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Diagnostic Accuracy of H. Pylori Fecal Antigen Test in Young Patients Presenting with Dyspepsia

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ABSTRACT

Background: Eighty percent of the Pakistani population is suffering from gastric issues due to H. Pylori associated gastritis. **Objective:** To evaluate the diagnostic accuracy of HpSA test for H. Pylori infection in young patients presenting with dyspepsia taking standard Endoscopic Gastric Biopsy as gold standard. **Study Design:** Cross sectional study. **Settings:** Gastroenterology Department Lahore General Hospital, Lahore Pakistan. **Duration:** 7 months from 20th June to 19th December 2016. **Methodology:** A total 110 patients (18-35 years) with dyspepsia were included after taking approval from ethics committee of LGH/PGMI. After taking consent, fecal antigen detection test and gastric biopsies were carried out on all patient. Biopsy specimens were processed and observed. Hp stool antigen test was assessed from stool samples using ELISA technique. Diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value was measured by 2x2 contingency table. **Results:** A total of 60 patients (54.5%) had H.pylori infection as determined by gold standard biopsy whereas 76 (69.1%%) patients were reported positive using fecal antigen. There was 83.3% sensitivity, 48.0% specificity, 65.8% positive predictive value, 70.6% negative predictive and 67.3% diagnostic accuracy. **Conclusion:** HpSA test has acceptable diagnostic accuracy in comparison with biopsy.

Keywords: *Biopsy, H Pylori, Dyspepsia.*

INTRODUCTION

Helicobacter pylori (H. pylori) are gram negative bacteria and they were isolated in 1983 by Warren and Marshall.[1] This bacterium has been described in the pathogenesis of gastritis, peptic ulcer and gastric carcinoma. H.pylori induced gastritis is affecting almost half of the world population. Asia and Western Europe have the highest prevalence of H. pylori.[2] Contaminated water and fecal matter are the sources of contracting infection. The association of H. pylori is 80-90% with all the duodenal ulcers and about 80% with all the gastric ulcers.[3]

Helicobacter pylori can be detected by invasive and non-invasive methods, based upon the need for endoscopy. Direct methods consist of microscopic demonstration of organism & indirect method is by using urease or response of antibody as an indicator of disease.[4] Preference of methods for test based upon price, accessibility, clinical condition, occurrence of infection and factors such as the use of PPI & antibiotics that may affect certain test outcomes.[5]

The biopsy urease test, culture & histology and phase contrast microscopy of gastric tissue need invasive endoscopy. But, urea breath test and stool antigen detection by EIA do not need invasive endoscopy.[6]

Fecal antigen detection is a newer test and it is more precise than antibody testing and cheap than other available invasive and non-invasive tests. The specificity & sensitivity reported is 90% for fecal antigen detection in the various studies. As upper GI endoscopy is invasive procedure so H. pylori fecal antigen detection test can be used as alternative.[7] The aim of our study is to assess the diagnostic accuracy of H. Pylori infection in young patients presenting with dyspepsia taking standard Endoscopic Gastric Biopsy as gold standard.

METHODOLOGY

Study Design: Cross sectional study.

Settings: Gastroenterology Department Lahore General Hospital, Lahore Pakistan.

Duration: 7 months from 20th June to 19th December 2016.

Sample Technique: Non-probability consecutive Sampling Technique.

Sample Size: The estimated sample size was 110 calculated by using 95% confidence level with an expected percentage of sensitivity as 90% with 7% margin of error, specificity 93% with 6 % margin of error of H Pylori fecal antigen test.[8]

Inclusion Criteria: Patients with age (18-35) years of either gender with dyspepsia (Postprandial fullness, early satiation, epigastric pain or burning) who were not responding to treatment after 4 weeks and reporting same symptoms, assessed on history and examination.

Exclusion Criteria: Patient with a history of alcoholism, history of either already diagnosed H. pylori infection or were previously treated for H. pylori and now who have presented with recurrence assessed from history and medical record. Patients with diagnosed pancreatitis, hepatitis C or hepatitis B, chronic liver disease of duration more than 5 years, malignancy, ischemic heart disease in the previous medical records.

Data Collection Procedure: Patients presenting with dyspepsia enrolled after taking approval from ethics committee of LGH/PGMI. A written consent was taken from all patients for participation in the study. All such patients who met the inclusion criteria were evaluated. Upper gastrointestinal endoscopy and fecal antigen detection test were done and gastric biopsies were taken. Biopsies were analyzed for histological examination. A patient was considered as H. pylori positive if the invasive tests was positive. Fecal antigen test was performed via lateral flow immuno-assay. Positive result was shown by pink red line appearing in the reading window after 5 minutes of incubation time.

Data Analysis: All data was analyzed using software i.e., SPSS version 20. Qualitative variables like gender, presence of H pylori infection on both tests i.e., fecal antigen test and gastric biopsy were measured as frequencies & percentages. Quantitative data like age, duration of symptoms was measured as means & standard deviation. Diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value was calculated by generating 2x2 contingency table. Diagnostic Accuracy is measured by this formula: TP+TN/TP+TN+FP+FN x 100. Data was stratified for age, gender, duration of dyspepsia level to deal with effect modifiers. X^2 test was used to calculate p value.

RESULTS

Average age of 110 patients with dyspepsia was 26.72 $\pm$ 2.78 years with most of the patients in the age range ≥25 years. Majority of the patients in the study were female (55.4%). Mean duration of disease was 5.4 $\pm$1.6 months.

60 patients (54.5%) had H.pylori infection as determined by gold standard biopsy whereas 76 (69.1%) patients were reported positive using fecal antigen test.

Diagnostic accuracy was then calculated in terms of sensitivity, specificity, positive predictive value and negative predictive value using 2x2 table. Sensitivity, specificity, positive predictive value and negative predictive, diagnostic accuracy are 83.3%, 48.0%, 65.8%, 70.6%, 67.3% respectively.

Table 1: Descriptive data of patients presented with dyspepsia

Variables		No. of patient (n)%
Age (In years)	<25	52 (47.2%)
	≥25	58 (52.8%)
Gender	Male	49 (44.5%)
	Female	61 (55.4%)
Duration (In months)	<6 months	58 (52.7%)
	≥6 months	52 (47.3%)
H.Pylori Detection on Biopsy	Yes	60 (54.5%)
	No	50 (45.5%)
H.Pylori Detection on Fecal Antigen Test	Yes	76 (69.1%)
	No	34 (30.9%)

Table 2: Diagnostic accuracy of fecal antigen test

Fecal Antigen Test	Biopsy	
	Positive	**Negative**
Positive	50	26
Negative	10	24

Sensitivity: 83.3%
Specificity: 48.0%
Positive Predictive Value: 65.8%
Negative Predictive Value: 70.6%
Diagnostic Accuracy: 67.27%

Table 3: Stratification of diagnostic accuracy of fecal antigen test with biopsy (n=110)

Parameters		H. Pylori on Biopsy	H. Pylori on Fecal Antigen Test		Sensitivity	Specificity	+ve Predictive Value	-ve Predictive Value	p value
			Positive	Negative					
Age (years)	<25	Positive	19	9	67.9%	29.2%	52.8%	43.8%	0.81
		Negative	17	7					
		Total	36	16					
	≥25	Positive	22	10	68.8%	30.8%	55.0%	44.4%	0.96
		Negative	18	8					
		Total	40	18					
Gender	Male	Positive	19	8	70.4%	30.4%	54.3%	46.7%	0.95
		Negative	16	7					
		Total	35	15					
	Female	Positive	22	11	66.7%	29.6%	53.7%	42.1%	0.76
		Negative	19	8					
		Total	41	19					
Disease Duration (months)	≥6	Positive	19	9	67.9%	29.2%	52.8%	43.8%	0.81
		Negative	17	7					
		Total	36	16					
	<6	Positive	22	10	68.8%	30.8%	55.0%	44.4%	0.96
		Negative	18	8					
		Total	40	18					

DISCUSSION

Our study showed that HpSA test has 83.3% sensitivity 48% specificity. The results are consistent with the study done by Syam AF *et al*.[9] We found high accuracy of HpSA test for the diagnosis of *H. pylori* infection in patients presenting with dyspepsia in current study. Another study done by Iannone A *et al*, showed 95.9% diagnostic accuracy, 90.2% sensitivity and 98.5% specificity.[10,11] The mean age of patients presented with dyspepsia was 26.72 $\pm$ 2.78 years and 76 (69.1%) patients were positive for HpSA test. These results are similar to studies done by Eshraghian A *et al* and by Kazemi S *et al* who included young patients and there were 64% and 48% patients positive for HpSA test respectively.[12,13,14] Monoclonal stool antigen test, histology & urease test were used as a reference standard in few studies.[15] In one study histology and urea breath test was used as standard as compared to our study where standard was gastric biopsy.[10,16]

Tameshkel FS *et al*, in his study showed that false negative results can occur because of mild Hp colonization in the gastric mucosa.[17] False positive results can also occur due to other *Helicobacter* species.[18] Stool sample condition may give false results as watery or unformed stool samples have diluted antigens so it gives less precise test results.[19] The HpSA test is fast and low-priced. In Pakistan, H. Pylori associated diseases are rising day by day so the findings of this study supported the use of non-invasive HpSA test.[20]

The accuracy of the stool antigen test was assessed in 270 patients in whom the diagnosis of *H. pylori* was recognized by endoscopy and UBT.[21] The results showed 94% sensitivity and 86% specificity of the test. Same findings were observed in a comparably designed study involving 272 infected patients.[22]

The stool antigen assay is also beneficial to judge either eradication has been effective or not.[23] In the study, the sensitivity and specificity for the test was 90 and 95 percent, respectively after four weeks of eradication therapy.[24] In similar study, the test was predictive of eradication as after seven days of completion of therapy.[25] However, few studies have noted a lower predictive accuracy of the tests in the situation of post-eradication testing and in cases of acute upper gastrointestinal bleeding.[26] In one, the test was falsely positive 32 % in whom *H. pylori* eradication was documented.[24] False-positive results have also been observed in patients with acute upper gastrointestinal bleeding due to cross-reactivity with blood constituents.[27] The main advantages of HpSA tests are less cost and easily performed with quick results as compared to the other tests. Moreover, these tests don't require expensive equipments.[28]

CONCLUSION

HpSA test has acceptable diagnostic accuracy in comparison to gastric biopsy results.

LIMITATIONS

Sample size is small. A single center study with a cross sectional design.

SUGGESTIONS / RECOMMENDATIONS

Further studies with large sample size and multi centric approach may be more informative.

CONFLICT OF INTEREST / DISCLOSURE

There was no conflict of interest and nothing to disclosed in this research.

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