IV Ibandronate Offers Effective Nonoral Option

BY HEIDI SPLETE
Senior Writer

WASHINGTON — Postmenopausal women with osteoporosis who can't tolerate oral ibandronate may welcome an intravenous option, Michael Bolognese, M.D., reported at an international symposium sponsored by the National Osteoporosis Foundation.

One-year results from the Dosing Intravenous Administration (DIVA) study, an ongoing randomized, double-blind, phase III trial, showed that rapid injections of ibandronate (Boniva) in amounts of 2 mg every 2 months or 3 mg every 3 months were more effective than the standard oral daily dose of 2.5 mg at increasing bone mineral density (BMD), Dr. Bolognese of Bethesda (Md.) Health Research and his colleagues wrote in a poster presentation of their findings.

The increases in the BMD at the lumbar spine were significantly greater for women on both the 2-mg/2-mo (5.1%) and 3-mg/3-mo (4.8%) regimens compared with the 2.5-mg daily oral dosage (3.8%). In addition, significantly more patients demonstrated increased BMD from baseline in both the lumbar spine and total hip in the 2-mg/2-mo and 3-mg/3-mo groups compared with the daily oral 2.5-mg group.

The study included 1,395 women aged 55-80 years with postmenopausal osteoporosis. In addition to their ibandronate regimens, women in all treatment groups received 500 mg of calcium and 400 IU of vitamin D daily.

The incidence of renal adverse events such as urinary incontinence, renal impairment, or nephrolithiasis, was 3% or less across all treatment arms, and there were no significant changes in serum creatinine levels in any of the patients compared with baseline. The incidence of flu-like illness was low as well—3.3%, 3.2%, and 0.6% in the 2-mg/2-mo, 3-mg/3-mo, and 2.5-mg oral groups, respectively.

In addition, the overall incidence of clinical fractures, including vertebral fractures, was 3.1%, and did not differ significantly among the three groups, although it was slightly higher in the oral group (3.7%) compared with the 2-mg/2-mo group (2.9%) and the 3-mg/3-mo group (2.8%).

Dr. Bolognese is a consultant for Eli Lilly & Co. and Procter & Gamble Co., and has received grants or research support from Aventis Pharmaceuticals Inc., Pfizer Inc., Lilly, and Wyeth. ■

Fracture Severity Linked to Low Bone Volume

WASHINGTON — The severity of vertebral fractures increases significantly in patients whose trabecular bone volume falls below the critical value of 15%, Harry K. Genant, M.D., said in his oral presentation of a poster at an international symposium sponsored by the National Osteoporosis Foundation.

Dr. Genant, a member of the Osteoporosis and Arthritis Research Group at the University of California, San Francisco, and his colleagues assessed the bone quality of 190 postmenopausal women, mean age 69 years, using radiographic data from 2D histomorphometry and 3D microCT.

The women were categorized into four groups based on varying severity of vertebral fractures, with 0 meaning "no fracture," and 1, 2, and 3, corresponding to mild, moderate, and severe levels of fracture, respectively.

Based on the radiographic data, patients in the moderate and severe fracture groups had significantly reduced 2-dimensional trabecular bone volumes (0.15 and 0.13, respectively), compared with patients who had no fractures (0.20). On further analysis of the radiographs, the researchers found that as the severity of vertebral fractures grew worse, patients had progressively worse bone quality based on measurements including trabecular separation, trabecular number, and 3-dimensional trabecular bone volume.

These latest results are consistent with earlier findings that patients are at significantly increased risk of fracture when the trabecular bone volume falls below approximately 15%. Dr. Genant said that he has received grants and research support, as well as an honorarium, from Eli Lilly & Co.

—Heidi Splete