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Balloon kyphoplasty an effective and safe early treatment for acute vertebral compression fractures

San Francisco, CA — Results of the international, multicenter, randomized controlled clinical study, the Fracture Reduction Evaluation (FREE) trial, showed that balloon kyphoplasty improved patients' quality of life and reduced back pain and disability. The findings were presented today at the North American Spine Society's 24th Annual Meeting in San Francisco.

"Kyphoplasty is an effective and safe early treatment option for patients with acute vertebral compression fractures," said Douglas Wardlaw, MD, consultant orthopedic and spinal surgeon, NHS Grampian, Orthopaedic Unit, Woodend Hospital.

Led by Wardlaw, the FREE trial compared the effectiveness and safety of balloon kyphoplasty, a minimally invasive procedure, to nonoperative care for treating acute, painful vertebral body compression fractures.

"FREE is the first randomized study comparing kyphoplasty to nonsurgical management — the standard of care — for treating acute vertebral compression fractures," Wardlaw said.

The study included 300 patients treated at 21 sites in eight countries. Mean patient age was 73 years; 78% of study participants were women. Primary osteoporosis caused most of the injuries in patients with vertebral body compression fractures.

For the primary end point, the researchers chose quality of life measured by the physical component summary (PCS) score of the SF-36 at one month. For secondary measures, they used the SF-36 subscales and summary scales, the Euroquol-5D (EQ-5D) global health measure, the Visual Analog Score for back pain, the Roland Morris Disability Questionnaire (to measure back function) and pain medication usage.

Surgeons performed a percutaneous, bilateral approach on the balloon kyphoplasty patients; nonsurgical treatment was based on the standard practices of each participating hospital.

At one month, the mean SF-36 PCS score improved 5.1 points in the kyphoplasty group than in the nonsurgical group (95% CI, 2.87.4; $P<0.0001$). For the kyphoplasty patients, the PCS score improved by an average of 3 points during the two-year follow-up (95% CI, 1.65.4; $P=0.002$).

Compared to nonoperative patients, kyphoplasty patients reported statistically significant improvements in quality of life, Wardlaw said. The EQ-5D scores improved an average of 0.13 points more than nonoperative patients over two years (95% CI; *P*=0.004).

The surgical procedure produced good results in other areas as well. “Kyphoplasty patients also had significantly less back pain and disability,” Wardlaw said. “These benefits persisted over two years.” Kyphoplasty resulted in fewer days of limited activity — within a two-week period — when averaged over two years.

About NASS
The North American Spine Society (NASS) is a multidisciplinary medical organization dedicated to fostering the highest quality, evidence-based, and ethical spine care by promoting education, research, and advocacy. NASS is comprised of more than 5,500 members from several disciplines including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research, physical therapy and other spine care professionals. For more information, visit **www.spine.org**.

About NASS’ 24th Annual Meeting
NASS’ 24th Annual Meeting is being held in San Francisco, November 10-14, 2009, at the Moscone Center South. For more information, or to view press releases related to the meeting, please visit NASS’ Annual Meeting Web site.