PTH Prevents First Fractures in Early Osteoporosis

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SAN ANTONIO — Intact human recombinant parathyroid hormone prevented both recurrent and first fractures in a multinational, randomized, placebo-controlled study of postmenopausal women with osteoporosis, Mark P. Ettinger, M.D., said at the annual meeting of the American College of Rheumatology.

Previous studies have shown that the parathyroid hormone (PTH) analog teriperatide can prevent fractures in patients with advanced disease who already have had a fracture. The Treatment of Osteoporosis With PTH (TOP) study was the first to demonstrate the prevention of first fractures in patients with earlier disease, Dr. Ettinger said.

"This is extremely important, because the presence of any existing fracture greatly increases the risk of subsequent fractures," he said in a late-breaking abstract session.

The TOP study included 2,532 women whose mean age was 64.4 years and whose mean spine, total hip, and femoral neck bone mineral density (BMD) T-scores were –3.0, –1.9, and –2.2, respectively.

The study population was very different from other osteoporosis treatment cohorts, in that the patients were younger, and only 19% already had fractures. In previous trials, fracture prevalence ranged from 37% to 100%, he said.

Patients were randomized to 100 mcg of subcutaneous PTH or placebo daily. All patients also took 700 mg calcium and 400 U vitamin D each day. A total of 1,737 patients completed the 18-month study.

At study completion, the vertebral fracture incidence was 3.3% in the placebo group and 1.1% in the PTH group, which represented a relative fracture risk reduction of 66%, said Dr. Ettinger, medical director emeritus of Radiant Research, Stuart, Fla.

In a per-protocol analysis, patients who had a fracture before entering the study had a 69% relative fracture risk reduction; those without a previous fracture had a risk reduction of 63%. At month 18 the mean spine, total hip, and femoral neck BMD had increased by 7.2%, 2.2%, and 2.5%, respectively, in the PTH group relative to the placebo group, he said.

About 9% of the PTH group withdrew because of headache, dizziness, nausea, or vomiting, or elevated serum or urine calcium levels. Overall, 16% of PTH patients and 12% of placebo patients withdrew during the course of the study. There were two deaths in the placebo group and one in the PTH group; this was judged to be unrelated to treatment.

"The results of the TOP study may change our treatment paradigm," said Dr. Ettinger who disclosed that he received research grants and consulting fees from many pharmaceutical companies including NPS Pharmaceuticals, the Salt Lake City–based manufacturer of PTH. ■

Ca Cuts Fractures In Healthy Seniors

SEATTLE — Calcium supplementation appears to reduce by 34% the 5-year risk of fracture in elderly women, according to a population-based study presented at the annual meeting of the American Society for Bone and Mineral Research.

The benefit was seen as early as 13 months, even though women were deemed at baseline to be getting adequate calcium—a mean of 960 mg/day, said Richard Prince, M.D., of Sir Charles Gairdner Hospital, Perth, Australia.

The 1,460 healthy ambulatory women, aged 70 or older, were randomly assigned to receive 600 mg calcium carbonate twice daily or placebo. Calcium intake was assessed and dual x-ray absorptiometry (DXA) scans were taken at baseline and again at least 1 year later. During the 5-year study, the rates of death, withdrawal, and treatment cessation were similar between the two groups. In all, 235 individuals sustained 296 fractures; 118 in those taking calcium and 178 in those taking placebo, for an overall 34% reduction in fractures in patients in the calcium group who stuck to the protocol for the entire study period.

Calcium appeared to improve bone mineral density at cortical bone sites, according to DXA findings. At 13 months, there were early indications of a reduction in fracture rates among patients in the calcium group.

—Timothy F. Kirn