Osteoporosis

## WHI Data Support RDAs for Calcium, Vitamin D

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BETHESDA, MD. — The current recommended dietary allowance for calcium of 1,200 mg/day for people older than 50 was supported by the results of the Women's Health Initiative's calcium and vitamin D trial

Although the trial's results failed to prove the study's primary hypothesis, that a daily supplement of calcium and vitamin

D would significantly cut the incidence of hip fractures in postmenopausal women aged 50-79, the trial produced enough positive results to support the existing recommended dietary allowance, Dr. Rebecca D. Jackson said at a conference on the Women's Health Initiative, sponsored by the Department of Health and Human Services

A practical guide for physicians is that each glass of milk or dairy serving provides about 300 mg of calcium. So if a postmenopausal woman eats three to four dairy servings a day, she is probably getting enough calcium. If not, a calcium supplement is a good idea, said Dr. Johnson, a professor of medicine at Ohio State University, Columbus, and a principal investigator of the WHI.

After the WHI's calcium and vitamin D study was designed, it was piggybacked onto the two other studies that had already begun, the hormone therapy and diet modification trials. More than 36,000

women who were already enrolled in one or both of these ongoing WHI studies were randomized to get a daily supplement of 500 mg elemental calcium and 200 IU vitamin D or placebo, and they were followed for an average of 7 years.

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The enrollment criteria did not contain exclusions based on calcium and vitamin D intake, and it specifically allowed women to take additional supplements of up to 1,000 mg calcium and 600 IU vitamin D per day. At baseline, before the study began, a third of the enrolled women had a total daily calcium intake of at least 1,200 mg calcium, and another 45% had a daily intake of at least 1,000 mg, which meant that 78% of the participants already had a sufficient supply and were "probably not the best candidates for a calcium supplement trial," said Joan A. Mc-Gowan, Ph.D., director of the musculoskeletal diseases branch of the National

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Institute of Arthritis and Musculoskeletal and Skin Diseases.

The study's primary end point was the incidence of hip fractures, with a secondary end point of incidence of all fractures.

The incidence of hip

fractures was 0.14% in the supplement group and 0.16% in the placebo group, a relative reduction of 12% that was not statistically significant (N. Engl. J. Med. 2006;354:669-83). The incidence of all fractures was 1.64% and 1.70% in the intervention and placebo groups, respectively, also a nonsignificant difference.

These analyses were done on an intention-to-treat basis. During the first 3 years of the study, 60%-63% of women were adherent to the regimen, taking at least 80% of their assigned supplements. By the end of the study, 59% were still taking at least 80%.

A secondary analysis that focused only on the adherent participants showed that the incidence of hip fracture was 29% lower in the women taking calcium and vitamin D, compared with the placebo group, a statistically significant difference.

Another secondary analysis focused only on women aged 60 or older, the group at highest risk of fracture. In this subgroup, the risk of hip fracture was 21% lower in the women in the active treatment arm, also a significant difference.

The main adverse effect of calcium supplementation was a 17% increased risk of having kidney stones, a significant difference. "Although there was an increased risk of kidney stones, the possible benefits of calcium with vitamin D supplementation for the risk of fracture cannot be totally ignored," Dr. Joel S. Finkelstein, an endocrinologist at Massachusetts General Hospital, Boston, wrote in an editorial that accompanied the published findings (N. Engl. J. Med. 2006;354:750-2).



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