

3. Famotidine May Prevent Peptic Ulcers, Esophagitis in Patients Taking Low-Dose Aspirin

Famotidine is effective in preventing gastric and duodenal ulcers, and erosive esophagitis in patients taking low-dose aspirin for vascular protection, according to results from the phase 3 FAMOUS trial reported online in the July 6 issue of *The Lancet*.

Low-dose aspirin is one of the most widely used drugs in the world. Increasingly, it is being bought over-the-counter or prescribed for its antithrombotic activity in cardiovascular and cerebrovascular diseases, and in diabetes mellitus. However, despite these benefits, there has been a rise in the incidence of major upper gastrointestinal complications in patients taking aspirin, such as peptic ulcer bleeding, perforation, and sometimes death. Although proton-pump inhibitors have been proven effective in treating and preventing ulcers related to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs), there have been concerns about their costs, safety, and risk of interaction with clopidogrel, which is frequently prescribed concurrently with aspirin.

Famotidine is a histamine H₂ receptor antagonist that has been proven effective in preventing and healing peptic ulcers in patients receiving conventional NSAIDs. The investigators designed this study to assess the drug's efficacy in preventing ulcers and esophagitis for those taking low-dose aspirin.

Adult patients older than 18 years and receiving antithrombotic low-dose aspirin (75 - 325 mg/day) were enrolled from the cardiovascular, cerebrovascular, and diabetes clinics at Crosshouse Hospital. A total of 404 patients who showed no evidence of ulcers or erosive esophagitis during an endoscopy at baseline were then randomly assigned to receive either a famotidine 20-mg tablet twice daily or a matching placebo tablet. The primary endpoint was the development of new ulcers (size = 3 mm) in the stomach or duodenum or erosive esophagitis at a final endoscopic examination 12 weeks after randomization. Clinical assessments were also done at baseline, at 6 weeks, and at 12 weeks.

At the end of the study, the proportion of patients in whom peptic ulcers of any size, erosive esophagitis, or both developed was significantly lower in the famotidine group vs the placebo group (5.4% vs 32.5%; odds ratio [OR], 0.12; 95% confidence interval [CI], 0.06 - 0.23; *P* < .0001). Gastric ulcers developed in only 7 (3.4%) of the famotidine-treated patients vs 30 (15%) of those treated with placebo, duodenal ulcers developed in only 1 patient (0.5%) vs 17, and erosive esophagitis occurred in 9 (4.4%) vs 38, respectively. In a subgroup analysis of patients in whom peptic ulcers developed, *Helicobacter pylori* infection was found in 42.1% of the patients treated with placebo and in none of those treated with famotidine.

Taha AS, et al. The Lancet, Volume 374, Issue 9684, Pages 119 - 125, 11 July 2009.