LOW-DOSE ACETYLSALICYLIC ACID-ASSOCIATED PEPTIC ULCERS AND DYSPEPTIC SYMPTOMS ARE REDUCED BY ESOMEPRAZOLE 20 MG AND 40 MG ONCE DAILY

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Background: Low-dose acetylsalicylic acid (ASA) is the mainstay of cardiovascular (CV) disease management, but may be associated with peptic ulcers (PU) and adverse upper gastrointestinal (GI) symptoms, which may lead to cessation of therapy. This post-hoc subanalysis of the OBERON study (NCT00441727; 204 centers in 20 countries) assessed the efficacy of esomeprazole (ESO) 20 and 40 mg once daily (qd) in reduction of PU and dyspeptic symptoms, stratified by ASA dose (75-100 mg or 101-325 mg qd).

Methods: Helicobacter pylori-negative (at screening visit) patients (pts) receiving low-dose ASA with ≥1 of the following criteria were included: age ≥65y; ≥18y with history of uncomplicated PU; ≥60y with stable coronary artery disease or upper GI symptoms and ≥5 peptic erosions, or low-dose ASA use begun within 1 mo. Pts with previous ulcer complications, PU, or reflux esophagitis (Los Angeles grade C or D) at baseline endoscopy, or need for continuous use of nonsteroidal anti-inflammatory drugs were excluded. Randomization was to ESO 20 or 40 mg, or placebo qd for 26 wks. Endoscopy-confirmed PU and dyspeptic symptoms (by Reflux Disease Questionnaire) at baseline, wks 8, and 26 or upon withdrawal were analyzed post-hoc, according to ASA dose stratification.

Results: Overall, 3.4% of pts received concomitant clopidogrel. Most pts (1911/2421; 79%) used low-dose ASA 75-100 mg. PUs occurred in 6.1% of these pts on placebo, versus 0.6% and 1.6% of pts on ESO 20 and 40 mg qd, respectively (both p<.0001). ESO 20 and 40 mg qd significantly reduced PU occurrence in pts using low-dose ASA at 101-325 mg versus placebo (2.3% and 0.6%, vs 8.7%, respectively; p < .02). Both ESO 20 and 40 mg qd significantly reduced dyspeptic symptoms (both p < .05 vs placebo). The treatment effect for PU and dyspeptic symptoms was not significantly different between the two ASA dose strata. No CV events occurred among pts taking concomitant clopidogrel treatment.

Conclusions: PU and dyspeptic symptoms occur in pts who use low-dose ASA at doses of 75-100 mg qd to manage CV risk. These side effects are reduced by ESO 20 or 40 mg qd.

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