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

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 (Table 1).

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

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INTRODUCTION
Helicobacter pylori infection is a major cause of chronic gastritis and peptic ulcer, and is associated with gastric cancer and gastric MALT lymphoma[1-4]. 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 13C or 14C 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[5-9]. Recently, the H pylori stool antigen (HpSA) test has been put in the market as another noninvasive technique[10-13], but has rarely validated in China[14]. 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 43.7 years 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. Patients treated with antibiotics, bismuth, or proton pump inhibitors within 4 weeks preceding the study were excluded. 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).
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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 13C or 14C 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, 13C-UBT needs special equipment and is expensive, and 14C-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 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 GastroenterologyWeek 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. It is an accurate test in all age groups of children too. 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. 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 an sensitivity of 96.1% and specificity of 90.6% at Gastrointestinal Pathology and Helicobacter Conference in 2002 in Athens, but and 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.

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

|                | Positive | Negative | Total |
|----------------|----------|----------|-------|
| ImmunoCard STAT HpSA | 25       | 3        | 28    |
| Gold standard | 22       | 6        | 28    |

|                | Positive | Negative | Total |
|----------------|----------|----------|-------|
| Positive       | 22       | 6        | 28    |
| Negative       | 2        | 23       | 25    |
| Total          | 24       | 29       | 53    |

22