Vertebroplasty for Osteoporotic Compression Fracture: Effective Treatment for a Neglected Disease

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AJNR Am J Neuroradiol 2001, 22 (3) 595
http://www.ajnr.org/content/22/3/595

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I read with great interest the editorial of Jarvik et al (1) in the September 2000 issue of *AJNR*, and feel compelled to respond with my thoughts and experience. Contrary to Dr. Jarvik's assertion that vertebroplasty is a ''technique for treating low back pain'', it truly is only a procedure for treating painful, unhealed, osteoporotic compression fractures of the spine. Dr. Jarvik apparently has little experience with the technique or with the dramatic results achieved in the great majority of individuals treated.

Conventional treatment for painful osteoporotic fractures of the spine typically includes bed rest, narcotic analgesics, and occasionally bracing. Many patients respond, but there is a subset who have persistent debilitating pain and resultant reduction in quality of life and medical complications of prolonged bed rest. Many require hospitalization or nursing home admission. Patents with untreated osteoporotic vertebral body fractures have been shown to have a 23% to 34% greater mortality than those treated in a recent study that followed such patients for 8 years (2).

My experience, and that reflected by others (3), suggests that vertebroplasty is a safe, relatively inexpensive, and highly efficacious treatment of a vexing problem for which there is no other treatment aside from a modified version of benign neglect. There are large numbers of patients who have been able to resume their active lifestyle, discontinue narcotic medication, and function independently.

The question of evaluating long-term outcomes is interesting but not valid in patients whose life expectancy may be significantly shortened. Even 1 year of painful existence in a patient with 3 years to live represents a very substantial benefit with very little risk and cost.

I question Dr. Jarvik. How would a randomized controlled study be designed that didn't exclude patients form an effective treatment for a potentially life-threatening disease?

Would a new treatment for fracture of the hip or radius require an untreated control group to prove long- term efficacy? What possible outcome of a prospective randomized study of vertebroplasty would result in any change in the practice of those of us performing this procedure?

For ethicists to insist that ''we stop'', merely to add pedantic scientific evidence to the demonstrated efficacy of the vertebroplasty procedure, flies in the face of common sense and compassion

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References

1. Jarvik JG, Deyo RA. **Cementing the evidence: time for a randomized trial of vertebroplasty.** *AJNR Am J Neuroradiol* 2000; 21:1373–1374
2. Kado, et al. **Vertebral fractures and mortality in older women.** *Arch Inter Med* 1999;159:1215–1220
3. Deramond, et al. **Percutaneous vertebroplasty with polymethylmethacrlate.** *Radiol Clin North Am* 1998;36:533–545

Reply

We thank Dr. Goltra for his interest and comments regarding our editorial; however, we stand firmly behind our basic message: that before a new technique becomes widely disseminated, there should be strong, scientifically sound evidence regarding its effectiveness.

Dr. Goltra began his letter with the semantic point that vertebroplasty is not a treatment for low back pain in general, but rather most commonly used for the treatment of painful, osteoporotic compression fractures. We did not mean to imply that vertebroplasty is being used for the vast majority of low back pain patients, but do point out that painful, osteoporotic compression fractures comprise an important subcategory of low back pain, especially in the elderly.

The data that Dr. Goltra cited from his own experience and the case series in the literature appear compelling. He stated that ''patients with untreated osteoporotic vertebral body fractures have been shown to have a 23% to 34% greater mortality. . . '' The study by Kado (1) reported a univariate analysis hazard ratio (also known as a relative risk) for mortality of 1.23 (95% CI, 1.10–1.37) for women with one or more fractures. For women with severe fractures, this increased to 1.34-fold (95% CI, 1.18–1.51). This does not imply a 23% to 34% greater mortality, as Dr. Goltra stated, but rather a 23% to 34% increase. When the authors controlled for multiple confounding variables, the hazard ratio decreased to 1.16 (95% CI, 1.03–1.30). Smoking, diabetes and hypertension all conveyed larger relative risks. Nevertheless, a 16% increase in mortality is an important difference seemingly attributable to compression fractures. However, it does not necessarily follow that vertebroplasty will decrease the risk of mortality.

Kado et al, pointed out that there was also an increase in cancer mortality in patients with vertebral fractures. They speculated that there may have been some misclassification of pathologic fractures due to tumor as benign osteoporotic fractures. Alternatively, the osteoporotic fractures may have been a marker of more severe underlying disease, such as occult malignancy. In any case, such patients are likely to be more frail and sedentary than other patients, and some may have osteoporosis precisely because their mobility is limited by comorbid diseases. Furthermore, vertebral fracture would represent a marker of increased risk for hip fracture and upper extremity fractures that can be debilitating, and in the case of hip fracture, directly related to morality. There is little reason to think that vetebroplasty would help these problems.

Hence, any benefit of vertebroplasty for survival remains speculative

Dr. Goltra went on to point out that his experience and others suggest that vertebroplasty is safe, relatively inexpensive, and efficacious. These arguments go to the very heart of the matter, which is what sort of evidence should be sufficient for making medical decisions?

In our commentary, we tried to point out the problems with relying on case reports and uncontrolled case series. At face value, these seem extremely convincing, but when examined closely, they can be extremely misleading. That is not to say that such reports are not useful as preliminary evidence. But the shortcomings of such evidence must be recognized, and major policy decisions, such as the widespread promotion of vertebroplasty, must be made from firmer scientific ground.

Dr. Goltra stated that evaluating long-term outcomes is interesting but not valid for these patients because they have a short life expectancy. The data in the article by Koda suggest that nearly 80% of patients with vertebral fractures would be alive at 8 years. Thus, for the vast majority of patients, 1-year outcomes are highly relevant. But more importantly, as we stated in our commentary, if the benefits of vertebroplasty are truly as great as the proponents suggest, proving its efficacy in a well-controlled trial should be simple and straightforward. It is still ethical to perform such a trial precisely because adequate evidence for efficacy does not yet exist.

Dr. Goltra asked, ''would a new treatment for fracture of the hip or radius require an untreated control group to prove efficacy?'' If there was no standard treatment, then we would certainly hope so. But, in fact, there is standard treatment for them, so comparing added benefit of a new treatment over the standard treatment is the correct question, rather than comparing a new treatment to no treatment at all.

Finally, Dr. Goltra wondered what possible outcome of a prospective randomized study of vertebroplasty would result in a change in practice of those performing the procedure? We would hope that if the procedure proved of no benefit or harmful, that people would stop doing it. Conversely, if it were proved effective, then its use should become more widespread, and centers that do not currently perform this treatment would want to begin. Thus, any result should have a major impact on use of the procedure.

The goal of a randomized clinical trial is to contribute valuable, scientifically rigorous information to the practice of modern medicine. Sometimes science must confront beliefs that appear unassailable by common sense. Our belief is that the practice of evidence-based medicine is far more compassionate than the practice of medicine based on anecdote.

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Reference

1. Kado DM, Browner WS, Palermo L, Nevitt MC, Genant HK, Cummings SR. **Vertebral fractures and mortality in older women: a prospective study. Study of Osteoporotic Fractures Research Group.** *Arch Intern Med* 1999;14;159:1215–1220