

Validity and reliability of faecal antigen test in identifying h. Pylori infection in adults with dyspepsia

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Abstract

Background: H. Pylori is one of underdiagnosed and undertreated in many developing countries, including in India. Faecal antigen test, which is a noninvasive, simple to conduct screening test is reported to be ideal for resource limited settings like India. But the reported validity and reliability of the test is quite variable and studies on the subject in Indian population are scarce. **Objectives:** To assess the validity and reliability of faecal antigen test in diagnosis of H. Pylori in adult with dyspepsia. **Materials and methods:** The current study is a prospective observational study conducted in a single tertiary care teaching hospital located in south India. Adults between 20 to 49 years, with symptoms of dyspepsia were included. Giemsa staining of Antral mucosal biopsy specimen was considered as gold standard. Faecal antigen test was conducted by ELISA. Sensitivity, specificity, predictive values and reliability (kappa statistic) were assessed. **Results:** Faecal antigen positivity was seen in 57 (71.25%) subjects, The Antral mucosal biopsy has given 59 (73.8%) positive results, The sensitivity, Specificity of the faecal antigen test were 94.92% (95% CI 89.30 to 100.5%), 95.24% (86.12% to 104.3%) respectively. The positive and negative predictive values were 98.25% (94.83% to 101.6%) and 86.96% (73.19% to 100.7%) respectively. The overall diagnostic accuracy was 95% (90.22% to 99.77%). Reliability as measured by kappa statistic was 0.875 (P value <0.001). **Conclusions:** Faecal antigen test has shown good validity and reliability in diagnosis of H. pylori infection.

Keywords: Faecal antigen test, h. Pylori infection, validity and reliability

Introduction

Helicobacter. Pylori is implicated in wide range of gastro intestinal diseases, in all age groups [1]. These diseases range from benign condition like gastritis and peptic ulcer disease to malignant conditions like mucosa-associated lymphoid tissue (MALT) lymphoma and gastric cancer [2-5]. The reported burden of H. pylori infection across the globe is quite variable in different population groups. The socio demographic conditions, eating habits etc are reported to contribute to this variability [6,7]. But in majority of the developing countries, H.Pylori infection is considered as one of the most underdiagnosed and hence under treated conditions. In adequate resources and poor availability of the diagnostic tests is an important reason for this [8,9]. Various noninvasive, simple to perform and economical screening test have been evaluated for their utility in diagnosis of H. Pylori infection in these resource limited settings [10-12]. Out of this faecal antigen testing

by various methods has been specially touted as high utility screening test in large population groups and children [13, 14]. But the reported sensitivity, specificity of this screening method are quite varied across the studies [13-25]. Hence documenting the validity of this screening tool in a particular population group is essential to make appropriate recommendations for its routine use.

Objectives: 1) To assess the validity of faecal antigen test (by ELISA) in diagnosis of H.Pylori infection against antral mucosal biopsy. 2) To assess the reliability of the faecal antigen test in diagnosis of H. Pylori infection as compared to antral mucosal biopsy

Materials and Methods

Study Setting: The study was conducted in the department of General Surgery Chettinad Hospital and Research Institute, which is a tertiary care teaching hospital.

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Study design: The study was a prospective observational study.

Study population: The study subjects were patients with symptoms of gastritis and dyspepsia seeking treatment from general surgery outpatient department in the study setting.

Study duration: The data collection for the study was conducted between June 2014 to June 2016

Inclusion criteria:

- 1) All patients with gastritis and dyspeptic symptoms
- 2) Age group 15 – 50 years
- 3) Both genders

Exclusion criteria: Patients who are contraindicated for Upper Gastro Intestinal endoscopy.

Sampling method: All the eligible subjects who were willing to participate in the study were sequentially recruited in to the study by convenient sampling, till the required sample size is reached.

Study procedure: All the patients presenting to the OPD with symptoms of dyspepsia, satisfying inclusion and exclusion criteria were included in the study. After

thorough clinical history and physical examination, Upper gastro intestinal endoscopy and biopsy was taken from each participant. The specimen was stained with Giemsa staining and assessed for presence of H. Pylori. Stool sample was collected from each participant and was tested for Faecal H. Pylori Antigen by Enzyme linked Immunosorbent Assay (ELISA)

Ethical considerations: The study was approved by institutional human ethics committee. Informed written consent was obtained from all the study participants, after explaining the purpose of the study, the risk and benefits involved and voluntary nature of their participation. (Annexure II) Confidentiality of the study participants was maintained throughout the study period.

Statistical methods: The diagnosis of Pylori by the Giemsa staining was considered as the gold standard in the study. The diagnosis by faecal antigen testing was considered as the explanatory variable. The validity (sensitivity & Specificity) and predictive values of faecal antigen test in diagnosing H. Pylori were calculated along with their 95% CI. The reliability of Serum markers and urea breath test in diagnosing Pylori were assessed by calculating kappa statistic and it's p value. IBM SPSS statistical software version 21 was used for statistical analysis.

Observations & Results

A total of 80 participants were included in the final analysis.

Table1: Descriptive analysis of socio demographic variables in study group (N=80).

Age Groups	Sex		Total
	Male	Female	
20-29	19 (39.6%)	6 (18.8%)	25 (31.3%)
30-39	9 (18.8%)	10(31.3%)	19 (23.8%)
40-49	20(41.7%)	16(50.0%)	36(45.0%)
Total	48	32	80

Majority (60%) of the participants were males and females constituted about 40% of the study subjects. Both among males and females, subjects between 40 to 49 years constituted highest proportion (41.7% and 50% respectively). Among males 39.6% of the participants were between 20 to 29 years, whereas this proportion was only 18.8% in females. 30 to 39 year age group people constituted 18.8% of males and 31.3% of females. (Table1).

Table-2: Descriptive analysis of clinical variables in study group (N=80)

Parameter	Frequency	Percent
I. Faecal Antigen		
Positive	57	71.25%
Negative	23	28.75%
II. Antral Mucosal Biopsy		
Positive	59	73.75%
Negative	21	26.25%

Faecal antigen positivity was seen in 57 (71.25%) subjects, and the remaining 23 (28.75%) were reported negative. The Antral mucosal biopsy has given 59 (73.8%) positive results, with remaining 21 (26.3%) participants reported negative by Antral mucosal biopsy (Table 2).

Table-3: Association of clinical variables with Antral Mucosal Biopsy (N=80).

Faecal Antigen	Antral Mucosal Biopsy		Chi-Square Value	P value
	Positive	Negative		
Positive	56	1	61.450	<0.001
	98.25%	1.75%		
Negative	3	20		
	13.04%	86.96%		

There was strong positive association between the Faecal antigen and Antral mucosal biopsy in study population, which was statistically significant (P value < 0.01). There was strong positive association between the serum IgG and Antral mucosal biopsy in study population, which was statistically significant (P value < 0.01) (Table 3).

Table-4: Validity and predictive values of FAECAL ANTIGEN test in study population (N=80)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	94.92%	89.30%	100.5%
Specificity	95.24%	86.12%	104.3%
False positive rate	4.76%	-4.34%	13.87%
False negative rate	5.08%	-0.52%	10.69%
Positive predictive value	98.25%	94.83%	101.6%
Negative predictive value	86.96%	73.19%	100.7%
Diagnostic accuracy	95%	90.22%	99.77%

Faecal antigen had 94.92% sensitivity (95% CI 89.30 to 100.5%), 95.24% specificity (86.12% to 104.3%) in study population. The positive predictive value was 98.25% (94.83% to 101.6%) and the negative predictive value was 86.96% (73.19% to 100.7%) in study population. The overall diagnostic accuracy was 95% (90.22% to 99.77%) in study population (Table 4).

Table-5: Reliability of Faecal antigen test in diagnosing Pylori infection

Measure of Agreement	Value	Std. Error ^a	P value
Kappa	.875	.061	<0.001

The kappa statistic, which indicates the measurement of agreement between the two modalities (Faecal antigen and antral mucosal biopsy) was 0.875, which indicated high degree of agreement. This was statistically significant (P value <0.001)

Discussion

The current study, which was conducted in a group of dyspeptic adults presenting to a tertiary care teaching hospital had included participants ranging from 20 to 49 years. Males in the age group of 40 to 49 years were predominant in the study. Faecal antigen positivity was seen in 57(71.25%), whereas 59(73.8%) ah shown positivity in Antral mucosal biopsy. There was strong positive association between the Faecal antigen and

Antral mucosal biopsy (P value < 0.01). The results of both the tests indicate a high prevalence of H. Pylori infection and corroborate with the reported incidence range by various previous studies [1,6,26] The reported prevalence by various other Indian studies is quite varied [4,27,28]. In the current study, the sensitivity, Specificity of the Faecal antigen test were 94.92% (95% CI 89.30 to 100.5%), 95.24% (86.12% to 104.3%) respectively. The

positive and negative predictive values were 98.25% (94.83% to 101.6%) and 86.96% (73.19% to 100.7%) respectively. The overall diagnostic accuracy was 95% (90.22% to 99.77%). Reliability as measured by kappa statistic was 0.875 (P value <0.001). Study by Andrews J, who have compared validity of various stool antigen tests have documented sensitivity ranging from 56% to 97.6 and recommended fetal antigen testing as an alternative to urea breath test for screening of H.Pylori [29]. Calik Z, et al have reported 86.8% cases positive for H. pylori infection. The reported sensitivity, specificity, positive and negative predictive values were 92.45%, 81.25%, 97.02%, and 61.90%, respectively [15].

Falsafi T, have reported a sensitivity and specificity of 94%, 86% and 96%, 98%, respectively with two different stool antigen detection kits and emphasized the sustained reliability of different varieties of kits [16] Gramley WA, et al reported a sensitivity of 73% and specificity of 100% for stool antigen assay [17]. Guslandi M et al.[18] have reported sensitivity, specificity, and positive and negative likelihood ratios of HpSA to be 85%, 93%, 89.7%, and 90%, respectively as compared to culture [13]. Segamwenge IL [30], in contrast to the other studies have reported a low overall sensitivity of 55.8%, and specificity of 74.2%.

Miftahussurur M, et al [10] in their review have emphasized that Stool antigen test (SAT) is one of the best methods to determine active H.Pylori infection. Even though serology is more sensitive than stool antigen test, the major limitation is poor specificity and inability to distinguish active infection from previous infection. Shimoyama Tet al [31] in their review pointed out that, the performance of Stool antigen test is on par with serology, but cautioned that accuracy may be lower, if stool samples are unformed or watery.

Temperature and the interval between stool sample collection and measurement also reported to be affect the results of SATs. The choice of test kit depends on the sensitivity and specificity in each region and the circumstances of each patient. Queiroz DM, e reported a kappa coefficient of 0.90 (0.87 to 0.92), similar to the current study and concluded stool monoclonal as a reliable alternative for other screening tests [32].

Conclusions

1. Faecal antigen test has shown good validity and reliability in diagnosis of H.pylori infection
2. Considering its noninvasive nature and ease of conducting, this Faecal antigen test will be ideal choice in resource limited settings.

Limitations

1. Generalizability of the study findings to wider sections of the population is limited.
2. The validity and reliability in different subsections based on key determining variables like age, gender and socio economic status etc. could not be evaluated, considering the smaller sample size.

Recommendations

1. Faecal antigen test shows good reliability and validity and can be considered as useful screening test in resource poor settings.
2. Further large scale studies in diverse population groups in India may throw light on performance of the test in these groups and enhance the generalizability

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