Continued from previous page

Task Force (USPSTF) noted that no evidence existed to support any screening interval (Ann. Intern. Med. 2010;153:99-111).

The results "were a surprise in a good way," said Dr. Gourlay, a family physician at the University of North Carolina in Chapel Hill. "This is good news for women with good BMD. For women with higher bone density, we're probably doing some unnecessary testing."

The new results also showed that the T score exerted the strongest influence on the osteoporosis screening interval, more so than clinical risk factors for fracture. Adjustment for "risk factors did not make too much of a difference, so physicians do not need to make a FRAX calculation" to decide a screening interval, she said. "They can just go by the BMD."

"With FRAX [the World Health Organization's Fracture Risk Assessment Tool] you don't just look at BMD, but primary care physicians can't stop [in the middle of a patient consultation] to calculate a FRAX score," Dr. Gourlay said.

"When a patient has a BMD result in the good range, the main value of the new results is that we can be less concerned about these women" and the need for rescreening in the near future, she noted.

"The importance [of the new findings] is not the absolute time estimates we found; it's the magnitude of the difference.

'When a patient has a BMD result in the good range, the main value of the new results is that we can be less concerned about these women' and the need for rescreening in the near future.

A 16-year interval [for 10% of women to develop osteoporosis] for women in the top two T score groups, and a 5-year interval [for women with a baseline T score of –1.50 to –1.99] is quite different" from the way most physicians practice today, she said.

She cautioned that the finding needs confirmation from similar analyses using different data sets, and that it remains up to health policy-setting groups, such as the USPSTF, to consider the findings and use them to formulate updated screening recommendations. But, she added, the findings have already influenced her own approach to handling screening intervals.

"If I have a patient who missed a test and her prior T score was more than –1.50, I'm not nearly as worried now," said Dr. Gourlay.

The analysis used data collected in the Study of Osteoporotic Fractures (SOF), which enrolled women aged 65 years or older in four U.S. cities starting in 1986 and has followed them since then.

Dr. Gourlay and her associates focused on 5,036 women in the study who underwent at least two serial BMD measures over a total of 15 years. Patients were excluded from analysis if they had osteoporosis at any hip site at baseline, had an incident hip fracture, or were treated with a bisphosphonate or calcitonin. Patients also were excluded if they died or dropped out of the study.

The analysis included 1,275 women who had at least one normal baseline BMD value (a T score of –1.00 or greater) and 4,279 women with at least one T score that identified them as having osteopenia (–1.01 to –2.49).

Some women fell into both categories if they underwent at least three DXA examinations starting with at least one normal T score followed by at least one osteopenic score.

At baseline, the rate of estrogen use ran 25% in women with a normal T score at baseline and 16% in women with osteopenia – relatively high rates by today's standards but typical for practice in the 1980s.

During follow-up, full transition to osteoporosis occurred in fewer than 1% of the participants with a T score of at least –1.00 at baseline, fewer than 5% of those with a T score of –1.01 to –1.49 at baseline, and 22% of women with a score of –1.50 to –1.99 at baseline. Transition to osteoporosis took place in 65% of women who had a T score of –2.00 to –2.49 at baseline.

After Dr. Gourlay and her associates adjusted for the covariates of age and continuous bone mineral density, they found that it took an estimated 16 years for 10% of women with a T score of –1.00 or higher at baseline to transition to osteoporosis.

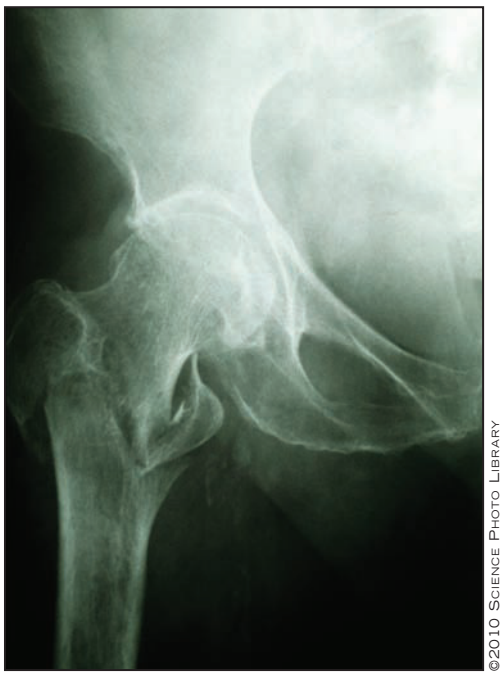
The other three T score subgroups that were analyzed underwent covariate adjustment for age, body mass index, current estrogen use, any fracture after age 50, current smoking, and oral glucocorticoid use.

After adjustment, the average time for 10% of women to transition to osteoporosis was found to be 15.5 years in women following a T score measure of –1.01 to –1.49, 4.5 years in women with a T score of –1.50 to –1.99, and 1.2 years in women with a T score of –2.00 to –2.49.

The investigators performed an additional analysis that stratified women by their age at the baseline DXA examination.

Even among women who were 85 years old, it took an average of nearly 11 years for 10% to develop osteoporosis following a baseline T score of –1.01 to –1.49.

Dr. Gourlay said that she had no disclosures relevant to this study. ■



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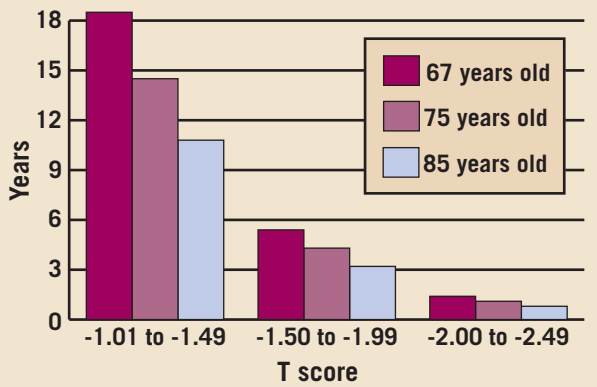
X-ray of the hip shows a fracture due to osteoporosis in an elderly woman. Less frequent screening may be indicated.

Impact of Baseline Age and T Score on Time to Develop Osteoporosis



Notes: Based on data for 5,036 women. Time for 10% of women studied to transition to osteoporosis after adjustment.
Source: Dr. Gourlay

Elsevier Global Medical News

UK Agency Recommends Denosumab for Osteoporosis

BY JENNIE SMITH

FROM THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

The U.K. National Institute for Health and Clinical Excellence said in September that it would recommend the osteoporosis drug denosumab for older women at risk of fractures who cannot take oral bisphosphonates.

NICE's standard treatment recommendation for this patient group is alendronate and either risedronate or etidronate.

All of these agents are oral medications associated with adverse upper-GI effects if not taken according to instructions. Patients must take the medicines before meals and should not lie down for at least half an hour afterward. Denosumab, by contrast, is an injection administered twice annually.

Denosumab (Prolia, Amgen) is a monoclonal antibody that reduces osteoclast activity, limiting bone breakdown.

The NICE reviewers, in deciding to recommend denosumab, considered results from a manufacturer-sponsored phase III randomized controlled trial of denosumab 60 mg subcutaneously every 6 months in 7,868 osteoporotic women aged 60-90 years.

After 3 years, 7.2% of the placebo patients sustained a new vertebral fracture, compared with 2.3% of those who were taking denosumab, a 68% reduction. Nonvertebral fractures were 6.5% with denosumab versus 8% with placebo, and hip fractures were reduced by 40% to 2.3% in the treatment arm.

The drug was also shown to increase bone mineral density at the lumbar spine by 9% over the 3 years compared with placebo, and by 6% at the hip.

The NICE reviewers, while acknowledging denosumab's effectiveness, nonetheless noted that it was not being considered as a replacement for the cheap and widely available oral bisphosphonates, but as an alternative only where these were unsuitable.

Denosumab is not being considered as a replacement for the cheap and widely available oral bisphosphonates, but as an alternative only where these agents are unsuitable.

Denosumab costs approximately $290.00 for a 1-mL prefilled syringe (60 mg per mL solution), and about $580.00 for 1 year of treatment.

Women eligible for treatment with denosumab must be intolerant of, have contraindications to, or be unable to comply with manufacturer instructions for taking alendronate and risedronate or etidronate.

They must also have bone density scores indicative of fracture risk. Other clinical risk factors for fracture that may be considered are alcohol consumption of more than 4 units per day, parental history of hip fracture, and rheumatoid arthritis.

NICE's guidance on denosumab, which is in final appraisal stage, mirrors its guidance on strontium ranelate, another treatment option for postmenopausal women at risk of fracture who cannot take bisphosphonates. ■