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HELICOBACTER PYLORI INFECTION;

COMPARISON OF STOOL ANTIGEN TEST AND HISTOLOGY OF ENDOSCOPIC BIOPSY FOR DIAGNOSIS

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ABSTRACT: Objectives: To determine diagnostic accuracy of H.pylori Stool Antigen test for diagnosing Helicobacter pylori infection, keeping histopathology as gold standard. **Study design:** Cross sectional Validation Study. **Place and duration:** Study was conducted in department of Gastroenterology Military Hospital, Rawalpindi for six months from 1st November 2014 to 30th April, 2015. **Patients and methods:** Serial patients presenting with dyspepsia fulfilling the inclusion criteria were entered in study program. Endoscopy was performed to take antral biopsies for histopathology and stool was taken to test H.pylori antigen. SPSS version 16.0 was used to analyze the data. **Results:** Eighty (72.2%) out of 110 patients were male, the mean age and standard deviation was 33 ±16yrs. Three patients left study just before starting endoscopy. Eighty (74.76%) cases out of 107 patients were both positive for histology and HpSA test. Stool for H.pylori test was positive in 82 (76.63%) while histopathological diagnosis was made in 83(77.57%) patients. The sensitivity and specificity were 96.3% and 91.66% while positive and negative predictive values of the stool H.pylori test were 97.56%, and 88.0% respectively. Overall the diagnostic accuracy of stool H.pylori test was 94.4% for diagnosis of H. pylori infection. **Conclusion:** Stool for H.pylori Antigen can be used as alternative to histopathology due to its non-invasive nature, patient's preference and ease of repetition.

Key words: Dyspepsia, Stool Antigen test, Histopathology, Helicobacter pylori

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INTRODUCTION

Many gastro-intestinal diseases like gastritis, duodenitis, peptic ulceration, gastric malignancies and gastric mucosa-associated lymphoid tissue (MALT) lymphoma are caused by Helicobacter pylori infection.[1,2,3] The diagnosis of H. pylori is a basic component in the management of these gastro-intestinal problems. Helicobacter pylori infection can be diagnosed through several invasive and non-invasive methods. Endoscope is used in invasive methods which include histopathology, culture, smear examination and rapid urease test or CLO (compylobactor like organism) test. Noninvasive tests include serological testing, stool for H.pylori antigen (HpSA) detection and urea breath testing.[4]

Among them histological examination of endoscopic biopsy has highest sensitivity and specificity.[5] But many factors are involved in this procedure that can alter the results like the experience of endoscopist, number, site and size of biopsies, methods of staining and interpretation of pathologist. Although histopathalogy is assumed as the gold standard for the detection of Helicobacter pylori[5] but due to its high cost, non-availability of endoscope and the need for properly trained personnel, it may not be routinely used in clinical practice.

That's why we required a diagnostic tool for detection of H.pylori which should be non-invasive, easier to perform, cost effective, quick and suitable for follow ups, does not require specialized expertise and performed easily in all laboratories. Detection of H.pylori antigen in the stool of the patient is an excellent tool for diagnosing this infection[6] and fulfills all the above mentioned criteria. In addition, many studies showed that the results of HpSA are

comparable with histology for diagnosis of H.pylori infection.[7,8,9,10] All these studies are done outside Pakistan, that's why we tried to compare the efficacy of these test in our local population which will be helpful for patients, clinician and making our local guidelines.

MATERIALS AND METHODS

The study was cross sectional validation type and carried out in the department of Gastroenterology, Military Hospital, Rawalpindi from 1st November 2014 to 30th April 2015. One hundred and ten patients were selected through non-probability consecutive sampling technique. Informed consent was taken from each individual after explaining the aim of study. Adults between 18 to 60 years (both males and females) presenting with dyspepsia who did not respond to 6 weeks trial of Proton pump inhibitors (PPI) or having alarm symptoms i.e, weight loss, anemia, dysphagia or blood in the stool were included in study. While the treatment experienced patients were excluded from the study. All the patients underwent esophageogastroduodenoscopy, three antral biopsies taken put in formalin and sent to Military Hospital labortary, and examined for H.pylori by pathologists. H.pylori was considered positive if it was identified on histological examination. A fresh stool sample was also collected from each patient and sent to hospital laboratory. Results were recorded in a preformed well-designed Performa. Information was entered and analyzed by utilizing SPSS 16.0. Frequency and percentages were calculated for qualitative variables like gender, H.Pylori Stool Antigen and histopathology. Quantitative variable like age was mentioned as Mean ± standard deviation. 2x2 Table was used to calculate sensitivity, specificity and predictive values either positive or negative.

	Histology Positive	Histology Negative
Stool H.Pylori Positive	**(a)**	**(b)**
Stool H.Pylori Negative	**(c)**	**(d)**

2x2 Table for Calculating Diagnostic Accuracy of HPSA

(a) True Positives;
(b) False Positives;
(c) False Positives;
(d) True Negatives.

- Sensitivity: a/a+c x 100
- Specificity: d/d+b x 100
- PPV: a/a+b x 100
- NPV: d/c+d x 100

RESULTS

Study composed of 110 paients, among them 80 were males (72.2%) and 30 females (27.27%). the mean and standard deviation of age was observed as 33 ±16yrs (range: 18-60yrs). Three participants were excluded due to refusal from performing endoscopy just before start of procedure. Eighty (74.76%) out of 107 patients were positive for both histology and H.pylori stool antigen test. Eighty two (76.63%) patients had positive HpSA while it was negative in 28 (26.16%). Histopathological diagnosis was made in 83(77.57%) patients. The sensitivity and specificity were 96.3% and 91.66% respectively. Positive predictive value was in 97.56% while 88% had negative predictive value for H.pylori stool antigen test. Overall the diagnostic accuracy of this test was 94.4% for detection of infection.

	Histology Positive	Histology Negative
Stool H.pylori Test Positive	80(a)	2 (b)
Stool H.pylori Test Negative	3(c)	22(d)

Table-I. "2x2" table for calculating diagnostic accuracy of stool h.pylori test for diagnosing h. Pylori infection

- Sensitivity: 80/80+3 x 100 = 96.3
- Specificity: 22/22+2 x 100 = 91.66
- PPV: 80/80+2 x 100= 97.56
- NPV: 22/3+22 x 100= 88
- Diagnostic accuracy=80+22/80+22+2+3 = 94.4%

DISCUSSION

In the present study endoscopic antral biopsy and patient's stool for H. pylori antigen (HpSA) test were utilized as diagnostic tools and then results were compared keeping histopathology as gold standard.

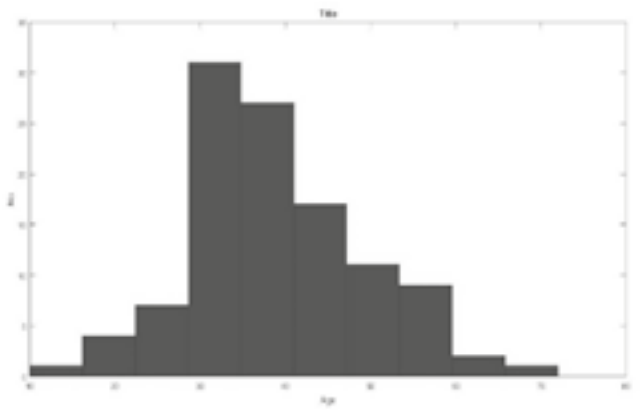

Figure-1. Age of the patients, majority (30-50years)

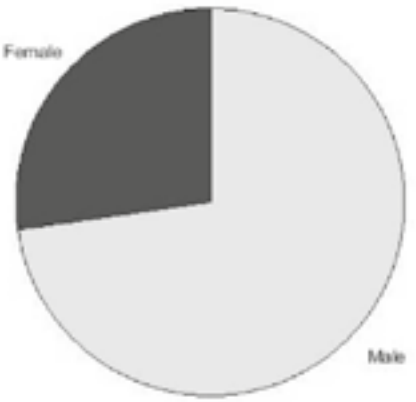

Figure-2. Gender distribution

Results showed that the histological test was mildly more accurate than H.pylori stool antigen test. HpSA had diagnostic accuracy of 94.4% for detection of this infection. The sensitivity and specificity of stool for H.pylori test in comparison to histopathological diagnosis was 96.3% and 91.66 % respectively in our study.

Our results were similar to many universal studies like Trevisani et al[11], they concluded that in treatment naïve patients H.pylori stool antigen test is an accurate tool for diagnosis of H.Plori infection. They used Rapid urease test (RUT) from gastric biopsies (invasive method) and H.pylori stool antigen test (non-invasive method) for detection of H.Pylori. Results showed that HpSA had 94% sensitivity and 90% specificity. In another study Li et al[12] demonstrated that HpSA was reliable, simple to perform and painless test for detection of H.pylori infection. It was 92.6% sensitive and 88.5% specific while diagnostic accuracy was 90.6%.

In a study conducted by Vaira et al[13] on treatment naïve patients, HpSA had sensitivity of 94% and specificity 92% for H.pylori detection. They analysed different results from variable tests like H. Pylori stool antigen tests, gastric biopsies for H.Pylori histology as well as culture, rapid urease test (RUT) and urea breath test. Almost similar results were found in a study by Tanaka et al[14], they found HpSA test useful and accurate for the rapid detection of Helicobactor pylori infection. In this study researchers made comparison of non-invasive test like HpSA with invasive tests like biopsy, culture and Rapid urease test (RUT). Results showed that the HpSA test was 98.3% sensitive and 95% specific.

In Pakistan Baqai et al[15] conducted a study on 43 treatment naïve patients in Karachi. Comparison was made between non- invasive methods like HpSA test and H.pylori IgG serology with an invasive test i.e. Campylobacter like organism (CLO) test. The sensitivity and specificity of H.pylori stool antigen test in this study was 65% and 76% respectively. This difference may be due to small sample size of the study, different testing techniques or dissimilar inclusion criteria.

CONCLUSION

We concluded that HpSA is an accurate, economical, painless, quick and easily performed test and as reliable as histopathology which is expensive, slow, requires team, difficult to perform and not available everywhere. It can be considered as a noninvasive first-line routine diagnostic test in our region.

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PREVIOUS RELATED STUDY

Farid Imanzadeh, Amir Imanzadeh, Ali Akbar Sayyari, Mehrnosh Yeganeh, Hazhir Javaherizadeh, Bizhan Hatamian. HELICOBACTER PYLORI INFECTION; IN CASES WITH AND WITHOUT SUBJECTIVE HALITOSIS (Original) Prof Med Jour 17(4) 543-545 Oct, Nov, Dec 2010.

Qurban Ali Khaskheli, Saleem A Kharal, Anjum Syed, Qazi Muhammad Rizwan, Muhammad Asif Durrani. SERODIAGNOSIS OF HELICOBACTER PYLORI INFECTION (Original) Prof Med Jour 9(2) 145-153 Apr, May, Jun, 2002.

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Dr. Adnan Qadir	Concept and design of study	
2	Dr. Irfan Younis	Data collection, Statistics, Manuscript writing	
3	Brig. Dr. Shahid Raza Khalid	Critical revision of article	
4	Dr. Zamir Butt	Data collection	
5	Dr. Shahid Sarwar	Drafting of articles	