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Long-Term Data for 884 Patients Show Vertebroplasty for Osteoporotic Spinal Fractures Provides Dramatic Pain Relief, Greatly Decreases Disability

Washington, D.C. (March 18, 2008)—The results of a five-year follow-up study of 884 osteoporosis patients bolster the use of vertebroplasty—an interventional radiology treatment for vertebral compression fractures—finding that the procedure provides dramatic pain relief and sustained benefit, announced researchers at the Society of Interventional Radiology's 33rd Annual Scientific Meeting. Vertebroplasty, the injection of medical-grade bone cement into a fractured vertebra, shores up the fracture similar to an internal cast and provides pain relief. It is indicated for painful vertebral compression fractures that fail to respond to conventional medical therapy, such as minimal or no pain relief with analgesics or narcotic doses that are intolerable. The average pre-treatment pain score on the 11-point Visual Analog Scale was 7.9 +/- 1.5, and it dropped significantly to an average of 1.3 +/- 1.8 after the vertebroplasty treatment.

One's ability to manage everyday life—such as washing, dressing or standing—was measured by the commonly used Oswestry Disability Questionnaire (ODQ), which was completed by patients before—and again one month after—vertebroplasty. The ODQ scores changed from an average of 69.3 percent +/- 13.5 to 18.8 percent +/- 6.9, showing a highly significant improvement in mobility.

"These data provide good news for physicians and osteoporosis patients. Many osteoporosis patients with compression fractures are in terrible pain and have a greatly diminished ability to perform basic daily activities, such as dressing themselves," said Giovanni C. Anselmetti, M.D., interventional radiologist at the Institute for Cancer Research and Treatment in Turin, Italy.

Vertebroplasty can greatly improve one's quality of life; however, the treatment is generally reserved for patients who have failed conventional medical management.

"Osteoporosis patients who have persistent spinal pain lasting more than three months should consult an interventional radiologist, and those who require constant narcotic pain relief should seek help immediately," noted Anselmetti. The treatment was completed in all patients without major complications and with good clinical results. The data add to the body of evidence in the United States for the minimally invasive treatment's safety, effectiveness and low-complication rate. The treatment is widely available in the United States at all major institutions and many smaller institutions and is generally covered by health insurance.

The study also showed that vertebroplasty does not increase the risk of fracture in nearby vertebra. "Vertebroplasty is already known to be a safe and effective treatment for osteoporotic vertebral fractures. Osteoporosis patients remain susceptible to new fractures, which often occur in the contiguous vertebra to an existing fracture. Our large-scale study shows that vertebroplasty does not increase the risk of fracture in the level contiguous to previously treated vertebra and that these new fractures occur at the same rate as they would in osteoporosis patients who did not have vertebroplasty," added Anselmetti.

Abstract 182, "Percutaneous Vertebroplasty in the Osteoporotic Patients: Five Years Prospective Follow-up in 884 Consecutive Patients," can be found at www.SIRmeeting.org.

About Vertebroplasty

Vertebroplasty was first performed in France in 1984 to treat compression fractures caused by bone cancer or bone metastasis and later to treat compression fractures caused by osteoporosis. Percutaneous vertebroplasty was introduced in the United States in 1994 and has become widely available since 1997 as a treatment for pain associated with compression fractures due to osteoporosis. The procedure has been shown to provide continued pain relief for osteoporotic compression fractures.

Vertebroplasty is indicated for painful vertebral compression fractures that fail to respond to conventional medical therapy, such as minimal or no pain relief with analgesics or narcotic doses that are intolerable. Vertebroplasty is an outpatient procedure performed under X-ray–imaging guidance and conscious sedation. The interventional radiologist inserts a needle through a nick in the skin in the back, directing it under fluoroscopy (continuous, moving X-ray imaging) into the fractured vertebra. The physician then injects the medical-grade bone cement into the vertebra. The cement hardens within about 15 minutes and stabilizes the fracture.

About Osteoporosis

Osteoporosis is characterized by low bone mass and structural deterioration of the bone, resulting in an increased susceptibility to fractures. A major public health issue, osteoporosis affects 10 million Americans and is responsible for 1.5 million vertebral fractures each year, according to National Institutes of Health estimates. Multiple vertebral fractures can result in chronic pain and disability, loss of independence, stooped posture and compression of the lungs and stomach. Nearly all vertebral fractures in otherwise healthy people are due to osteoporosis and can occur from a minor impact, such as a bump or a fall, in those who suffer from this bone-weakening disease.

About the Society of Interventional Radiology

Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use

X-ray, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease internally. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine.

Today many conditions that once required surgery can be treated less invasively by interventional radiologists. Interventional radiology treatments offer less risk, less pain and less recovery time compared to open surgery. Visit <u>www.SIRweb.org</u>.

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