SOUTHWESTERN NEWS

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RESEARCHERS FIND THAT SUSTAINED-RELEASE FLUORIDE SIGNIFICANTLY REDUCES RISK FOR VERTEBRAL FRACTURES

DALLAS – Oct. 24, 2001 – Researchers at UT Southwestern Medical Center at Dallas have found that using sustained-release sodium fluoride with calcium citrate and vitamin D safely reduces the risk for vertebral fractures while increasing spinal bone mass in older women with osteoporosis.

The 42-month study, published in today's *Archives of Internal Medicine*, followed 85 women who were 65 years and older and had one or more nontraumatic vertebral fractures. The researchers sought to determine the safety and effectiveness of treating established osteoporosis in older women by using a bone-forming agent.

"The efficacy of sodium fluoride therapy has been debated in a previous study, which promulgated the thought that fluoride only makes weaker bone but not strong bone," said Dr. Craig Rubin, director of the Mildred Wyatt and Ivor P. Wold Center for Geriatric Care at UT Southwestern.

"Our study showed that this combination of therapy safely reduces the risk for vertebral fractures by stimulating new bone formation by fluoride-mediated increased osteoblastic (bone-forming cell) activity. In addition, the adequate provision of calcium and vitamin D reduces bone resorption."

Osteoporosis is a disease characterized by the loss of bone mass and poor bone quality. According to the National Osteoporosis Foundation, more than 28 million Americans suffer from this disease, which causes bones to become fragile and susceptible to fractures, especially in the hip, spine and wrist. Eighty percent of those afflicted are women.

"Since age-related bone loss is caused by decreased bone formation and altered calcium metabolism, we incorporated an anabolic agent to stimulate osteoblastic activity and adequate calcium and vitamin D to blunt secondary hyperparathyroidism and reduce mobilization of calcium from the skeleton," said Rubin.

A group of women with multiple medical problems were specifically selected to mimic

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a typical outpatient population of older women with osteoporosis. Women who were taking estrogen were also allowed in the study but were stratified to ensure equal distribution between groups.

"This study raises questions on current therapies, which all contain anti-resorptive agents," Rubin said. "Previously it was thought that the only way to reduce fractures was to reduce bone turnover. We showed that using a bone-forming agent, like fluoride, doesn't reduce bone turnover but can reduce risk of fractures."

The study group was treated with sustained-released sodium fluoride combined with calcium citrate and vitamin D while the control group received calcium citrate and vitamin D alone. After three treatment cycles, bone-mineral density increased by 5.4 percent in the study group and by 3.2 percent in the control group. The analysis of spinal fracture data showed a 68 percent reduction in new or recurrent fractures in the study group compared with the control group.

Complaints reported in earlier sodium-fluoride studies using a different dose and formulation than used in this study noted gastrointestinal problems, such as gastritis, and acute lower extremity pain. Patients in Rubin's study were evaluated for adverse side effects every three months; there were no significant differences between groups.

Dr. Charles Pak, director of the Center for Mineral Metabolism and Clinical Research, has developed a sustained-release sodium fluoride medication, which is awaiting Food and Drug Administration approval, and calcium citrate, a calcium supplement that is readily absorbed by the body and is sold over-the-counter as Citracal.

In addition to Rubin and Pak, Beverley Adams-Huet, a faculty associate of internal medicine at UT Southwestern, participated in the study, as well as researchers from the University of California, San Francisco, and Henry Ford Hospital in Detroit.

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