Noninvasive tests were as accurate as invasive tests for detecting *Helicobacter pylori*


Objective
To compare the diagnostic accuracy of 6 tests (3 invasive and 3 noninvasive) for the diagnosis of *Helicobacter pylori*.

Design
A blinded comparison of 6 independent tests (7 sets of readings) for detecting *H. pylori*.

Setting
A large urban U.S. gastroenterology clinic.

Patients
268 patients (mean age 54 y, 59% < 60 years of age, 53% men, 53% non-white races) who were not previously treated for *H. pylori* infection and who were referred for endoscopy.

Description of Tests and Diagnostic Standard
The presence of *H. pylori* was invasively confirmed by endoscopy evaluation of chronic and acute inflammation in the gastric antral biopsy specimens, by Warthin-Starry (silver) stain, and by the CLO test. Noninvasive tests included 13C-urea breath tests (UBT) and serologic examination for IgG and IgA antibodies for *H. pylori*. The diagnostic standard was concordance of ≥4 of the 7 test results.

Main Outcome Measures
Sensitivity, specificity, and likelihood ratios for a positive (LR+) and negative (LR-) test result.

Main Results
82 patients had duodenal ulcer, 49 had gastric ulcer, 8 had pyloric channel ulcers, 55 had nonulcer dyspepsia, and the remainder had noncontributory findings. 81% of patients had concordance of ≥6 of 7 test results. 65% of patients were considered to be *H. pylori* positive. The respective sensitivity, specificity, LR+, and LR- were 100%, 66.3%, [3.0, and 0]* for chronic inflammation; 86.7%, 93.7%, [13.8, and 0.1]* for acute inflammation; 93.1%, 99.0%, [93.1, and 0.07]* for Warthin-Starry (silver) stain; 89.6%, 100%, [approaching infinity, and 0.01]* for the CLO test; 90.2%, 95.8%, [21.5, and 0.01]* for UBT; 91.3%, 91.6%, [10.9, and 0.09]* for serum IgG; and 71.1%, 85.3%, [4.8, and 0.3]* for serum IgA. Warthin-Starry (silver) stain had the best combination of sensitivity and specificity but was not statistically superior to CLO, UBT, and IgG antibody tests in diagnostic accuracy (P = 0.18, P = 0.27, and P = 0.43, respectively).

Conclusion
The noninvasive 13C-urea breath test and serologic examination for IgG antibodies were as accurate as the invasive Warthin-Starry (silver) stain and CLO test in diagnosing *Helicobacter pylori* in untreated patients.

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Commentary
With increasing media exposure, many patients know about *H. pylori* and now request testing. The studies by Cutler and Fallone and their colleagues expand our understanding of the diagnostic accuracy of *H. pylori* testing. Now we can address which tests are cost-effective and which patients should be tested.

To overcome the lack of a true "diagnostic standard," Cutler and colleagues reasonably used consistency of results among several tests to represent true infection. This group also examined a large population that included patients with gastroesophageal reflux disease and a lower pretest probability of *H. pylori* infection. This cohort may have produced less accurate positive and negative likelihood ratios than a more selected group of patients with peptic ulcer. Fallone and colleagues confirm that UBT and antral biopsies have essentially equivalent diagnostic accuracy.

The results from these studies indicate that CLO, Warthin-Starry (silver) stain, UBT, Giemsa stain, and tests for serum IgG have large positive likelihood ratios. Therefore, any positive *H. pylori* test result eliminates the need for further confirmatory testing. Because all of these tests have equivalent diagnostic accuracy in untreated patients, the method of testing should be chosen by cost and ease of use.

For patients with ulcers diagnosed by barium, *H. pylori* IgG testing probably will be the least expensive and easiest to obtain. For patients diagnosed at endoscopy, antral biopsies and a CLO test should be done. Only in the event of a negative CLO would the biopsy specimens be sent for special staining. Patients who do not have duodenal ulcers caused by nonsteroidal anti-inflammatory drugs, however, have a 95% to 99% pretest probability of infection. Empiric treatment in this subgroup of patients with duodenal ulcers may be a reasonable alternative.

Current studies do not support the diagnosis or treatment of *H. pylori* infection in nonulcer dyspepsia (1). Future research may, however, define a subgroup of patients with nonulcer dyspepsia for whom treatment of *H. pylori* infection would be advantageous. Physicians who choose to diagnose and treat on an individual basis (Continued on page 59).