

Men's Osteopenia Dx Unlikely to Change at 3 Years

BY CAROLYN SACHS
Contributing Writer

HONOLULU — Men diagnosed with osteopenia through dual-energy x-ray absorptiometry are unlikely to have a change in diagnosis at a 3-year follow-up DXA test, according to a study presented in a poster at the annual meeting of the American Society for Bone and Mineral Research.

"The interval for a follow-up bone density should be lengthened, or perhaps the repeat DXA should not be done unless there is an additional risk factor noted," wrote Dr. Robert A. Adler of the endocrinology section of McGuire Veterans Affairs Medical Center and Virginia Commonwealth University, Richmond, and his colleagues. Increased risk for developing osteoporosis could, for example, be a concern for prostate cancer patients on androgen deprivation therapy.

The researchers followed 78 men with osteopenia (T score of lumbar spine, femoral neck, total hip, total forearm or distal 1/3 forearm between -1 and -2.4)

from a baseline DXA test through follow-up DXA testing an average of 998 days later. Mean age and weight at baseline were 70.7 years and 76.4 kg, respectively.

The men, patients from primary care practices at a Veterans Affairs medical center, had been referred for an initial DXA test after a screening program using the Osteoporosis Self-Assessment Tool had found them to be at greater risk for osteoporosis.

Mean percent changes in bone mineral density (BMD) from baseline to follow-up

were 1.8% for lumbar spine, -0.4% for femoral neck, -0.7% for total hip, -1.1% for 1/3 radius, and -1.6% for total forearm.

"The BMD changes were minimal, approximately plus or minus 2%," the researchers noted, and affected diagnosis very rarely: Only one patient started therapy for osteoporosis after the follow-up DXA test because of a significant change in BMD.

Although the patients were advised at diagnosis with osteopenia to begin taking calcium and vitamin D supplements, only

about one-fourth to one-third of the 78 actually received the supplementation after the baseline DXA test. But after the second DXA, "an additional 17 men were prescribed supplements," the authors wrote.

Although these results suggest a second DXA test may encourage clinicians to prescribe such preventive measures for their patients, "there should be cheaper ways to improve clinician behavior," wrote the authors. Dr. Adler said he had no conflicts of interest to disclose. ■

Bazedoxifene Nips Postmenopausal Osteoporosis Risk

HONOLULU — Bazedoxifene is effective in preventing osteoporosis in postmenopausal women, according to the results of a 2-year, phase III, placebo-controlled trial presented at the annual meeting of the American Society for Bone and Mineral Research.

Participants were postmenopausal women aged 45 years, whose femoral neck bone or lumbar spine T scores were above -2.5. Women with vasomotor symptoms, bone diseases, prior vertebral fractures, or endometrial hyperplasia, were excluded.

A total of 1,583 postmenopausal women were randomized to daily bazedoxifene regimens of 10 mg, 20 mg, or 40 mg, or to raloxifene (60 mg), or to placebo. All received a daily 600-mg calcium supplement.

Of the total, 1,113 (70%) completed the study. More than 90% in each group were white. Mean range in body mass index (kg/m²) in the treatment groups was 25.3 to 25.9, and mean range of number of years since menopause was 10.7 to 11.3 (mean age 57.6 years). Primary outcome was percent change in BMD of the lumbar spine after 24 months of treatment. BMD at other sites was a secondary outcome.

By month 24, BMD loss was prevented in all groups except in women using placebo, who had a significant decline in BMD. The percent change in lumbar spine BMD from baseline (relative to placebo) was 1.1%, 1.4%, and 1.5%, for bazedoxifene 10 mg, 20 mg, and 40 mg, respectively; it was 1.5% for raloxifene 60 mg. Similar dose-response results were found at other skeletal sites for those on bazedoxifene. Adverse event rates were similar among the groups. The study was supported by Wyeth Research and Wyeth Pharmaceuticals.

—Greg Muirhead



*Model is for illustrative purposes only.

Indications and usage

Levemir is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Important safety information

Levemir is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Levemir is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic

ketoacidosis. Levemir should not be diluted or mixed with any other insulin preparations. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir from other intermediate or long-acting insulin preparations. The dose of Levemir may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation.

Whether these observed differences represent true differences in the effects of Levemir, NPH insulin, and insulin glargine is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

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- 24-hour action at a once-daily dose^{3,4}
- Provides consistent insulin absorption and action, day after day^{3,5,6}
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References: 1. Meneghini LF, Rosenberg KH, Koenen C, Meriläinen MJ, Lüddeke H-J. Insulin detemir improves glycaemic control with less hypoglycaemia and no weight gain in patients with type 2 diabetes who were insulin naive or treated with NPH or insulin glargine: clinical practice experience from a German subgroup of the PREDICTIVE study. *Diabetes Obes Metab*. 2007;9(3):418-427. 2. Hermansen K, Davies M, Derezinski T, Ravn GM, Clauson P, Home P, for the Levemir Treat-to-Target Study Group. A 26-week, randomized, parallel, treat-to-target trial comparing insulin detemir with NPH insulin as add-on therapy to oral glucose-lowering drugs in insulin-naïve people with type 2 diabetes. *Diabetes Care*. 2006;29(6):1269-1274. 3. Klein O, Lyngø J, Endahl L, Damholt B, Nosek L, Heise T. Albumin-bound basal insulin analogues (insulin detemir and NN344): comparable time-action profiles but less variability than insulin glargine in type 2 diabetes. *Diabetes Obes Metab*. 2007;9(3):290-299. 4. Phillis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther*. 2006;28(10):1569-1581. 5. Data on file. Novo Nordisk Inc, Princeton, NJ. 6. Heise T, Nosek L, Rønn BB, et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes*. 2004;53(6):1614-1620. 7. Data on file. NDA21-536. Novo Nordisk Inc, Princeton, NJ.



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