San Francisco — A majority of 1,356 elderly women taking medication to prevent or treat osteoporosis were deficient in vitamin D, a study of community-dwelling patients found.

The findings echo a previous study that found 56% of medical inpatients had vitamin D deficiency. "This is a very common problem" that deserves more attention, Dolores M. Shoback, M.D., said at a meeting on osteoporosis sponsored by the University of California, San Francisco.

Physicians should look more carefully for vitamin D deficiency in inpatients and outpatients, Dr. Shoback said. Among those who are ambulatory, on prescription therapy for osteoporosis, and lacking risk factors for vitamin D deficiency—"many of the patients, probably in our own practices," said Dr. Shoback, professor of medicine at the university.

The recent outpatient study included postmenopausal women at 61 locations in North America who had been taking bisphosphonates, calcitonin, or a selective estrogen receptor modulator for at least 3 months under a physician’s care to prevent or treat osteoporosis. They averaged 75 years in age, and were 92% white. Administrators administered a questionnaire to assess risk factors for vitamin D deficiency and measured the women’s serum concentrations of parathyroid hormone (PTH) and 25-hydroxyvitamin D—known as 25(OH)D—the form of vitamin D stored in the body.

They found that 92% of the 1,356 women had levels of 25(OH)D lower than 30 ng/mL. Of these, 36% had levels below 25 ng/mL, and 18% were below 20 ng/mL, showing that most of the women with inadequate vitamin D were severely deficient (J. Clin. Endocrinol. Metab. 2005;90:3215-24). "We aren’t doing a good job with the people we’re actively treating for osteoporosis," said Dr. Shoback. Vitamin D deficiency is one of the most common causes of secondary osteoporosis.

Although there’s no consensus on how much vitamin D the human body needs, the idea that 15-25 ng/mL is adequate has been replaced in the last few years by general cutoffs closer to 30 ng/mL or higher, she said. Some experts say people need at least 20 ng/mL. "We aren’t discussing vitamin D and bone health with their doctors more than we should," Dr. Shoback said.

"It appears we have a new first-line treatment for postmenopausal osteoporosis," he declared.

Dr. Ortolani presented a prespecified subgroup analysis drawn from two large phase-III multinational placebo-controlled randomized trials of strontium ranelate for the reduction of fracture risk in osteoporotic postmenopausal women. The Spinal Osteoporosis Therapeutic Intervention (SOTI) involved 1,649 women randomized to 2 g/day of oral strontium ranelate or placebo, while the Treatment of Peripheral Osteoporosis Study (TROPOS) included 5,091 women. Both Servier Laboratories-sponsored trials will run for 5 years, although the 3-year primary outcome data have been published.

Among 2,605 combined study participants without prior vertebral fractures at baseline, the 3-year incidence of new vertebral fractures was 14.4% with placebo and 7.5% with strontium ranelate, for a 48% relative risk reduction. Among the 734 participants with two or more prevalent vertebral fractures at enrollment, the absolute 3-year new vertebral fracture rates were far higher—42.7% in the placebo group, compared with 28.5% in those taking strontium ranelate—but the relative risk reduction conferred by strontium ranelate remained highly robust at 41%.

Strontium ranelate has a unique mode of action. It simultaneously increases bone formation and reduces bone resorption. The antiresorptive effect is less potent than with bisphosphonates; however, in combination with the simultaneous bone-forming effect, strontium ranelate becomes a highly effective antosteoporosis medication, Dr. Ortolani said at the meeting sponsored by the European League Against Rheumatism.

The drug’s chief adverse effect is diarrhea, which was limited to the first few months of therapy in the clinical trials. When the data from TROPOS and SOTI were pooled, there was a small but statistically significant increase in deep venous thrombosis in strontium ranelate–treated patients, but no increase in strokes or cardiovascular events. "The absolute incidence of DVT is much less than with raloxifene or estrogen replacement therapy," Dr. Ortolani added.

Strontium ranelate is approved in several European countries and soon will be marketed throughout Europe. Dr. Ortolani said that regulatory authorities have not required construction of a U.S. clinical trial before filing for marketing approval in the United States, Dr. Ortolani said.

Don’t Miss Vitamin D Deficiency in Osteoporotics

More than 50% of women being treated for the bone disorder had serum D levels lower than 30 ng/mL.

By Sherry Boschert
San Francisco Bureau

Vienna — Strontium ranelate reduced the risk of new vertebral fractures by 41% over 3 years in a very-high-risk population of osteoporotic women with at least two prevalent vertebral fractures at baseline, Sergio Ortolani, M.D., reported at the annual European congress of rheumatology.

That’s roughly as robust a relative risk reduction as seen in much lower-risk postmenopausal osteoporotic women with no previous vertebral fractures, noted Dr. Ortolani of the Center for Metabolic Bone Disease, Milan.

"It appears we have a new first-line treatment for postmenopausal osteoporosis," he declared.

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In Paget’s Disease Patients, Zoledronic Acid Packs a Bigger Punch Than Oral Risedronate

By Bruce Jancin
Denver Bureau

Vienna — A single 5-mg IV infusion of zoledronic acid produces significantly greater therapeutic efficacy and a longer-lasting biochemical remission than 2 full months of oral risedronate at 30 mg/day in patients with Paget’s disease of bone, Jacques P. Brown, M.D., reported at the annual European congress of rheumatology.

Zoledronic acid (Zometa) is clearly the clinically advantageous drug, both in bisphosphonate-naive patients and in those previously on risedronate (Actonel) or other oral bisphosphonates, added Dr. Brown of the Centre Hospitalier Universitaire de Quebec, Sainte-Foy.

At the meeting, sponsored by the European League Against Rheumatism, he presented a pooled analysis combining the data from two randomized, double-blind, multicenter trials of 349 patients with Paget’s disease of bone. Participants received a single 15-minute 5-mg infusion of zoledronic acid or 30 mg/day of oral risedronate for 2 months. The primary end point was a re- duction of 75% or more in excess serum alkaline phosphatase (SAP) at 6 months. Ninety-six percent of patients in the zoledronic acid group achieved it vs. 74% in the risedronate arm. Eighty-nine percent of zoledronic acid–treated pa-