Effect of Screening and Treatment for *H. pylori* on Dyspepsia

Moayyedi P, Feltbower R, Brown J, Mason S, Mason J, Nathan J, et al. Effect of population screening and treatment for Helicobacter pylori on dyspepsia and quality of life in the community: a randomised controlled trial. Lancet 2000;355:1665–9.

Study Overview

Objective. To determine if a community-based program of screening and treatment for *Helicobacter pylori* infection decreases prevalence of dyspepsia and improves quality of life.

Design. Randomized, double-blind, placebo-controlled trial. Analysis was by intention-to-treat, with robustness analyses assuming that either all or none of the patients lost to follow-up had dyspepsia.

Setting and participants. 32,929 patients randomly selected from 36 general medicine practices in the Leeds and Bradford area of northern England (population, 1.2 million) were invited to attend *H. pylori* screening and treatment clinics. Of those invited, 9262 attended the clinics and 8455 attendees (25.6% of invited patients) were eligible for the study. Patients were excluded if they had had treatment with antibiotics, proton-pump inhibitors, or bismuth salts within 2 weeks of their visit; refused to abstain from alcohol for 1 week; had allergies to macrolides, proton-pump inhibitors, or 5-nitroimidazoles; or were taking warfarin, digoxin, cisapride, antihistamines, or theophyllines at the time of their visit.

Intervention. Patients were screened for *H. pylori* using a non-fasting carbon-13–labelled urea breath test. Those testing positive were randomly assigned to either omeprazole (20 mg twice daily), clarithromycin (250 mg twice daily), and tinidazole (500 mg twice daily) or identical-appearing placebos.

Main outcome measures. The primary outcome was prevalence of dyspepsia; secondary outcomes included severity of dyspepsia, type of dyspepsia symptom (epigastric pain, heartburn / reflux, or other), and quality of life as assessed by the validated psychological general well-being index (PGWB).

Main results. 2329 participants were positive for *H. pylori* and all but 5 were randomized. Study groups were similar (prevalence of dyspepsia at baseline: 43% treatment group, 45% control group, $P > 0.2$). *H. pylori* was eradicated in 74% of the treatment group and 5% of the control group. At 2-year follow-up, 28% of the treatment group and 33% of the control group had dyspepsia (16% relative risk reduction; number needed to treat [NNT], 20 [95% confidence interval {CI}, 10 to 100; $P = 0.015$]). Dyspepsia scores (as measured by the Leeds dyspepsia questionnaire) were lower in the treatment group than in the control group (baseline, 4.03 versus 4.24; at 2 years, 2.57 versus 3.09, $P < 0.05$). Specific dyspepsia symptoms also appeared less frequently in the treatment group, although none of the differences reached the prespecified significance level of $P < 0.01$. Among participants with *H. pylori*, baseline PGWB scores were significantly lower in those with dyspepsia. At 2 years, the overall and subscale values of the PGWB were not significantly changed or different between the treatment and control groups.

Conclusion

Population-based screening and treatment for *H. pylori* infection accomplishes a small reduction in the prevalence of dyspepsia without a benefit in quality of life.

Commentary

A year and a half ago, 2 contradictory studies addressing a possible link between dyspepsia and *H. pylori* infection appeared in the *New England Journal of Medicine*. Both studies treated patients with nonulcer dyspepsia and *H. pylori*; however, one reported no advantage to eliminating *H. pylori* [1], while the other reported a small benefit in relief of dyspepsia (NNT, 7 [95% CI, 5 to 15]) [2]. In the context of this debate, Moayyedi and colleagues' well-executed study adds important information by suggesting that *H. pylori* is causally linked to nonulcer dyspepsia in a small number of patients and that this dyspepsia may be relieved by treating the infection. The authors' findings would be more generalizable if a

(continued on page 14)

"Outcomes Research in Review" is edited by Adam Jonas, MD, MPH, Medical Director for Health Services, Washington State Department of Corrections, Olympia, WA, and Benoit Tonneau, MD, Assistant Professor of Medicine, Department of Medicine, Albany Medical College, Albany, NY. Dr. Jonas prepared reviews 1–3; Dr. Tonneau prepared reviews 4–6.

(continued from page 8)

larger portion of invited patients had participated, and the study's internal validity would be greater if the 2-year follow-up rate had been higher. Nevertheless, the results of Moayyedi and colleagues' work contributes strongly to the literature on this controversial issue. The authors' conclusion also addressed the clinical importance of the relationship between syndrome and organism and noted that economic data collected during the trial will be reported. This information will be of great value for policy makers struggling to find the best practice for treating dyspepsia.

Applications for Clinical Practice

Given the effect size—small in terms of dyspepsia prevalence and none in quality of life—this study does not merit broad implementation of community-based programs for eradicating *H. pylori*. The pending economic analysis from these authors and from long-term studies of gastric cancer and *H. pylori* may provide more definitive information on this matter. Moayyedi et al's study does not resolve the matter of how to deal with infection in individual patients without peptic ulcer disease or mucosa-associated lymphatic tissue lymphoma of the stomach. Individual clinicians should wait for more research to aid in identifying individual patients likely to benefit from treatment.

References

1. Blum AL, Talley NJ, O'Morain C, van Zanten SV, Labenz J, Stolte M, et al. Lack of effect of treating Helicobacter pylori infection in patients with nonulcer dyspepsia. Omeprazole plus Clarithromycin and Amoxicillin Effect One Year after Treatment (OCAY) Study Group. N Engl J Med 1998;339: 1875–81.
2. McColl K, Murray L, El-Omar E, Dickson A, El-Nujumi A, Wirz A, et al. Symptomatic benefit from eradication Helicobacter pylori infection in patients with nonulcer dyspepsia. N Engl J Med 1998;339:1869–74.