Zoledronic Acid Cuts Fractures at All Risk Levels

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FROM THE ANNUAL MEETING OF THE AMERICAN SOCIETY FOR BONE AND MINERAL RESEARCH
TORONTO – Among postmenopausal women with osteoporosis, treatment with zoledronic acid had a similar effect on fracture reduction regardless of whether women had a low, intermediate, or high baseline fracture risk, based on a post-hoc analysis of nearly 3,900 women who received the agent in the drug’s pivotal trial for fracture prevention.

The analysis showed that rates of vertebral fractures and total clinical fractures fell by roughly similar amounts, regardless of the women’s baseline fracture risk. The annual injection of zoledronic acid during 3 years of treatment and follow-up.

The rate of hip fractures showed a greater reduction in women who entered the study in the lowest tertile for fracture risk relative to the placebo group than in women with intermediate or high risk, but this difference failed to reach statistical significance, Jane A. Cauley, Dr.PH, said at the meeting.

The message is that postmenopausal women with osteoporosis should feel comfortable starting zoledronic acid treatment regardless of the severity of their fracture risk at baseline, said Dr. Cauley, professor of epidemiology at the University of Pittsburgh. It is not necessary to target treatment to women with an especially elevated fracture risk, such as those with a high FRAX (Fracture Risk Assessment Tool) score, she explained.

The results support a prior report with similar findings from the Women’s Health Initiative on the impact of estrogen...
Given alone or mixed with Humulin N, Humalog results in a more rapid absorption and glucose-lowering effect compared with regular human insulin.

Humalog is an analogue of human insulin that is produced through genetic engineering (rDNA origin). Humalog is available as a sterile, single-use, ready-to-use solution. It contains 100 units of insulin lispro per mL (100 U/mL) and is available in vials for subcutaneous administration and as a prefilled cartridge for use in insulin pumps.

Humalog (insulin lispro injection, USP [rDNA origin]) is available in the following package sizes (with each presentation containing 100 units insulin lispro per mL [U-100]):

- 10 mL vials NDC 0002-7510-01 (VL-7510)
- 3 mL vial NDC 0002-7510-17 (VL-7533)
- 3 mL cartridge 1 (Pen) NDC 0002-7516-59 (VL-7598)
- 3 mL prefilled insulin delivery devices (Pen) NDC 0002-7527-59 (RP-7825)
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**Storage—**Unopened Humalog should be stored in a refrigerator (2° to 8°C [36° to 46°F]), but not in the freezer. Do not use Humalog if it has been frozen. Unrefrigerated (below 30°C [86°F]) vials, cartridges, Pens, and KwikPens must be used within 28 days or be discarded, even if they still contain Humalog. Protect from direct heat and light.

Use in an External Insulin Pump—A Humalog 3 mL cartridge used in the D-TRON®1,2,3 or D-TRON®+1,2,3 device should be discarded within 28 days or be discarded if it has been frozen. Humalog, Humulin R, Humulin 70/30, and Humulin® R U-500 to a concentration of 1:10 solution and the container permit. If the solution is cloudy, contains particulate matter, or has an odor, the contents must not be injected. Humalog should not be used after its expiration date. The cartridge containing Humalog is not designed to allow any other insulin to be mixed in the cartridge or for the cartridge to be refilled with insulin.

**HOW SUPPLIED:**

Humalog insulin lispro injection, USP (rDNA origin) is available in the following package sizes (with each presentation containing 100 units insulin lispro per mL [U-100]):

- 10 mL vials
- 3 mL vial
- 3 mL cartridge
- 3 mL prefilled insulin delivery devices
- 3 mL prefilled insulin delivery devices (Humalog® Karpen®)

Cauley said.

The rate of hip fractures with zoledronic acid significantly cut the risk of a fracture among the placebo women during follow-up by 11%, a statistically significant difference.

The researchers then assessed follow-up fracture rates among the low-, intermediate-, and high-risk women who received zoledronic acid. The rate of morphometric vertebral fractures compared with the placebo group fell by 45% in the low-risk tertile of women, by 69% in the intermediate-risk tertile, and by 68% in the high-risk women, differences that were not statistically significant.

The rate of all clinical fractures dropped by 35% in the low-risk women, 38% in the intermediate-risk women, and 30% in the high-risk women, also nonsignificant differences.

The rate of hip fractures with zoledronic acid treatment compared with placebo fell by 71% in the low-risk women, 41% in intermediate-risk women, and 22% in high-risk women. These between-group differences just missed being statistically significant.

Additional analyses also showed that the zoledronic acid treatment consistently increased bone mineral density, and reduced two biomarkers of osteoporosis, procollagen type I N-terminal propeptide and C-telopeptide cross-linked collagen, compared with the placebo group, regardless of baseline fracture risk, Dr. Cauley said.