SEROPOSITIVITY OF H. PYLORI AMONG DYSPEPTIC PATIENTSShavi Nagpal¹, Aroma Oberoi², Navjot Singh³¹Postgraduate Student, Department of Microbiology, Christian Medical College and Hospital, Ludhiana, Punjab.²Professor and HOD, Department of Microbiology, Christian Medical College and Hospital, Ludhiana, Punjab.³Professor and HOD, Department of Medicine, Christian Medical College and Hospital, Ludhiana, Punjab.**ABSTRACT****BACKGROUND**

H. pylori infection affects nearly half of the world's population. In developing countries, the prevalence of infection is as high as 90%. Various diagnostic tests (invasive and non-invasive) are available to detect *H. pylori* infections. The invasive tests include histology, rapid urease test, culture and PCR; while non-invasive tests include serology (qualitative and quantitative IgG), urea breath test and stool antigen assay.

Aims and Objectives- In this study, we evaluated the prevalence of *H. pylori* among patients with dyspepsia visiting our hospital using the *Helicobacter pylori* IgG antibody test kit (Demeditec Diagnostics, Germany). The test kit is based on the principle of the enzyme immunoassay (EIA).

MATERIALS AND METHODS

This is a hospital-based observational study from January 2015 to August 2017. Serum samples of 1980 patients (both inpatients and outpatients) with dyspepsia/ non-specific pain abdomen were included in this study. Immunoglobulin G (IgG) antibody to *H. pylori* is detected using a commercial kit (Demeditec Diagnostics, Germany).

RESULTS

Of 1980 patients 1907 (96.32%) were adults (> 16 years of age), while the remaining 73 (3.68%) were from paediatric age group. Among adults the seropositivity of *H. pylori* was seen in 42.73% (815 out of 1907), while paediatric group had seropositivity of 17.80% (13 out of 73 patients).

CONCLUSION

Serological testing can be used as a screening test for initial evaluation of dyspeptic patients. Serological tests avert UGI endoscopy in many, thus reducing the cost of treatment burden on patients and at the same time reducing endoscopy load on the specialist. The serological test is cost effective, easily available and rapid.

KEYWORDS

H. pylori, Dyspepsia.

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BACKGROUND

Helicobacter pylori (*H. pylori*) is a Gram-negative flagellate bacterium (2.4 - 4.0 µm long and 0.5 - 1.0 µm wide) and is recognised as the most important aetiological agent for chronic antral gastritis in humans, the major predisposing factor in the pathogenesis of duodenal and gastric ulcer as well as a probable cofactor in the development of gastric cancer.¹⁻³ *H. pylori* infection affects nearly half of the world's population. In developing countries the prevalence of infection is as high as 90%, whereas in developed countries excluding Japan the prevalence is below 40%.⁴ Many studies have been done in India to look for the prevalence of *H. pylori* and reported prevalence range from 31% - 84%, most centres report a figure of around 60%.⁵⁻⁷ Also, a high prevalence is noted in populations with low socioeconomic status, low

educational level, family members and spouses of index cases, endoscopists and nurses.⁸ The epidemiology of *H. pylori* in India suggests that infection occurs early in life and more than half of the population acquires the infection by early adult life.⁹

The recent American College of Gastroenterology guidelines (2017) on *H. pylori* recommends that patients with active peptic ulcer disease (PUD), a past history of PUD, low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma or a history of endoscopic resection of early gastric cancer (EGC) should be tested for *H. pylori* infection. Also, in patients with uninvestigated dyspepsia who are under the age of 60 years and without alarm features, non-endoscopic testing for *H. pylori* infection is a consideration.¹⁰

Various diagnostic tests (invasive and non-invasive) are available to detect *H. pylori* infections. The invasive tests include histology, rapid urease test, culture and PCR, while non-invasive includes serology (Qualitative and quantitative IgG), urea breath test and stools antigen assay. The advantage of urea breath test and stool antigen test is that they can be used to document the eradication of *H. pylori*; however, serology cannot be used for that as once positive it does not turn negative after eradication. The choice of test depends on several factors such as the availability of diagnostic tests, need to perform an endoscopy, cost, accessibility, advantages and disadvantages of each method and age of patients.¹¹

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In this study, we evaluated the commercially available *H. pylori* IgG ELISA to evaluate the prevalence of *H. pylori* among patients with dyspepsia visiting our hospital.

MATERIALS AND METHODS

This is a hospital-based observational study. Patients who were diagnosed by the physicians to have dyspeptic symptoms or non-specific pain abdomen were selected for this study. Serum samples of a total of 1980 patients (Including both outpatient and inpatients) with above symptoms was taken up for the study from January 2015 to August 2017. Serology is based on the presence of immunoglobulin G (IgG) antibody to the *H. pylori* infection. Positive testing denotes present or past infection to *H. pylori*. There is no need to stop the treatment before testing and previous antibiotic treatment does not change the test.

The *Helicobacter pylori* IgG antibody test kit (Demeditec Diagnostics, Germany) is based on the principle of the enzyme immunoassay (EIA). *Helicobacter* antigen is bound on the surface of the microtiter strips. Diluted patient serum or ready-to-use standards are pipetted into the wells of the microtiter plate. A binding between the IgG antibodies of the serum and the immobilised *Helicobacter* antigen takes place. After one hour incubation at room temperature, the plate is rinsed with diluted wash solution in order to remove unbound material. Then ready-to-use anti-human-IgG peroxidase conjugate is added and incubated for 30 minutes. After a further washing step, the substrate (TMB) solution is pipetted and incubated for 20 minutes inducing the development of a blue dye in the wells. The colour development is terminated by the addition of a stop solution, which changes the colour from blue to yellow. The resulting dye is measured spectrophotometrically at the wave length of 450 nm. The concentration of the IgG antibodies is directly proportional to the intensity of the colour.¹²

RESULTS

A total of 1980 patients were included in this study. Out of 1980 patients 1907 (96.32%) were adults (> 16 years of age), while the remaining 73 (3.68%) were from paediatric age group [Fig. 1]. The male-to-female ratio among study population was 1.2: 1.

Figure 1. Figure showing Percentage of Paediatric and Adult Population among Total Study Sample (n= 1980)

Figure 2. Figure showing Number of Positive and Negative Samples for Serological Test (IgG *H. pylori*)

The seropositivity of *H. pylori* was seen in 41.8% (828 out of 1980) patients. Among adults the seropositivity of *H. pylori* was seen in 42.73 % (815 out of 1907), while paediatric group had seropositivity of 17.80% (13 out of 73 patients) [Fig. 2]. Among adults with positive serology for *H. pylori*, the males constituted 52.02% (424 out of 815) and the rest 47.98% were females (391 out of 815). The number of patients who were detected seropositive were 308, 289 and 231 in 2015 (Jan - Dec), 2016 (Jan - Dec) and 2017 (Jan - Aug) respectively.

DISCUSSION

In a study by Kate et al from Pondicherry (India), the prevalence of *H. pylori* was 74%, 76% and 91% among patients with non-ulcer dyspepsia, gastric ulcer and duodenal ulcer respectively.¹³ In another study from same author, overall prevalence of *H. pylori* in children was 45% and in adults was 67%.¹⁴ In a study from Chennai, a 21.1% prevalence rate was seen in individuals between 12 - 20 years of age. Study also showed a trend of rising prevalence with age with maximum prevalence of 76.2% in those older than 75 years.¹⁵ Our study shows a similar trend as the seropositivity is more among adults when compared to children. Also, the seropositivity among adults is less when compared with other studies from India.

In the study by Kate et al, gender did not affect the prevalence in children and adults.¹⁰ This is akin to our results, as the positivity was similar among male and female adults. However, Patel MS et al concluded that male sex was associated with a higher incidence of *H. pylori* infection.¹⁶

Crabtree et al concluded that the sensitivity of commercial ELISA (*H. pylori* IgG AB) kit was 93.8% and specificity of 79.3%.¹⁷ In a study by Daivasikamai P et al, serological test (IgG AB to *H. pylori*) was found to have sensitivity and specificity of 98% and 97.5% respectively.¹⁸ Author also concluded that serological tests assess the global presence of *H. pylori* in stomach even when bacteria are irregularly distributed on gastric mucosa.

Esmaeilli and Saberi et al evaluated the efficacy of two commonly used commercial IgG based ELISA kits against endoscopy based tests.¹⁹ They concluded that caution should be practiced when serological tests are used as sole basis of medical decision making. It was so because of the sensitivity rate and more drastically the specificity rates (against biopsy based tests) claimed by two commercial kits were significantly reduced.

Endoscopic biopsy requires a gastroenterologist and an endoscopic setup. The upper GI Endoscopy is not only costly,

but an invasive procedure. Once endoscopy is done, an additional test e.g. biopsy, rapid urease test is needed to confirm the diagnosis. These tests further add on to high cost of endoscopic procedure. In comparison serological test is simple, can be easily done and does not need an expensive setup. The cost of serological test is 5 - 10 times less than any endoscopic method for *H. pylori* diagnosis.

Patients with vague abdominal pain regularly come for evaluation to medical practitioner. Differentiating dyspepsia, peptic ulcer disease or Irritable Bowel Syndrome (IBS) at times become difficult, as these subgroups usually have normal blood tests and radiological investigations. Getting UGI endoscopy in each patient is practically not feasible to rule out peptic ulcer disease. Firstly, endoscopic facilities are available only at tertiary health care. Secondly, the cost of procedure is enormous, preventing people to get it done. Lastly, endoscopy in each patient will increase the burden on endoscopist.

Serological testing can help by screening the patients for *H. pylori*. Those who are negative for *H. pylori*, an endoscopy can be averted provided they do not have other risk factors or alarm signs.

CONCLUSION

Serological testing can be used as a screening test for initial evaluation of dyspeptic patients. Serological tests avert UGI endoscopy in many, thus reducing the cost of treatment burden on patients and at the same time reducing endoscopy load on the specialist.

The serological test is cost effective, easily available and rapid. So, this should be done in situations where additional information yielded by an endoscopy is not needed.

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