## Threat of Subsequent Fracture Risk Haunts Vertebroplasty

BY MARK S. LESNEY
Senior Editor

Washington — Percutaneous vertebroplasty, while effective for relieving pain, has not been shown to prevent new fractures, Dr. Gregg H. Zoarski said in a state of the art review at a symposium sponsored by the Society of Interventional Radiology.

The procedure works in 85%-95% of patients who have pain localized to one or two nonsclerotic vertebrae and osteoporotic fractures that have occurred within less than 2-3 months. When pain is not localized and there are no observable deformities on imaging or fractures have been present for over 1 year, patients seldom respond well to vertebroplasty, Dr. Zoarski said.

Vertebroplasty also can be used to relieve pain caused by soft tumors in the vertebrae, including myelomas. For patients with neoplastic fractures, pain relief ranges from 60% to 90%, said Dr. Zoarski, professor of diagnostic radiology at the University of Maryland, Baltimore, and director of diagnostic and interventional radiology at the University of Maryland Hospital.

In addition, vertebroplasty and kyphoplasty are "tremendously safe procedures," according to Dr. Zoarski. "Minor complications should be less than 3% and major complications should be well less than 1%," he stated. Less clear is whether vertebroplasty, like surgical intervention, actually increases the risk of adjacent vertebral fractures.

In small follow-up studies, there was

no statistically significant increase in adjacent fractures with vertebroplasty. A retrospective study of 177 patients, however, found a significantly higher rate of adjacent fractures within 30 days of the procedure, and 67% of new fractures occurred adjacent to treated vertebrae, he said.

The natural history of osteoporosis and nonuniform stress within the spine may create a "hot spot" where subsequent fractures are likely to occur, irrespective of intervention. Biomechanical studies are uneven in terms of predicting fracture location.

With regard to both vertebroplasty and kyphoplasty, "I think we have to conclude that there is mixed data on this and we cannot clearly state whether the procedure is going to prevent or cause adjacent fractures," Dr. Zoarski said. The need for vertebroplasty or other interventional treatments is relatively high, especially because surgery isn't an option for many patients with poor bony substrate or comorbidities.

Noninterventional alternatives have their own complications. Bed rest can exacerbate bone deterioration and decrease patient strength. Bracing has compliance problems, and removal of the brace causes patients "to regress to the same level of deformity that they would have [had] without the brace." Medications for pain can interact with other drugs as well as directly contribute to morbidity. Dr. Zoarski stated that he had no financial relationships to disclose in regard to percutaneous vertebroplasty.

## Weekly Dose of Parathyroid Hormone Thickens Spine

BY KERRI WACHTER

Senior Writer

PHILADELPHIA — Weekly parathyroid hormone increases bone mineral density and bone formation biomarkers, but only slightly, Dennis M. Black, Ph.D., reported at the annual meeting of the American Society for Bone and Mineral Research.

Spine bone mineral density (BMD) increased 2.1% in women on parathyroid hormone (PTH) at the end of 1 year, compared with women receiving no treatment, a significant finding. Trabecular spine volumetric BMD assessed with quantitative CT increased 3.8% in women in the treatment group, compared with those in the control group, though this result was not significant, Dr. Black said. There also were trends toward increases in trabecular number and cortical thickness, though these were not statistically significant.

In the PTH Once Weekly Research (POWR) study, 50 women were randomized evenly to treatment with PTH (1-84) at a dosage of 100 mcg daily for 1 month followed by 11 months of once weekly PTH (also 100 mcg) or no treatment. All women also received 500 mg calcium and 400 IU vitamin D per day, reported Dr. Black, professor of epidemiology and biostatistics at the University of California, San Francisco. Women had to be postmenopausal and aged between 45 and 70 years, with minimal previous use of bisphosphonates. They also had to have a femoral neck BMD T score between –1 and –2 and a spine BMD T score greater than –2.5.

The primary end point was spine BMD measured by dual-energy x-ray absorptiom-

etry (DXA). Secondary end points included BMD at the hip, trabecular, and cortical bone measured by quantitative CT at the spine and hip and bone biomarkers. Based on injection diaries, 94% of the women were found to have at least an 80% compliance with the injection regimen, he said.

Bone formation during daily treatment with PTH, as measured by procollagen type 1 N-propeptide (P1NP) levels, increased roughly 100% compared with untreated women. However, levels slowly decreased during weekly injections, remaining 15% greater than for untreated women at 12 months. There were no significant changes in resorption markers in either group.

He compared the results of this pilot study with those for daily PTH treatment at 12 months from the Parathyroid Hormone and Alendronate (PaTH) study (N. Engl. J. Med. 2005;353:555-65).

Once-weekly PTH following daily PTH for 1 month significantly increased spine BMD. However, compared with daily PTH in the PaTh study, "there was no significant increase in trabecular BMD, a small increase in DXA spine BMD, a smaller increase in bone formation markers, and generally a smaller anabolic response," he said.

Once weekly PTH may not be frequent enough. A longer loading period may be necessary, he noted. In terms of adverse events, there was one case of chest pain in the placebo group, and there were four mild cases of hypercalcemia in the PTH group.

Dr. Black disclosed that he has significant financial relationships with Novartis, Merck & Co., Hoffmann–La Roche Inc., and GlaxoSmithKline.

## Nighttime Hot Flashes May Identify Women at Low BMD Risk

BY KATE JOHNSON

Montreal Bureau

NEW ORLEANS — Premenopausal vasomotor symptoms, particularly night sweats, are a previously unrecognized risk factor for low bone mineral density and enhanced bone turnover in infertile women—and probably in fertile women as well, although this has not yet been confirmed, according to Dr. Lubna Pal of the Albert Einstein College of Medicine, N.Y.

Her study won the prize paper from the Society for Reproductive Endocrinology and Infertility at the annual meeting of the American Society for Reproductive Medicine. Based on these data, "I would advise providers to specifically ask about vasomotor symptoms in premenopausal women and, for those who are symptomatic, to focus on unmasking additional factors that may enhance their fracture risk, such as low body mass; family or personal history of fractures; or smoking," she said in an interview. "I don't think we are there yet in terms of recommending bone density screening for this population ... but these women need to be advised that a further deterioration in their bone density parameters is likely to occur in the postmenopausal period, and measures to optimize skeletal health should be addressed now rather than later."

The cross-sectional study included 86 premenopausal infertile women aged 42 years or younger without premature ovarian failure or oophorectomy. A questionnaire was used to ask about the presence and frequency of vasomotor symptoms, including hot flashes and night sweats.

The study also measured subjects' bone mineral density (BMD) and levels of serum N-telopeptide (NTx), a marker of bone turnover. A total of 12% of respondents reported one or both vasomotor symptoms, and 21% of respondents had evidence of low BMD, Dr. Pal reported.

There was a highly significant correlation between vasomotor symptoms and low BMD, with 62.5% of symptomatic women showing evidence of low BMD, compared with 14% of asymptomatic women (odds ratio 10.18). Similarly, 36% of women with low BMD reported vasomotor symptoms, compared with 5% of those with normal BMD.

After controlling for age, body mass index, menstrual regularity, race, and smoking, the study found that vasomotor symptoms (night sweats and/or hot flashes)

were independent predictors of low bone density in the study population. The magnitude of this association was most robust for night sweats, with an adjusted odds ratio (AOR) of 52.47, followed by both symptoms combined (AOR 24.10), and then hot flashes alone (AOR 15.10).

The presence of night sweats was also

an independent predictor of bone turnover, with higher levels of serum NTx seen in symptomatic compared with asymptomatic women, she said.

Levels of inhibin B, a marker of ovarian reserve, were also significantly lower in women with night sweats compared with asymptomatic women, she said.

