Urate Levels May Be Normal in Gout

BY BRUCE JANCIN
Denver Bureau

PARIS — Serum urate levels are often normal during acute gouty arthritis attacks, according to Dr. Naomi Schlesinger.

In a study of 339 patients, 29% of individuals on chronicallopurinol had a true-normal serum urate level, defined as 6 mg/dL or less. Among patients not on the hypouricemic agent, 11% had a true-normal serum urate level during an acute episode, said Dr. Schlesinger, chief of rheumatology at Robert Wood Johnson Medical School, Camden, N.J.

With a less stringent definition of normal serum urate—a value of 8 mg/dL or less—49% of allopurinol users were classified as having a normal level during their acute attack, as were 29% not on allopurinol, according to data she presented at the annual congress of the European League Against Rheumatism.

The mean serum urate at baseline was 7.6 mg/dL in patients on long-term allopurinol and 8.5 mg/dL in those who weren't. Similarly, on day 8, following a week of nonsteroidal anti-inflammatory drug therapy, the mean serum urate was 7.4 mg/dL in those on allopurinol and 8.7 mg/dL in those who were not.

Dr. Schlesinger disclosed that Merck & Co. provided her with access to data from two company-sponsored clinical trials as well as support in data analysis. ■

Osteoarthritis Knee Pain Eased By Duloxetine

BY BRUCE JANCIN
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PARIS — Duloxetine once daily at 60 and 120 mg significantly improved knee osteoarthritis pain starting in week 1 of a 13-week placebo-controlled double-blind trial.

Results of this positive study served as the partial basis for a recent supplemental New Drug Application to the Food and Drug Administration seeking approval for a broad new indication for duloxetine (Cymbalta) in the management of chronic pain, Dr. Amy Chappell reported at the annual European Congress of Rheumatology.

Other data in support of the application came from Eli Lilly & Co.–sponsored clinical trials of duloxetine for chronic low back pain. Duloxetine, a balanced inhibitor of reuptake of serotonin and norepinephrine, is approved in the United States for treatment of major depressive disorder, generalized anxiety disorder, and diabetic peripheral neuropathy. In mid-June duloxetine also received FDA marketing approval for the treatment of fibromyalgia.

Dr. Chappell of Lilly, Indianapolis, reported on 231 patients with moderately severe chronic pain from knee osteoarthritis who were randomized to 60 mg of duloxetine once daily or placebo. Patients diagnosed with major depression in the previous 6 months were ineligible for the study.

At week 7, those in the duloxetine arm were rerandomized to either 60 mg or 120 mg of the drug once daily. No significant differences were found between the two drug regimens in most efficacy measures or in adverse events, so the two groups were combined for purposes of data analysis.

A total of 47% of duloxetine-treated patients experienced at least a 50% improvement in their mean 24-hour average pain scores—the primary study end point—compared with 29% on placebo. A total of 59% of those on duloxetine showed at least a 30% improvement in pain scores over the 13 weeks, as did 45% on placebo.

The duloxetine group also showed significantly improved physical functioning, compared with placebo, as reflected in scores on the Western Ontario and McMaster Universities physical functioning subscale. It was also superior on the Brief Pain Inventory Interference and Severity items, Clinical Global Impressions of Severity, Patient Global Impressions of Improvement, and weekly mean of 24-hour worst pain scores.

Treatment discontinuation due to adverse events occurred in 13.5% of the duloxetine group and 5.8% on placebo, a nonsignificant difference. Adverse events occurring in at least 3% of the duloxetine group and at a rate at least double that of the placebo were nausea, sleepiness, fatigue, hypertension, constipation, dizziness, and reduced libido.

Patients and physicians are most interested in randomized data comparing a novel drug such as duloxetine with standard nonsteroidal anti-inflammatory therapy in managing knee osteoarthritis pain, but the FDA requires comparison with placebo. ■