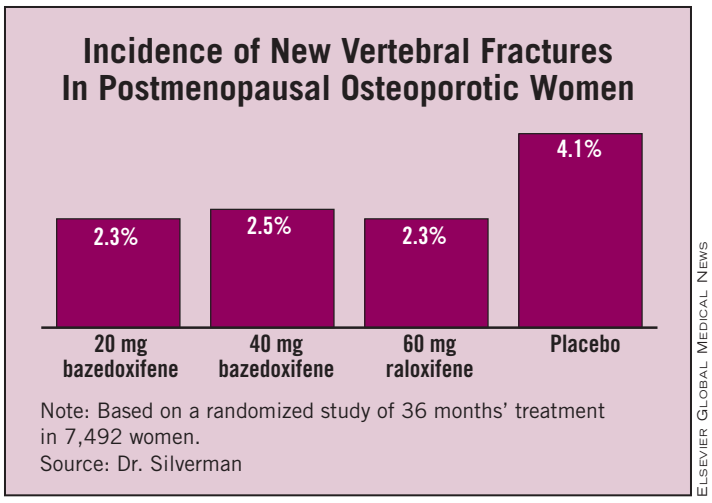

ELSEVIER GLOBAL MEDICAL NEWS

Bazedoxifene Trims Vertebral Fracture Risk in Osteoporosis

BY GREG MUIRHEAD
Contributing Writer

HONOLULU — Bazedoxifene reduced the risk of new vertebral fractures in postmenopausal women with osteoporosis, according to the results of a 3-year, phase III, placebo-controlled trial presented at the annual meeting of the American Society for Bone and Mineral Research.

"In postmenopausal women with osteoporosis, bazedoxifene reduced the incidence of new vertebral fractures up to 42%," said Dr. Stuart L. Silverman, medical director of the Osteoporosis Medical Center, in Beverly Hills, Calif. Funding for this study came from Wyeth Pharmaceuticals. Dr. Silverman disclosed that he had received research grants from Wyeth as well as several other pharmaceutical companies

"The treatment effect did not appear to be different between women with or without prevalent vertebral fractures," he said, and added, however, "Overall there was no significant treatment effect on nonvertebral fracture."

The trial included 7,492 healthy postmenopausal women, aged 55-85 years, who had lumbar spine or femoral neck T scores less than or equal to –2.5 and no vertebral fractures, or who had no lumbar spine or femoral neck T scores greater than or equal to –4.0 but had vertebral fractures. Their mean age was 66 years, and all were postmenopausal by at least 2 years. At baseline, 56% of the women had one or more vertebral fractures, most of which were mild.

The objective of the trial was to assess the efficacy and safety of therapy with bazedoxifene, compared with raloxifene and placebo, in postmenopausal osteoporotic women.

The women were randomized to receive, daily, 20 mg or 40 mg bazedoxifene, 60 mg raloxifene, or placebo. In addition, participants received daily supplements of up to 1,200 mg oral calcium and up to 800 IU oral vitamin D.

The primary outcome was incidence of new vertebral fractures by month 36 of treatment, whereas incidence of new nonvertebral fractures was a secondary outcome. As of month 36, incidence of new vertebral fractures was 2.3% and 2.5%, respectively, for women taking 20 mg or 40 mg bazedoxifene; 2.3% for those taking 60 mg raloxifene; and 4.1% for those taking placebo.

As for the secondary outcome, no overall effect from treatment was found in the prevention of nonvertebral fractures. However, a post hoc analysis found that in 1,782 women at higher risk for fractures, reduction of nonvertebral fracture incidence was 3.0% and 3.8% for women taking 20 mg or 40 mg bazedoxifene, respectively; 5.9% for those taking 60 mg raloxifene; and 6.3% for those taking placebo (Osteoporos. Int. 2007;18:761-70).

Of the 7,492 patients who enrolled in the trial, 2,501 discontinued participation. Overall, 7,186 patients reported at least one adverse event. Almost all of the adverse events were treatment emergent, and the incidence of these was similar for all treatment groups.

In patients using bazedoxifene, no safety concerns were found regarding gynecologic and cardiovascular systems. However, a higher incidence of deep vein thrombosis was found in bazedoxifene users, compared with patients using placebo.

Differences in mortality among the treatment groups were not statistically significant. Two subjects from each treatment group—a total of eight—died from myocardial infarction. ■

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