Teriparatide Benefits Bone Density

ARTICLES BY KERRI WACHTER Senior Writer

PHILADELPHIA — Teriparatide appears to increase bone mineral density regardless of prior antiresorptive therapy response, said Dr. Barbara Obermayer-Pietsch at the annual meeting of the American Society for Bone and Mineral Research.

Dr. Obermayer-Pietsch of Universitätsklinik für Innere Medizin in Graz, Austria, and her colleagues looked at bone mineral density (BMD) changes at the lumbar spine, femoral neck, and total hip in 503 women who received teriparatide (Forteo) for 2 years.

The women were grouped by exposure and response to previous antiresorptive therapy (no prior therapy, adequate response to prior therapy, and inadequate response to prior therapy).

Inadequate response was defined as at least one new clinical fragility fracture after 12 months of therapy, a T score less than or equal to -3 after 24 months of therapy, or a BMD decrease of at least 3.5% after more than 24 months of therapy.

In all, 84 women were antiresorptivetreatment naive, 109 were adequate responders, and 310 were inadequate responders.

In terms of previous treatment, 86% of bisphosphonate users in the adequate-response group and 93% of bisphosphonate users in the inadequate-response group used alendronate, risedronate, or etidronate.

The remaining patients used selective estrogen-receptor modulators, hormone therapy, or vitamin supplements.

"We found an immediate and continuous increase of BMD at the lumbar spine in all groups. However, this was more pronounced in the treatment-naive group," said Dr. Obermayer-Pietsch.

The antiresorptive-therapy inadequate responders initially had a transient decrease in lumbar spine, total hip, and femoral neck BMD but caught up with the other two groups at the end of 2 years (see box, below right).

The women were enrolled as part of the European Forteo Study trial, which compared three different teriparatide treatment regimens in p o s t m e n o p a u s al women with established osteoporosis. All enrolled women

(868) were treated with teriparatide (20 mcg/day), calcium (500 mg/day), and vitamin D (400-800 IU/day) supplements for 1 year.

At the end of the

first year, the women were randomized at a ratio of 3:1:1 to 1 year of treatment with 20 mcg/day teriparatide, treatment with 60 mg/day raloxifene (Evista), or treatment with calcium and vitamin D supplements alone.

A fourth cohort of women who were determined to have had an inadequate response to prior antiresorptive therapy received 20 mcg/day teriparatide for 2 years.

This study was funded in part by Eli Lilly & Co., the manufacturer of teriparatide. Dr. Obermayer-Pietsch disclosed that she has received grants from Eli Lilly & Co.



Antiresorptives Cut Recurrent Hip Fractures

PHILADELPHIA — Antiresorptive therapy reduces the risk of recurrent hip fracture by more than 25%, according to one analysis presented at the annual meeting of the American Society for Bone and Mineral Research.

Patients who were exposed to bisphosphonate therapy following a first hip fracture had a 26% reduction in recurrent hip fracture (hazard ratio [HR] 0.74), after adjusting for age, sex, comorbidity, and medication, Dr. Suzanne N. Morin, an internist at the McGill University Health Centre in Montreal said at the meeting.

Dr. Morin and her colleagues performed a retrospective cohort study, using administrative databases to identify patients who were aged 65 years and older and who had been hospitalized for a first hip fracture between 1996 and 2003.

A total of 20,644 patients were identified and classified based on whether they had been exposed to antiresorptive therapy following hospital discharge after treatment of hip fracture, Dr. Morin said.

Exposure was defined as being dispensed a prescription for bisphosphonates, raloxifene, calcitonin, or hormone replacement therapy.

Of the 20,644 patients, 6,779 were exposed to antiresorptive therapy (mean time to first exposure after hospital discharge was 3 months) and 13,865 were not exposed.

Most of the patients—90% of those exposed and 73% of those not exposed—were women.

"In general, the exposed patients tended to be younger and to have fewer comorbidities than the nonexposed," Dr. Morin said.

The patients who had been exposed to antiresorptives were also more likely to take calcium and vitamin D supplements and to use corticosteroids.

Bisphosphonates were prescribed the most frequently.

For exposed patients, follow-up began on the day that the prescription for an antiresorptive was filled.

Patients who had not been exposed to antiresorptives were assigned starting dates that were frequency matched to those of the exposed patients.

Mean follow-up was 2.2 years, during which time 9,146 patients died and 992 recurrent fractures occurred.

The refracture rate was 2.17 per 100 person-years for the exposed group and 2.9 per 100 person-years for the non-exposed group.

Men in the study were also less likely to have a recurrent hip fracture (HR 0.75). For each 1-year increase in age, the risk of recurrent hip fracture increased by 3%, Dr. Morin said. The presence of osteoporosis was associated with a twofold increase in the risk of recurrent hip fracture.

Ibandronate Injections Boost BMD at 2 Years PHILADELPHIA — Intermittent intra- perior to oral daily ibandronate at 1 and 2 has received research grants from both

venous injections of ibandronate continue to improve bone mineral density of the spine and hip at 2 years, according to data presented at the annual meeting of the American Society for Bone and Mineral Research.

The 2-year results from the Dosing IntraVenous Administration (DIVA) study show that IV ibandronate injections every 2 or 3 months were superior to oral daily ibandronate (Boniva) in terms of increased bone mineral density (BMD) at the lumbar spine.

The periodic IV injections were also su-

perior to oral daily ibandronate at 1 and 2 years follow-up in terms of increased BMD for the total hip, femoral neck, and trochanter.

"IV ibandronate injections improve BMD at the spine and the hip [and] they produce superior BMD gains to oral dosing," said Dr. E. Michael Lewiecki, osteoporosis director of the New Mexico Clinical Research and Osteoporosis Center and professor of medicine at the University of New Mexico in Albuquerque.

The study was funded in part by F. Hoffmann-La Roche Ltd. and Glaxo-SmithKline. Dr. Lewiecki disclosed that he

Raseline in Rivid Mith Idandronate			
	Daily oral (n = 469)	Bimonthly injection (n = 454)	Trimonthly injection (n = 472)
Lumbar Spine			
Year 1	3.8	5.1	4.8
Year 2	4.8	6.4	6.3
Total Hip			
Year 1	1.8	2.5	2.4
Year 2	2.2	3.4	3.1
Femoral Neck			
Year 1	1.6	2.0	2.3
Year 2	2.2	2.7	2.8
Trochanter			
Year 1	3.0	4.0	3.8
Year 2	3.5	5.0	4.9

has received research grants from both companies.

DIVA was a randomized, double-blind, active-control study involving women aged 55-80 years, who were at least 5 years postmenopausal and who had a lumbar spine T score less than –2.5.

Overall 1,395 women were randomized to receive 2-mg IV ibandronate injections every 2 months (454 women), 3 mg IV ibandronate every 3 months (472 women), or 2.5 mg daily oral ibandronate (469 women).

All women received daily calcium (500 mg) and vitamin D (400 IU) supplements, Dr. Lewiecki said.

The study's primary end point was mean percent change from baseline in lumbar spine BMD at 1 year, and these results were presented at the 2005 annual meeting of the American College of Rheumatology.

Secondary end points included mean percent change from baseline in lumbar spine BMD at 2 years, and mean percent change from baseline in total hip, femoral neck, and trochanter BMD at 1 and 2 years.

In early 2006, the Food and Drug Administration approved the 3-mg trimonthly ibandronate IV injection for the treatment of postmenopausal osteoporosis.

"These data support the use of the every-3-month regimen in clinical practice," Dr. Lewiecki said.