Celecoxib was as effective as diclofenac plus omeprazole in reducing recurrent ulcer bleeding in arthritis


Introduction

In patients with arthritis at high risk for ulcer bleeding, is celecoxib noninferior (i.e., similar) to diclofenac plus omeprazole in reducing the risk for recurrent ulcer bleeding?

Design

Randomized (allocation concealed), blinded (clinicians, patients, outcome assessors, data collectors, and data analysts), controlled trial with 6-month follow-up.

Setting

The Endoscopy Center of the Prince of Wales Hospital in Hong Kong, China.

Patients

290 patients who had rheumatoid arthritis, osteoarthritis, or other forms of arthritis; confirmed ulcer healing; a negative test result for Helicobacter pylori; and anticipated regular use of nonsteroidal antiinflammatory drugs (NSAIDs) during the trial. Exclusion criteria were concomitant use of anticoagulant agents or corticosteroids, gastric or duodenal surgery other than a patch repair, erosive esophagitis, gastric-outlet obstruction, renal failure, terminal illness, or cancer. 287 patients (99%) (mean age 68 y, 56% women) were included in the analysis.

Intervention

Patients were allocated to celecoxib, 200 mg twice daily, plus omeprazole placebo daily (n = 144) or extended-release diclofenac 75 mg twice daily, plus omeprazole, 20 mg daily (n = 143) for 6 months. Patients were permitted to take antacids, acetaminophen or other non-NSAID analgesics, and disease-modifying antirheumatic drugs.

Main Outcome Measures

Recurrent ulcer bleeding (hematemesis or melena with ulcers [a circumscribed mucosal break ≥ 0.5 cm in diameter with a perceptible depth] or bleeding erosions [a flat mucosal break of any size that occurred in the presence of blood in the stomach] confirmed by endoscopy, or a decrease in the hemoglobin level ≥ 2 g/dL in the presence of endoscopically proven ulcers or bleeding erosions). Secondary endpoints were efficacy (patients’ assessment of global disease activity and arthritis pain); recurrent ulcer bleeding if not taking low-dose aspirin (≤ 325 mg/d); and other adverse gastrointestinal, renal, and cardiovascular events.

Results

Analysis was by intention to treat. The groups did not differ for recurrent ulcer bleeding (Table) or for any of the secondary endpoints.

Conclusion

In patients with arthritis at high risk for ulcer bleeding, celecoxib was noninferior to diclofenac plus omeprazole in reducing the risk for recurrent ulcer bleeding.

References