Acetaminophen's Role in OA Upheld by New Data

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — A new study confirms that acetaminophen is safe and effective for the treatment of pain associated with osteoarthritis of the knee and hip.

The results reinforce the American College of Rheumatology guidelines that recommend acetaminophen as a first-line therapy to relieve osteoarthritis (OA) pain, but contradict other studies that suggest acetaminophen may not be useful in treating OA pain.

"People were questioning whether acetaminophen had any role, and I think this study clearly shows it does," lead author Roy D. Altman, M.D., reported in a poster presentation at the 2004 World Congress on Osteoarthritis. "People with mild to moderate pain with osteoarthritis often get adequate pain relief from acetaminophen."

These findings are particularly relevant in the post-Vioxx environment, which has many patients concerned about the safety of some prescription arthritis medications.

ACR guidelines instruct physicians to start treatment with acetaminophen and then move on to nonsteroidal anti-inflammatory drugs and cyclooxygenase-2 (COX-2) inhibitors as the second and third lines of treatment, if pain control is not adequate.

Inadequate pain relief with acetaminophen may result from the adherence to the dosing schedule, said Dr. Altman at the meeting, which was sponsored by the Osteoarthritis Research Society International. The maximum recommended dosage is 1 g four times per day.

The study randomized 483 patients—who were at least 40 years old with moderate to moderately severe OA pain—to treatment with acetaminophen extended-release (ER) caplets at daily doses of 1,950 mg, 3,900 mg, or placebo. The long-acting formulation reduced the number of daily doses to just two for those taking the higher dose.

"One of the benefits of this dosing is that people will take it twice a day," said Dr. Altman, of the division of rheumatology and arthritis at the University of California, Los Angeles. "Part of the problem is that people haven't been taking acetaminophen in doses that were adequate enough to give them pain relief because they start forgetting to take it."

At 12 weeks, acetaminophen ER 3,900 mg/day was superior to placebo for all

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three primary efficacy end points: the average change in the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index pain score (mean decrease of 25 mm vs. 19 mm), the WOMAC physical function score (mean decrease of 24 mm vs. 18 mm), and the patient's global assessment of symptom of the past 0-4 Likert scale (mean change 2.11 vs. 1.81).

In contrast, acetaminophen ER at 1,950 mg/day was superior to placebo only in the patient's global assessment of therapy (mean change 2.09 vs. 1.81). "I think when you get into 2 grams a day, [the dosage] just isn't adequate, and this [study] shows that," Dr. Altman said.

No serious drug-related adverse events occurred, which was supported by McNeil Consumer & Specialty Pharmaceuticals, the manufacturer of Tylenol.

"There has been an unnecessary battle between NSAIDs and acetaminophen," Dr. Altman said. "Some areas work better than others. My feeling is that combination therapy has to be looked at more carefully."

A second study presented at the meeting found that 4,000 mg/day of acetaminophen was safe for up to 12 months of use.

The double-blind study involved 571 patients with mild to moderately severe OA pain of the hip or knee who were randomized to treatment with 4,000 mg/day of acetaminophen or 750 mg/day of naproxen.

The WOMAC scores in pain, stiffness, and physical function among the 290 patients treated with acetaminophen were comparable to those of patients treated with naproxen, without any clinically important adverse effects, reported lead author Anthony Temple, M.D., vice president of medical affairs at McNeil Consumer & Specialty Pharmaceuticals in Fort Washington, Pa. ■