

Back Pain Avoided 30 Months After Teriparatide

BY BRUCE JANCIN
Denver Bureau

VIENNA — The risk of developing new-onset back pain is markedly decreased during and for at least 30 months after stopping teriparatide (Forteo) for the treatment of osteoporosis, Jean-Yves Reginster, M.D., Ph.D., reported at the annual European congress of rheumatology.

He presented a metaanalysis of four Eli Lilly-sponsored randomized double-blind clinical trials involving 1,222 teriparatide-treated patients and 691 controls. Control groups in two trials received placebo. In the other two, controls got either 10 mg/day alendronate or hormone therapy. The median follow-up after discontinuing teriparatide was more than 31 months.

The incidence of any new back pain during 4,157 patient-years at risk was 6.9 cases per 100 patient-years among subjects in the teriparatide-treated group, compared with 9.3 cases per 100 patient-years in controls. (See box.)

There was no significant difference in the incidence of new back pain between patients who received 20 mcg/day of subcutaneous teriparatide and those who got 40 mcg/day. Rates in teriparatide-treated patients and controls appeared to diverge after about 6 months of therapy, noted Dr.

Low Back Pain Stays With Single Steroid Dose

NEW YORK — A single intramuscular injection of methylprednisolone failed to relieve idiopathic, nontraumatic, low back pain any better than a placebo in a small, double-blind, randomized trial.

Corticosteroids previously had not been tested in a randomized, controlled trial for acute low back pain in young adult patients in the emergency department, Benjamin W. Friedman, M.D., said at the annual meeting of the Society for Academic Emergency Medicine.

In the trial, the pain level of 44 patients who received 160 mg of the methylprednisolone acetate did not improve significantly more than the pain level of 43 patients who received a saline injection.

On a 1-10 scale—with mild pain rated 1 and excruciating pain, rated 10—pain scores shifted from 7.6 at baseline in the corticosteroid group to 3.5 at 1 week and 2.9 at 1 month.

In the placebo group, scores improved from 8.1 at baseline to 3.3 at 1 week and 2.3 at 1 month, reported Dr. Friedman of the Montefiore Medical Center, New York.

After 1 month, similar percentages of patients in the corticosteroid and placebo groups reported having had low back pain in the previous 24 hours.

All of the patients were 50 years of age or younger (with an average age of 36 years) and reported low back pain for 1 week or less.

—Jeff Evans

Reginster, director and professor of epidemiology, public health, and health economics at the University of Liège, Belgium.

The relative risk of developing severe back pain during teriparatide therapy or for 30 months after treatment ended was reduced by 61%, compared with controls. The risk of developing moderate or severe back pain was reduced by 28%. And the risk of any new-onset back pain was 27% lower in the teriparatide group.

In a separate presentation, Thomas

Nickelsen, M.D., said that postmenopausal osteoporotic women showed a significant decrease in self-assessed back pain after 1 and 6 months of teriparatide in the ongoing European Forteo Study (EUROFORS). At baseline, the women rated their back pain as scoring a mean of roughly 50 points out of a possible 100 on a visual analog scale. After 6 months of open-label teriparatide, their score had dropped by nearly a 10-point absolute margin, or 20%.

These back pain findings are incidental

to the primary purpose of EUROFORS, which is to study the impact of sequential antiosteoporosis therapy—a year of teriparatide followed by a year of raloxifene—compared with 2 years of teriparatide, explained Dr. Nickelsen of Lilly Deutschland GmbH, Bad Homburg, Germany.

EUROFORS involves 866 severely osteoporotic postmenopausal women who fall into one of three subgroups: those with no history of antiresorptive therapy, those who'd been on antiresorptive ther-

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apy—primarily with bisphosphonates—prior to EUROFORs and responded adequately, and inadequate responders to prior antiresorptive agents. Women in all three groups receive a year of teriparatide. Those in the first two groups are then randomized to a year of raloxifene or a second year on teriparatide. For ethical reasons, all prior inadequate responders to antiresorptive therapy get 2 years of teriparatide.

Teriparatide is a bone anabolic agent that directly stimulates osteoblast activity. Its mechanism is essentially opposite that of antiresorptive drugs.

The primary end point in EURO-

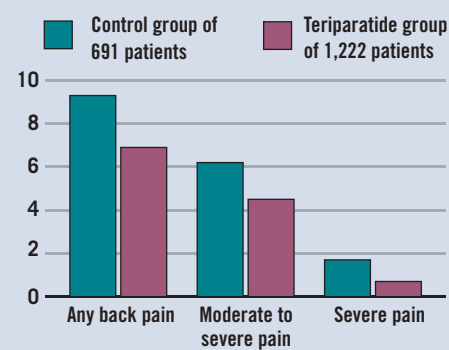
FORS will be the 2-year change in lumbar spine bone mineral density (BMD). After 6 months of teriparatide, mean lumbar spine BMD was up by 5.2% in the treatment-naïve patients, 4.2% in prior adequate responders to antiresorptive therapy, and 3.7% in the inadequate responders. There was also a small but statistically significant increase in hip BMD in treatment-naïve patients, no change in the adequate responders, and a small but significant decrease in the prior inadequate responders.

Side effects were similar to what has been seen in other teriparatide trials: nausea in 10% of patients, arthralgias in

5%, headache in 6%, pain in the extremities in 3%, and hypercalcemia in 2.1%.

“From what we’ve seen so far after 6 months—and it’s still very early—my conclusion would be that teriparatide can safely be used in both types of patients. It can be used as a primary therapy in treatment-naïve patients who are very poorly off and have advanced osteoporosis with multiple prior fractures. And I think what the data are teaching us is it can also be used in patients who have had extensive antiresorptive therapy,” Dr. Nickelsen said at the meeting sponsored by the European League Against Rheumatism. ■

New Cases of Back Pain Per 100 Patient-Years



Source: Dr. Reginster

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* An open-label, randomized, crossover trial of 97 patients with type 2 diabetes inadequately controlled on once- or twice-daily insulin alone or in combination with other oral agents

† PAIR-PI average daily dose of insulin for Humalog Mix75/25 vs glargine: 0.42 ± 0.20 vs 0.36 ± 0.18

Reference:

1. Malone JK et al. Combined therapy with insulin lispro mix 75/25 plus metformin or insulin glargine plus metformin. *Clin Ther*. 2004;26(12):2034-2044.