Extended-Release OTC Agent Relieves Knee OA

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AMSTERDAM — Extended-release acetaminophen is a possible alternative to cyclooxygenase-2 inhibitors for pain associated with knee osteoarthritis, Dr. Thomas J. Schnitzer reported at the annual European Congress of Rheumatology.

Current osteoarthritis (OA) guidelines recommend the original shorter-acting formulation of acetaminophen at 4 g/day as a first-line treatment for pain associated with the disease. The extended-release formulation, which is commercially available, offers the advantage of less frequent dosing, explained Dr. Schnitzer, professor of medicine at Northwestern University, Chicago.

He reported on 403 adults with knee OA who participated in a 4-week, 23-center, double-blind U.S. clinical trial. Participants were randomized to extended-release acetaminophen at the recommended adult dosage of 1,300 mg t.i.d., rofecoxib at 12.5 mg/day, or rofecoxib at 25 mg/day.

The mean 143.5-mm drop on the 0- to 500-mm visual analog scale in the acetaminophen group was not significantly different from the results with rofecoxib at 12.5 mg/day, but it was inferior to the 175.9-mm drop with high-dose rofecoxib.

Study withdrawal rates for lack of efficacy were 1.5% with extended-release acetaminophen and 3.6% and 1.6%, respectively, for low- and high-dose rofecoxib. Dropout due to adverse events occurred in 5.9% of the acetaminophen group, 6.5% with rofecoxib 12.5 mg, and 7.0% with 25 mg. Headache was reported by 6.6% of patients on extended-release acetaminophen, compared with 0.7% on the low dose and 5.4% on the high dose of rofecoxib, Dr. Schnitzer noted. Two patients had an acute MI during the 4-week study, both in the rofecoxib 12.5-mg arm. Investigators deemed the MIs unrelated to the study medication.

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