Medical Xpress

Controversial Studies Trigger Dropoff in Osteoporosis Treatment

February 22 2010

(PhysOrg.com) -- Dr. Angelo Malamis says that 90 percent of his patients who have undergone a treatment called balloon kyphoplasty for vertebral fractures report significant reductions in pain and disability.

But the number of kyphoplasty referrals Malamis has received from primary care doctors has dropped sharply since two controversial studies were published last year in the [New England Journal of Medicine](#). In findings that have been disputed by two medical societies, researchers reported that a procedure related to kyphoplasty was not significantly better than a placebo-like procedure in reducing pain and disability.

The North American Spine Society and the Society of Interventional Radiology have pointed to flaws in both studies. And earlier studies, published over 15 years, found major benefits to kyphoplasty and a related procedure called [vertebroplasty](#).

"We're missing opportunities for patients to receive a safe and effective treatment that can significantly reduce their pain and disability," said Malamis, an interventional radiologist.

The procedures are used to treat vertebral compression fractures in patients with osteoporosis and other conditions that result in brittle bones. In a vertebroplasty, an acrylic cement is injected into a fractured vertebra. In a kyphoplasty, a balloon-tipped [catheter](#) first is inserted into the fracture. The balloon is inflated to restore the height and shape of the vertebra before the cement is injected.

Neva Nelson, 74, of Naperville, Ill., said a kyphoplasty that Malamis performed in October, 2009, has greatly reduced her pain in a vertebra in her lower back that she fractured after falling on ice. Before her kyphoplasty, Nelson had to sit on cushions. Walking, and especially standing, were painful. "I had to do something," she said. "I could not go on like that."

Nelson said that since undergoing her kyphoplasty, "I don't have to worry about my back any more."

In the controversial studies, patients were randomly assigned to receive a vertebroplasty or a placebo-like "sham" procedure. In the sham procedure, patients received an injection of anesthetic, but no cement.

However, patients in severe pain are reluctant to enroll in a trial where there's a 50 percent chance of receiving a sham treatment. In one of the studies, researchers had to screen 1,813 patients to enroll just 131 subjects. In the other study, only 78 of 219 eligible patients were enrolled. This low enrollment rate raises the possibility that the patients who did enroll were not representative.

Patients experience the greatest pain during the first three months after a compression fracture. Thereafter, pain gradually subsides. Thus, a vertebroplasty or kyphoplasty provides the greatest benefit when performed within a week or two of the fracture. But the studies enrolled patients up to 12 months after fractures.

In addition to reducing pain and disability, a kyphoplasty can reduce the risk of subsequent fractures by improving the angle and height of the spine. The studies evaluated vertebroplasty alone, and did not include the more innovative and very different kyphoplasty procedure.

Malamis suggests the medical community wait for the results of

additional studies now underway before passing final judgment on vertebroplasty or kyphoplasty. In the mean time, he notes that Medicare still covers the procedures.

Malamis is an assistant professor in the Department of Radiology at Loyola University Chicago Stritch School of Medicine.

Provided by Loyola University Health System

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