Clinical Capsules

Alendronate Benefits Linger

Postmenopausal women who discontinue alendronate after 5 years of treatment may experience a moderate decline in bone mineral density but are not at a significantly higher risk for fracture compared with those who continue alendronate for an additional 5 years, reported Dennis M. Black, Ph.D., of the University of California, San Francisco, and his colleagues.

But women at high risk of clinical vertebral fractures may benefit by continuing beyond 5 years, they wrote (JAMA 2006; 296:2927-38).

The FIT Long-Term Extension (FLEX) study was open to women who had been assigned to the alendronate treatment arm in the Fracture Intervention Trial (FIT) and who had completed at least 3 years of alendronate treatment. Patients were randomly assigned to receive daily treatment with 10 mg alendronate (30%), 5 mg alendronate (30%), or placebo (40%). Of 1,099 women participating in FLEX, 437 were assigned to placebo, 329 were assigned to 5 mg alendronate, and 333 were assigned to 10 mg alendronate.

After 5 years, total hip bone mineral density declined 3.38% from baseline values in the placebo group and 1.02% in the combination of the two alendronate groups.

The combined alendronate group experienced a mean 5.26% increase from FLEX baseline in lumbar spine BMD, compared with a mean 1.52% increase in the placebo group.

The two alendronate groups did not differ significantly in their incidence of total clinical fractures or nonvertebral fractures. However, the risk of clinical vertebral fractures was significantly higher in the placebo group (5.3%) than in the combined alendronate group (2.4%).

Foot Ulcers Court Comorbidity

Many diabetic patients with foot ulcers have peripheral arterial disease, infection, and disabling comorbidities, according to a large European study.

Of 1,229 consecutive patients presenting with new foot ulcers at 14 hospitals in 10 European countries, only 24% had neither peripheral arterial disease (PAD) nor infection, reported Dr. Leonne Prompers of University Hospital Maastricht, the Netherlands, and colleagues (Diabetologia 2007;50:18-25). Twenty-seven percent of the patients had infection alone, 18% had PAD alone, and 31% had both PAD and infection.

In addition, 32% had one or more disabling comorbidities, including 15% with severe visual impairment, 6% with end-stage renal disease, and 11% with heart failure or severe angina pectoris. Ten percent were unable to stand or walk without help.

The European Study Group on Diabetes and the Lower Extremity (Eurodiale) enrolled the patients between September 2003 and October 2004 and followed them for 1 year. This report tabulates the patients' baseline data; follow-up data will be published at a later date.

"[The data] contain an important message: many patients with diabetic foot ulcers are severely ill, and this is reflected by the severe underlying pathology and the presence of disabling comorbidity," the authors wrote.

HbA_{1c} Levels Predict Sepsis Outcomes

Hemoglobin A_{1c} levels at hospital admission are predictive for hospital mortality and length of stay in diabetic patients with sepsis, reported Dr. Ivan Gornik of Rebro University Hospital in Zagreb, Croatia, and associates.

The investigators conducted a prospective, observational study of adults with type 2 diabetes admitted to a medical ward or medical intensive care unit because of sepsis. APACHE II and sequential organ failure assessment (SOFA) scores, plasma glucose levels, C-reactive protein (CRP), and leukocyte counts were determined upon hospital admission. HbA_{1c} levels were determined the following day.

The study was conducted from November 2003 to December 2005 and enrolled 286 adults, of which 121 (42%) were female. A total of 224 patients survived, with a median length of stay of 9 days (range 7-13). Of the 62 patients (22%) who died in the hospital, 32 (52%) were female, according to the study.

Survivors were significantly younger than nonsurvivors were and had better APACHE II and SOFA scores. Median ages of survivors and nonsurvivors were 61 years (range 38-72) and 66 years (range 48-76), respectively (Diab. Res. Clin. Pract. 2006 [Epub doi:10.1016/j.diabres.2006.10.017]).

Survivors had significantly lower HbA_{1c} values (median 8.2) than did nonsurvivors (median 9.8). In multivariate logistic regression analysis, HbA_{1c} level was an independent predictor of hospital mortality, with an adjusted odds ratio of 1.36 for each increase of 1%. In the same analysis, female gender, APACHE II score, and SOFA score were also independent predictors of hospital mortality, whereas age, plasma glucose levels at admission, and CRP were not.

—From staff reports