The near-patient test FlexSure had low sensitivity and high specificity for detecting *Helicobacter pylori* infection

Duggan AE, Elliott C, Logan RF. **Testing for *Helicobacter pylori* infection: validation and diagnostic yield of a near patient test in primary care.** BMJ. 1999 Nov 6:319:1236-9.

QUESTION

In adults who have symptoms of dyspepsia and consult a general practitioner, is a near-patient test (FlexSure) accurate for detecting *Helicobacter pylori* infection?

DESIGN

Blinded comparison of a near-patient test with an enzyme-linked immunosorbent assay (ELISA) within a randomized controlled trial of 4 management strategies for dyspepsia.

SETTING

43 general practices in Nottinghamshire, England, United Kingdom.

PARTICIPANTS

762 adults who were 18 to 73 years of age (mean age 42 y) and had symptoms of dyspepsia of sufficient severity to justify empiric treatment with H_2-antagonists or proton-pump inhibitors. Exclusion criteria were symptoms consistent with malignant tumors, a history of peptic ulcer or reflux esophagitis, investigation for dyspepsia in the previous 5 years, treatment in the previous 6 months with nonsteroidal anti-inflammatory drugs or *H. pylori* eradication therapy, or ≥ 3 prescriptions in the previous 6 months for acid-suppression treatment. 394 patients in 39 general practices were in the 2 management groups that received the FlexSure and ELISA tests.

DESCRIPTION OF TEST AND DIAGNOSTIC STANDARD

After randomization, a 7-mL blood sample was taken, and the physician or practice nurse followed the manufacturer's instructions for testing serum from the clotted sample with FlexSure (SmithKline Diagnostics; San Jose, CA, USA). The diagnostic standard was an ELISA (HM-CAP, Enteric Products; Westbury, NY, USA).

MAIN OUTCOME MEASURES

Sensitivity and specificity for detecting *H. pylori* infection.

MAIN RESULTS

Results were available for 375 patients (9 patients had indeterminate ELISA results, 5 had invalid FlexSure results, and 8 had no serum available). 36% of patients had *H. pylori* infection. The sensitivity, specificity, and likelihood ratios are shown in the Table.

CONCLUSION

In adults who have symptoms of dyspepsia and consult a general practitioner, the near-test FlexSure had low sensitivity and high specificity for detecting *Helicobacter pylori* infection.

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FlexSure test characteristics for detecting *Helicobacter pylori* infection*

Sensitivity (95% CI)	Specificity (CI)	+LR	–LR
67% (59 to 75)	98% (95 to 99)	32.4	0.3

*Abbreviations defined in Glossary; LRs calculated from data in article.

COMMENTARY

Dyspeptic patients most likely to benefit from therapy are those with *H. pylori*–associated peptic ulcer disease. Determining who has a peptic ulcer generally requires endoscopy, which is a minimally invasive but relatively expensive diagnostic test. One management algorithm designed to decrease the use of endoscopy in dyspeptic patients involves testing for *H. pylori*, treating those who are positive, and doing endoscopy in those who remain symptomatic. This test-and-treat strategy assumes that patients with *H. pylori* and peptic ulcer disease are usually cured (and thus spared endoscopy) and that patients with *H. pylori* and nonulcer dyspepsia will at least not be harmed by antimicrobial therapy. Such a strategy values highly sensitive diagnostic tests for *H. pylori*, thereby maximizing the number of patients with peptic ulcer who have therapy. The standard laboratory ELISA has long been the favored screening test for *H. pylori*. Recently, more convenient in-office serologic or whole-blood tests have become popular.

In the study by Duggan and colleagues, the accuracy of 1 such serologic test (FlexSure) was assessed using a laboratory ELISA as the diagnostic standard. The in-office test had excellent specificity (98%) but a sensitivity of only 67%, which means that one third of patients infected with *H. pylori* and a proportionate number of those with peptic ulcer would be missed. The authors conclude that tests with such poor sensitivity should not be used for the test-and-treat strategy. An alternate approach exists, however. Given its high specificity, the in-office test could be used to rapidly and reliably diagnose two thirds of infected patients; the more sensitive laboratory ELISA could be reserved for those with negative results. However, the cost-effectiveness of this strategy would be highly dependent on the relative costs of the tests (the in-office test would have to be much less expensive than the ELISA) and on the prevalence of *H. pylori* in the population (the fewer people infected, the larger the number who would need a second test). All of these factors should be considered before an in-office test is used for the test-and-treat strategy.

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