Original Article

Evaluating the Role of Serological Testing Versus Rapid Urease Test for Planning *Helicobacter pylori* Eradication

K Y Santosh Kumar¹, Milind H Iddalagi²

¹Associate Professor, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India, ²Assistant Professor, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India

Abstract

Introduction: The prevalence of *Helicobacter pylori* infection is high in India. The testing of *H. pylori* has a significant role to play in evaluating patients presenting with upper abdominal symptoms. There is a wide variety of tests available for detecting *H. pylori* infection including invasive and non-invasive tests. In this study, authors have attempted to evaluate the role of serological testing for planning *H. pylori* eradication in the era where the upper gastrointestinal (GI) endoscopy is widely available at an affordable cost.

Material and Methods: In our hospital, we selected patients with chronic upper abdominal symptoms who were evaluated for *H. pylori* infection with both serological testing and rapid urease test (RUT) after their consent.

Results: It was found that serological positivity (70%) was significantly higher than RUT positivity (18%).

Conclusion: In the era, where upper GI endoscopy is widely available at an affordable cost we feel that RUT needs to be considered before planning *H. pylori* eradication based on the serological results alone thereby avoiding unnecessary treatment. Such an approach seems to be cost-effective in the long run and also avoids exposure of patients to significant side effects of the therapy.

Key words: Eradication, Helicobacter pylori, Rapid urease test, Serology

INTRODUCTION

H. pylori, a Gram-negative microaerophilic fastidious human pathogen has colonized humans for at least 1000 of years. [1] Since its discovery by Marshall and Warren in 1983, there has been a significant change in our understanding of acid peptic diseases. It is now believed that 90% of duodenal ulcers and roughly 75% of gastric ulcers are associated with H. pylori infection. [2,3] When this organism is eradicated as part of ulcer treatment, ulcer recurrence is extremely rare. Warren and Marshall were the first to identify and isolate the organism and note its close relationship with inflammatory gastritis that

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occurred in the stomach. H. pylori testing should also be done in all patients with the suspected acid peptic disease. Diagnostic tests for H. pylori are divided between tests that do or do not require a sample of gastric mucosa. The non-invasive tests available are serology and the carbonlabeled urea breath test. The invasive tests available are the rapid urease test (RUT), polymerase chain reaction (PCR), histology, and culture. Non-invasive tests do not require endoscopy, whereas invasive tests done. As each test has its own advantages and disadvantages, none of these tests can be considered as gold standard. [4] However, as detection of H. pylori infection is part of the evaluation of cases in whom peptic ulcer disease is suspected, patients should be offered one or more of these tests for planning eradication therapy. In this article, we intend to review the two most common tests performed for detection of H. pylori.

Urease test or RUT

This test is based on the ability of *H. pylori* to hydrolyze urea. The enzyme urease catalyzes the degradation of

Corresponding Author: H I Milind, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India. E-mail: milindvimsms@gmail.com

urea to ammonia and bicarbonate, creating an alkaline environment that can be detected by a pH indicator. Consequently, endoscopy is performed and gastric mucosal tissue biopsied. Mucosal biopsy samples are placed into a liquid or solid medium containing urea and a pH indicator. Sensitivity is about 90% and specificity 98%, and the results are available within hours. [5-7] The test can also be performed per endoscopically by using pH-sensitive biosensor within minute, giving sensitivity and specificity of 92% and 95%, respectively. [8] The low cost, ease, and speed of diagnosis of *H. pylori* infection give RUT upper hand on culture and histology. [9]

Serological Test

Due to the fact that H. pylori infection elicits a local as well as a systemic immunoglobulin G -mediated immune response, serology can be used to diagnose H. pylori. There are a variety of enzyme-linked immunosorbent assay laboratorybased tests available as well as some rapid office-based immunoassays. The studies have shown the sensitivity and specificity ranging between 80% and 90%.[10,11] As the host immune response varies from person to person and also the duration of exposure, nutritional status, and cross antigenicity with related bacteria, for example, campylobacter, etc. serological testing cannot be fully reliable.[12] In addition, the most importantly serological test cannot differentiate between active and cured infection as antibody titers can remain high for a year or more, and consequently, this test cannot be used to assess eradication after therapy.[12,13]

MATERIALS AND METHODS

In our institution, we evaluated 100 patients who presented to us with chronic upper abdominal symptoms. All patients were enrolled in the study after their consent. All the patients were instructed to discontinue antacids or proton pump inhibitors 30 days before evaluation. They were

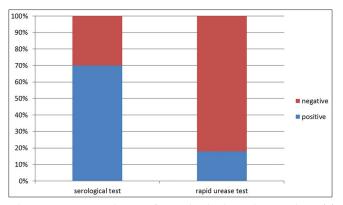


Figure 1: comparison of serological testing and RUT results.

evaluated with a serological test for *H. pylori* and upper gastrointestinal (GI) endoscopy with RUT.

Upper GI endoscopy was done using Pentax gastroscope, and biopsies taken from antrum and tissues were tested with RUT kits, and results were interpreted as positive, negative, or equivocal as per manufacturer's instructions.

About 5–10 ml of blood was drawn from the patients and tested for *H. pylori* antibody using commercially available kits, and results were interpreted as per manufacturer's guidelines.

RESULTS

In our study, 75 out of 100 patients were found to be positive for *H. pylori* serologically, whereas only 18 out of 100 patients were positive for RUT [Figure 1].

This means 57 patients who were positive for *H. pylori* as per serological test were *H. pylori* negative according to RUT, and therefore, were not candidates for eradication.

DISCUSSION

The test to diagnose *H. pylori* infection should preferably be rapid and reasonably accurate so as not to delay the eradication therapy. A variety of methods are available including both invasive and non-invasive tests.

Even though histopathological diagnosis is considered to be accurate and is one of the earliest investigations, it suffers interobserver variation.^[14,15]

RUT has been reported to have high sensitivity and specificity in many clinical studies. [16-18] It is easy to perform, and results are reproducible and rapidly available.

Serological tests are inexpensive, and results are available rapidly. However, some studies have showed that the results are less accurate and less specific. This low accuracy may be attributable to the inability of these tests to differentiate between present and past infections.

One clinical study found the accuracy of the tests for *H. pylori* diagnosis in order as follows: RUT > PCR > histology > stool antigen test > serology.^[19] None of the tests can be considered as gold standard. However, in general, like most of the studies conclude biopsybased tests are preferable to non-invasive tests especially when upper GI endoscopy is available in a large number of centers.^[19,20] We, therefore, conclude that instead of considering *H. pylori* eradication solely on the basis of serological test RUT or a combined approach is preferable.

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