

Vertebroplasty: An International Expert Opinion

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Two randomized controlled trials have shown no significant differences in outcome between vertebroplasty and a sham procedure in patients with back pain and vertebral fracture. What conclusions can be drawn from these results?

In August 2009, the New England Journal of Medicine published the results of two randomized controlled trials of vertebroplasty for the treatment of painful osteoporotic vertebral fractures [1,2]. The findings have generated significant national and international interest both because of a recent dramatic increase in the number of vertebroplasty procedures performed in the US and Europe, [3] and because the studies failed to show significant differences in the outcomes of the treatment and control groups.

The study by Buchbinder et al. [1] was performed at four sites in Australia. Of 468 patients assessed for eligibility, 78 were randomly assigned to receive either vertebroplasty or a sham intervention. The sham procedure involved inserting a needle down to the lamina and gently tapping it to simulate the vertebroplasty technique; bone cement was then prepared so that its smell permeated the room. Patients were assessed for up to 6 months, and overall pain (measured on a 0–10 scale) at 3 months was chosen as the primary end point. Secondary outcomes included quality of life measures and a modified version of the Roland Morris Disability Questionnaire. The characteristics of the patients in both groups were similar at baseline, and 91% completed the 6-month assessment period. No significant differences were observed between the groups at 3 months. By 6 months, seven patients had experienced an incident vertebral fracture (three in the vertebroplasty group, four in the placebo group).

Kallmes et al. [2] conducted a multicenter trial comparing

vertebroplasty with a sham procedure, similar to that used by Buchbinder and colleagues [1], in patients suffering from painful compression fractures. Of 1,813 patients assessed at five centers, 113 were enrolled and assessed at 1 month and 3 months. The primary outcome measures at 1 month were modified Roland Morris Disability Questionnaire scores and the patient's rating of average back pain intensity during the preceding 24 h. A number of secondary outcomes were also assessed. As in the other study, the baseline characteristics of the two groups were similar, and only a few patients in each group were lost to follow-up. Once again, the primary and secondary outcome measures at 1 month did not differ significantly between the two groups. A trend was shown, however, towards a higher rate of clinically meaningful improvement in pain (defined as a 30% decrease in intensity scores from baseline) in the vertebroplasty group compared with controls.

The studies by Kallmes et al. [2] and Buchbinder et al. [1] could be taken as evidence that vertebroplasty is an ineffective treatment option in patients with osteoporotic vertebral fractures. As vertebroplasty is not without risks, therefore, it is clearly important to carefully consider whether this is indeed a valid conclusion. Technically, both of the studies were well done: the use of a sham procedure will have reduced the placebo effect, the outcome measures were well chosen, and the percentage of patients who remained at the end of both studies was high. Nonetheless, a few aspects are worth further discussion.

One interesting finding from the Buchbinder et al. [1] study was the minimal changes observed in both groups: the average overall pain scores were reduced from 7.5 to 5 out of 10, and the average Roland Morris Questionnaire Score was reduced from 17 to 14 out of 23. These changes are surprisingly small, and considerably smaller than those reported in studies that compared vertebroplasty with no treatment [4-6]. Importantly, the findings suggest that the chronic back pain in these patients might have originated from

somewhere other than the fractured vertebra.

The duration of the patients' symptoms in the Buchbinder et al. [1] study varied from less than 1 month to 4.5 months. Although the small number of patients included in the study precludes conclusions about whether or not the timing of the intervention affected outcomes, the authors report that the duration of symptoms did not affect the results. The average duration of pain at baseline in the Kallmes et al. [2] study was substantially longer than in the Buchbinder et al. [1] trial, but again this did not influence outcomes.

The outcomes of patients in Kallmes et al.'s trial were better than those of the other study, but they were again surprisingly modest. Specifically, average pain intensity scores decreased from 6.9 to 3.9 out of 10 in the vertebroplasty group, and from 7.2 to 4.6 in the control group; and the Roland Morris disability score went from 16.6 to 12 out of 23 in the vertebroplasty group, and from 17.5 to 13 in the control group [2]. The number of patients in this study who crossed over to the other group was high at 3 months (12% in the vertebroplasty group and 43% of controls), but even at 1 month one patient in the vertebroplasty group and two in the control group crossed over. This degree of crossover is an obvious limitation of the study, as it tends to reduce the value of randomization.

Of note, use of the vertebroplasty procedure itself could have resulted in the different outcomes seen in these studies compared with other investigations of similar fracture pain therapies such as kyphoplasty. In addition, the cement was injected unilaterally, which might have made it difficult to adequately fill the vertebral body, potentially affecting the results. Furthermore, both studies were plagued by a slow rate of enrollment and extremely high numbers of patients declining to participate (30% in the Buchbinder et al. [1] study and almost 17% in the Kallmes et al. [2] study). This raises the question of whether the fracture pain in these patients was so severe that they were unwilling to be randomized. Patients with severe fracture pain could in fact be the 'ideal' vertebroplasty candidates, and their inclusion in both studies might have had a significant effect on outcomes.

So, what can we deduce from these new results? Certainly, the studies suggest that patients with chronic back pain and a vertebral fracture should not automatically undergo a vertebroplasty, as the cause of a patient's pain cannot always be attributed to the fracture. Interventional radiologists, although technically superb, are rarely trained to evaluate the source of back pain. Careful selection of patients by physicians with broad expertise in the management of spinal disorders could produce different results. Neither of these two articles mentions the presence of concomitant, potentially painful disorders of the spine, and the exclusion criteria fail to eliminate common spinal disorders such as degenerative changes, stenosis or spondylolisthesis.

Another important consideration, which is highlighted in an editorial accompanying the published results [3], is the need to involve patients in the treatment decision-making process. When

evidence on the treatment choices available is conflicting, the physician and patient should carefully review the options before a decision is made (informed patient choice).

Finally, we need to question whether or not the two articles should be viewed without consideration of the body of published articles on this topic. Were these studies so superior in quality that others should be discounted? This question raises the complex issue of how the evidence should be evaluated. Although the studies by Kallmes et al. [2] and Buchbinder et al. [1] are the only ones known to this author that compare vertebroplasty with a sham procedure, other randomized controlled studies have been conducted. Wardlaw and colleagues [7] for example, showed that kyphoplasty is superior to nonoperative care in carefully selected patients. Although that study did not use a sham procedure, the results remained stable over 1 year, suggesting that the effect was procedure-related. Other surgical approaches to vertebral fracture treatment, therefore, should not be judged solely by the results of these two latest trials. There are 74 published studies to date reporting the outcomes of patients receiving Vertebroplasty for osteoporotic vertebral body compression fractures. According to the level of evidence rating of the NASS (level I-V), there is only a single level I study to date (high quality prospective randomized controlled trial) comparing vertebroplasty to medical management [8]. There are another two ongoing randomized trials. Voormolen et al randomized 18 patients to vertebroplasty and 16 patients to optimal medical management. Vertebroplasty was associated with significantly greater pain reduction, less analgesic use, and physical function when compared with that in optimal medical management 1 days and two weeks after treatment. Furthermore, 14 of the 18 patients randomized to medical management requested vertebroplasty by 2 weeks [8].

In our opinion, this weakness in study design does not preclude a level I rating of the study's 2-weeks assessment by NASS criteria but should be considered a limitation of this study.

There are three level II studies (nonrandomized, prospective, controlled trials) published to date. Alvarez et al. prospectively compared 101 patients receiving vertebroplasty versus 27 receiving optimal medical management for osteoporotic vertebral body fractures.

Vertebroplasty was associated with significantly greater pain reduction 3 and 6 months after intervention. Vertebroplasty was also associated with a greater decrease in analgesia use, a greater improvement in disability score, and greater improvement in 36-item Short Health Survey of the Medical Outcomes Study (SF-36) general health and bodily pain subscores at 3 months. There were no differences between vertebroplasty and optimal medical management in any outcome measure at 12 months. Diamond et al prospectively compared 55 patients receiving vertebroplasty versus 24 receiving optimal management for osteoporotic VCFs and found significantly greater reduction in pain and greater improvement in physical functioning 24 hours after intervention [8].

There were no differences in VAS or Barthel functional index at 1.5, 6 or 12 months.

Diamond et al. also performed a prospective, 2-year comparison of 88 patients receiving vertebroplasty versus 38 receiving optimal medical management for osteoporotic VBFs.

This study demonstrated a greater reduction of pain and return with vertebroplasty at 6 weeks, but there were no differences in any outcome measure at 12 and 24 months. Notably, the incidence of adjacent VCFs was not increased at 2 years in the vertebroplasty cohort [8]. According to us, vertebroplasty has been increasingly used with the expectation of more rapid pain relief and earlier mobilization than that achieved with medical pain management.

In conclusion, surgery is likely to be unnecessary for a subgroup of patients with painful osteoporotic fractures. As is true in many areas of spinal care, careful patient selection is paramount to the success of any intervention. We need to better define who will truly benefit from surgery and not use this approach indiscriminately. Effectiveness studies of vertebroplasty and other similar procedures are under way, and should be helpful in this regard.

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