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Article in Press

Similar Efficacy of Proton-Pump Inhibitors vs H2-Receptor Antagonists in Reducing Risk of Upper Gastrointestinal Bleeding or Ulcers in High-risk Users of Low-dose Aspirin

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Article Info

Abstract

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Background & Aims

It is not clear whether H2-receptor antagonists (H2RAs) reduce the risk of gastrointestinal (GI) bleeding in aspirin users at high risk. We performed a double-blind randomized trial to compare the effects of a proton pump inhibitor (PPI) vs a H2RA antagonist in preventing recurrent upper gastrointestinal (GI) bleeding and ulcers in high-risk aspirin users.

Methods

We studied 270 users of low-dose aspirin (325 mg or less per day) with a history of endoscopically confirmed ulcer bleeding at 8 sites in Hong Kong and Japan. After healing of ulcers, subjects with negative results from tests for *Helicobacter pylori* resumed aspirin (80 mg) daily and were randomly assigned to groups given a once daily PPI (rabeprazole, 20 mg, n=138) or H2RA (famotidine, 40 mg, n=132) for up to 12 months. Subjects were evaluated every 2 months; endoscopy was repeated if they developed symptoms of upper GI bleeding or had a reduction in hemoglobin >2 gram/decilitre and after 12 months of follow up. The adequacy of upper GI protection was assessed by endpoints of recurrent upper GI bleeding and a composite of recurrent upper GI bleeding or recurrent endoscopic ulcers at month 12.

Results

During the 12-month study period, upper GI bleeding recurred in 1 patient receiving rabeprazole (0.7%; 95% CI, 0.1% to 5.1%) and 4 receiving famotidine (3.1%, 95% CI, 1.2%–8.1%) (P=.16). The composite endpoint of recurrent bleeding or endoscopic ulcers at month 12 was reached by 9 patients receiving rabeprazole (7.9%; 95% CI, 4.2%–14.7%) and 13 receiving famotidine (12.4%; 95% CI, 7.4%–20.4%) (P=.26).

Conclusions

In a randomized controlled trial of users of low-dose aspirin at risk for recurrent GI bleeding, a slightly lower proportion of patients receiving a PPI along with aspirin developed recurrent bleeding or ulcer than of patients receiving an H2RA with the aspirin, although this different was not statistically significant. ClincialTrials.gov no: NCT01408186.

Key Words:
Acid-suppressive drugs, hemorrhage, ASA, anti-platelet

Abbreviations:
GI (gastrointestinal), H2RA (H2-receptor antagonists), PPI (proton pump inhibitor)

Study
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Contributions: Francis K.L. Chan and Moe Kyaw made equal contributions to this study. Francis Chan and Tetsuo Arakawa designed the study. Tetsuya Tanigawa, Kazuhide Higuchi, Kazuma Fujimoto, Yoshikazu Kinoshita, Yuji Naito, Toshio Watanabe, Toshihisa Takeuchi, Yasuhisa Sakata, Toshihisa Takeuchi, Osamu Handa, Hiroko Nebiki, Takashi Abe, Tsuyoshi Mishiro, Kelvin Lam, Angeline Lo, Heyson Chan, Rashid Lui and Raymond S.Y. Tang recruited and followed up patients. Pui Kuan Cheong coordinated the studies from multiple centers and database clearing. Data analysis was done by Moe Kyaw and Yee Kit Tse. Jessica Y.L. Ching was responsible for study monitoring. Justin C.Y. Wu, Siew C Ng and Tetsuya Tanigawa were members of the adjudication committee. Vivian Lee is responsible for monitoring the study drugs dispensing practice in HK site. The manuscript was prepared by Francis K.L. Chan, Moe Kyaw, Yee Kit Tse, Pui Kuan Cheong and Jessica Y.L. Ching without editorial support. All authors read, revised, and approved the final report.

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