Continuous Celecoxib Prevented OA Flares Best

BY MICHELE G. SULLIVAN

FROM WONCA 2010

CANCÚN, MEXICO — Osteoarthritis flares were reduced by 42% in patients who took 200 mg of celecoxib every day, compared with those who took the medication only when they experienced a disease flare, judging from randomized, placebo-controlled trial findings.

Osteoarthritis patients who took the drug daily were no more likely than intermittent users to experience either new-onset hypertension or an aggravation of existing hypertension, Dr. George Sands reported.

"Over the 22-week treatment period, continuous daily celecoxib was more effective in terms of fewer osteoarthritis flares, less pain, and less stiffness than intermittent celecoxib, with no difference in overall adverse effects or in hypertension," said Dr. Sands, senior medical director at Pfizer Inc., which sponsored the study.

The study group comprised 875 patients with hip or knee osteoarthritis. All patients had to be taking a daily NSAID to control their disease. The study consisted of three phases: In phase I, patients stopped their NSAID until they had a flare at their index joint. In phase II, patients with flares received open-label celecoxib until the flare resolved. Phase III consisted of the 22-week randomized, placebo-controlled study. Patients had two study medications, one for daily use and one for use during a flare. Half of the patients (440) received celecoxib every day and a placebo during the flare. The rest of the group (435) received daily placebo and celecoxib during the flare. Treatment continued for 22 weeks.

"Only patients who had resolved flares could be entered into the trial," Dr Sands said. "This is different from the usual arthritis studies, where they stop their NSAID, get worse, and are treated. In this study, patients were randomized after a successful treatment of a flare."

The patients' mean age was 58 years; 30% were 65 or older. Their mean weight was 83 kg. Most (80%) had knee osteoarthritis; the hip was the affected joint in the remaining 20%. The baseline WOMAC (Western Ontario and McMaster Universities) Osteoarthritis Index score was 25 in both groups. Hypertension was present in 45%. Most of the continuous-use patients (80%) and 74% of the intermittent-use patients completed the trial.

The primary end point was the number of flares occurring during the randomized portion of the study. The median time to first flare was significantly longer in the continuous-use group than in the intermittent-use group (16 days vs. 8 days, respectively). "This is not surprising, since in this part of the study, before anyone had a flare, you were testing celecoxib against placebo," noted Dr. Sands.

By the end of the 22-week treatment period, continuous users had a mean of 0.54 flares per month, significantly fewer than the mean 0.93 flares experienced by the intermittent users. "This translates into 42% fewer flares per month, which is equivalent to about two fewer flares per month," Dr. Sands said.

At the end of the treatment period, WOMAC scores were significantly better in the continuous-use group than in the intermittent-use group. The change in total WOMAC score was 1.6 in the continuous users vs. 4.99 in the intermittent users. The WOMAC subscore change for pain was also significantly better in the continuous users than the intermittent users (0.37 vs. 1.88), as was the change in the stiffness subscore (0.12 vs. 0.4).

At the final visit, 23% of the continuous-use group and 11% of the intermittent-use group had been flare free—a significant difference in favor of continuous treatment. At that time, 16% of the continuous-use patients and 9% of the intermittent-use patients reported their overall symptoms to be "very good."

Adverse events were similar between both groups, occurring in 57% of the continuous users and 59% of the intermittent users. Headache was the most frequent complaint (15% continuous vs. 16% intermittent), followed by back pain (5% vs. 7%). ■

Disclosures: *Dr. Sands is senior medical director at Pfizer Inc., which makes celecoxib and sponsored the study.*

Pages 52a—52b