

WHI Results Support Existing Calcium RDA

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

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, however, 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 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, professor of medicine at Ohio State University, Columbus, and a WHI principal investigator.

After the WHI's calcium and vitamin D study was designed, it was piggybacked onto the hormone therapy and diet modification trials. More than 36,000 women already enrolled in one or both of these ongoing WHI studies were randomized to get a daily supplement of 500 mg ele-

mental calcium and 200 IU vitamin D or placebo, and followed for about 7 years.

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, one-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. McGowan, Ph.D., director of the musculoskeletal diseases branch of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

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 inci-

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dence of all fractures was 1.64% and 1.70% in the intervention and placebo groups, respectively, also nonsignificant.

These analyses were done on an intention-to-treat basis. During the first 3 years of the study, 60%-63% of women adhered to the regimen, taking at least 80% of the assigned supplements. By the end of the study, 59% were still taking at least 80%. In a secondary analysis focusing only on the adherent participants, 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, hip fracture risk was 21% lower in the women in the active treatment arm, also a significant difference.

"We believe this is strong enough information to support a role for calcium and vitamin D in reducing fracture risk," Dr. Jackson said in an interview.

The main adverse effect of calcium supplementation was a 17% increased risk of kidney stones, a significant difference. However, "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). "Calcium with vitamin D supplementation by itself is not enough to ensure optimal bone health. Additional therapy with agents that have been proved to reduce the risk of fracture in women with osteoporosis, such as antiresorptive medications or teriparatide, may be indicated," he wrote. ■

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