RESEARCH COMMUNICATION

Comparison of Helicobacter pylori Antibody Detection in Stool with other Diagnostic Tests for Infection

Nihan Ceken¹, Sureyya Gul Yurtsever¹*, Nurten Baran¹, Emrah Alper², Zafer Buyrac², Belkis Unsal²

Abstract

For detection of *Helicobacter pylori*, bacterial culture and histopathological examination are invasive in nature, whereas the fast urease test and urea breath test are non-invasive and indirect methods of detection. Stool antibody tests and polymerase chain reaction (PCR) to detect genomic DNA are serological methods, which are preferred to invasive examinations. Our aim was to assess diagnostic specifity and sensitivity of stool antibody tests, with histopathological examination as the golden standard and to compare results with fast urease test findings. Biopsy samples of patients in the study were evaluated as examples of invasive methods, and also stool antibody screening were made (HpSA). When urease and HpSA test results were compared with histopathological results, sensitivity and specificity of urease test were 62.2% and 100%, respectively, and 68.9% and 100% for the HpSA test. General accuracy was 80% and 81%, respectively , positive predictive value 100% with each and negative predictive values 66.1% and 67.2% . The differences were not statistically significant, and the confidence intervals were approximately in the same range. Thus results obtained with biopsy urease and HpSA tests were generally similar to those obtained by histopathological examination. A review of national and international literature showed similar findings.

Keywords: Helicobacter pylori - diagnosis - invasive tests - non-invasive tests

Introduction

Helicobacter pylori is the most common chronic bacterial illness. There are a number of gastrointestinal illnesses interrelated with an infection that had marked the end of 20th century and beginning of 21st century. For this reason, it is very important to diagnose and eradicate this infection (Blaser, 2000; Blaser, 2005; Cutler et al, 1995).

Today, H. pylori is a common pathogen in humans and it is accepted that the infection is acquired before 10 years of age (Dalgıc, 2003). In developing countries like Turkey, prevalence between 5-10 years of age is 60-70%, and 85-90%, due to insufficiency of socio-economical conditions and inability to create healthy living conditions. The decrease in *H. pylori* prevalence observed in developed countries is not seen in Turkey. This prevalence was 78% in children under the age 14 ten years before, and 62% in 2000 (Dimson, 1971; Fiedorek et al., 1991).

Invasive and non-invasive tests are used in the diagnosis of *H.pylori* infection (Gurkan, 2000). Invasive diagnostic tests include histopathological examination of the biopsy specimens, fast urease test and direct identification of the microorganism by culture. Non-invasive tests include serological tests which do not require endoscopic examination, antibody tests in stool and urea breath test (Cutler et al, 1995; Ishihara et al.,

2000; Kato et al., 2000).

It is important to correctly diagnose *H.pylori* infection. The diagnostic method chosen should be easy and applicable to all age groups. We compared the non-invasive test, antibody detection in stool with invasive tests of biopsy, fast urease test and histopathological diagnosis in terms of sensitivity, specifity, positive and negative predictive value.

Materials and Methods

One hundred patients who were examined at the outpatient clinics of gastrointestinal diseases of ours hospital between 1st of October and 31st of December, 2007 because of dyspeptic complaints and an upper gastrointestinal endoscopic examination was scheduled were included in this study. The patients' endoscopic biopsy specimens from stomach and stool specimens were examined by biopsy urease test, histopathological examination and HpSA tests. The patients' age, gender, and complaints were recorded in the patient forms before upper gastrointestinal endoscopic examinations were done. The mean age of the patients was 47.6±17, between 16 and 83. Two thirds were females and three-quarters below the age of 60 years.

In order to be eligible for this study, patients with non-specific dyspeptic complaints should not have been

¹Microbiology and Clinical Microbiology Department, ²Gastroenterology Department, İzmir Atatürk Training and Research Hospital, Karabaglar/İzmir, Turkey *For correspondence: sgul71@yahoo.com

treated with antibiotics in the last four weeks, also not have been treated with proton pump inhibitors (PPIs), H2 receptor blockers or bismuth salts, and should not have had a gastric surgery.

The presence of urease at the gastric mucosal biopsy specimen taken from the corpus at gastroscopic examination was tested by a pH indicator, HpFAST (Diagmed Healthhcare Ltd. England). Two gastric mucosal specimens one taken from corpus and the other from antrum were examined histopathologically. Stool specimens were taken concurrently with the endoscopic examination, and presence of *H.pylori* antibody was sought by a test kit (Helicobacter Antigen Quick Castte [GENERIC ASSAYS GmbH, Germany]).

Statistical Analysis

Diagnostic methods were compared by chi- square and Student T-test statistical analysis, and a p value of <0.05 was considered statistically significant. The statistical analysis of the data were done with SPSS (Statistical Package for Social Sciences) 11.5 for Windows software. Histopathological examination was considered as the gold standard.

Results

Histopathological diagnosis of biopsy specimens from antrum and corpus of the 100 patients were basically active or superficial gastritis (81%) or normal (18%), with some cases of intestinal metaplasia. *H.pylori* detection ratios by different diagnostic methods were, 61% by histopathological examination, 41% by biopsy urease test and 42% by HpSA test. The gold standard in this study was histopathological examination.

Specificity was 100% with both tests. Sensitivity was 62.2% with biopsy urease test and 68.9% with HpSA test. Although the difference was not statistically significant, an overlap of the confidence intervals of these two tests was observed. Diagnostic values of biopsy urease test and HpSA tests in comparison with histopathological diagnosis was generally similar.

Discussion

As the invasive diagnostic methods used for Helicobacter pylori detection not only require endoscopic examination, but also are more expensive and inconvenient for the patients, they are not preferred as the first choice. Also, as H.pylori colonization in the stomach is patchy, presence of infection may not be shown in every attempt. Specifity and sensitivity of a diagnostic test should be over 95%. False negative results may be seen in invasive diagnostic tests like culture, fast urease test and histopathological examination. The most important advantage of invasive diagnostic tests is, apart from showing the microorganism itself, allowing application of molecular methods and in vitro sensitivity testing of the isolated organism against antimicrobial agents. Detection by visualization of pathological changes in the gastric mucosa is also an important advantage (Makrishathis et al., 1998; Plebani & Basso, 1999; Logan & Walker, 2002;

Lehours& Yilmaz, 2007).

Another method used in the diagnosis of Helicobacter pylori is detection of antibodies in stool. These tests are inexpensive and easy to apply and show the presence of active infection. Their advantages in comparison with urea breath test and biopsy fast urease test are: medications like PPIs and bismuth compounds do not affect them and they are easy methods that can be used in the follow-up of patients after eradication treatment. These tests also have the very important advantages of being relatively inexpensive, ease of obtaining specimen for them, and the possibility of being used easily in pregnant women, children and the elderly. They do not require a very complicated laboratory facility (Salyers & Whitt, 2002; Suerbaum & Michetti, 2002; Tuncer et al, 2004).

The gold standard in this study was the histopathological diagnosis of the endoscopic biopsy material, in the light of literature. Specifity of biopsy urease test in comparison with histopathological diagnosis was 100%, sensitivity 62.2%, general precision 80%, positive predictive value (PPV) 100%, and negative predictive value (NPV) was 66.1%. In the global literature, Specifity of biopsy urease test is reported as 95%, and sensitivity 80–95% (Suerbaum & Michetti, 2002). Ozdemir & Baykan (2005) found specificity of biopsy urease test as 67.5%, sensitivity 62.1%, PPV 77.3%, and NPV 50%. This study is of interest as it was also done in this country and the results are similar to our data. We believe that further investigations are needed to find an answer for the differences between our results and reports in the literature in the specifity and sensitivity of biopsy urease test.

Every test has specific superior and inferior characteristics and the search for new methods for both primary diagnosis and follow-up after eradication treatment continues. Thus, there is an interesting increase in the number of studies on HpSA test. In comparison with invasive methods in primary diagnosis, the sensitivity and specifity of HpSA test was reported as 88.9% and 96.4% by (Makrishathis et al., 1998) and 94% and 91% by (Vaira et al., 1999). In this study, specificity of HpSA in comparison with histopathological examination was 100%, sensitivity 68.9%, general precision 81%, PPV 100% and NPV 67.2%. In a study by Ozdemir & Baykan (2005) done in Turkey, specifity of HpSA test was 94.6%, sensitivity 87.9%, PPV 96.7%, and NPV 81.4%. In the study by Tuncer et al (2004), specifity of HpSA was 80%, sensitivity 81.8%, PPV 93.3%, and NPV 56.3%. In a study from Poland by Wissniewska et al (2002), similar to our findings, specifity was 97%, and sensitivity 57%. In a multicenter study from Europe (Suerbaum et al, 2002), after eradication treatment the specificity and sensitivity of HpSA was 100% while others in the US (Vandenplas, 1999; Vakil et al., 2000; Versalovic & Fox, 2003; Wu et al., 2003) found the specifity and sensitivity as 90% - 98%.

The specifity of HpSA and biopsy urease tests in comparison with the histopathological diagnosis was 100%. These results are generally in agreament with the literature. A diagnosis of *H.pylori* may be excluded if HpSA and biopsy urease tests are both negative. The sensitivity of HpSA test was 68.9%, and of the biopsy urease test was 62.2%. Although the difference between

these two tests were not statistically significant, HpSA test detected more patients than biopsy urease test, nearer to the gold standart – histopathological test.

In conclusion, in this study HpSA and biopsy urease tests were both specific tests in comparison with histopathological examination. Although the sensitivity of HpSA test was somewhat lower, as it gives positive results in 2/3rd of the patients, it may be used as a second choice to detect the presence of *Helicobacter pylori* when endoscopical examination and gastric biopsy cannot be made. Also, important advantages of this test are that it is easy, inexpensive and fast in the diagnosis of infection and evaluation of the efficacy of treatment after *H.pylori* eradication.

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