

# Lansoprazole reduced recurrence of ulcer complications in long-term use of low-dose aspirin

Lai KC, Lam SK, Chu KM, et al. Lansoprazole for the prevention of recurrences of ulcer complications from long-term low-dose aspirin use. *N Engl J Med*. 2002; 346:2033-8.

## QUESTION

In patients receiving continuous treatment with low-dose aspirin, is *Helicobacter pylori* eradication plus lansoprazole more effective than *H. pylori* eradication alone for preventing the recurrence of ulcer complications?

## DESIGN

Randomized {allocation concealed\*}†, blinded (clinicians, patients, outcome assessors, monitoring committee, and data analysts),\* placebo-controlled trial with a median follow-up of 12 months.

## SETTING

A university hospital in Hong Kong, China.

## PATIENTS

123 patients who were 18 to 80 years of age (mean age 70 y, 72% men) and had ulcers (gastric, duodenal, or gastroduodenal), were receiving low-dose aspirin for > 1 month before developing ulcers, had a disease such as stroke or ischemic heart disease that required long-term continuous treatment with low-dose aspirin, and had *H. pylori* infection that was objectively diagnosed. Exclusion criteria included esophagitis; a

history of gastric or duodenal surgery other than oversewing of a perforation; allergy to study drugs; *H. pylori* infection that could not be eradicated after 2 attempts with eradication therapies; and concomitant treatment with nonsteroidal anti-inflammatory drugs, corticosteroids, or anticoagulants. Follow-up was 92%.

## INTERVENTION

After healing of the ulcers and eradication of *H. pylori* infection, 62 patients were allocated to aspirin (100 mg/d) plus lansoprazole (30 mg/d), and 61 patients were allocated to aspirin (100 mg/d) plus placebo, all taken once daily for 12 months.

## MAIN OUTCOME MEASURES

Recurrence of ulcer complications (bleeding, perforation, or obstruction).

## MAIN RESULTS

Analysis was by intention to treat. Fewer patients in the lansoprazole group than in the placebo group had a recurrence of ulcer complications (Table).

## CONCLUSION

In patients receiving continuous treatment with low-dose aspirin, *Helicobacter pylori* eradication plus lansoprazole was more effective than *H. pylori* eradication alone for preventing the recurrence of ulcer complications.

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\*See Glossary.

†Information provided by author.

## Lansoprazole vs placebo in continuous treatment with low-dose aspirin at 12 months‡

Outcome	Lansoprazole	Placebo	RRR (95% CI)	NNT (CI)
Recurrence of ulcer complications	1.6%	14.8%	89% (37 to 98)	8 (5 to 24)

‡Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.

## COMMENTARY

Even low doses of aspirin can cause serious ulcer complications. *H. pylori* infection, which is a risk factor for aspirin-associated ulcers (1), is more prevalent in Hong Kong (where the study by Lai and colleagues was done) than in North America. Lai and colleagues showed that eradication of *H. pylori* infection alone was inadequate for preventing recurrence of ulcer complications in Chinese patients who were restarted on low-dose aspirin after ulcer healing. The combination of *H. pylori* eradication and subsequent maintenance with lansoprazole was substantially superior to *H. pylori* eradication alone in preventing ulcer complications within 1 year. We do not know the "natural" rate of recurrent ulcer complications without either of these interventions because the inclusion of a control group in which patients were not offered treatment for *H. pylori* infection would have been unethical.

A recent multinational study (currently only available in abstract form) found a point prevalence of endoscopic ulcers of 11% in patients who were receiving aspirin, 75 to 325 mg/d, but not nonsteroidal anti-inflammatory drugs, proton-pump inhibitors, or H<sub>2</sub>-antagonists (1).

Advancing age and *H. pylori* infection were risk factors for ulcers, while dyspepsia was a negative predictor. Therefore, some patients receiving low-dose aspirin (particularly elderly and asymptomatic persons) will have ulcers and will be at risk for complications. This does not mean that they all require long-term treatment with proton-pump inhibitors. However, those who have an ulcer complication should be tested for *H. pylori* infection, which should be treated if present. For such patients who are resuming low-dose aspirin because of a medical necessity, long-term proton-pump inhibitor co-therapy after documented ulcer healing and *H. pylori* eradication is recommended.

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## Reference

- Yeomans ND, Hawkey C, Lanan A, et al. Prevalence of gastric and duodenal ulcers during "low dose" aspirin. *Gastroenterology*. 2002;122:A-87.