

What Is a Cost-effective Approach to Proving *Helicobacter pylori* Eradication after Antibiotic Treatment?

Vaira D, Vakil N, Menegatti M, et al. The stool antigen test for detection of *Helicobacter pylori* after eradication therapy. *Ann Intern Med* 2002;136:280–7.

Study Overview

Objective. To determine whether the stool antigen test, a novel test for detecting *Helicobacter pylori*, can be used to indicate if eradication therapy is successful.

Design. Prospective blinded cohort study.

Setting and participants. 84 patients from 6 clinical centers in the United States and Europe were recruited. All patients were referred by their primary care physician to a gastroenterologist for dyspepsia. Patients taking proton-pump inhibitors, H₂ receptor antagonists, NSAIDs, or antibiotics in the previous 4 weeks were excluded. Patients who were found to be *H. pylori* positive by endoscopically collected culture or rapid urease test were included. All patients underwent endoscopy and a stool antigen test at baseline. After baseline measurements, patients were given a 3-agent regimen over 7 to 10 days to eradicate *H. pylori*. Patients collected stool for the antigen test at days 3, 7, 15, 21, 29, and 35 after completion of eradication therapy.

Main outcome measures. Sensitivity and specificity of the stool antigen test was calculated using a gold standard of 3 tests—histologic examination of gastric biopsy, gastric culture, and rapid urease test.

Main results. The stool antigen test at day 35 following therapy had a sensitivity of 94% (95% confidence interval [CI], 71% to 100%) and a specificity of 97% (95% CI, 94% to 100%). The urea breath test had a comparable sensitivity of 94% (95% CI, 71% to 100%) and specificity of 100% (95% CI, 94% to 100%). On day 7 after treatment, the stool antigen test was predictive of cure as determined by follow-up endoscopy studies with a positive predictive value of 100% (95% CI, 69% to 100%) and negative predictive value of 91% (95% CI, 82% to 97%).

Conclusion. A positive stool antigen test for *H. pylori* 7 days after therapy predicts eradication.

Commentary

H. pylori infection continues to be highly prevalent in the pri-

mary care population and frequently causes gastritis and ulceration. Antibiotic therapy remains the most effective treatment option, but the failure rate is still 10% to 20% and resistant strains of *H. pylori* have recently been identified. These trends indicate the need for a cost-effective and noninvasive test to check for *H. pylori* eradication after treatment. The authors found that a stool antigen test completed at 7 days after *H. pylori* therapy predicted endoscopically proven cure in every case studied. The antigen test had similar sensitivity and specificity to the urea breath test, which is the current champion of noninvasive *H. pylori* testing. Such findings would potentially allow physicians to quickly identify and re-treat patients who failed the initial regimen.

The calculated sensitivity and specificity were limited by the modest number of patients studied, which led to wide confidence intervals. Recruiting patients referred to endoscopy centers may have led to a population not representative of the broader primary care population. Further study of this test is warranted before widespread adoption. All of the participants in this study were infected, and a false-positive rate for patients without *H. pylori* infection could not be calculated. Studying a larger cohort to validate the recommendation to measure antigen at 7 days also would increase the test's merit.

The stool antigen test is a welcome addition to the array of noninvasive tests for *H. pylori* detection. Unlike the serum or urine antibody test, it indicates active disease and it can be used to measure recurrence after known exposure to *H. pylori*. Unlike the urea breath test, it can be used soon after eradication therapy, as Vaira et al demonstrated in this study. In addition, stool antigen tests are less costly than the gold-standard gastric culture or urea breath test, and, conveniently, it can be distributed in advance for use at home.

Applications for Clinical Practice

The stool antigen test for *H. pylori* is a promising new technique that predicts successful eradication. If follow-up studies confirm the authors' findings, the test could replace more expensive and less convenient alternatives.

—Review by Josh F. Peterson, MD