Aimed at Primary Care

Guideline *from page 1*

The ACP committee that created the guideline mined hundreds of published studies as the basis of its four recommendations—something that sets it apart from other guidelines on the topic. "We don't issue guidelines that rely on expert opinion," said Dr. Amir Qaseem, the document's primary author and senior medical associate of ACP's medical education and publishing division. "This one is based on high-quality evidence and is not a consensus statement."

Dr. Qaseem emphasized that the guideline is aimed at primary care physicians. "Our target is always primary care physicians, and making sure we get them information that's accurate, accessible, and useful," he said.

The guideline was based on a review of 76 randomized controlled trials and 24 meta-analyses of efficacy, as well as almost 500 trials, observational studies, and case reports, all of which discussed adverse events (Ann. Int. Med. 2008;149:404-15).

The authors graded the evidence according to the type of study and strength of the findings, and came up with four recommendations.

► Clinicians should offer pharmacologic treatment to men and women with known osteoporosis and those who have experienced fragility fractures (strong recommendation, high-quality evidence).

The authors considered evidence for bisphosphonates, estrogen, vitamin D, and calcium. They found good evidence that bisphosphonates and estrogen reduce the risk of osteoporotic fracture, and less compelling evidence for the efficacy of vitamin D and calcium—alone or in combination. However, the modest effect of the two supplements warrants their adjunctive use in any treatment regimen. The authors found no strong evidence indicating just how long any pharmacologic treatment should last, however.

► Clinicians should consider pharmacologic treatment for men and women at risk for osteoporosis (weak recommendation; moderate-quality evidence).

There was evidence supporting the treatment of select patients at risk of osteoporosis but with a T score higher than –2.5, the authors said. The evidence was slightly stronger in favor of treating patients considered at moderate risk—those "who have a T score from –1.5 to –2.5, are receiving glucocorticoids, or are older than 62 years of age."

The ACP guideline should be 'a little more proactive' regarding prevention.

DR. GAYLIS

This recommendation also included a discussion of risk factors including age, body weight, weight loss, physical inactivity, and intake of alcohol, caffeine, vitamin D, and calcium.

It makes brief reference to the Fracture Risk Assessment Tool (FRAX), which predicts risk of osteoporotic fracture based on age, gender, weight, medical and pharmacotherapy history, and bone mineral density at the femoral neck (www.shef.ac.uk/FRAX).

► Clinicians should choose from the approved treatments based on a risk/benefit analysis for each patient (strong recommendation; moderate-quality evidence).

The guideline recommends a bisphosphonate as the first-line therapy, particularly for patients who have a high risk of hip fracture. But, said Dr. Qaseem, "The lack of head-to-head trials makes it impossible to recommend one drug over another." Instead, the guideline recommends treatment based on an assessment of how each drug's potential side effects balance with its potential benefit for the individual patient.

► Further research is needed to evaluate the treatment of osteoporosis.

Most studies have focused on postmenopausal women, who are not the only ones at risk for developing osteoporosis. The authors noted that more research is needed in other patient groups, including men. Further studies are also necessary to determine optimal treatment duration. Additionally, they said, not enough is known about the association of bisphosphonates and osteonecrosis of the jaw; this disorder requires more study.

No matter who a patient sees for osteoporosis treatment, 'he should be treated in a similar manner.'

DR. PETAK

By recommending that physicians perform an individual osteoporosis risk assessment, instead of using a computerized risk calculator, the ACP guideline may inadvertently lead to inconsistent treatment, Dr. Stephan Petak, past president of the American Association of Clinical Endocrinologists, said in an interview.

"No matter which physician a patient goes to for osteoporosis treatment, he should be treated in a similar manner," he said. "If a physician adopts the new ACP guideline, patients with a T score of –1.25 might be treated in one place and not treated in another. [Under] the National Osteoporosis Foundation guideline [which stresses the use of the World Health Organization's Fracture Risk Assessment Tool], the patient will almost certainly be treated similarly in every office."

Dr. Petak, an endocrinologist at the Texas Institute for Reproductive Medicine and Endocrinology in Houston, said that the guideline is concise and easy to understand. But, he added, it's not very useful.

"I think we have too many guidelines already, and this one adds to the confusion by providing conflicting recommendations that may, in fact, adversely affect physicians' getting on the same page with regard to osteoporosis care," he said.

By recommending that physicians make treatment decisions based on their own assessment of a patient's osteoporotic fracture risk, the ACP guideline detracts from the current body of knowledge by presenting a very vague recommendation in the place of a previously published, very concrete one," issued last February by the National Osteoporosis Foundation and available at the Web site www.nof.org.

The Clinicians' Guide to Prevention and Treatment of Osteoporosis encompasses risk assessment using both the FRAX tool and clinical characteristics, lifestyle modification , individual discussions of each of the approved medications, and physical therapy and rehabilitation.

The ACP guideline minimizes the impact and usefulness of the FRAX tool, Dr. Petak said. " It represents a major paradigm shift in risk assessment. It's the biggest change in the field since 1994, when we first characterized risk factors by using T scores. FRAX takes the guesswork out of risk assessment because it weighs all the risk factors and gives you the chance of a major osteoporotic or hip fracture over the next 10 years."

As far as the other three ACP recommendations, Dr. Petak said, "They're not harmful—but they don't move the field forward at all. "The first recommendation is fine, except that it's subsumed in everyone else's recommendations. Everyone agrees that high-risk patients should be treated. It doesn't add anything to what we're already doing."

The recommendations to balance risks and benefits of treatment and to continue research "are so obvious that they're noncontributory," Dr. Petak said.

The ACP guideline on osteoporosis treatment are the second it has issued on the topic. Last spring, the group addressed the issue of osteoporosis screening in men (Ann. Int. Med. 2008;148:680-4). ■

Clinical Factors May Predict Fracture Risk Better Than FRAX

BY JEFF EVANS
Senior Writer

MONTREAL — The clinical risk factors of age and bone mineral density at the hip appear to predict the probability of a hip fracture or a major osteoporotic fracture significantly better than the World Health Organization's more complex Fracture Risk Assessment Tool, according to an analysis of data from a prospective study of 6,252 older white women.

The results suggest that "the addition of [complex] clinical risk factor information to age and BMD alone does not enhance the prediction of these fractures in older women," said Dr. Kristine E. Ensrud, professor of medicine at the University of Minnesota, Minneapolis.

The FRAX algorithm is designed to predict only the 10-year probability of a hip fracture or a major osteoporotic fracture. It builds a risk profile based on nine clinical risk factors (age, sex, prior history of fracture, oral glucocorticoid use, presence of rheumatoid arthritis, parental history of hip fracture, smoking status, alcohol consumption, and body mass index).

The FRAX algorithm is designed to predict only the 10-year probability of a hip fracture or a major osteoporotic fracture.

Dr. Ensrud and her colleagues used data from 6,252 participants in the Study of Osteoporotic Fractures, which enrolled women during 1986-1988. Hip BMD measurements and all of the FRAX clinical risk factors were available for these women, who had an average age of 71 years. Incident fractures were confirmed in 98% of cases reported during the study's 10-year follow-up period.

A combination of age and hip BMD had significantly greater ability to predict the 10-year risk of a hip fracture than did the FRAX algorithm alone, based on area-under-the-curve (AUC) statistics that the investigators calculated from receiver operating characteristic curves that were built with data from the study. However, the AUC statistic that was derived from the age-plus-hip-BMD model (0.76) was similar to that obtained with FRAX plus hip BMD (0.75). The AUC statistic for FRAX alone was 0.71. (An AUC of 0.50 reflects a predictive ability equal to chance.)

Similarly, age plus hip BMD had a significantly greater ability to predict both major osteoporotic fractures (hip, clinical spine, wrist, or humerus) and clinical fractures (defined as nonvertebral or clinical vertebral fractures) than did the FRAX algorithm alone, Dr. Ensrud reported at the annual meeting of the American Society for Bone and Mineral Research.

To refine their analysis further, Dr. Ensrud and her associates compared the proportion of women across the models who were classified in the highest decile of fracture risk and who actually experienced a fracture outcome. This type of assessment enhances the clinical usefulness of a risk prediction model because it contains a higher proportion of women who actually experienced the outcome in question, she said.

This simple model of age and prior fracture history (rather than hip BMD) also predicted the 10-year risk of hip, osteoporotic, and clinical fractures just as well as the FRAX algorithm alone did. This finding suggests that "in a setting where BMD is not available, the addition of [complex] clinical risk factor information to age and prior fracture history alone does not enhance the prediction of these fractures in older women," Dr. Ensrud said.

The study was funded by the National Institute on Aging. ■