Non-Invasive Detection of Helicobacter Pylori Infection: A Comparative Study

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Original Research Article

ABSTRACT

The present study aimed to determine the diagnostic accuracy of serological testing in endoscopic Rapid Urease Test(RUT) positive *H. pylori* infections. The study included 50 participants, above the age of 18 years, who attended Outpatient Department or were admitted in the tertiary a care hospital complaining dyspepsia and were positive for *H. pylori* on endoscopic RUT. Those patients who were found positive were subjected to serological testing for *H. pylori* infection by card test (Immunochromatography method). The results of RUT biopsy and serological testing were compared. Among the 50 patients enrolled in the study, 62% (n=31) were males while 38% (n=19) were females (Male to Female ratio 1.63:1). Majority of patients belonged to the age group, 31 to 60 years (50%, n=25). Sixty percent (n=30) of the patients belonged to upper-lower class according to the Kuppuswamy's scale. Out of the 50 patients who were positive for *H. pylori* on RUT assay, 84% (n=42) came out to be positive on Immunochromatography. Thus, keeping RUT assay as the reference test, the sensitivity of immunochromatography was found to be 84%.There was a significant association found between between age and the positivity of immunochromatography (p value 0.03). The ICT used in this study is commercially available, inexpensive, and easy to perform. Positive predictive value of 84% implies that the test could be used to identify *H. pylori* infections in patients with upper gastrointestinal symptoms. Attributed to the rapidity of test results, clinical decisions regarding patient care could be made during the visit.

KEY WORDS: helicobacter pylori, immunochromatography, infection, serological test

INTRODUCTION:

There have been numerous associations of Helibacter pylori with various human diseases including gastric ulcer and even malignancies[1]. Attributed to its cytotoxin-associated geneA (cagA), vacuolating toxin A (vacA) and adherence factors, this Gram-negative bacterium shows a strong predilection to gastric mucosa, thus leading to clinical manifestations such as dyspepsia[1]. Early detection and treatment of *H. pylori* infection is of utmost importance as it may otherwise lead to great morbidity and mortality in later stages. Various investigations can be used for detection of *H. pylori* infection. Endoscopy-based biopsy followed by biopsy urease test, histological examination and microbiological culture of the biopsy specimen have proven to be helpful diagnostic methods. However, non-invasive tests like serology, ^{13}C urea breath test and stool antigen test are simpler and inexpensive methods of *H. pylori* detection. Urea breath test has been a good screening tool for detection of *H. pylori* but it requires fasting. Stool antigen test being non-invasive is helpful as well but specimen collection can slightly delay the diagnosis. Various serological tests can also be used for the detection of *H. pylori*, via measurement of IgG, IgM and IgA antibodies in the serum. These have excellent sensitivity and specificity of about 95%. The exact role of serology in the management of *H. pylori* is still to be defined although there is evidence that using this as a screening procedure can reduce endoscopy cost and work overload[2]. Moreover, serological tests are the only tests which are not likely to give false negative results in patients who have taken antibiotics, bismuth compounds or omeprazole in the recent past[3].

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MATERIALS AND METHODS:

This study was a prospective, observational study conducted among patients presenting with features of dyspepsia at People's College of Medical Sciences and Research Centre, Bhanpur, Bhopal.

The study aimed to determine the diagnostic accuracy of serological testing in endoscopic RUT positive *H. pylori* infections. The study included 50 participants, above the age of 18 years, who reported to the Outpatient Department or were admitted in the hospital with dyspepsia and were positive for *H. pylori* on endoscopic RUT.

The study excluded patients negative for *H. pylori* on endoscopic Rapid urease test (RUT), chronic alcoholics, patients on long term NSAIDs/ proton pump inhibitors, patients with past history of *H. pylori* eradication or who have undergone upper gastrointestinal surgery.

After obtaining written, informed consent, detailed history was taken and each patient was assessed for symptoms of GERD. For assessing the patient's socioeconomic status, modified Kuppuswamy's socio-economic classification was used. Upper GI endoscopy was done to test the presence of *H. pylori* by obtaining biopsy followed by RUT. Those patients who were found positive were subjected to serological testing for *H. pylori* infection by card test (Immunochromatography method).All the *H. pylori* positive patients were administered eradication therapy for 14 days followed by acid suppression therapy for 6 weeks. The results of RUT biopsy and serological testing were compared and statistically analyzed using SPSS software ver. 19.0. p value <0.05 was considered as significant.

RESULTS:

Among the 50 patients enrolled in the study, 62% (n=31) were males, while 38% (n=19) were females depicting a male to female ratio of 1.63:1. Majority of patients belonged to the age group, 31 to 60 years (50%, n=25). Sixty percent (n=30) of the patients belonged to upper-lower class according to the Kuppuswamy's scale (Table 1).

Table 1: Study population according to socio economic status

Socio economic status	Number of patients	Percentage
Lower middle	13	26
Upper lower	30	60
Upper middle	7	14
Total	50	100

Out of the 50 patients who were positive for *H. pylori* on RUT assay, 84% (n=42) came out to be positive on Immunochromatography. Thus, keeping RUT assay as the reference test, the sensitivity of immunochromatography was found to be 84%.

Out of the 42 patients who were found positive for *H. pylori* in immunochromatography, 47.6% (n=20) patients belonged to the age group of 31-60years (Table 2). There was significant association found between age and the positivity of immunochromatography (p-value 0.03). No significant association was found among gender, educational status, socio-economic status and the results of positivity of immunochromatography (Table 3).

Table 2: Association between age group and immunochromatography (ICT) findings.

Age group	ICT negative	ICT positive
18 to 30 years	3 (37.5%)	12 (28.6%)
31 to 60 years	5 (62.5%)	20 (47.6%)
>60 years	0	10 (23.8%)

DISCUSSION:

Humans harboring *H. pylori* in their gastric mucosa develop serum antibodies to the organism. Currently, these antibodies can be detected by several methods, including ELISA we evaluated the accuracy of an immunochromatographic method to detect anti-H. pylori IgG in human serum. The ICT had a high sensitivity and specificity for detection of *H. pylori* IgG antibody in serum from randomly selected patients. Similar results have been reported by another study[4].

In the current study, majority of the patients were in the age group between 31-60 years (50%, n=25). Gill et al[8] (1993) from India reported most of the clinical suspects in the age group between 30-39 years. In this study, 62% (n=) were male while rest were female. Similar findings of male dominance (91%) was reported in another study by Morshed et al[9] (2008) from Bangladesh.

In this study, majority of the patients (60%) were from upper lower class and rest were from upper middle and lower middle class. The prevalence of infection is correlated with low socioeconomic status during childhood, high density of living and low household income. Poor hygiene and crowded conditions may facilitate transmission of infection among family members and is consistent with intrafamilial and institutional clustering of *H. pylori*

Table 3: Association between gender, educational status and socio-economic status with the findings of immunochromatography (ICT).

Group	ICT negative	ICT positive
Gender (p value 0.4)		
Females	2 (25%)	17 (40.5%)
Males	6 (75%)	25 (59.5%)
Educational status (p value 0.51)		
Graduate	2 (25%)	11 (26.2%)
Higher secondary	2 (25%)	3 (7.1%)
High school	1 (12.5%)	7 (16.7%)
Middle school	1 (12.5%)	3 (7.1%)
Primary school	0	9 (21.4%)
Illiterate	2 (25%)	9 (21.4%)
Socio-economic status (p value 0.42)		
Lower middle	2 (25%)	11 (26.2%)
Upper lower	6 (75%)	24 (57.1%)
Upper middle	0	7 (16.7%)

infection. In a study by Mahalanabis et al (1996) from Bangladesh reported high *H. pylori* infection rate in children, in poor community and explained an association with contaminated environment, crowding, lack of proper sanitation and lack of sufficiently clean water. These findings from previous study are not in agreement with our study because the population of patients visiting in our OPD are from upper and middle class. In our study, ICT was found positive in 84% of the study population which almost correlates with a study done by Andersen et al[10] (1996). They studied Danish population and found positive ICT results in 70.6% cases and suggested that ICT measurements in future serologic screening may improve diagnostic sensitivity considerably.

Average values of sensitivity and specificities of both tests were calculated in an overview of epidemiology and diagnosis of *H. pylori* infection by Logan and Walker. With the sensitivity of 84%, immunochromatography was within the range of average values. For serology, the sensitivities were 80-95% and specificities ranged between 80-95%.

Monotherapy with commonly used antibiotics, such as metronidazole or clarithromycin, can achieve H. pylori eradication rates in up to 17±20% patients. Serum antibody tests remain positive for a significant period, or perhaps indefinitely, after *H. pylori* eradication. Remote ingestion of certain antibiotics in potential study candidates could therefore result in eradication of *H. pylori*. Such patients would have negative tests for urease activity and (or) non visualization of bacteria on histology in presence of detectable serum antibodies (positive ICT). Such asituation would result in 'false-positive' antibody test results and could contribute to a lower specificity of the ICT. Other conditions that could potentially lower the specificity of antibody-based tests include recent antibiotics ingestion, bismuth compounds, and proton pump inhibitors. These agents alter gastric mucosal inflammation, bacterial distribution, and urease activity, making histologic detection of *H. pylori* more difficult and thereby increase the chances for false-negative *H. pylori* infection status[5,6,7,8]. The use of such products was and exclusion criteria for our study. Identification of *H. pylori* infection has become critical in the management of patients with gastroduodenal ulcer disease. The pathogenesis of *H. pylori*-related diseases is not clearly understood, but eradication of this infection favorably alters the natural history of gastroduodenal ulcer disease. Currently, serology plays an important role in two situations, i.e., screening of various populations to understand the epidemiology of *H. pylori* infection, and to identify those patients with gastroduodenal ulcer disease who are infected. Infected patients with active or quiescent gastroduodenal disease require antibiotic therapy. Absence of *H. pylori* infection, as manifested by negative serologic tests, in patients who are not exposed to non-steroidal anti-inflammatory drugs almost completely excludes the presence of gastroduodenal ulcer disease as well as the precursor lesions of gastric carcinoma[10-14].

CONCLUSION:

The ICT used in this study is commercially available, inexpensive, and easy to perform. Positive predictive value of 84% implies that the test could be

used to identify *H. pylori* infections in patients with upper gastrointestinal symptoms. Attributed to the rapidity of test results, clinical decisions regarding patient care can be made during the visit. Thus, antibody testing is expected to continue to improve and play an ever-increasing role in the primary clinician's diagnostic evaluation. As the *H. pylori* infection rate is known to be high in Indian population, recommendations regarding investigations with serological testing can be of great benefit in this population.

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