Rx Cut Fracture Risk by 61%

Male Bone Health *from page 1*

cluding type I collagen C-telopeptide, type I collagen N-telopeptide/creatinine, and bone-specific alkaline phosphatase also were measured at various time points throughout the study. "Beginning at the first measurement, at 3 months, there was a significant reduction of approximately 40% in these markers, which is very much in line with what we see in postmenopausal women," Dr. Boonen said in an interview.

The overall safety profiles were similar among men in the study taking risedronate and those receiving placebo, with any adverse event being reported by 70% and 73% of the groups, respectively. A total of 15% and 16% of those in the risedronate and placebo groups reported serious adverse events, while 1% and 3% reported serious drug-related adverse events. Again, the safety is similar to what is seen in women, he said.

The trial was sponsored by the Alliance for Better Bone Health (Procter & Gamble Pharmaceuticals and Sanofi-Aventis U.S.).

Benefits also were seen with risedronate therapy in a prospective open-label trial that included 316 men whose T scores were below –2.5 at the lumbar spine and below –2.0 at the femoral neck, Dr. Johann D. Ringe wrote in another poster session.

A total of 158 of the patients received 5 mg risedronate, plus 1,000 mg calcium, and 800 IU vitamin D, daily for 2 years. Among another 158 men who acted as controls, those with a previous vertebral fracture were given the alfacalcidol form of vitamin D (1 mcg), plus 500 mg calcium, daily, while those without vertebral fractures were treated with 800 IU plain vitamin D, plus 1,000 mg calcium, daily.

Increases in lumbar spine BMD of 4.7% and 6.5% were seen at months 12 and 24, respectively, in the risedronate group, wrote Dr. Ringe of Klinikum Leverkusen (Germany), University of Cologne.

By comparison, BMD increases of 1.0% at 12 months and 2.2% at 24 months were observed in the control patients. The difference between the two groups was statistically significant, Dr. Ringe reported at the meeting, which was sponsored by the International Osteoporosis Foundation.

Mean changes in total hip BMD among patients in the risedronate-treated patients were 2.7% and 4.4% after 12 and 24 months, respectively, while a mean change of 0.4% seen in controls at 12 months remained unchanged at 24 months. These differences, too, were statistically significant, Dr. Ringe wrote.

During the first year of the study 8 patients receiving risedronate and 20 of those receiving only the vitamin D and calcium supplements sustained new vertebral fractures. By 2 years, with 14 and 35 new fractures in the two groups, respectively, fracture risk reduction was 61% for those taking the bisphosphonate, according to Dr. Ringe.

Relief of back pain also was significantly more pronounced among patients receiving risedronate, he noted. ■

Middle-Age Factors Predict Fracture Risk

BY NANCY WALSH
New York Bureau

TORONTO — Risk factors for fractures in later life are already present in middle age, and their early identification can provide a window of opportunity for intervention, Dr. Anna H. Holmberg said at a world congress on osteoporosis.

The Malmö Preventive Project was a prospective study that followed 22,444 men and 10,902 women from 1974 through 1999, said Dr. Holmberg of the department of orthopedics, Malmö (Sweden) University Hospital.

During follow-up, which averaged 19 years for men and 15 years for women, 1,262 men (5.6%) had 1,975 low-energy fractures, while 1,257 women (11.5%) had 1,805 low-energy fractures.

Among men, the risk factor with the highest impact on later fragility fracture was diabetes, with a relative risk (RR) of 2.38. Other strong risk factors among men were prior hospitalization for mental health problems (RR 1.92), poor appetite (RR 1.72), sleep disturbances (RR 1.53), and poor self-rated health (RR 1.25), Dr. Holmberg said at the meeting, which was sponsored by the International Osteoporosis Foundation.

Diabetes also was a strong risk factor for fractures in general among women (RR 1.87), and specifically was a significant risk factor for vertebral, ankle, and hip fractures. ■