

# Helicobacter pylori testing plus eradication was as effective and safe as prompt endoscopy for dyspepsia

Lassen AT, Pedersen FM, Bytzer P, Schaffalitzky de Muckadell OB. *Helicobacter pylori* test-and-eradicate versus prompt endoscopy for management of dyspeptic patients: a randomised trial. *Lancet*. 2000 Aug 5;356:455-60.

## QUESTION

Is *Helicobacter pylori* testing plus eradication as effective and safe as prompt endoscopy in patients with dyspepsia?

## DESIGN

Randomized (allocation concealed\*), unblinded,\* controlled trial with 1-year follow-up.

## SETTING

Primary care clinics in Odense, Denmark.

## PATIENTS

500 patients  $\geq$  18 years of age (median age 45 y, 54% women) who had had  $\geq$  2 weeks of dyspeptic symptoms (pain or discomfort in the epigastrium with or without heartburn, regurgitation, nausea, vomiting, or bloating) with a severity that required treatment or investigation. Exclusion criteria included treatment with ulcer-healing drugs in the previous month, bleeding or anemia, unintentional weight loss  $>$  3 kg, or previous gastric surgery. Follow-up was 89%.

## INTERVENTION

At entry, all patients were asked to discontinue any nonsteroidal anti-inflammatory drug (NSAID) use. 250 patients were allocated to *H. pylori* testing plus eradication. In this group, *H. pylori*-infected patients received 2 weeks of lansoprazole, 30 mg twice daily;

metronidazole, 500 mg 3 times daily; and amoxicillin, 1000 mg twice daily, and were offered endoscopy if symptoms did not improve. For patients who had negative results on *H. pylori* testing, those who had previously used NSAIDs had endoscopy, and those who had reflux symptoms but were not using NSAIDs were treated with a proton-pump inhibitor (PPI). 250 patients were allocated to prompt endoscopy and received treatment based on their endoscopic results. Patients with normal endoscopic results received reassurance and lifestyle advice.

## MAIN OUTCOME MEASURES

Self-reported dyspeptic symptoms; gastrointestinal symptoms; overall influence of dyspeptic symptoms; quality of life; symptom improvement; patient satisfaction; general practitioner (GP) visits; sick-leave days; and use of endoscopy, PPI, *H. pylori* tests, and eradication treatments.

## MAIN RESULTS

141 patients (28%)—64 (26%) in the group that received testing plus eradication and 77 (31%) in the prompt endoscopy group—had *H. pylori* infection. Testing plus eradication and prompt endoscopy did not differ for the median proportion of days without dyspeptic symptoms (0.63 vs 0.67 d,  $P = 0.12$ ), gastrointestinal symptoms, overall

influence of dyspeptic symptoms, quality of life, symptom improvement, GP visits, or sick-leave days. More patients who received testing plus eradication were dissatisfied with their treatment than were those who received prompt endoscopy (12% vs 4%,  $P = 0.013$ ). Patients who received testing plus eradication had lower per-patient means for use of endoscopy (0.5 vs 1.25,  $P < 0.001$ ) and PPI (52.2 vs 58.7,  $P = 0.03$ ) than did those who received prompt endoscopy and higher per-patient means for use of *H. pylori* tests (1.13 vs 0.14,  $P < 0.001$ ) and eradication treatments (0.26 vs 0.17,  $P = 0.009$ ).

## CONCLUSION

*Helicobacter pylori* testing plus eradication was as effective and safe as prompt endoscopy for the primary care treatment of patients with dyspepsia but had greater patient dissatisfaction.

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\*See Glossary.

## COMMENTARY

In this well-done study by Lassen and colleagues, a noninvasive *H. pylori* test with a treat-if-positive strategy was compared with prompt endoscopy. This study convincingly showed that no clinically important differences existed between the 2 strategies for most outcomes, including number of days without dyspepsia, severity of symptoms, and quality of life. Another recent randomized trial showed that noninvasive *H. pylori* testing and treatment was superior to and more cost-effective than placebo in improving uninvestigated dyspeptic symptoms (1). These studies add to the increasing literature that shows the benefits of evaluating patients with dyspepsia for *H. pylori* infection before referral (2).

Several key aspects of this study by Lassen and colleagues deserve mention. One aspect was the absence of an upper age limit for inclusion. Furthermore, by excluding patients with alarm symptoms, no patients with cancer were misdiagnosed. Most dyspepsia guidelines recommend endoscopy for patients between 50 and 55 years of age. Another design feature worth noting was that patients with heartburn (even dominant heartburn) were not excluded from the study. This is in

contrast to the Rome II dyspepsia definition, which excludes heartburn symptoms. Results were similar in a subset of such patients (3).

The proportion of dissatisfied patients randomly allocated to the test-and-treat group was higher than that of the endoscopy group (12% vs 4%,  $P = 0.013$ ), although the absolute numbers were small. Reasons for this difference may be the reassuring effect of endoscopy or that patients who were negative for *H. pylori* and without heartburn only received lifestyle advice. Increasing evidence exists that PPIs are superior to placebo in such patients.

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## References

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