

## Who should receive vertebroplasty?

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### EVIDENCE-BASED ANSWER

Percutaneous vertebroplasty has been used to treat aggressive vertebral hemangiomas, osteoporotic vertebral compression fractures, and vertebral lesions from metastatic disease or myeloma. Consider it for patients with severe acute or chronic pain related to one of these lesions who have failed a reasonable course of medical therapy (strength of recommendation [SOR]: **B**, based on structured reviews of

observational studies). Contraindications include an uncorrectable coagulation disorder, infection in the area, spinal cord compression, destruction of the posterior wall of the vertebral body, and severe degrees of vertebral body collapse (SOR: **B**, based on structured reviews of observational studies). Pain relief from vertebroplasty for osteoporotic vertebral fractures may be less for older fractures (SOR: **C**).

### CLINICAL COMMENTARY

#### Long-term sequelae of this procedure are unknown, so proceed with caution

Vertebroplasty appears to be becoming the standard of care for back pain due to compression fractures. It has become the next step, in the absence of contraindications, when conservative measures fail. The long-term sequelae of this relatively new procedure are unknown, so it is prudent to proceed with caution. I am following a few patients who have had this procedure due to osteoporotic vertebral fractures and back

pain. All are living remarkably pain-free lives.

Future studies should probably be focused on the best types and the appropriate amount of bone cement to inject for relief of pain symptoms and minimize leakage. Another important study would involve comparing the clinical outcomes and long-term complications for patients who have had vertebroplasty vs kyphoplasty.

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#### Evidence summary

No randomized controlled trials have been published regarding percutaneous vertebroplasty. A 2005 Technology Assessment by the Centers for Medicare and Medicaid Services (CMS) provides the best evidence about indications and efficacy of percutaneous vertebroplasty for vertebral fractures.<sup>1</sup> The CMS report is based on a search of Medline and Current Contents through April 2005 for

relevant studies, along with hand searches of retrieved articles' references and of recent pertinent journals. Study inclusion criteria included English language, vertebral fractures due to osteoporosis or malignancy, consecutive patient enrollment, outcomes reported for pain, functional status, and quality of life, and study size  $\geq 20$  patients for studies of osteoporosis or  $\geq 10$  patients for studies of malignancy. There was no description

**FAST TRACK****Consider vertebroplasty for patients with severe acute or chronic pain related to vertebral lesions when medical therapy has failed**

of a formal study validity assessment or attempts to control bias by use of multiple reviewers.

Fifteen studies were included, representing 1056 patients. Fourteen of the studies were observational and 1 was a nonrandomized controlled trial. The common inclusion requirement was severe pain attributable to vertebral fracture. Nine of the studies further specified failure of analgesics or conservative treatments. The studies showed statistically significant decreases in comparative visual analog pain scale scores in the short term. Four studies showed pain reduction lasting up to 1 year. These results favor the conclusion that percutaneous vertebroplasty provides short- and long-term pain reduction for patients meeting the inclusion criteria. However, the lack of randomized trials cannot control for the placebo effect, the natural history of vertebral fractures, and regression to the mean as possible reasons for the apparent efficacy of percutaneous vertebroplasty.

Two structured, but not systematic, reviews of percutaneous vertebroplasty in vertebral fractures<sup>2,3</sup> included 15 small observational studies, of which only 1 was included in the CMS report. These reviews examined outcomes of vertebroplasty performed from less than 1 month to a mean of 7 months after fracture, using similar inclusion criteria to those used in the CMS report. The studies' common patient exclusion criteria were uncorrectable coagulation disorder, infection in the area, spinal cord compression, destruction of the posterior vertebral wall, and severe degrees of vertebral body collapse (defined as >67% collapse). The 2 reviews found between 67% and 100% of patients reported pain reduction after vertebroplasty in follow-up periods ranging from 24 hours to up to 10 years. Based on this limited evidence, 1 review suggested that the likelihood of alleviation of pain decreases over time and is low for fractures occurring more than 6 months in the past.<sup>3</sup> In contradistinction, 3 subsequent observational studies,

involving a total of 233 patients with 365 vertebral compression fractures failed to find an association between postprocedural pain and age of fracture (ranging from less than 2 weeks to more than 24 months from injury).<sup>4-6</sup>

**Recommendations from others**

In their guideline on rehabilitation of the patient with osteoporosis, the National Osteoporosis Foundation states an experienced practitioner may perform percutaneous vertebroplasty on a patient with unremitting pain for whom conservative medical therapy has not helped.<sup>7</sup> They qualify this recommendation by further stating long-term clinical studies are required before vertebroplasty becomes standard of care. The Medicare Coverage Advisory Committee, in its review of the 2005 CMS report, suggested that percutaneous vertebroplasty produces a clinically important net health benefit for patients with vertebral compression fracture compared to conservative care for both acute and chronic fractures.<sup>8</sup>

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