Vertebroplasty No More Beneficial Than Placebo

BY MARY ANN MOON

Vertebroplasty was no more beneficial than a sham procedure for painful osteoporotic vertebral fractures in the first two blinded, randomized, controlled trials ever to assess the technique, according to two separate reports.

These findings are likely to transform percutaneous vertebroplasty—a widely accepted method of pain relief that has become routine therapy—from "a procedure that is virtually always considered to be successful" into one "considered no better than placebo," James N. Weinstein, D.O., of Dartmouth-Hitchcock Medical Center, Hanover, N.H., said in an editorial.

Public institutions such as the Centers for Medicare and Medicaid Services, as well as radiologic and neurologic surgery societies, have recommended reimbursement of vertebroplasty—endorsements that have boosted a dramatic rise in its popularity. The number of vertebroplasties performed in the United States has more than doubled in the past 6 years, Dr. Weinstein noted (N. Engl. J. Med. 2009;361:619-21).

The procedure involves injecting medical cement directly into a vertebral fracture to stabilize it and immediately relieve pain. Many case series and small, unblinded, nonrandomized, noncontrolled studies have suggested that it is effective, though the precise mechanism of action has never been delineated.

In one of the reports, Rachelle Buchbinder, Ph.D., of Monash University, Malvern, Australia, and her associates randomly assigned 38 patients with one or two recent vertebral fractures to vertebroplasty and 40 to a sham procedure.

The primary outcome measure, overall pain score, was no different between the two groups at 1-week, 1-month, 3-month, or 6-month assessments. Pain at rest, pain during the night, physical functioning, and quality of life measures also did not differ significantly, nor did the use of opioid analgesics, the researchers said (N. Engl. J. Med. 2009;361:557-68).

These results were consistent regardless of patients' duration of symptoms and history of previous fractures.

One subject who underwent vertebroplasty and could not receive prophylactic cephalothin because of drug allergies developed an adjacent new fracture and osteomyelitis requiring surgery. Some studies have suggested that vertebroplasty raises the risk of subsequent fractures, particularly in vertebrae adjacent to treated areas, sometimes after the medical cement has leaked into those areas, they added.

"Our results show …the hazards of relying on the results of uncontrolled or poorly controlled studies to assess treatment efficacy," Dr. Buchbinder and her colleagues noted.

Earlier studies may have overestimated the benefit of vertebroplasty "by failing to take into account the favorable natural history of the condition, the tendency of regression to the mean, and the placebo response to treatment, which may be amplified when the treatment is invasive," they added.

In the other study, Dr. David F. Kallmes of the Mayo Clinic, Rochester, Minn., and his associates enrolled patients at 11 medical centers in the United States, the United Kingdon, and Australia. A total of 68 were randomly assigned to vertebroplasty and 63 to a sham procedure.

At 1 month, the two groups did not differ significantly on the two primary outcomes, which were separate measures of pain and disability. Secondary outcomes of pain intensity, disability, and quality of life also were not significantly different, Dr. Kallmes and colleagues said (N. Engl. J. Med. 2009;361:569-79).

One patient who underwent vertebroplasty sustained an injury to the thecal sac during the procedure and required hospitalization, they added.

Dr. Buchbinder reports receiving grant support for the trial from Cook Australia, a manufacturer of medical products and devices. Dr. Kallmes reports receiving consulting fees from Zelos Therapeutics and grant support from ArthroCare, Stryker, Cardinal, and Cook and serving as an unpaid consultant to Bone Support. Dr. Weinstein reported no disclosures. ■