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Famotidine Prevents GI Damage in Patients Who Take Low-Dose Aspirin

Gastric ulcers, duodenal ulcers, and erosive esophagitis were less common with famotidine use.

The growing popularity of low-dose aspirin for cardiovascular prophylaxis is associated with a rising incidence of upper gastrointestinal complications. Proton-pump inhibitors are useful for preventing and treating aspirin-related ulcers, but they can have adverse effects and might reduce the effectiveness of clopidogrel. Famotidine (Pepcid) is effective for preventing and treating nonsteroidal anti-inflammatory drug-related ulcers but has not been studied in patients who use low-dose aspirin.

With manufacturer support, U.K. researchers randomized 404 adults who took low-dose aspirin for cardiovascular prophylaxis to receive twice-daily famotidine (20 mg) or placebo for 12 weeks. Baseline upper GI endoscopies were normal for all patients; none had ever been treated for *Helicobacter pylori* infection. Patients were allowed to take antacids for relief of heartburn and dyspepsia. At 12 weeks, 322 patients underwent repeat endoscopy; the others were assumed to have had normal findings.

Significantly more placebo recipients than famotidine recipients developed gastric ulcers >3 mm (15.0% vs. 3.4%), duodenal ulcers >3 mm (8.5% vs. 0.5%), and erosive esophagitis (19.0% vs. 4.4%). Lesions occurred more commonly in patients who had mucosal scarring or erosions at baseline. Four patients, all in the placebo group, experienced upper GI hemorrhages; two required transfusion. Other adverse events were similar in the two groups.

Comment: Although this trial was not powered to study serious GI complications, the substantial relative reduction in subclinical lesions suggests that famotidine is useful for GI protection in patients who take prophylactic low-dose aspirin.

— [Bruce Soloway, MD](#)

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Citation(s):

Taha AS et al. Famotidine for the prevention of peptic ulcers and oesophagitis in patients taking low-dose aspirin (FAMOUS): A phase III, randomised, double-blind, placebo-controlled trial. *Lancet* 2009 Jul 11; 374:119.