-up periods.

A randomized trial of vertebroplasty for osteoporotic spinal fractures

Kallmes DF, Comstock BA, Heagerty PJ, Turner JA, Wilson DJ, Diamond TH, *et al.*
***N Engl J Med.* 2009; 361(6): 569-79**

The second article, published in the same journal, concerned a series in which there were 131 patients. The method of investigation of this series was similar to the other series. The patients were also randomised into two groups and either received an injection of cement or a sham procedure.

The results were also similar to the other series except at 1 month, there was a trend towards a higher rate of clinically meaningful improvement in pain in the vertebroplasty group (64% vs 48%, P=0.06) but this was not statistically significant. This could be due to the small sample size. At 3 months there was also a higher crossover rate in the control group than in the vertebroplasty group (43% vs 12%, P<0.001). This means that a very high percentage of the sham groups elected to eventually have the other procedure. This was statistically significant. Sadly their results after having the procedure were not significantly better but this could be due to the 1 month delay in treatment.

Discussion

The North American Spine Society published an answer to the above controversy on its website, www.spine.org, entitled: "North American Spine Society: Newly Released Vertebroplasty RCTs: A Tale of Two Trials".

In this response they attempt to answer some of the questions that the above articles have asked. The reason for their critical evaluation of the above studies is summed up in this statement, taken from the article:

> Moreover, for any physician who has performed vertebral augmentation procedures for osteoporotic compression fractures, experience has indicated that patients have dramatic pain relief, often within hours of the intervention. Some of the authors have personally seen these seemingly miraculous cases in which a bed-bound elderly person has had one or two vertebrae augmented after which they became nearly pain-free and ambulatory. The evidence and experience up to the publication of the studies by Buchbinder *et al.* and Kallmes *et al.* have been overwhelmingly positive. Spine care providers are now, however, faced with a large chasm between these previous data and experiences and the latest, highest quality data.

It seems that the only possible bias in these studies could be found in the inclusion criteria and that the majority of patients excluded from the study were patients who did not want to be part of a study that had the possibility of their receiving a sham procedure. It is possible that this group of patients were those patients who had more severe pain and would have profited more from the procedure. It would have been interesting to see the results of the procedures done on this group of patients and compare it to the study group.

There was also a concern about the different ages of the compression fractures as well as the criteria used to decide if the fracture was acute or not. It was felt that the cut-off point of 6 months for an acute fracture was too long.

In both the studies the exact origin of the back pain was not assessed. Back pain, due to causes other than compression fractures, are very prevalent in this age group of patients. It is possible that the patients may have had other reasons for back pain than the compression fractures.

An international multicenter randomized comparison of balloon kyphoplasty and non-surgical management in patients with acute vertebral body compression fractures

D Warlaw, S Cummings, J van Meirhaeghe, *et al*
***The Spine Journal* October 2009; 9(10S)**

This recent randomised study on kyphoplasty showed a statistically significant improvement in pain and quality of life in the group that had the kyphoplasty when compared to the control. There was no sham procedure done in this series so it is not a double-blind study. Also the technique used is kyphoplasty which differs from vertebroplasty in that the vertebral height is restored using bone tamps before the cement is injected. Whether this makes a difference is unclear.

The data from the two articles has to be taken seriously and considered carefully and thoughtfully. It is obvious from this data that if the indications for this procedure are not carefully followed it is no better than a placebo with potential serious complications. This is thus not a panacea for all vertebral compression fractures. The specific indications will be refined as more literature becomes available on the procedure. It is the responsibility of all physicians involved in this procedure to avail themselves of the latest scientific knowledge on the subject. This will enable them to identify the patient who will benefit the most from the procedure.

The data from the two articles has to be taken seriously and considered carefully and thoughtfully. This is not a panacea for all vertebral compression fractures

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Current concepts in metatarsal osteotomies A remedy for metatarsalgia

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Metatarsalgia is briefly discussed including the definition, classification and aetiology. Aetiologies include disturbances in foot biomechanics, systemic conditions (arthritides) and conditions unrelated to weight bearing (neurologic, vascular).

The history of metatarsal osteotomies for biomechanical overload is discussed noting more than 20 variations in literature and with results reported between 57% and 100% success rate. The above goals are achieved by dorsally elevating and metatarsal shortening osteotomies (proximal, shaft and distal) with rigid internal fixation. This article focuses on the shortening osteotomies including Weil, Helal, midshaft segmental and asymmetric distal V-osteotomies.

Under the heading of 'Indications and contraindications' I would like to highlight their opinion of pursuing disease-specific therapy (for instance equines or dysfunctional first ray), and in general utilising conservative measures as the first line of treatment. The distinction between symptoms during the stance (usually elevation osteotomies) and pathologic propulsive phases (shortening osteotomies) are a practical guideline. Absolute contraindications include the usual local infection and vascular insufficiency but also very importantly a neuropathy.

Pre-operative planning is based on the understanding of disease pathophysiology and the article concentrates on the role of X-rays here.

Under 'Technique' a short description is given of the Weil, Helal, proximal V-osteotomy, the distal V-osteotomy and the midshaft osteotomy. These procedures are not without risk of complications, and non-union, hardware problems, transfer metatarsalgia and floating toes are mentioned. The summary of some of the literature results again highlights the risks of these procedures, but also the fact that good results can be obtained.

Under 'Possible concerns and future of the technique' the comment is rightly made that these procedures can be technically demanding. First ray stabilisation procedures, gastrocnemius recession to address equinus contractures, hallux valgus corrections and hammertoe realignments may influence results (may sometimes be all that is necessary in my opinion).

Shortcomings

This is a huge and important topic that can probably only be covered fully in a book format. For instance, the pre-operative planning only covers some aspects of radiology. The techniques include some of the osteotomies and only give short descriptions of such. Important technical options, for instance removing a sliver of bone with a Wiel osteotomy, are not covered here. There are however some important principles that come out of this article that make it worthwhile reading.