

the lack of postoperative AMP; however, this analysis was confounded by procedure type and hospital.

### Interpretation

Antibiotic prophylaxis is most effective when administered less than or equal to 30 min before surgical incision, although the risk only slightly increases when administered 31–120 min before incision. The risk substantially increases when antibiotics are administered after incision. This study reinforces antibiotic timing guidelines. Because elective surgeries have a low risk of SSI, this study may not be adequately powered to address specific details of nonelective surgeries, timing of antibiotic administration, and SSI.

*Suggested by: Hervé Dupont, M.D., Ph.D.*

## Pain Medicine

*Timothy J. Brennan, Ph.D., M.D., Editor*

### A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009; 361:557–68

Osteoporotic vertebral fractures are a common cause of pain and disability occurring in 1.4 million people worldwide and are associated with increased mortality and direct care expenditures as high as 18 billion US dollars. Observational studies suggest an immediate and sustained reduction in pain after vertebroplasty, the percutaneous injection of cement (polymethylmethacrylate) into the affected vertebral body. Despite the paucity of randomized, controlled trials evaluating the true safety and efficacy of vertebroplasty, the number of vertebroplasty procedures doubled in the past 6 yr.

This blinded, randomized, parallel-group, multicenter, placebo-controlled trial analyzed the short-term efficacy of vertebroplasty for alleviating pain and improving physical function in patients with painful osteoporotic vertebral fractures. Patients with back pain of less than 12 months' duration and one or two recent fractures ( $\geq$  grade 1) were randomly assigned to undergo either vertebroplasty or a sham procedure. Gentle tapping guided the needle through the pedicle into the anterior two thirds of the fractured vertebral body, and images were recorded to ensure the correct position before polymethylmethacrylate was injected. Patients in the sham group underwent the same procedures, except the vertebral body was gently tapped, and polymethylmethacrylate was prepared.

Although significant mean reductions in overall pain occurred in the 71 patients enrolled who completed the 6-month follow-up, reductions were similar in the vertebroplasty and sham groups at 3 months ( $2.6 \pm 2.9$  and  $1.9 \pm 3.3$ , respectively). There were no significant between-group differences in any other health-related outcome scores except for one of three measurements at 1 week, which favored the sham group. Results were consistent irrespec-

tive of the duration of symptoms, sex, treatment center, or presence or absence of previous vertebral fractures. Although use of opioids decreased over time, there were no between-group differences.

### Interpretation

Both vertebroplasty and placebo were equally efficacious for pain relief in patients with painful vertebral compression fractures. The significant analgesic effect of placebo may warrant investigating the effectiveness of bupivacaine infiltration of the pedicles for pain relief of fractured vertebrae.

*Suggested by: Salim Hayek, M.D., Ph.D.*

### A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009; 361:569–79

The Investigational Vertebroplasty Safety and Efficacy Trial (INVEST), a global, multicenter, randomized, controlled trial, evaluated the efficacy of polymethylmethacrylate (PMMA) infusion in vertebroplasty for patients with painful osteoporotic compression fractures compared with a simulated procedure in the absence of PMMA. Patients ( $>50$  yr of age) with new fractures ( $<1$ -yr old) between vertebral levels T4 and L5, with inadequate pain relief with standard medical therapy, and a current rating for pain intensity of more than or equal to 3 were enrolled. All procedures were performed by experienced practitioners having performed a mean of approximately 250 procedures. PMMA was infused under constant lateral fluoroscopy into the vertebral body until PMMA reached to the posterior aspect of the vertebral body or entered an extraosseous space. During the control intervention, vertebral and physical cues were given, and the methacrylate monomer was opened to simulate mixing of PMMA.

The primary outcomes at 1 month did not differ significantly between the two study groups (vertebroplasty,  $n = 68$ ; control,  $n = 63$ ). The mean Roland-Morris Disability Questionnaire scores were  $12.0 \pm 6.3$  and  $13.0 \pm 6.4$ , and the mean pain-intensity ratings were  $3.9 \pm 2.9$  and  $4.6 \pm 3.0$  in the vertebroplasty and control groups, respectively. Both groups had substantial improvement in back-related disability and pain immediately (3 days) after the procedure that was maintained at 1 month, with similar improvement in both groups. Pain measures, quality of life, or proportion of patients with clinically meaningful improvement in physical disability were similar between the two groups. Crossover to the alternative treatment did not demonstrate any additional benefit.

### Interpretation

This trial showed no significant benefit of vertebroplasty compared with the sham procedure during the 6-month follow-up period. Larger trials may identify subgroups of patients that benefit from vertebroplasty. In this trial, duration

of pain was not a factor. Further evaluation of long-term outcomes between groups should be considered.

*Suggested by: Sean Mackey, M.D., Ph.D.*

**Comparison of fluoroscopically guided and blind corticosteroid injections for greater trochanteric pain syndrome: Multicenter randomized controlled trial. BMJ 2009; 338:b1088**

Greater trochanteric pain syndrome, also known as trochanteric bursitis, is a common, chronic, and often misdiagnosed form of lateral hip pain. Corticosteroid injections may provide pain relief; however, few studies evaluating their efficacy have been published. Furthermore, none of these were controlled or used techniques to guide the location of the injection (*e.g.*, fluoroscopy or ultrasonography).

This multicenter, randomized, controlled study compared fluoroscopically guided and blinded techniques for trochanteric bursa corticosteroid injections. Patients with pain for more than or equal to 3 months duration were included. The physician used landmarks to guide needle insertion for patients in the control group, injected contrast, and determined contrast distribution. Patients received 60 mg of depo-methylprednisolone and 2.5 ml of 0.5% bupivacaine regardless of whether the contrast entered the bursa in the blind group, and only if the image revealed intrabursal

spread in the fluoroscopy group. The primary outcome was pain scores at 1 month postinjection, and secondary outcomes included global health outcome indices and reduction in drug use.

The majority of the 64 patients enrolled were women, approximately 55 yr of age, not obese, and not using opioid analgesics. The accuracy rates for injections entering the bursa on the first attempt were similar between groups (12/32 and 12/33 in the fluoroscopy and blind groups, respectively). Overall, 61% of patients experienced more than or equal to 50% pain relief and satisfaction with the results at 1-month follow-up and 44% at 3 months. No differences were observed between treatment groups. Patients in both groups reported significantly reduced pain after 1 month compared with baseline ( $P < 0.0001$ ). None of the patients had a significant reduction in drug use at 1 or 3 months. Location of injection (intrabursal *vs.* extrabursal) did not significantly affect pain scores.

**Interpretation**

Injection of corticosteroid plus local anesthetic into the region of the greater trochanteric bursa produced long-term pain relief in approximately 50% of the patients. Injections based on anatomical landmarks *versus* fluoroscopy were equally effective. Use of fluoroscopy is not required to achieve more than or equal to 50% pain relief for 3 months after greater trochanteric bursa injection.

*Suggested by: Timothy J. Brennan, Ph.D., M.D.*