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ORIGINAL ARTICLE

Diagnostic Accuracy of Serologic (IGG) in Diagnosis of Helicobacter Pylori among Patients of Dyspepsia by Taking Stool Antigen (HPSA) as Gold Standard

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ABSTRACT

Objective: To determine the diagnostic accuracy of serologic (*IgG*) in the diagnosis of Helicobacter Pylori among patients of dyspepsia by taking Helicobacter pylori Stool Antigen (HpSA) as the gold standard.

Material and methods: The study was conducted in Microbiology Department, Basic Medical Sciences Institute, Jinnah Postgraduate Medical Centre, Karachi with the collaboration of gastroenterology OPD. All the patients with a history of dyspepsia, above 25 years of age and of either gender were included. After taking informed consent the clinical samples of blood and stool from patients were taken. A 6 ml venous blood was taken from the antecubital vein for detecting IgG antibody to H. pylori. Stool samples were collected for detecting H. pylori antigen in a wide mouth, sterile, leak proof container properly labeled by serial number and stool samples were stored in a refrigerator at 4°C up to 72h. On the specimens containing H. pylori antibodies, a colored line appeared in the test line region consider a positive result. H. pylori antigen was detected in stool (HpSA) by rapid chromatographic immunoassay. During analysis, the specimen responds with an anti-H. pylori antibody-coated particle. By capillary action, the mixture migrates upward on the membrane, reacting with anti-H. pylori antibodies on the membrane to produce a colorful line. A positive result is indicated by the presence of this colored line in the test zone, whereas a negative result is indicated by its absence. All the data were obtained using a study proforma, and the data was analyzed using SPSS version 26.

Results: A total of 210 patients presented with dyspepsia were studied, their mean age was 49.07±10.97 and females were in majority (71.9%). H. Pylori was positive among 137 cases, those who underwent serological test (IgG) and 127 were positive for stool antigen (HpSA). The diagnostic accuracy of serological test (IgG) was found 95.23% by taking Stool Antigen (HpSA) test gold standard followed by sensitivity 92.7%, specificity 100%, PPV 100% and NPV 87.95%.

Conclusion: The diagnostic accuracy of serological test (IgG) was found 95.23% by taking Stool Antigen (HpSA) test gold standard followed by sensitivity 92.7%, specificity 100%, PPV 100% and NPV 87.95%.

Key words: H. pylori, diagnosis, IgG, Stool antigen

INTRODUCTION

In general practice the gastrointestinal diseases, dyspepsia is the commonest condition. 1 There is a strong link between Helicobacter pylori and gastroduodenal illness.[1] Infection with Helicobacter pylori (H. pylori) is exceedingly common around the world, with evidence from a recent comprehensive study indicating that more than half of the worldwide population are infected.[2,3] Infections rates are in developing nations and resource-poor settings the risk is substantially much higher, with estimated prevalence in Africa exceeding 70%, the very high in world.[2,3] Poor sanitation, dirty water supplies, poor housing and overcrowding, have all been linked to the higher incidence in underdeveloped countries.[2] H. pylori causes functional dyspepsia as well as gastroduodenal illnesses such as gastritis, peptic ulcers, MALT lymphoma and gastric cancer. Most gastroduodenal symptoms, such as heartburn, nausea, abdominal discomfort, and postprandial fullness, resolve after this infection is eradicated. Despite the fact that functional dyspepsia is a highly common disease that affects around 10% of the overall population, the socioeconomic prevalence of illness is significant due to frequent trips to health facilities and recurrent prescriptions and examinations.[4,5] In individuals having dyspepsia, the infection of H. pylori was predicted to be 2.3 times higher than in healthy controls, and H. pylori was discovered in about half of the dyspepsia patients.[4] Invasive procedures (histological examination, culture, and quick urease test) and non-invasive approaches (serology, urea breath test, and stool antigen) can all be used to identify H. pylori infection, with various degrees of sensitivity and specificity.[6] In a developing countries like Pakistan, the accessibility, expense, invasiveness, nature, and easiness of achievement of these tests all play a role.[6] A accurate identification and delivery of H. pylori eradication therapy will decrease the occurrence of gastroduodenal disorders, such as gastric carcinoma, linked to H. pylori infection, as well as the number of new infections in the future.[7] H. pylori antibodies, including immunoglobulin A (IgA), immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies, are tested serologically.[8,9] H. pylori IgG test is the most sensitive of the serologic tests, however the H.

pylori IgM and IgA tests are arguably of no therapeutic value.[8,9] There are several controversies on serological tests. Hence this study has been conducted to assess the diagnostic accuracy of serologic (*IgG*) in the diagnosis of Helicobacter Pylori among patients of dyspepsia by taking Helicobacter pylori Stool Antigen (HpSA) as the gold standard.

MATERIAL AND METHODS

This was a cross-sectional study and was done at Department of Microbiology, Basic Medical Sciences Institute, Jinnah Postgraduate Medical Centre, Karachi with the collaboration of gastroenterology OPD. The ethical permission was obtained from the Institutional Review Board (IRB) Committee of Jinnah Postgraduate Medical Centre (JPMC), Karachi. Patients with a history of epigastric burning, epigastric pain, belching, bloating, nausea, vomiting for more than one month, above 25 years of age, patients having no history of recently taken non-steroidal anti-inflammatory drugs, antibiotics, proton pump inhibitor or H2 antagonists, and bismuth compounds and of either gender were included. Patients taking antibiotics for a prolonged period, already taken steroids, nonsteroidal anti-inflammatory drugs, immunosuppressive or Helicobacter pylori eradication therapy, patients with GI bleeding history and who were not willing to be the part of this study were excluded. After taking informed consent the clinical samples of blood and stool from patients were taken. After taking all aseptic measures and patient sitting comfortably in upright position, 6 ml venous blood was taken from the antecubital vein for the detection of IgG antibody to H. pylori. Stool samples were collected for the detection of H. pylori antigen in a wide mouth, sterile, leak proof container properly labeled by serial number and stool samples were stored in a refrigerator at 4°C up to 72h. For serum separation, blood coagulation was allowed to occur for 30 minutes and then centrifuged for at least 15 minutes. Obtained sera were transferred to a plastic-screw vial for transport to the laboratory, and stored at -80°C until analyzed. For the qualitative detection of anti-H pylori IgG, H. pylori Antibody Rapid test Cassette was used. The specimen reacts with H. pylori antigen coated particles in the test after being placed in the specimen well of the cassette. This mixture chromatographically moves along the length of the test and interacts with the immobilized anti-human IgG. A colorful line was shown in the test line region if the material included H. pylori antibodies, was indicated as positive result. H. pylori antigens were detected in stool (HpSA) by rapid chromatographic immunoassay. During analysis, the specimens respond with an anti-H. pylori antibody-coated particle. By capillary action, the mixture migrates upward on the membrane, reacting with anti-H. pylori antibodies on the membrane to produce a colorful line. A positive result is indicated by the presence of this colored line in the test zone, whereas a negative result is indicated by its absence. All the data were obtained using a study proforma, and the data was analyzed using SPSS version 26.

RESULTS

A total of 210 patients presented with dyspepsia at gastroenterology OPD were studied, their mean age was 49.07±10.97, mean weight was 70.26±10.91 and females were in majority (71.9%) as compared to males (28.1%). As per clinical presentation 78.6% patients had epigastrium pain, 36.7% had flatulence, 67.1% had belching, 40.0 had nausea, 12.4% had vomiting, 80.5% had bloating and 81.9% had burning. Table.1

H. Pylori was positive among 137 cases, those who underwent serological test (IgG) and 127 were positive for stool antigen (HpSA). The diagnostic accuracy of serological test (IgG) was found 95.23% by taking Stool Antigen (HpSA) test gold standard followed by sensitivity 92.7%, specificity 100%, PPV 100% and NPV 87.95%. Tbale.2

Table 1: Baseline Characteristics of Studied Samples (n=210)

Characteristics		Statistics	
Age (years)	Mean± SD	49.07±10.97	
Weight (kg)	Mean± SD	70.26±10.91	
Gender	Male	59	28.1
	Female	151	71.9
Gastrointestinal symptoms	Epigastric pain	165	78.6
	Flatulence	77	36.7
	Belching	141	67.1
	Nausea	84	40.0
	Vomiting	26	12.4
	Bloating	169	80.5
	Burning	172	81.9

Table 12: Sensitivity, Specificity, PPV and NPV of IgG test by taking HpSA gold standard n=210

IgG Test	HpSA		Total
	Positive	Negative	
Positive	127	10	137
Negative	10	73	73
Total	127	83	210

TP=127, FP=0, FN=10, TN=73
Sensitivity = 127/127+10 × 100 = 92.7%
Specificity= 73/73+0 × 100 = 100%
PPV = 127 / 127+0 × 100 = 100%
NPV = 73/ 73+10 × 100 = 87.95%
Diagnostic accuracy = (127+73)/(73+0+10+127) × 100 =95.23%

DISCUSSION

H. pylori is the Gram-negative bacterium that colonizes the stomachs of around two-thirds of the world's population, and It contributes to the pathophysiology of diseases of the gastroduodenal tract.[10] In this study a total of 210 patients presented with dyspepsia at gastroenterology OPD were studied, their mean age was 49.07±10.97, mean weight was 70.26±10.91, and females were in majority (71.9%) compared to males (28.1%). Consistently Kouitcheu Mabeku LB et al[10] reported that the average age of study subjects was 53.79 ± 11.11 years with age range of 35 to 75 years and out of all females were 127 and males were 78 males with male to female ratio of 1:1.7. In the study of Aminde JA et[2] reported that the average age of the participants was 40.7 ± 19.1 years with age range of 7 to 96 years and out of all 452 cases females were in majority 63.6%. In the retrospective Study of Naushad VA et al[11] from Qatar found inconsistent findings regarding gender as out of all 638 cases males were 58.8%, while consistently mean age was 42.2 years with age range of 18 to 79 years. The variation in the average age and gender between this

study and others could be due to studies sample size, sample selection and lifestyle modification variations.

In this study as per clinical presentation 78.6% patients had epigastrium pain, 36.7% had flatulence, 67.1% had belching, 40.0 had nausea, 12.4% had vomiting, 80.5% had bloating and 81.9% had burning. Similarly, Kouitcheu Mabeku LB et al[10] demonstrated that as per clinical signs and symptoms the epigastric pain and burning and recurrent burping were the commonest among all the cases (100%) followed by Flatulence/ bloating was in 70.45% cases and Nausea/Vomiting in 34.1% of the cases. Despite the fact that the study of Naushad VA et al[11] from Qatar reported that the commonest symptom was epigastrium pain 80.6% followed by belching 8.8%, nausea 10.2%, vomiting 9.6%, heart burn 26.2% and melena 6%.

In this study H. Pylori was positive among 137 cases, those who underwent serological test (IgG) and 127 were positive for stool antigen (HpSA). Consistently Douraghi M et al[12] reported that the serum H. pylori antigens (IgG antibody) were found in 85.1% of the cases, while Helicobacter pylori was diagnosed in 93.1% of the cases by stool antigen test. While inconsistently H. pylori infection positive in 61.4% cases on serology test and it was diagnosed in 56.4% cases through the stool antigen test. The prevalence of H. pylori was high in this study on both tests and this difference may because of sample selection criteria, because in this study all the patients those who were suspected of H. pylori infection were included.

In this study, the diagnostic accuracy of serological test (IgG) was found 95.23% by taking Stool Antigen (HpSA) test gold standard followed by sensitivity 92.7%, specificity 100%, PPV 100% and NPV 87.95%. Similarly, She RC et al[13] concluded that IgG was the performance overall by using the HpSA test as the gold standard with a sensitivity of 87.6% and specificity of 61.0%. In contrast, the stool antigen detection had specificity and sensitivity of 100 percent and 94.9 percent cases respectively,[15] but the EIA utilized in this investigation to identify the IgG antibodies to H. pylori had a sensitivity of just 80 to 90% in the cases.[16] In the comparison of this study, Hung HH et al[17] conducted a study to determine the diagnostic accuracy of the immunoglobulin G (IgG) antibody in the detection of H pylori and they observed that the sensitivity of ELISA was 93.5%, specificity 94.4%, PPV 95.6%, NPV 91.9%, and accuracy was 93.9% in the cases those were < 45 years old, that the sensitivity of ELISA was 100%, specificity 81.3% PPV 94.3%, NPV 100%, and accuracy was 93.9% in the cases those were more than 45 years old. Out of several tests the serology and urea breath tests, antibody detection in urine, and antigen detection in feces are all non-invasive procedures. Nevertheless, no single test has yet been proven to be sufficiently trustworthy to serve as a gold standard.[7] Hence further large-scale studies still recommended on the accuracy of these non-invasive tests.

CONCLUSION

The serological test (*IgG*) was observed to be accurate and noninvasive diagnostic tool for the detection of H pylori. The diagnostic accuracy of serological test (IgG) was found 95.23% by taking Stool Antigen (HpSA) test gold standard followed by sensitivity 92.7%, specificity 100%, PPV 100% and NPV 87.95% although these findings still unproven to be sufficiently trustworthy to serve as a gold standard. More large-scale studies are suggested to prove the trustworthy findings.

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