

# German Study Results Back Balloon Kyphoplasty

BY BRUCE JANCIN  
Denver Bureau

VIENNA — Balloon kyphoplasty for vertebral compression fractures proved to be a safe and markedly more effective alternative to conservative management in a prospective 12-month comparative study, Arnd Lienert, M.D., Ph.D., said at the annual European congress of rheumatology.

He reported on 19 patients who underwent balloon kyphoplasty and 17 who opted instead for conservative management of monosegmental osteoporotic vertebral fractures in a non-randomized study.

During 1 year of follow-up, 13 of 17 conservatively managed patients developed a total of 23 new radiographically proven vertebral fractures, of which 19 occurred



adjacent to the index fracture. In contrast, only 8 of 19 balloon kyphoplasty patients developed 10 new fractures, of which 6 were in a vertebra next to the index fracture, said Dr. Lienert, an orthopedic surgeon at the University of Witten/Herdecke, Germany.

The balloon kyphoplasty group had significantly faster and greater reductions in pain and functional disability as assessed by a visual analog scale and a North American Spine Society questionnaire.

Moreover, their slumping due to spinal deformity was significantly less over time. Their pretreatment kyphotic angle of 34 degrees was reduced to 7 degrees at 1 year,

compared with 19 degrees in the conservatively managed group, he added at the meeting sponsored by the European League Against Rheumatism.

There were no periprocedural complications associated with balloon kyphoplasty. The procedure restored vertebral compression fractures to more than 50% of the original vertebral height in all 19 treated patients, and to more than two-thirds of original height in 11 patients. All patients in the balloon kyphoplasty group indicated that they would be willing to undergo the procedure again if necessary.

**The best time to perform the procedure, and how well the results hold up after 1 year are still unknown.**

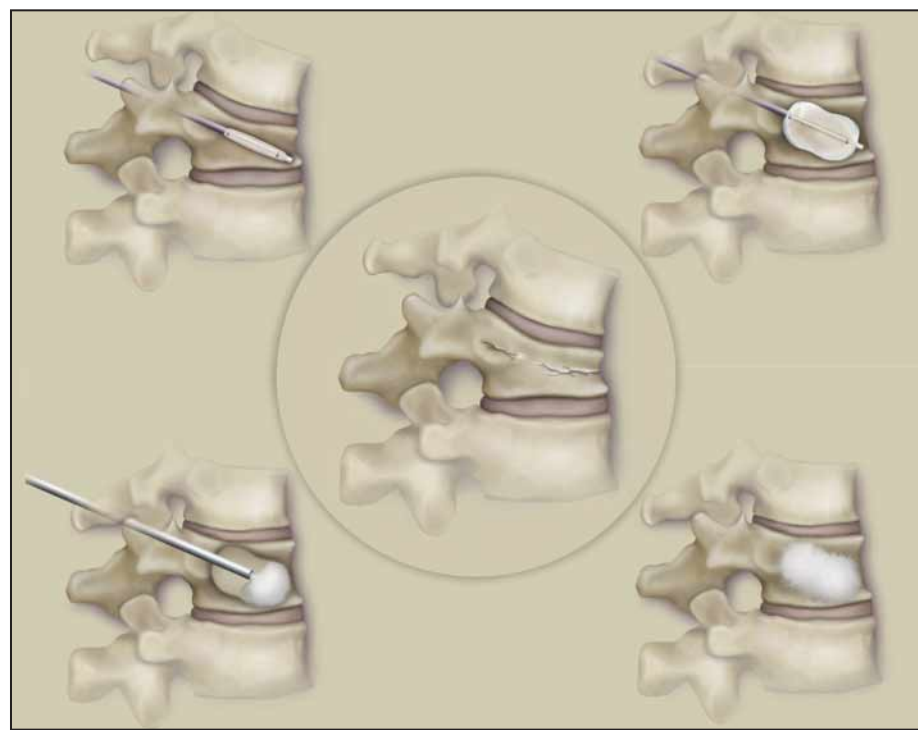
DR. LIENERT

Patients in both study arms received antiosteoporosis medication. Conservative management consisted of bracing, physical therapy, and non-steroidal anti-inflammatory drugs.

Balloon kyphoplasty is a minimally invasive procedure in which the balloon inflation creates an intravertebral void that allows injection of high-viscosity bone cement to stabilize and reduce the fracture. A promising recent development involves the investigational use of a resorbable artificial bone scaffold capable of undergoing bone remodeling in lieu of the standard bone cement used in this study, according to the surgeon.

The best time to perform the procedure is still not known, and how well the results hold up beyond the 1-year mark also remains a question, Dr. Lienert observed.

The study was conducted by Dr. Lienert



During the procedure, balloon inflation creates an intravertebral void that allows injection of high-viscosity bone cement to stabilize and reduce the fracture.

and his orthopedist colleagues at St. Anna Hospital in Herne, Germany, without outside sponsorship.

One audience member said he found it surprising that the incidence of adjacent fractures was significantly lower in the balloon kyphoplasty group than in conservatively managed patients given that some reports in the literature suggest balloon kyphoplasty might actually predispose patients to adjacent vertebral fractures. Dr. Lienert replied that he, too, is aware of such reports, adding that it's possible his findings to the contrary could simply be

due to chance in a study with relatively small patient numbers.

Session cochair Winfried B. Graninger, M.D., a rheumatologist at the Medical University of Vienna, commented that a nonrandomized trial in which pain is a major end point is so methodologically problematic that he views it as "almost an uncontrolled study."

Dr. Lienert responded that in his experience, it's much tougher to get patients to consent to randomization in studies involving surgical procedures than in drug trials. ■

## Check Eyesight to Cut Fracture Risk in Osteoporotic Patients

BY SHERRY BOSCHERT  
San Francisco Bureau

SAN FRANCISCO — Physicians who see patients with osteoporosis should have a visual acuity chart on the office wall to check eyesight, Steven R. Cummings, M.D., advised at a meeting on osteoporosis sponsored by the University of California, San Francisco.

Reduced visual acuity greatly increases the risk for falling and hip fractures. Usually poor vision is due to treatable factors such as the need for an updated glasses prescription, or cataracts, said Dr. Cummings, professor emeritus of epidemiology and biostatistics at the university and director of clinical research at the California Pacific Medical Center Research Institute.

Impaired vision can double or quadruple the risk for hip fracture. At least one study shows that repairing cataracts can reduce the risk of falling by 34% (Br. J. Ophthalmol. 2005;89:53-9).

Dr. Cummings noted that the following additional risk factors are worth addressing to prevent fractures:

► **Vertebral fracture.** Having a vertebral fracture—even a painless, asymptomatic one that's detected only by x-ray—increases the risk for future vertebral frac-

ture two- to fourfold. Older women with a previous vertebral fracture have a 1%-3% annual rate of hip fracture, and randomized trials suggest that pharmacologic treatment can lower that risk.

► **Nonspine fractures.** Having any kind of nonspine fracture nearly doubles or triples the risk for having a future nonspine fracture. This is especially true in men, and is independent of bone mineral density. Even with normal bone density, having a nonspine fracture makes a future nonspine fracture more likely.

► **Familial history.**

People who had a parent develop a hip fracture have double the risk for hip fracture themselves, compared with people whose parents did not have hip fractures. This is true regardless of bone mineral density. A wrist fracture in a parent increases an offspring's risk of wrist fracture. "There's some suggestion that this increased familial risk may be specific to the type of fracture," he said.

Studies have found no association, however, between patients' reports of parents

who had osteoporosis or spine fractures and the patients' own risk for those problems, probably because "osteoporosis" and "spine fracture" are rather nonspecific terms used with different meanings.

► **Weight.** Women have a higher risk for serious fractures if they are losing weight involuntarily compared with maintaining or gaining weight. Involuntary weight loss is a marker for frailty. Fractures of the hip, humerus, spine or pelvis commonly are referred to as "frailty fractures," he noted. Voluntary weight loss through diet or exercise diminishes a

woman's bone mineral density, but it's not clear whether this increases fracture risk.

► **Corticosteroid use.** Taking more than 10 mg/day of prednisone or comparable doses of other corticosteroids reduces spinal bone density by 5%-10% in the first year, with most of the loss during the first 6 months. Higher doses of steroids reduce spinal bone density even more. Fracture risk increases even more quickly—within 1-2 months of starting corticosteroids. "There's a suggestion here that cortico-

steroids increase your risk for fractures in ways besides causing bone loss," perhaps by killing osteocytes in bone and limiting the ability of bone to respond to stimulators, he said. Consider starting preventive therapy to prevent fractures if patients who will be taking steroids for at least several months have low bone densities or a history of fracture, Dr. Cummings suggested.

► **Smoking.** Cigarette smoking about doubles the risk for hip fracture regardless of a person's bone density, probably because smoking is associated with poorer health, weaker muscles, and impaired balance.

► **Diabetes.** Patients with diabetes have triple the risk for foot fractures and double the risk for humerus or hip fractures, compared with nondiabetic patients. If you see a patient with one of these fractures, look for diabetes, and watch for these fractures in patients already diagnosed with diabetes, he advised.

► **Stroke.** Patients who have had a stroke or are in nursing homes are at very high risk for hip fractures, warranting pharmacotherapy to preserve and strengthen bone. Each year 4%-6% of nursing home patients develop hip fractures. In patients over age 70 who have had a stroke, 3%-5% of women and 2% of men develop hip fractures per year. ■

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