DIAGNOSTIC EFFICACY OF STOOL ANTIGEN TEST (HPSA), CLO TEST AND SEROLOGY FOR THE DETECTION OF HELICOBACTER PYLORI INFECTION

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Background: The diagnosis of *Helicobacter pylori* infection was initially being made through invasive methods but now non invasive methods have been developed to make the diagnosis easier. The present study was done to evaluate the diagnostic efficacy of a two non invasive tests i.e. *Helicobacter pylori* Stool antigen test (HpSA) and *Helicobacter pylori IgG* serology with an invasive method i.e. Campylobacter like organism (CLO) gel test. **Methods.** The study was conducted in the gastroenterology unit of Pakistan Medical Research Council Research Centre Karachi. Adult patients with gastroduodenal disease were selected for study and their medical history was recorded. Endoscopy was done on all patients and the antral biopsy sample was tested for *H.pylori using* CLO test. Serology (IgG) was done elsewhere using ELISA and titers of over 50 units were recorded as positive. HpSA was done to determine the presence of *H.pylori* antigen in stool. **Results.** Out of 43 patients 34 (79%) were males and 9 (21%) females. The main presenting symptom was epigastric pain in 74 % cases. Although *H.pylori* IgG antibody titers of over 50 were taken as positive but for this study titres of over 100 were taken as significant for comparison with other tests . CLO test was positive in 26 (60.5%) cases, H. Pylori antibody titers of over 100 IU were present in 33 (76.7%) cases and HpSA in 21 (48.8 %). Using CLO test as the gold standard the sensitivity of serology was 81 % and that of HpSA 65% with a 29% and 76 % specificity respectively. **Conclusion**. In our setting CLO test is still the best diagnostic test for H. Pylori detection. Both non invasive tests i.e. serology and stool HpSA are less sensitive than CLO but amongst each other both are equally sensitive.

Keywords: Helicobacter Pylori, Stool Antigen Test, Serology

INTRODUCTION

Helicobacter pylori infection has been reported worldwide [1] In Pakistan infection rate with *H.pylori* was about 83 % in adult patients undergoing upper GI endoscopy for various reasons.[2] Colonization of *H.pylori* was found in all types of lesions, and in apparently normal upper GI tract, the CLO colonization was 76 % [3] . *H pylori* causes peptic ulcer disease and has been associated with gastric malignancies [4.] This infection is mainly acquired in children and may predispose to peptic ulcer disease later in life [5]. Various factors like over crowding large family size, ethnic group, socioeconomic group, hot and humid climate [6] may play a role in the spread of *H.pylori* infection.[7] For the diagnosis of *H.pylori*, various techniques both invasive and non invasive have been developed. The invasive tests include endoscopic biopsy for histology or CLO test or culture. In culture viable organisms are present in a small percentage of cases[8]. Culture though time consuming is useful in determining sensitivity patterns and line of treatment[9] .The non invasive tests are urea breath test, serology and HpSA. Although 13C UBT gives accurate results in both pre treatment and post treatment cases but it requires expensive radioisotope setting and instruments and is not suitable for infants, very young children and patients with certain neurological disorders[10].

The CLO test yields result in 15 minutes, this test being easy, rapid and sensitive should be used for screening of *H. pylori* infection followed by histology for further confirmation [11]. Scanning Electron microscopy of biopsy specimens showed concentration of *H. pylori* in the intracellular areas of epithelial cells. Transmission Electron microscopy studies indicated clustering of bacilli in the intracellular areas and decrease of microvilli where bacilli were present [12]. Immunofluorescence test was done with antigen made from local strains of *H. pylori* but it requires special microscope which is not easily available [13] PCR is also used to detect *H. pylori* infection [14]. *H pylori* serology either qualitative or quantitative will yield false positive results in-patients who have previously been treated for *H pylori* and should therefore not be used to determine infection status in the population[15.] HpSA , a new non invasive stool antigen test has been introduced recently [16-17.].This study was done to evaluate the efficacy of HpSA test and compare it with other methods of diagnosis.

MATERIAL AND METHODS

Thirty four patients reporting to the Gastroenterology clinic for investigation of peptic

Table-1: Diagnostic value for the detection of Helicobacter Pylori infection

Parameter	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)	Overall diagnostic accuracy (%)
HpSA	65	76	81	59	70
Serology (IgG)	81	29	64	50	60

ulcer disease or dyspepsia were selected for the study. Their clinical history was recorded. Endoscopy and rapid urease test (CLO) was performed on all cases while serology was done elsewhere using IgG antibody titers (ELISA). Stool samples were collected and examined by direct microscopy and stored at -20^0 C for HpSA stool antigen test by ELISA.

RESULTS

A total of 34 patients were included in the study of whom majority were males and only 7 were females. The ages of the patients ranged between 20-62 years. The main presenting symptoms were epigastric pain (74%) which was mostly nocturnal in nature followed by indigestion (65%) and vomiting (20%). Though IgG antibody titers of more than 50 are taken as positive but for this study values of over 100 were taken as positive. Out of 34 patients, CLO test was positive in 26 cases, serology was positive in 33 cases and HpSA in 21 cases. Taking CLO test as the gold standard the sensitivity of serology and HpSA test was 81% and 65% with 29% and 76% specificity. The sensitivity, specificity, positive and negative predictive value of serology and stool HpSA are shown in the table. Overall diagnostic accuracy of stool antigen was 70% and that of serology was 60%, indicating that both the non invasive tests have similar diagnostic efficacy. Direct microscopy of stool indicated the presence of *Entamoeba histolytica, Ascarias lumbricoides* and *Hymenolipis nana* in three cases but there was no cross reactivity.

It is concluded the present study that for early and reliable diagnosis of H.Pylori CLO test is still the best test in our setting. Of the non invasive tests stool HpSA and serology have almost similar diagnostic efficacy.

DISCUSSION

Detection of *H pylori* antigen in the stool by HpSA assay is a new, non invasive method for the diagnosis of H.pylori. This test is done from the stool therefore it can be performed in any routine laboratory settings making it more patient friendly when compared with the other invasive tests. This study showed that CLO test was still the gold standard with stool HpSA and serology going very close to each other. One of the two non invasive tests can be used as the initial screening test especially when large number of patients need to be screened. Stool collection appears to be easy then blood collection especially in children in our setup. In one study of 501 naïve cases the accuracy of HpSA was assessed before and after treatment by comparing results with gastric biopsies using special stains as well as culture, rapid urease test and urea breath test [19.] The stool test had 94% sensitivity and 92% specificity with similar i.e. 95% and 97% pretreatment sensitivity and specificity for urea breath test. Post treatment the sensitivity and specificity

of stool HpSA was 90% and 95% respectively with similar i.e. 90% and 98% results for urea breath test. They concluded that stool test is easier to perform then breath test and both have good sensitivity both pre and post treatment. A study by Trevisani et al evaluated the stool HpSA test in H. pylori treated and untreated cases and they found that specificity of stool test dropped from 90% to 82% in post treatment cases; the authors thus concluded that HpSA is a good test for the diagnosis of the disease but is not specific once treatment has been instituted. [20]. In another study from Spain the stool HpSA test was evaluated pre and post treatment and compared with other standard tests like rapid ureas, urea breath and histology. The specificity of stool test fell from 89% pretreatment to 79% post treatment and the authors thus suggested that stool test is not a useful test for monitoring treatment efficacy at 6 weeks or 6 months post treatment when compared to urea breath test (UBT) [21]. Similar results were reported by others [22]. In another study from Italy the accuracy of HpSA and urea breath test were shown to decrease immediately after treatment due to omeprazole, the sensitivity of both the tests returned after 2 weeks of stopping omeprazole [23]. Keeping all studies in mind it appears that stool test can be used as a reliable maker for initial screening of infection but post treatment the test has to evaluated along with other non invasive tests to check response.

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