# BREAKTHROUGH STUDY USING CALCIUM AND VITAMIN D CALLS INTO QUESTION THE NEED FOR FOSAMAX AND OTHER DRUGS TO MANAGE OSTEOPOROSIS

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The medical management of osteoporosis includes the prescribing of any combination of anti-resorptive drugs such as Alendronate (Fosamax) and Risedronate (Actonel), and/or calcitonin (a hormone that decreases bone loss), Raloxifene (Evista), a selective estrogen receptor modulator (SERM), parathyroid hormone and hormone replacement therapy.

Unfortunately, each of these drug treatments is associated with significant adverse side effects. For example, Alendronate and Risedronate can produce esophageal dysfunction and reflux disease, and are known to cause burning irritation to the esophagus. Thus, the patient must remain standing for 30 minutes after drug ingestion to reduce contact of the drug with the mucosal lining of the esophagus. More recently, concerns have arisen in regards to these drugs also causing osteocronois of the mandible. Osteocronosis of the jaw, also known as dead jaw or rotting of the jaw, is the destruction (necrosis) of bone tissue, often due to an interference with the supply of blood to the bones of the jaw. The hormone calcitonin is delivered via an intranasal spray and often causes rhinitis, nasal crusts, dryness, erythemia, irritation and/or epistaxis.

Raloxifene is known to increase risk of thromboembolic disease (deep vein thrombosis) and can produce hot flashes and leg cramps. Parathyroid hormone treatment can cause dizziness, tachycardia and leg cramps after injection, which is the way in which the drug is administered. Thus, it is reserved for special situations only.

Hormone replacement therapy fell out of favor in 2002 when the Women's Health Initiative Study demonstrated that estrogen- progesterone treatment increased risk of fatal and nonfatal heart attacks by approximately 29%, with a 40% increase in risk of stroke, and a 100% increase in venous thromboembolic disease (clots in the lungs, legs and pelvis) and a 26% increase in breast cancer. (1, 2)

**Calcium and Vitamin D**

During the past 10-15 years a number of studies have shown that calcium supplementation can reduce bone loss in postmenopausal women and that the combination of calcium and vitamin D supplementation could significantly reduce fracture occurrence in elderly women. (3,4). However, the question remained as to whether or not calcium and vitamin D supplementation could be used as the sole intervention (without concurrent use of osteoporosis drugs) in the management of high risk, fracture-prone, postmenopausal women, and whether or not calcium and vitamin D, when applied together, could increase bone mineral density in postmenopausal women who exhibited suboptimal bone density scores. These are important questions, as calcium and vitamin D supplementation do not cause significant or life-threatening side effects (as do osteoporosis drugs), with proper dosing and monitoring, and unlike osteoporosis drugs there are very few cases where supplementation with these two nutrients is contra-indicated.

To help resolve these questions MF Hitz, JB Jenson and P Eskildsen published the results of their study in the American Journal of Clinical Nutrition (July 2007) showing that calcium and vitamin D supplementation increased bone mineral density (in the lumbar spine) of postmenopausal women who previously experienced a recent low-energy fracture and exhibited low bone mineral density upon base-line testing. In this double-blinded study involving 122 subjects, over 50 years of age (84% were postmenopausal women), who had sustained a low energy fracture of the hip or upper extremity, subjects were randomly assigned 1550 mg of elemental calcium (from 3000 mg of calcium carbonate) plus 1400 IU of vitamin D or a placebo (containing 200 IU of vitamin D). Bone density of their hips and lumbar spine were taken at base-line and after 12 months of intervention. Other markers of bone turnover as well as parathyroid hormone levels were also evaluated during the study period. The timed *Up & Go* test was used to assess physical performance. After 12 months of intervention the group receiving the calcium and vitamin D supplements showed reduced bone turnover, and significantly increased their bone

mineral density (specifically in the lumbar spine). Bone density increases were greater in individuals under 70 years of age compared to those older than 70. As a rule, older individuals tend to be more frail and less capable of performing adequate physical activity to enhance the efficacy of calcium and vitamin D supplementation on bone mineralization. The sub-group of individuals who were the most physically active, within the group ingesting the calcium and vitamin D supplements (1400 IU) realized the best overall outcomes in regards to increased bone density and bone turnover indicators. In contrast to the group receiving calcium and vitamin D (1400 IU) supplementation, subjects in the placebo group showed a decrease in bone density during the 12-month study period, including those who were physically active.

Another striking finding of this study pertains to the rise in blood levels of vitamin D (25-hydroxycholecalciferol) from an average of 33nmol/L to 85nmol/L, in the group supplemented with 1400 IU of vitamin D per day. This is an important finding as various studies have shown that blood levels of vitamin D at or above 85 nmol/L (some argue that 75nmol/L is the threshold level (4)) is associated with a decreased risk of osteoporosis, as well as colon, prostate and breast cancer, multiple sclerosis and the preservation of muscle strength as one ages. (4,5,6). A recent review by Veith et al suggested that a daily intake of approximately 1700 IU of vitamin D is required to raise blood levels of vitamin D from 50 to 80nmol/L. (4) However, the study by Hitz et al demonstrates that 1400 IU per day of vitamin D supplementation is likely to be sufficient to enable most adults to achieve a blood level of vitamin D (25-hydroxycholecalciferol) of 85nmol/L or higher. (5) Note that vitamin D toxicity is not a concern as long as one maintains blood vitamin D level below 225nmol/L. Thus, there is a wide margin of safety when recommending a daily dosage of 1700 IU of vitamin D. (7)

**Clinical Application In The Prevention And Management Of Osteoporosis**

The study by Hitz et al calls into the question the need for Fosamax and other drugs to be used in the routine management of osteoporosis. These researchers showed that men and women who were at high risk for a low energy fracture, and who exhibited sub-optimal bone density were able to increase their bone density over a one year period by simply taking vitamin D and calcium supplements, in the absence of concurrent use of any other osteoporosis drugs. Compliance to the use of calcium and vitamin D was very high and no significant side effects were noted during the course of the study and no cases of hypercalcemia were recorded. (5) The take home message appears to be that health practitioners should consider recommending 1400 IU of vitamin D per day (from supplement sources) along with 1550 mg per day of elemental calcium as a means to prevent osteoporosis and as a means to treat patients with low bone mineral density, including those who have sustained previous osteoporotic fractures. Health practitioners should monitor patient's blood levels of 25-hydroxycholecalciferol, ensuring that the recommended supplementation program enables the patient to achieve a minimum threshold level of 85nmol/L (and does not exceed 200nmolL). In conjunction with these recommendations practitioners should ensure that their patients are physically active and performing an adequate amount of weight bearing or resisted exercise training to enhance the efficacy of calcium and vitamin D supplementation on bone mineralization.

A final note includes the fact that these researchers used calcium carbonate as their source of calcium supplementation. A number of holistic practitioners discourage the use of calcium carbonate due to the popular belief in some circles that this form of calcium demonstrates poor bioavailability or is inferior to other forms of calcium. This is indeed unfortunate, as many studies have shown that calcium carbonate supports bone health and demonstrates the same level of bioavailability as calcium citrate and other forms of calcium (especially if taken with meals). For example a head-to-head study conducted in 2001, which tested calcium carbonate against calcium citrate, showed that both forms of calcium are equally bioavailable. Thus, health practitioners should not be surprised to learn that researchers in the osteoporosis field choose to use calcium carbonate in their study design, as it is not only bioavailable and shown to support bone health, but is the most affordable form of calcium for patients to use. (3,8)

*For more information on this or other related topics, visit Dr. Meschino's website at: http://www.renaisante.com/*

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