

# Comparison of stool immunoassay with standard methods for detecting *Helicobacter pylori* infection

Frank Lehmann, Jürgen Drewe, Luigi Terracciano, Robert Stuber, Reno Frei, Christoph Beglinger

*Helicobacter pylori* is the cause of type B gastritis and associated with peptic ulcer disease. Various methods are available for detecting *H pylori*, but all have limitations.<sup>1</sup> *H pylori* infection can be diagnosed by tests requiring endoscopy (rapid urease test, histology, culture) and by non-invasive tests (carbon-13 urea breath test, serology, stool tests). The urea breath test is currently the most important test for follow up after *H pylori* treatment.<sup>1</sup> Serology is widely used for screening patients for *H pylori* infection; it has a good sensitivity, is fast, and relatively inexpensive.<sup>1</sup> However, the urea breath test is expensive and requires specialised equipment, and serological tests cannot be used after *H pylori* treatment and may have a lower specificity.

Most patients infected with *H pylori* are treated by general practitioners, who need an easy test for it. Recently, an immunoassay has been developed that can detect *H pylori* antigen in human faeces,<sup>2</sup> but it has not been validated for clinical use. We studied patients undergoing routine endoscopy to determine sensitivity and specificity of this immunoassay in comparison with standard methods.

## Subjects, methods, and results

We recruited 102 consecutive patients (58 men, 44 women) undergoing upper endoscopy. Our study was approved by the local ethics committee. We determined *H pylori* status in all patients by rapid urease test, histology, and culture using standard methods.<sup>1</sup> Patients were considered positive if at least two of the three tests were positive. Patients were asked to collect a specimen from their first stool after endoscopy and to post it to us. We analysed the stool specimens for *H pylori* antigen using the Premier Platinum HpSA Immunoassay as described by the manufacturer (Meridian Diagnostics, Cincinnati, OH, USA). The test is based on a capture of polyclonal antibodies to *H pylori* adsorbed to microwells. The results were analysed by spectrophotometric determination and considered positive if the optical density was >0.12 and negative if it was <0.10. We calculated the test's sensitivity, specificity, and positive and negative predictive values.

Forty nine of the patients had dyspepsia, 33 had active ulcer disease, 16 had gastric or duodenal erosions, and four had gastric polyps. The table shows the results of the immunoassay compared with the standard tests: two stool tests were classified as false negative and four as false positive. The immunoassay

thus had a sensitivity of 96% (95% confidence interval 90.6% to 100%), specificity of 93% (85.1% to 99.5%), positive predictive value of 92%, and negative predictive value of 96%.<sup>3</sup>

## Comment

Our study indicates that this immunoassay could be used as a routine diagnostic tool for *H pylori* infection. It seems to overcome some limitations of previous tests. We found a high sensitivity and specificity compared with reference tests. This new immunoassay has the advantage of being non-invasive, easy and fast to perform, and cheaper than the urea breath test. The bacterium does not need to be alive; preliminary data suggest that the test can be used even during *H pylori* treatment.<sup>4</sup>

The new immunoassay seems to meet the requirements of general practitioners, who treat most patients infected with *H pylori*, because it is easy to perform, requires no blood samples to be taken, and its costs are similar to those of serological tests. Other stool tests have been developed,<sup>5</sup> but they cannot be used for clinical practice, either because they require specialised equipment (culture, polymerase chain reaction, etc) or because they have not been validated for clinical use (immunoassay).

This stool immunoassay represents a new, accurate, and non-invasive method for *H pylori* infection that overcomes the limitations of existing tests.

Contributors: FL coordinated the study, collected samples, and helped with data analysis. JD performed the statistical analysis. LT made the histological assessments. RS and RF helped with collecting samples and supervised and performed the stool analyses. The paper was jointly written by FL, RF, and CB, who had the original idea for the study. CB is guarantor for the study. Competing interests: None declared.

- Mégraud F. The most important diagnostic modalities for *Helicobacter pylori*, now and in the future. *Eur J Gastroenterol Hepatol* 1997;9(suppl):13-5.
- Thomas JE, Gibson GR, Darboe MK, Dale A, Weaver LT. Isolation of *Helicobacter pylori* from human faeces. *Lancet* 1992;340:1194-5.
- Simel DL, Samsa GP, Matchar DB. Likelihood ratios with confidence: sample size estimation for diagnostic test studies. *J Clin Epidemiol* 1991;44:763-70.
- Vaira D, Malfertheiner P, Mégraud F, Axon A, Deltenre M, Dixon M, et al. A novel antigen assay based on stool specimen for *Helicobacter pylori*: European multicenter study. *Gut* 1998;43(suppl 2):A47.
- Cutler AF, Havstad S, Ma CK, Blaser MJ, Perez-Perez GI, Schubert TT. Accuracy of invasive and noninvasive tests to diagnose *Helicobacter pylori* infection. *Gastroenterology* 1995;109:136-41. (Accepted 23 August 1999)

Division of Gastroenterology, University Hospital, CH-4031 Basle, Switzerland

Frank Lehmann  
consultant in gastroenterology  
Christoph Beglinger  
professor of medicine

Department of Clinical Pharmacology, University Hospital, Basle

Jürgen Drewe  
associate professor

Department of Bacteriology, Central Laboratory, University Hospital, Basle

Reno Frei  
head of bacteriology laboratory

Robert Stuber  
consultant in laboratory analyses

Department of Pathology, University Hospital, Basle

Luigi Terracciano  
head of gastrointestinal pathology

Correspondence to: C Beglinger  
beglinger@tmm.ch

BMJ 1999;319:1409

Detection of *H pylori* infection by stool immunoassay in comparison with standard tests (histology, rapid urease test, and bacteriology). Values are numbers of tests

	Standard tests	
	<i>H pylori</i> positive (n=50)	<i>H pylori</i> negative (n=52)
Stool immunoassay:		
Positive	48	4
Negative	2	48

## Endpiece

### On ageing: oh dear!

Youth is a blunder; manhood a struggle; old age a regret.

Coningsby, Benjamin Disraeli, 1804-81

Submitted by Fred Charatan,  
retired geriatric psychiatrist, Florida