

## Evaluation of Stool Antigen Test in patients infected by *Helicobacter pylori* after Eradication Therapy

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### ABSTRACT

Noninvasive tests for *Helicobacter pylori* are important in primary care, both for initial diagnosis of *H. pylori* infection and for confirmation of eradication. The objective of the present study was to evaluate the effectiveness of a stool antigen test after therapy. We studied 30 patients (16 males & 14 females) infected with *H. pylori* at the outpatient clinic in Azady teaching hospital. After the completion of triple eradication therapy, all patients were subjected to the examination of the stool antigen test. Of the total 30 cases, there were 23 cases with negative stool Ag test after therapy. All seven cases without therapy were positive stool, Ag. The result of the stool antigen test after therapy was 76% (negative in 23 patients, false-negative in 7 patients). We concluded that a negative result on stool antigen testing after completion of therapy recognizes patients in whom the eradication of *H. pylori* was successful.

### Keywords

*H. pylori*, HpSA, Peptic ulcer.

### Introduction

*Helicobacter pylori* (*H. pylori*) is a new bacterium discovered first by Barry Marshall and Robin Warren in 1983 [1]. It lives in the stomach and has been estimated that about half of the population is infected with *H. pylori* globally. However, the prevalence, incidence, age distribution, and outcomes of infection are significantly different in developed and developing countries [1-3].

Improved standards of living have effects on the incidence of *H. pylori* infection. Yet the prevalence of *H. pylori* is still pervasive, especially in the Far East. It is one of the main causes of a variety of gastrointestinal diseases such as chronic gastritis and the principal causative agent for gastric cancer and gastric ulcer and non-ulcer dyspepsia [4,5].

Diagnostic tests of *H. pylori* infection include invasive tests, such as histology, rapid urease test (RUT), and culture, as well as non-invasive tests, such as 13C-urea breath test (13C-UBT), serum *H. pylori* antibodies, and *H. pylori*, stool antigen tests (HpSA) [6,7].

Noninvasive tests for *H. pylori* are significant in primary care, both for initial diagnosis of *H. pylori* infection and for confirmation of eradication. Routine testing to confirm eradication in cases of complicated ulcer disease, such as bleeding peptic ulcer, is necessary because the risk for rebleeding is significantly increased in patients with insistent infection [8].

The choice of tests in the post-therapy setting is limited. Serologic tests are unpredictable in determining eradication. Endoscopic tests (rapid urease test, histologic examination, or culture) are reliable, but endoscopy is expensive and inconvenient. Until recently, the fecal antigen test was a single non-invasive test that consistently demonstrated whether eradication was successful. The stool antigen test is a comparatively recent non-invasive test for the detection of *H. pylori* [9]. Detection of *H. pylori* infection depends on measuring *H. pylori* antigens in the fecal excretion. It has been approved by the U.S. Food and Drug Administration for the finding of *H. pylori* pre-and post- therapy [10].

The aim of the study was to assess the significance of fecal antigen tests after the eradication of *H. pylori* infection.

## Materials & Methods

**Patients:** We studied 30 patients (16 male and 14 female) infected with *H. pylori* at the outpatient clinic in Azady teaching hospital. Their age was ranged between 22-53 years with a mean of 34.7 years  $\pm$  8.25.

The sample consisted of consecutive patients with dyspepsia (defined as pain or discomfort centered in the upper abdomen) who were referred by primary care physicians for upper endoscopy. All patients were infected with *H. pylori*, as demonstrated by positive results on both rapid qualitative serum testing (Acon Laboratories, Inc.) and histologic examination for *H. pylori*.

After the completion of triple eradication therapy, all patients underwent the stool antigen test was performed by SD Bioline *H. pylori* Ag kit (SD Standard Diagnostics, INC, Korea). All of the stool samples were collected in a stool container that is free of media, preservatives, animal serum, or detergents. Seven cases without therapy were also tested by both serum and stool Ag tests.

### Principle of *H. pylori* Test Device (Serum/Plasma)

The one-step *H. pylori* test device (Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of *H. pylori* antibodies in serum or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to specimen well of the device, it reacts with *H. pylori* Ag coated particles in the test. This mixture migrates chromatographically along the length of the test & interacts with the immobilized anti-human IgG. If the specimen contains *H. pylori* antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored will always appear in the control line region, indicating that proper volume of specimen has been added & membrane wicking has occurred.

### Principle of *H. pylori* Ag

The SD BIOLINE *H. pylori* Ag rapid test kit result window has 2 pre-coated lines, "T" (*H. pylori* Ag Test Line) & "C" (Control Line). Both Test Line & the Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control & should always appear if the test procedure is performed correctly. The SD BIOLINE *H. pylori* Ag rapid test kit can identify *H. pylori* Ag in human fecal specimen with a high degree sensitivity & specificity.

### Statistical analysis

The descriptive statistics were summarized as number of observations, mean, and standard deviation, were tabulated as frequency and percentage for categorical variables. All statistical analyses were two-sided under significance level of 0.05.

## Results

The overall prevalence of *H. pylori* infection in the present study was 30 and the prevalence was slightly higher in males (53%, 16/30) than in females (47%, 14/30) (Table 1). The result of stool antigen tests showed 23 positive cases in which male cases comprised 43% in males (Figure-2). There were 23 cases with negative stool Ag test after therapy.

In subgroup analysis, the study subjects were categorized into four groups according to their ages as 20-29 years (younger age), 30-39 years, 40-49 years, and  $\geq$  50 years. We found that subjects in the age group 30-39 years had a higher prevalence of *H. pylori* infection (50%, 15/30) than younger subjects (26.7%, 8/30,  $p < 0.05$ , Figure 3).

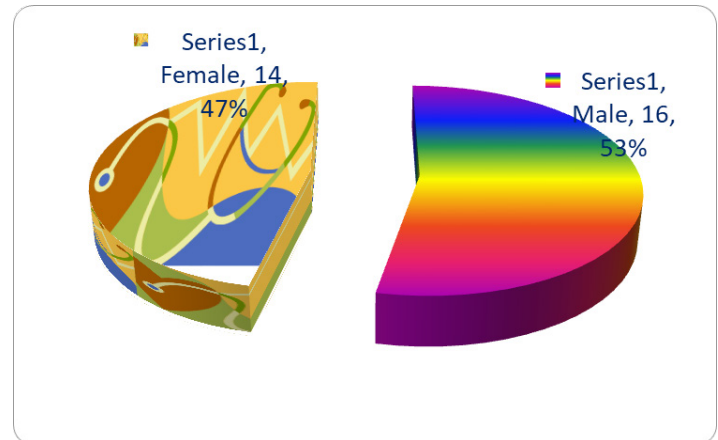


Figure 1: Number of cases according to the sex.

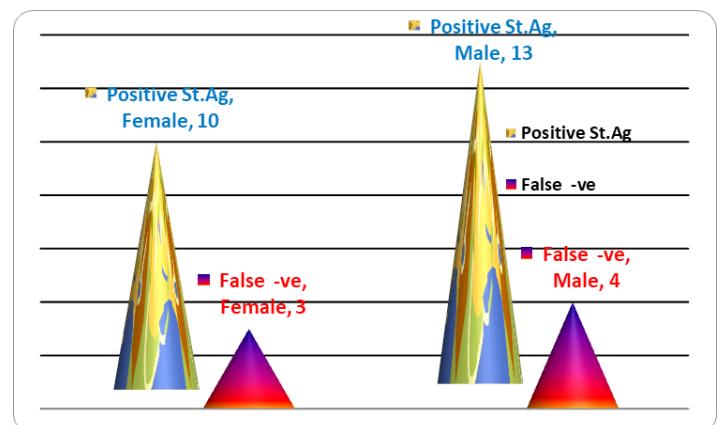


Figure 2: Positive and negative stool antigen in both sexes.

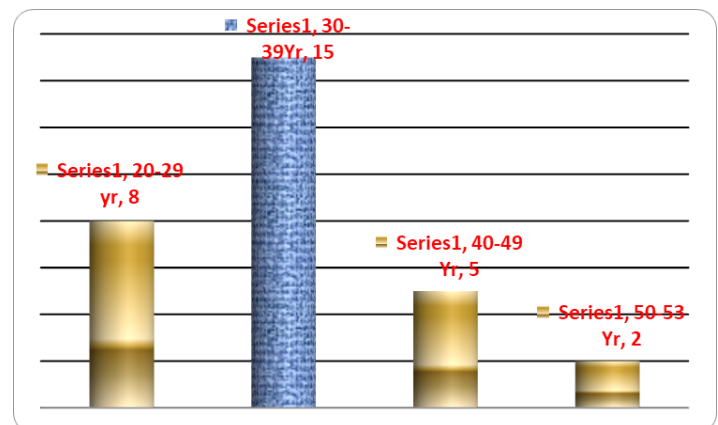


Figure 3: Number of cases according to age groups.

## Discussion

The detection of *H. pylori* can be confirmed in gastric mucosal biopsy samples by culture, special histology, or rapid urease tests and rapid qualitative serum testing, but these approaches require the expense and inconvenience of endoscopy [2]. As a result, accurate yet non-invasive alternatives have been sought. Some patients with ulcer disease remain symptomatic despite successful eradication of *H. pylori* and healing of the ulcer [4]. Routine testing to confirm eradication in patients with complicated ulcer disease, such as bleeding peptic ulcer is necessary because the risk for rebleeding is greatly increased in patients with persistent infection [3].

Diagnostic tests of *H. pylori* infection include invasive tests, such as histology, rapid urease test (RUT), and culture, as well as non-invasive tests, such as 13C-urea breath test (13C-UBT), serum *H. pylori* antibodies, and *H. pylori*, stool antigen tests (HpSA) [11]. Serology tests may not distinguish between past or active infection. 13C-UBT and monoclonal stool antigen tests are non-invasive tests recommended for confirmation of *H. pylori* infection [12]. However, the 13C-UBT is more expensive. HpSA is a less expensive alternative to the 13C-UBT for the diagnosis of *H. pylori* infection and is a potential test for mass screening of *H. pylori* infection for gastric cancer prevention in the community [10].

The V strip *H. pylori* Antigen Rapid test (Vstrip HpSA) is a new ICA-based medical device designed to quickly detect *H. pylori* antigens in stool samples. [13].

The choice of tests in the post-therapy setting is limited. Serologic tests are unreliable in determining eradication. Endoscopic tests (rapid urease test, histologic examination, or culture) are reliable, but endoscopy is expensive and inconvenient. Until recently, the only non-invasive test that reliably demonstrated whether eradication was successful was the fecal antigen test. The fecal antigen test is a relatively new non-invasive test for the detection of *H. pylori* [3]. This test detects the presence of infection by measuring the fecal excretion of *H. pylori* antigens. It has been approved by the U.S. Food and Drug Administration for the detection of *H. pylori* before and after therapy [4].

In the present study, the result of stool antigen tests showed 23 positive cases of which male cases comprised 43% in males. There were 23 cases with negative stool Ag test after therapy.

In subgroup analysis, the study subjects were categorized into four groups according to their ages as 20-29 years (younger age), 30-39 years, 40-49 years, and  $\geq 50$  years. We found that subjects in the age group 30-39 years had a higher prevalence of *H. pylori* infection (50%, 15/30) than younger subjects (26.7%, 8/30). The same findings were seen in a study carried out to demonstrate the prevalence of infection between children and adults [2].

Concerning the microbiological methods used to diagnose Hp infection, Miqueleiz Z, et al. [14] found that stool antigen detection was the most frequent after the culture of gastric biopsies. Our results indicated that the rapid stool antigen-test achieves high

specificity. This is in agreement with the findings of Ian G. and his colleagues [15].

## Conclusion

We concluded that a negative result on stool antigen testing after completion of therapy identifies patients in whom eradication of *H. pylori* was successful. Further studies are suggested to validate the accuracy of this assay in other ethnic populations or countries.

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