

Evidence in Action

78-Year-Old Female With a Compression Fracture

By John Stites, DC, DACBR, FACO

On a tour of Northern Africa, a 78-year-old female was riding as a passenger in an old truck over rugged terrain. The truck hit a bump, causing her to be tossed up and then come down hard on her buttocks. She felt immediate pain in her lower thoracic spine. When I spoke with her 2 weeks later, she had already been diagnosed with a compression fracture. This was 2008 and I recommended that she should consider vertebroplasty/kyphoplasty. She elected to undergo the procedure. It improved her pain and slightly reduced the kyphotic deformity.

The recommendation was very reasonable. A systematic review published in the *European Spine Journal* in 2006 identified 15 articles meeting the authors' inclusion criteria. These included 11 prospective observational studies, 3 retrospective studies, and 1 controlled trial. This review clearly outlined inclusion and exclusion criteria for the papers they selected. It had a reasonable process for selecting papers to minimize bias, and clear criteria for grading the evidence. This study pooled outcomes on 793 patients, showing that there was a significant reduction in pain following intervention.¹

The controlled trial included in the systematic review compared vertebroplasty with conservative therapy. This was not a randomized trial. Patients meeting the inclusion criteria elected either vertebroplasty or conservative care consisting of a variety of pain medications, hot packs, gentle mobilization, and osteoporosis treatment. In this study, those patients receiving vertebroplasty reported a significant reduction in pain at 24 hours. The 2 groups looked similar in pain levels at 6 weeks and 6 months.² The fact that this trial was not randomized reduces the confidence that the outcomes reflect true effects because the 2 groups may be prognostically different.

Despite the absence of strong, well-designed clinical studies, I felt quite comfortable recommending the procedure. I based this on my own experience in which patients I referred for the procedure benefited, on the fact that the patient was interested in pursuing the intervention, and because the best available evidence supported its use.

In August of 2009, there were 2 papers published in the *New England Journal of Medicine* that seriously questioned the value of the procedure.^{3,4} These were well-designed multi-center trials comparing vertebroplasty to a sham procedure at centers in Australia, the United Kingdom, and the United States. In 1 study, the sham procedure mimicked the intervention in all aspects including the odor in the room but only pressure was applied to the back. Sixty-three percent of patients correctly guessed that they were in the control group, and 51% of those having the intervention guessed their correct group. The sham treatment in the other study included needle insertion, but the sharp point was replaced with a blunt tip that tapped the vertebral body to simulate vertebroplasty. In these 2 studies, pain improved for those patients receiving vertebroplasty. However, those receiving the sham treatment improved at about the same rate.

There was no meaningful difference between the intervention groups and the sham control groups.

These results, not surprisingly, prompted a number of responses. Some criticized the patient selection and postulated that some patients experience reduction in pain originating at the facet rather than the fracture.^{5,6} In contrast, the American Academy of Orthopaedic Surgeons published a guideline recommending against the use of vertebroplasty.⁷

That was certainly not the last word. From June 2011 to June 2012, 275 articles on vertebroplasty have been indexed in Pubmed. In April 2012 and June 2012, 2 systematic reviews, 1 in the *European Spine Journal* and the other in *Clinical Orthopedics and Related Research*, were published in an attempt to summarize the more recent literature.^{8,9} The reviews were consistent with each other, finding that patients who elect vertebroplasty have a notable decrease in pain compared to conservative care but no notable advantage over sham treatment.

This may at first glance seem discouraging to practitioners who wish to use current evidence to inform their practice. However, on reflection, this serves to illustrate the importance of the process of evidence-based clinical practice (EBCP) and the integral role of both the clinician and the patient. When looking at the scientific literature, it is the exception rather than the rule that evidence provides definitive answers. Generally, it informs the decision-making process between the doctor and the patient.

The process of EBCP includes asking a clinical question, acquiring the best available evidence, appraising that evidence, and applying it to patient care. This is followed by assessing the patient's outcomes. In this approach, critical appraisal skills come into play and the importance of understanding the evidence hierarchy is key. One way to think about the state

of the current best evidence is to postulate whether further studies are likely or unlikely to change your recommendations.

This story also illustrates the importance of looking at current evidence. If you examined a clinical topic 2 years ago, you cannot assume your understanding matches the current state of knowledge.

What would I do based on the current best evidence? It depends on the patient. I would probably not recommend the procedure but at the same time I would not discourage it. If patients ask if anything else might help with the pain of an osteoporotic compression fracture, I would certainly talk to them about vertebroplasty. I would let patients know that there is a good chance that they will find relief after the treatment but its value has been questioned because there seems to be the same relief after a sham treatment. I would also inform patients that there does not appear to be any difference in pain levels after a few months and, although it's generally a safe procedure, there is a slight increase in the likelihood of additional fractures. If the patient was in pain and felt they had to do something, I would say "go for it." Of course, it may be weeks to months before I am again faced with a patient who is dealing with pain from a compression fracture. I would have to reassess the current literature at that time.

References

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