

# *Helicobacter pylori* eradication had no effect on heartburn or gastroesophageal reflux in *H. pylori* infection

Harvey RF, Lane JA, Murray LJ, et al. Randomised controlled trial of effects of *Helicobacter pylori* infection and its eradication on heartburn and gastro-oesophageal reflux: Bristol helicobacter project. *BMJ*. 2004;328:1417-20.

## QUESTION

In patients with *Helicobacter pylori* infection, what is the effect of its eradication on symptoms of heartburn and gastroesophageal reflux?

## METHODS

**Design:** Randomized placebo-controlled trial (Bristol Helicobacter project).

**Allocation:** {Concealed}†.\*

**Blinding:** Blinded {clinicians, patients, data collectors, and outcome assessors}†.\*

**Follow-up period:** 2 years.

**Setting:** 7 general practices in northeastern Bristol, England, UK.

**Patients:** 1558 patients who were 20 to 59 years of age (mean age 46 y, 51% women) with a 13C-urea breath test (UBT) showing *H. pylori* infection.

**Intervention:** Clarithromycin, 500 mg, and ranitidine bismuth citrate, 400 mg, twice daily for 2 weeks ( $n = 787$ ) or placebo ( $n = 771$ ).

**Outcomes:** Symptoms of heartburn and gastroesophageal reflux.

**Patient follow-up:** 92% (intention-to-treat analysis).

## MAIN RESULTS

At 6 months, repeated UBT results were negative in 91% of patients in the eradication treatment group and 14% of those in the placebo group. The eradication-treatment group did not differ from the placebo group for rates of heartburn and gastroesophageal reflux (Table).

## CONCLUSION

In patients with *Helicobacter pylori* infection, treatment to eradicate *H. pylori* had no effect on heartburn or gastroesophageal reflux.

*Sources of funding:* NHS South and West Regional Research and Development Directorate and GlaxoSmithKline UK.

*For correspondence:* Dr. R.F. Harvey, North Bristol NHS Trust, Bristol, England, UK. E-mail [richard.harvey1@virgin.net](mailto:richard.harvey1@virgin.net). ■

\*See Glossary.

†Information provided by author.

### *Helicobacter pylori* eradication treatment with clarithromycin and ranitidine bismuth citrate vs placebo at 2 years‡

Outcomes	Eradication treatment	Placebo	RRR (95% CI)	NNT
Heartburn	23.9%	24.2%	1.4% (-19 to 18)	Not significant
			RRI (CI)	NNH
Gastroesophageal reflux	18.9%	17.6%	7% (-14 to 34)	Not significant

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

## COMMENTARY

The study by Harvey and colleagues found that *H. pylori* eradication did not result in new or worsening gastroesophageal reflux disease (GERD) symptoms. Several points of this study deserve consideration. First, although the terms “heartburn” and “acid reflux” are central to this study, they are not clearly defined in the report or in the reference cited by the authors (1). This is potentially problematic because terms used to describe the symptoms of GERD are fraught with ambiguity (2). Also notable was the high rate of “spontaneous” *H. pylori* clearance in the placebo group. As the authors suggest, this was probably due to lowering the cut-off for a positive UBT result, which probably improved sensitivity at the expense of specificity.

In the placebo group, 75 of 99 patients with “spontaneous” resolution had borderline positive UBT results, suggesting that these patients may not have ever been infected. One wonders about the corresponding number of patients with false-positive UBT results in the *H. pylori* eradication group.

Further, these results may or may not be relevant to other parts of the world. The finding of a slightly higher prevalence of heartburn in patients infected with *H. pylori* is consistent with the greater probability of antral gastritis and acid hypersecretion reported in western countries. In such patients, *H. pylori* eradication would not be expected to induce

or exacerbate GERD. On the other hand, eradication of *H. pylori* in populations where associated pangastritis and its attendant acid hyposecretion predominate could lead to different clinical outcomes, particularly in persons with preexisting GERD or a predisposition to GERD (3).

These issues notwithstanding, this study provides further evidence that in western countries, concerns about the possibility of worsening GERD should not influence the decision to eradicate *H. pylori*.

William D. Chey, MD  
Richard Saad, MD  
University of Michigan  
Ann Arbor, Michigan, USA

## References

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