Prompt Vertebroplasty Eased Acute Fracture Pain

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FROM THE LANCET

Vertebroplasty provided quicker, stronger, and more durable pain relief from acute, osteoporotic vertebral compression fractures than did conservative pain management, judging from the findings of a randomized, open-label trial.

"In a subgroup of patients with acute [fractures] and persistent pain, percutaneous vertebroplasty is effective and safe," concluded Dr. Caroline Klazen, a radiologist at St. Elisabeth Hospital in Tilburg, the Netherlands, and her colleagues (Lancet 2010 Aug. 10 [doi:10.1016/S0140-6736(10)60954-3]).

Two previous studies found no benefit for vertebroplasty compared with bed rest, analgesics, and other conservative measures, but both trials included patients with fractures that were up to a year old (N. Engl. J. Med. 2009;361:557-68; N. Engl. J. Med. 2009;361:569-79).

The Lancet study pitted vertebroplasty against conservative treatment within a mean of 5.6 weeks of fracture symptom onset; vertebroplasty patients experienced greater pain relief initially and throughout the trial's year-long follow-up.

"Apparently," vertebroplasty shortly after a fracture "is more effective for pain relief" than vertebroplasty performed months afterward, Dr. Klazen and her colleagues wrote.

Recruited from the radiology departments of six hospitals in the Netherlands and Belgium, 101 patients were randomized to vertebroplasty and 101 to conservative measures. Patients were at least 50 years old, and 69% were female.

All of the patients had radiologically confirmed compression fractures at or below thoracic vertebrae 5 with bone edema on magnetic resonance imaging and a minimum height loss of 15%, the authors noted.

They also had tenderness at the fracture level; bone density T scores at or below –1; back pain for 6 weeks or less; and a pain score of at least 5 on a 10-point visual analog scale (VAS), with 10 being the worst pain.

In the vertebroplasty group, fractures were injected with a mean volume of 4.1 mL of polymethylmethacrylate bone cement under fluoroscopic guidance.

At 1 month, those injected with the bone cement had a mean reduction of 5.2 VAS points from baseline (95% CI, 5.88-4.72), compared with a mean reduction of 2.7 points (95% CI, 3.22-1.98) in those who were treated conservatively.

At 1 year, vertebroplasty subjects had a mean reduction of 5.7 VAS points from baseline (95% CI, 6.22-4.98); conservatively treated patients had a mean reduction of 3.7 points (95% CI, 4.35-3.05).

During the study, vertebroplasty patients used significantly less pain-relieving medication at day 1, week 1, and month 1, but the difference in drug use was not significant at later stages of follow-up.

The authors noted that the intervention was not blinded, and that "knowledge of the treatment assignment might

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Major Finding: 101 patients randomized to vertebroplasty for acute osteoporotic compression fractures had a mean reduction of 5.2 points on a 10-point pain scale a month after the procedure; 101 randomized to conservative treatment had a mean reduction of 2.7 points.

Data Source: Randomized, open-label trial.

Disclosures: The authors reported no conflicts of interest. The study was funded by a ZonMw, a Dutch health care research organization, and Cook Medical, which makes the bone cement used in the trial. The commentators reported receiving consulting fees and travel and accommodation expenses from Medtronic Spinal and Biologics Europa BVBA for their role in the FREE balloon kyphoplasty trial.

have affected patient responses to questions or radiologist assessments."

Computed tomographic scanning found that polymethylmethacrylate bone cement leaked out of 97 of the 134 vertebral bodies injected in the 101 vertebroplasty subjects. "Most leaks were discal or into segmental veins; none were into the spinal canal," the authors noted.

Cement did deposit into a segmental pulmonary artery in one patient, however all cement leaks remained asymptomatic.

In a commentary, orthopedic surgeons Dr. Douglas Wardlaw, of Woodend Hospital in Aberdeen, Scotland, and Dr. Jan Van Meirhaeghe, of St. Jan General Hospital in Brugge, Belgium, noted that the study "lends support to the large body of medical opinion that vertebroplasty has a part to play in the management of the pain of vertebral compression fractures" (Lancet 2010 Aug. 10 [doi:10.1016/S0140-6736(10)61162-2]).

But they noted "an unexplained significant difference at baseline" in quality of life and disability measurements between the two groups that suggests "the control group might have been generally healthier than the vertebroplasty group."

Dr. Klazen and her colleagues attributed the differences to chance.

Dr. Wardlaw and Dr. Van Meirhaeghe also noted that in the two previous studies that found no benefit for vertebroplasty, the comparators were sham treatments, not conservative pain management.

In one of the trials, the sham treatment included injecting bupivacaine, a long-acting local anesthetic, directly into fractures, which in itself might have brought relief, the commentators wrote.

By using conservative pain management as a comparator, Dr. Klazen and her colleagues noted, vertebroplasty was tested against "the reference treatment and thus provides the clinician with directly applicable information about how to best treat the patient."

Dr. Klazen and her colleagues noted that ZonMw and Cook Medical, the sponsors of the study "had no role in study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit for publication." ■