PPIs in patients receiving anticoagulation may not reduce upper GI events

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Routine use of proton-pump inhibitors (PPIs) in patients receiving low-dose anticoagulation and/or aspirin for stable cardiovascular disease does not reduce upper GI events but may reduce bleeding from gastroduodenal lesions, an industry-funded study found.

Researchers conducted a randomized, placebo-controlled trial of 17,598 patients with stable cardiovascular disease and peripheral artery disease. Patients were randomly assigned to receive pantoprazole, 40 mg/d, or placebo, as well as rivaroxaban, 2.5 mg twice daily, with aspirin, 100 mg once daily; rivaroxaban, 5 mg twice daily; or aspirin, 100 mg/d alone.

The primary outcome was time to first upper GI event, defined as a composite of overt bleeding, upper GI bleeding from a gastroduodenal lesion or of unknown origin, occult bleeding, symptomatic gastroduodenal ulcer or five or more erosions, upper GI obstruction, or perforation. The results of the trial, which was funded by Bayer AG, were published May 2 by *Gastroenterology*.

No significant difference was seen in upper GI events between the pantoprazole group (102 of 8,791 events) and the placebo group (116 of 8,807 events) (hazard ratio [HR], 0.88; 95% CI, 0.67 to 1.15). Pantoprazole was associated with a significant reduction in bleeding of gastroduodenal lesions (HR, 0.52; 95% CI, 0.28 to 0.94; P=0.03), with no difference in overt or occult upper GI bleeding events between the two groups. This reduction was greater when researchers applied a post hoc definition of bleeding gastroduodenal

lesion (HR, 0.45; 95% CI, 0.27 to 0.74), although the number needed to treat still was high (982; 95% CI, 609 to 2,528). For pantoprazole to prevent one overt bleeding gastroduodenal lesion compared to placebo each year, the number needed to treat was 1,770 (95% CI, 933.5 to 17,111).

The researchers noted that the number of bleeding upper GI events in their study was small, among other limitations. However, they concluded, "[There] is no benefit in routinely giving PPI therapy to patients with stable cardiovascular disease deemed to be at low risk of GI events and needing anticoagulant therapy or aspirin. PPI therapy reduces the risk of peptic ulcer complications and PPI therapy may be warranted in patients at high risk of this event."