

# Clinical value of *Helicobacter pylori* stool antigen test, ImmunoCard STAT HpSA, for detecting *H pylori* infection

Yi-Hui Li, Hong Guo, Peng-Bin Zhang, Xiao-Yan Zhao, Si-Ping Da

**Yi-Hui Li, Hong Guo, Peng-Bin Zhang, Xiao-Yan Zhao, Si-Ping Da**, Department of Gastroenterology, Xinqiao Hospital, Third Military Medical University, Chongqing 400037, China

**Correspondence to:** Hong Guo, Department of Gastroenterology, Xinqiao Hospital, Third Military Medical University, Chongqing 400037, China. haoguo11@yahoo.com

**Telephone:** +86-23-68755604

**Received:** 2003-08-23 **Accepted:** 2003-10-12

## Abstract

**AIM:** To evaluate the reliability of the *Helicobacter pylori* stool antigen test, ImmunoCard STAT HpSA, for detecting *H pylori* infection.

**METHODS:** Stool specimens were collected from 53 patients who received upper endoscopy examination due to gastrointestinal symptoms. ImmunoCard STAT HpSA was used to detect *H pylori* stool antigens. *H pylori* infection was detected based on three different tests: the urease test, Warthin-Starry staining and culture. *H pylori* status was defined as positive when both the urease test and histology or culture alone was positive.

**RESULTS:** Sensitivity, specificity, positive predictive and negative predictive values and the total accuracy of ImmunoCard STAT HpSA for the diagnosis of *H pylori* infection were 92.6% (25/27), 88.5% (23/26), 89.3% (25/28), 92% (23/25) and 90.6% (48/53), respectively.

**CONCLUSION:** The stool antigen test, ImmunoCard STAT HpSA, is a simple noninvasive and accurate test for the diagnosis of *H pylori* infection.

Li YH, Guo H, Zhang PB, Zhao XY, Da SP. Clinical value of *Helicobacter pylori* stool antigen test, ImmunoCard STAT HpSA, for detecting *H pylori* infection. *World J Gastroenterol* 2004; 10(6): 913-914

<http://www.wjgnet.com/1007-9327/10/913.asp>

## INTRODUCTION

*Helicobacter pylori* infection is a major cause of chronic gastritis and peptic ulcer, and is associated with gastric cancer and gastric MALT lymphoma<sup>[1-4]</sup>. There are several methods of diagnosing *H pylori* infection including invasive procedures using mucosa biopsies taken during endoscopy (mainly culture, histology and the rapid urease test) and noninvasive procedures (mainly <sup>13</sup>C or <sup>14</sup>C urea breath tests (UBTs) and serological tests). But invasive procedures suffer from biopsies and endoscopy, and the UBTs require expensive equipment or is harmful to patients. Because *H pylori* antibody titers fall very slowly even after successful eradication, tests lack of specificity and sensitivity<sup>[5-9]</sup>. Recently, the *H pylori* stool antigen (HpSA) test has been put in the market as another noninvasive technique<sup>[10-13]</sup>, but has rarely validated in China<sup>[14]</sup>. The aim of this study is to evaluate the

clinical value of a new test, ImmunoCard STAT HpSA, for the diagnosis of *H pylori* infection.

## MATERIALS AND METHODS

### Patients

A total of 56 patients (33 males and 23 females, average age 43.7years old) participated in this study. Chronic gastritis and peptic ulcer were endoscopically diagnosed in 47 and 9 patients, respectively. Patients treated with antibiotics, bismuth, or proton pump inhibitors within 4 weeks preceding the study were excluded.

### Methods

Invasive tests using mucosal biopsies including culture, histology (Warthin-Starry staining) and the rapid urease test (RUT) were used to establish the "gold standard", in order to evaluate the accuracy of the new stool antigen test, ImmunoCard STAT HpSA.

### Mucosal biopsies for detecting Hp

During upper endoscopy, three gastric biopsies were taken. One biopsy was used for RUT and the remaining two were used for Warthin-Starry staining and culture. The gold standard for the presence of *H pylori* infection was defined when both RUT and Warthin-Starry staining or culture alone was positive. The absence of *H pylori* infection required all three tests to be negative.

### ImmunoCard STAT HpSA

On the same day of endoscopy, patients collected stool into an air tight container. The stool assay was performed using the same test series of the ImmunoCard STAT HpSA (Meridian Diagnostics, Inc, USA). A small portion (5-6 mm diameter) of stool specimen was transferred into the sample diluent vial using the applicator stick, vortexed for 15 s, and then 4 drops were dispensed into the round window at the lower end of the device. The results were read 5 min later. Positive and negative results were judged as recommended by the manufactures. The endoscopy-based tests and HpSA test were carried out by different people with double blind procedures.

### Statistical analysis

Sensitivity, specificity, PPV, NPV and accuracy of the kit were calculated according to the gold standard.

## RESULTS

Altogether, 53 patients were enrolled and tested by ImmunoCard STAT HpSA and the endoscopy-based tests. *H pylori* infection was present in 27 patients as determined by the gold standard. The HpSA test produced positive and negative results in 28 and 25 patients, respectively. Compared with the gold standard, the HpSA was inaccurate in five patients (three false positive, and two false negative), giving a sensitivity, specificity, positive predictive and negative predictive values and total accuracy of the ImmunoCard STAT HpSA of 92.6% (25/27), 88.5% (23/26), 89.3% (25/28), 92% (23/25) and 90.6% (48/53), respectively (Table 1).

**Table 1** Performance of the ImmunoCard STAT HpSA test in the detection of *H pylori* infection, according to the biopsy-based gold standard

ImmunoCard STAT HpSA	Gold standard		Total
	Positive	Negative	
Positive	25	3	28
Negative	2	23	25
Total	27	26	53

## DISCUSSION

A variety of highly sensitive and specific tests are available to diagnose *H pylori* infection. Invasive tests using mucosal biopsies taken during endoscopy might lead to cross infection. In addition, some patients refuse to undergo endoscopy, especially after eradication therapy, due to its invasive nature. Fortunately, there are several noninvasive tests including  $^{13}\text{C}$  or  $^{14}\text{C}$  urea breath tests (UBT) and serological tests. The UBT tests are currently proven to have high sensitivity and specificity, and considered to be the optimal test for monitoring *H pylori* eradication therapy. However,  $^{13}\text{C}$ -UBT needs special equipment and is expensive, and  $^{14}\text{C}$ -UBT requires a radioactive isotope, and cannot be used for children and pregnant women. As a result, UBTs are not widely available. Therefore, it is necessary to find a new, easy, cheaper and accurate noninvasive test.

Gastric epithelial cells renew once in one to three days, and are output in feces with *H pylori*, which can be detected by polyclonal capture anti-*H pylori* antibodies. The HpSA was reported in America Gastroenterology Week in 1997, and put in the market by Meridian Company in the same year, with the name Premier Platinum HpSA. Premier Platinum HpSA is a microplate enzyme-immunoassay for the qualitative detection of *H pylori* antigens in human stool, and was approved by FDA to be used in clinic in 1998. The HpSA test has been widely evaluated around the world, with a weighted mean sensitivity and specificity of 90-98%, respectively<sup>[13,15,16]</sup>. The HpSA test is a cheap and useful method for the diagnosis of *H pylori* infection before and after eradication therapy<sup>[17,18]</sup>. It is an accurate test in all age groups of children too<sup>[19]</sup>. However, Peitz *et al* reported that the diagnostic accuracy, in particular the sensitivity, of the HpSA stool test was reduced by upper gastrointestinal bleeding, and a negative test result should be confirmed by a further diagnostic method<sup>[20,21]</sup>. Although the HpSA test seems to be less accurate than the UBT, both UBT and stool antigen tests are reliable noninvasive tests for monitoring the efficacy of *H pylori* eradication therapy.

A novel easier stool antigen test named ImmunoCard STAT HpSA has recently been put in the market by Meridian Company. This test was first reported to have a sensitivity of 96.1% and specificity of 90.6% at Gastrointestinal Pathology and *Helicobacter* Conference in 2002 in Athens, but have not been reported since. In the present study, we conclude that the ImmunoCard STAT HpSA test has a diagnostic value comparable to the gold standard in detecting *H pylori*. The sensitivity and specificity of the ImmunoCard STAT HpSA for the diagnosis of *H pylori* infection were 92.6% and 88.5%, respectively, with an accuracy of 90.6%. Because it is easy and convenient to perform, the ImmunoCard STAT HpSA could be used at many situations, especially for children, pregnant women, old people and others who are not suitable for endoscopy. The ImmunoCard STAT HpSA is an ideal test for the diagnosis of *H pylori* infection in clinical practice.

## REFERENCES

1 **Hobsley M**, Tovey FI. *Helicobacter pylori*: the primary cause of

- duodenal ulceration or a secondary infection? *World J Gastroenterol* 2001; **7**: 149-151
- 2 **Xia HHX**. Association between *Helicobacter pylori* and gastric cancer: current knowledge and future research. *World J Gastroenterol* 1998; **4**: 93-96
- 3 **Wang KX**, Wang XF, Peng JL, Cui YB, Wang J, Li CP. Detection of serum anti-*Helicobacter pylori* immunoglobulin G in patients with different digestive malignant tumors. *World J Gastroenterol* 2003; **9**: 2501-2504
- 4 **Wang RT**, Wang T, Chen K, Wang JY, Zhang JP, Lin SR, Zhu YM, Zhang WM, Cao YX, Zhu CW, Yu H, Cong YJ, Zheng S, Wu BQ. *Helicobacter pylori* infection and gastric cancer: evidence from a retrospective cohort study and nested case-control study in China. *World J Gastroenterol* 2002; **8**: 1103-1107
- 5 **Wang XZ**, Li D. The serodiagnosis of *Helicobacter pylori*. *Shijie Huaren Xiaohua Zazhi* 2000; **8**: 550-551
- 6 **Sun T**, Ye JX, Ma GX, Cui LH, Liu CQ, Pu J, Fu SF, Jiang Y. Using  $^{13}\text{C}$ -urea breath test to diagnose *Helicobacter pylori* infection. *Shijie Huaren Xiaohua Zazhi* 2000; **8**: 270
- 7 **Li ZJ**, Jiang T, Zhou WM. The value of detecting *Helicobacter pylori* antibody in saliva by enzyme-linked immuno-sorbent assay. *Shijie Huaren Xiaohua Zazhi* 2000; **8**: 241-242
- 8 **Wang CD**, Lu XQ. Clinical application of *Helicobacter pylori* urea breath test. *Shijie Huaren Xiaohua Zazhi* 2000; **8**: 789-792
- 9 **Huang Y**, Xu LN. The dependent test of *Helicobacter pylori* urea enzyme. *Shijie Huaren Xiaohua Zazhi* 2000; **8**: 549-550
- 10 **Makrithathis A**, Pasching E, Schutze K, Wimmer M, Rotter ML, Hirschl AM. Detection of *Helicobacter pylori* in stool specimens by PCR and antigen enzyme immunoassay. *J Clin Microbiol* 1998; **36**: 2772-2774
- 11 **Vaira D**, Malfertheiner P, Megraud F, Axon AT, Deltenre M, Hirschl AM, Gasbarrini G, O' Morain C, Garcia JM, Quina M, Tytgat GN. Diagnosis of *Helicobacter pylori* infection with a new non-invasive antigen-based assay. HpSA European study group. *Lancet* 1999; **354**: 30-33
- 12 **Fanti L**, Mezzi G, Cavallero A, Gesu G, Bonato C, Masci E. A new simple immunoassay for detecting *Helicobacter pylori* infection: antigen in stool specimens. *Digestion* 1999; **60**: 456-460
- 13 **Metz DC**. Stool testing for *Helicobacter pylori* infection: yet another noninvasive alternation. *Am J Gastroenterol* 2000; **95**: 546-548
- 14 **Liu X**, Zhi M, Dong L, Chang BX. The evaluation of *Helicobacter pylori* stool antigen test. *Shijie Huaren Xiaohua Zazhi* 2002; **10**: 726-728
- 15 **Monteiro L**, de Mascarel A, Sarrasqueta AM, Bergey B, Barberis C, Talby P, Roux D, Shouler L, Goldfain D, Lamouliatte H, Megraud F. Diagnosis of *Helicobacter pylori* infection: noninvasive methods compared to invasive methods and evaluation of two new tests. *Am J Gastroenterol* 2001; **96**: 353-358
- 16 **Manes G**, Balzano A, Iaquinto G, Ricci C, Piccirillo MM, Giardullo N, Todisco A, Lioniello M, Vaira D. Accuracy of the stool antigen test in the diagnosis of *Helicobacter pylori* infection before treatment and in patients on omeprazole therapy. *Aliment Pharmacol Ther* 2001; **15**: 73-79
- 17 **Aksoy DY**, Aybar M, Ozaslan E, Kav T, Engin D, Ercis S, Altinok G, Hascelik G, Uzunalimoglu B, Arslan S. Evaluation of the *Helicobacter pylori* stool antigen test (HpSA) for the detection of *Helicobacter pylori* infection and comparison with other methods. *Hepatogastroenterology* 2003; **50**: 1047-1049
- 18 **Tanaka A**, Watanabe K, Tokunaga K, Hoshiya S, Imase K, Sugano H, Shingaki M, Kai A, Itoh T, Ishida H, Takahashi S. Evaluation of *Helicobacter pylori* stool antigen test before and after eradication therapy. *J Gastroenterol Hepatol* 2003; **18**: 732-738
- 19 **Kato S**, Ozawa K, Okuda M, Fujisawa T, Kagimoto S, Konno M, Maisawa S, Iinuma K. Accuracy of the stool antigen test for the diagnosis of childhood *Helicobacter pylori* infection: a multicenter Japanese study. *Am J Gastroenterol* 2003; **98**: 296-300
- 20 **Peitz U**, Leodolter A, Kahl S, Agha-Amiri K, Wex T, Wolle K, Gunther T, Steinbrink B, Malfertheiner P. Antigen stool test for assessment of *Helicobacter pylori* infection in patients with upper gastrointestinal bleeding. *Aliment Pharmacol Ther* 2003; **17**: 1075-1084
- 21 **van Leerdam ME**, van der Ende A, ten Kate FJ, Rauws EA, Tytgat GN. Lack of accuracy of the noninvasive *Helicobacter pylori* stool antigen test in patients with gastroduodenal ulcer bleeding. *Am J Gastroenterol* 2003; **98**: 798-801