Fracture Risk Reduction on Teriparatide Is Robust

BY SHERRY BOSCHERT

San Francisco Bureau

SAN FRANCISCO — Osteoporotic women treated with teriparatide often gain lumbar spine bone mineral density and lower their risk of vertebral fracture, even if they lose hip bone mineral density, Dr. Nelson B. Watts reported in a poster presentation at the annual meeting of the International Society for Clinical Densitometry.

Previous studies have shown that increased areal lumbar spine bone mineral density (BMD) accounts for 30%-41% of the reduction in vertebral fracture risk from teriparatide treatment. In clinical practice, loss of BMD in other areas, such as the femoral neck, has been viewed by some as a lack of response to therapy.

The current post hoc analysis of data on 1,216 women found that vertebral fracture risk was independent of gains or losses in femoral neck BMD in women taking teri-



Vertebral fracture risk was independent of gains and losses in femoral neck BMD.

DR. WATTS

paratide, compared with women on placebo, reported Dr. Watts, program director of the bone health and osteoporosis center at the University of Cincinnati, and his associates.

The investigators analyzed data on women with a history of vertebral fractures who were randomized to take 20 or 40 mcg/day of teriparatide or placebo in the double-blind Fracture Prevention Trial. The women self-administered the treatments subcutaneously and also received daily supplements of 1,000 mg of calcium and 400-1,200 IU of vitamin D.

The current analysis focused on a subset of 1,216 women who had femoral neck BMD measured both at baseline and after 12 months of therapy by dual-energy x-ray absorptiometry (DXA) and who had lateral thoracic and lumbar spine radiographs taken both at baseline and at the study end point, a median of 19 months from baseline.

The risk of vertebral fracture was calculated for women on placebo and for women in four subgroups of teriparatide therapy based on changes in femoral neck BMD 1 year from baseline. The women on teriparatide were divided as follows: those who lost more than 4% of femoral neck BMD, those who lost up to 4% in density, those who gained up to 4% in density, and those who gained more than 4% in femoral neck BMD.

In the combined teriparatide groups, a significantly greater proportion (35%) gained more than 4% in femoral neck BMD, compared with those on placebo (17%). This finding supports previous studies that showed that teriparatide can improve bone geometric strength at the femoral neck, compared with placebo.

Women in the current study showed significant reductions in vertebral fracture risk on teriparatide therapy, compared with placebo, regardless of changes in femoral neck BMD at 1 year, Dr. Watts reported.

Among women with greater than a 4% loss in femoral neck density, 2 (2%) of 82 women on teriparatide developed vertebral fractures, compared with 14 (23%) of 61 women on placebo. Among women with up to a 4% loss in femoral neck den-

sity, 5 (3%) of 182 women on teriparatide and 15 (10%) of 149 women on placebo developed vertebral fractures.

Among women with up to a 4% gain in femoral neck BMD, vertebral fractures were seen in 5 (3%) of 182 women on teriparatide and 19 (15%) of 124 women on placebo. Among women with greater than a 4% gain in femoral neck density, 14 (5%) of 282 on teriparatide and 9 (14%) of 66 on placebo developed vertebral fractures.

Lumbar spine BMD increased signifi-

cantly more in women on teriparatide, compared with placebo, regardless of changes in femoral neck density. Lumbar spine density increased by 3% or greater in 78%-92% of women on teriparatide in the four femoral neck subgroups.

The study was funded by the company that makes teriparatide, Eli Lilly & Co., which also provided the layout for the poster. Dr. Watts is a consultant for the company. His report was rated one of the top posters at the meeting.

Find out more about a therapy she can stay with.





It's simple.
It's convenient.

It's effective.¹
It's well tolerated.¹

FOR INFORMATION VISIT NOVOMEDLINK.COM.

Please see adjacent page for brief summary of prescribing information.

Vagifem® is a registered trademark of Novo Nordisk FemCare AG.

Reference: 1. Rioux JE, Devlin MC, Gelfand MM, Steinberg WM, Hepburn DS. 17β-Estradiol vaginal tablet versus conjugated equine estrogen vaginal cream to relieve menopausal atrophic vaginitis. *Menopause*. 2000;7:156-161.

© 2008 Novo Nordisk Inc. Printed in the U.S.A. 134966 April 2008

AGIFEM®

THERAPY SHE CAN STAY WITH

IMPORTANT SAFETY INFORMATION

ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA.

Three independent, case-controlled studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incident rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer-reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade.

The three case-controlled studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed, on at least a semiannual basis, to determine the need for continued therapy.

Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or reoccurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equi-estrogenic doses.

Other warnings include: induction of malignant neoplasms, gallbladder disease, effects similar to those caused by estrogen-progestogen oral contraceptives (such as thromboembolic disease, hepatic adenoma, elevated blood pressure, worsening of glucose tolerance), hypercalcemia, and rarely, trauma induced by the Vagifem® applicator.

In a placebo-controlled clinical trial, the most commonly reported adverse events included: headache (9%), abdominal pain (7%), upper respiratory tract infection (5%), genital moniliasis (5%), and back pain (7%).

The use of Vagifem® is contraindicated in women who exhibit one or more of the following: known or suspected breast carcinoma, known or suspected estrogen-dependent neoplasia, e.g., endometrial carcinoma, abnormal genital bleeding of unknown etiology, known or suspected pregnancy, porphyria, hypersensitivity to any Vagifem® constituents, active thrombophlebitis or thromboembolic disorders, or a past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast malignancy).