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Society of Interventional Radiology Supports Treatment for Painful Spine Fractures: Patient Selection Key

Society Supports Additional Scientific Studies, Fights Negative Backlash From Two Controversial Studies That Compared Vertebroplasty to Placebo That Possibly Places Patients With Osteoporosis in Jeopardy of Losing Beneficial Treatment

FAIRFAX, Va.—Given the current controversy over vertebroplasty—a minimally invasive treatment performed by interventional radiologists in individuals with painful osteoporotic vertebral compression fractures that fail to respond to conventional medical therapy—what’s a patient to do? Trust your medical team to decide if you are an appropriate candidate for vertebroplasty and trust the experience of hundreds of thousands of other patients who have undergone the spine treatment successfully and received life-improving effects, says the Society of Interventional Radiology.

“Hundreds of thousands of patients have greatly benefited from vertebroplasty with almost complete resolution of their pain; tens of thousands dependent on intravenous narcotics have been discharged from the hospital virtually pain- and drug-free following their treatment,” noted SIR President Brian F. Stainken, M.D., FSIR, who represents the national organization of nearly 4,500 doctors, scientists and allied health professionals dedicated to improving health care through minimally invasive treatments. “Before treatment, many of these osteoporotic patients are in constant pain and cannot manage everyday activities. Many are confined to bed for up to six weeks. These are the people we help; with vertebroplasty they can go home in one to two days. Candidates for the procedure are those who have failed to respond to conventional medical treatment (such as rest, analgesics and narcotic drugs). Vertebroplasty can give patients their lives back,” said Stainken, president of the Imaging Network of Rhode Island and chair of the diagnostic imaging department at Roger Williams Medical Center in Providence, R.I. “Interventional radiologists have the critical skills in imaging and patient care that make them experts at determining which patients are the most appropriate candidates to receive the treatment,” he added.

Two studies published in the *New England Journal of Medicine* in August were the first clinical trials to test vertebroplasty against a placebo, and many experts were stunned by the results that suggested that patients got equal amounts of modest pain relief whether they got vertebroplasty, where medical-grade bone cement is injected into broken vertebrae, or a dummy injection. “SIR supports the use of vertebral augmentation (vertebroplasty and kyphoplasty) for patients with painful compression fractures. In addition, SIR supports the important role of research regarding the role of vertebral augmentation, but we should take note that it is increasingly clear that these studies did not tell the whole story,” said Stainken. “The groups of patients studied and the analysis raised as many questions as were answered,” he said. Based on the NEJM findings, the society recommended that interventional radiologists inform patients of the studies’ controversial results during consultation. “The studies demonstrate the importance of debate and rigorous analysis of all data prior to rushing to conclusions. We must closely monitor trends in vertebroplasty research. There will be additional studies at SIR’s Annual Scientific Meeting in March that will provide new perspective on the aforementioned studies and reaffirm our perspective that vertebroplasty provides long-term and rapid pain relief for appropriately selected patients,” said Stainken.

“We are concerned about the possibility that insurance coverage may be withdrawn for vertebroplasty and possibly kyphoplasty because of the controversy generated by the two NEJM studies,” said Stainken. If that occurs, access to these procedures would be limited to patients enrolled in approved trials, leaving many patients in severe pain without a solution. SIR is keeping a watchful eye on this to protect patients’ access to medical treatment. SIR will continue to serve as a leader in future trials of vertebroplasty that may confirm or contradict these studies or may identify subsets of patients more likely to benefit from vertebral augmentation, noted the SIR president.

SIR member and vertebroplasty expert J. Kevin McGraw, M.D., FSIR, agrees. “While we welcome the two studies by researchers David F. Kallmes, M.D., and Rachele Buchbinder, Ph.D., to the body of literature on this technique, the results of these trials are discordant with personal experience and more than

15 years of accumulated medical literature espousing the benefits of vertebroplasty,” said McGraw, section head, interventional radiology, at Riverside Radiology and Interventional Associates in Columbus, Ohio. “SIR recognizes the value of randomized controlled trials and evidence-based medicine; however, the weakness in the studies and the degree of discordance between the outcomes of these studies, prior studies and experience, suggest that it is premature—and possibly incorrect—to conclude that vertebroplasty is no better than a control sham procedure,” he noted.

Criticisms of both studies include the small numbers of patients treated; the small percentage of eligible patients who were actually enrolled in the trial; inclusion of patients with milder degrees of pain and disability than are usually treated in a typical practice; the small amount of cement injected; treatment of patients with chronic compression fractures; the incomplete use of MRI or CT to confirm that the fracture was the likely source of pain; and the high rate of crossover from placebo to vertebroplasty in one of the studies, explained McGraw.

Criticism has also come from one of the studies’ investigators. William Clark, M.D., St. George Private Hospital, Sydney, Australia, an investigator with the Kallmes study, said he regarded that study as “meaningless.” In addition, he called the Buchbinder study “a rush to judgment on ‘science-based medicine’ without applying scientific technique in appraising the studies” in comments posted to the Arthritis Today Web site. Clark noted numerous flaws in the studies, indicating they had “inappropriate patient selection, terrible recruitment and selection bias with the majority not followed.”

Osteoporosis, the most common type of bone disease, is characterized by low bone mass and structural deterioration of the bone resulting in an increased susceptibility to fractures. Osteoporosis affects 10 million Americans and is responsible for 700,000 vertebral fractures each year. Multiple vertebral fractures can result in chronic pain and disability, loss of independence, stooped posture and compression of the lungs and stomach.

Vertebroplasty, a minimally invasive treatment performed by interventional radiologists under imaging guidance, stabilizes collapsed vertebra with the injection of medical-grade bone cement into the spine. “This reduces pain and can prevent further collapse of the vertebra, thereby preventing the height loss and spine curvature commonly seen as a result of osteoporosis. Vertebroplasty, when used appropriately in accordance with established practice standards by expert providers, dramatically improves back pain within hours of the procedure, provides long-term pain relief and has a low complication rate, as demonstrated in multiple studies. We must not rush to new conclusions, especially based on these recent controversial studies,” said McGraw.

More information about the Society of Interventional Radiology, interventional radiologists and vertebroplasty can be found online at www.SIRweb.org. SIR’s Research Reporting Standards for Percutaneous Vertebral Augmentation were published recently in the Journal of Vascular and Interventional Radiology as an additional reference for physicians. SIR’s Commentary on Vertebroplasty and the August Studies in the New England Journal of Medicine is also available on the society’s Web site.

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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, such as 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, interventional oncology is a growing specialty area of interventional radiology. Interventional radiologists can deliver treatments for cancer directly to the tumor without significant side effects or damage to nearby normal tissue.

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 www.SIRweb.org.

Local interviews and medical illustrations are available by contacting SIR’s communications department via e-mail at mverrillo@SIRweb.org or by phone at (703) 476-5572. A vertebroplasty fact sheet can be found in the Media section at SIRweb.org.