Original Article

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Association of H. Pylori antibody Titer With Stool Antigen Test for Diagnosis of H. Pylori Infection in Patients with Dyspepsia.

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Abstract

Background: *Helicobacter pylori* infection remains a major public health concern in Bangladesh. Although serology is no longer recommended as a first-line diagnostic tool, it is still widely used in Bangladesh, leading to potential over-diagnosis and unnecessary treatment. The diagnostic utility of high antibody titers, however remains uncertain. In this context, it is unclear whether the antibody test should be abandoned or selectively used.

Objective: To assess the association between anti-*H. pylori* antibody titers and Stool Antigen Test for diagnosis of *H. Pylori* infection.

Methods: This cross-sectional observational study was conducted in the Department of Gastroenterology, BMU, from January to December 2024. A total of 125 dyspeptic patients were consecutively enrolled. Demographic, clinical, and laboratory data were analyzed. Stool Antigen Test and anti-*H. pylori* IgG (IMMULITE® 2000) were performed.

Results: The mean age of participants was 38.9 years; 62.6% were female. Stool Antigen Test was positive in 40.8% of patients, while IgG seropositivity was observed in 72%. Only patients with titers ≥3.0 U/mL showed a significant association with stool antigen positivity ($p < 0.01$). Correlation between anti-*H. pylori* antibody titers and Stool Antigen Test was weak ($r = 0.53$) and agreement between tests was fair ($\kappa = 0.22$).

Conclusion: The antibody test has limited diagnostic reliability when used alone and confirmatory testing with definite methods remains necessary for detection of H pylori infection in clinical practice.

Keywords: *Helicobacter pylori*, Stool Antigen Test, Anti-H. pylori IgG.

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Introduction:

Helicobacter pylori (H. pylori), is a major public health concern in Bangladesh, first identified by Warren and Marshall in 1983.[1] It is classified as a Group I carcinogen by the IARC and WHO for its role in gastric cancer. Eradication can reduce gastric cancer risk by up to 75%. [2,3] Globally, more than 50% of the population is infected, with higher prevalence in developing countries.[4,5] Bangladesh reports one of the highest rates in Asia, ranging from 86% to over 92% in various studies.[6,7,8]

But the current healthcare system faces several challenges in its diagnosis. Though current international guidelines do not recommend H. pylori antibody test as a first-line diagnostic tool but it remains widely used in Bangladesh due to its affordability, simplicity and availability.[9,10] However, this practice leading to potential over-diagnosis, unnecessary antibiotic prescriptions and impose financial burdens on patients. Despite its limitations, antibody test remains attractive in many clinical settings and it is unclear whether it should be completely discontinued or retained for selective use in specific circumstances. An important unanswered question is whether a high anti-H. pylori antibody titer could serve as a useful indicator of active infection.

This study was designed to address this critical gap by evaluating the relationship between anti-H. pylori antibody titers and the results of stool antigen test in patients with dyspepsia.

Methods:

This was a cross-sectional observational study carried out at Department of Gastroenterology, Bangladesh Medical University (BMU), a tertiary care hospital in Dhaka. The study took place from January 2024 to December 2024. After approval from the BMU Institutional Review Board (IRB).

A total of 125 patients aged 18 years or older presenting with dyspepsia were enrolled using a consecutive sampling method. Informed written consent was obtained from all participants. Patients with predominant reflux symptoms, recent use of PPI or antibiotics, regular NSAID/steroid intake, history of gastric surgery or malignancy, major comorbidities or pregnancy were excluded.

Stool antigen test and anti-H. pylori IgG antibody titer were carried out in the Department of Microbiology at BMU on an outpatient basis. Fresh stool samples were collected from all dyspeptic patients in sterile containers for the stool antigen test, which was conducted using a one-step chromatographic immunoassay (CerTest Biotec S.L., Spain). Additionally, 5 ml of venous blood was collected from each patient by a lab technician and transferred to the laboratory within 4 hours. The anti-H. pylori IgG antibody titer was measured using a chemiluminescent immunoassay system (IMMULITE 2000 XPi) in the Department of Microbiology at BMU. The measurable titers ranged from 0.4 U/mL to 8 U/mL, with the manufacturer recommending a cut-off value of 1.1 U/mL for H. pylori positivity. In this study, subjects were divided into four groups based on their serum antibody titer as follows: Group A: Titer < 1.1 U/mL (negative), Group B: 1.1-2.9 U/mL (low-positive), Group C: 3-4.9 U/mL (positive) and Group D: ≥ 5 U/mL (high-positive) [11].

Data was collected from all eligible participants using a structured data collection sheet. Information encompassed socio-demographic variables (age, gender, occupation, educational status), clinical characteristics (symptoms, medical history) and laboratory parameters (blood investigations and other diagnostic tests).

Data were cleaned and analyzed using Python-based software. Continuous variables were expressed as mean ± SD, categorical variables as percentages. Associations were assessed using Chi-square, while correlations between antibody titer and active infection were assessed using Spearman's rank and Cohen's kappa. A P-value <0.05 was considered significant.

Results:

In this study, the demographic and clinical profiles of 125 dyspeptic patients were evaluated. The mean age was 38.88 years, with 28% aged between 38 and 47 years; females comprised 62.6% of the cohort. Stool Antigen Test was positive in 40.8% of patients. Anti-H. pylori IgG seropositivity was observed in 72% of participants. Antibody titers were categorized as: Group A (<1.1 U/mL), Group B (1.1–2.9 U/mL), Group C (3.0–4.9 U/mL) and Group D (≥ 5.0 U/mL). Only Group C and D demonstrated a significant association with Stool Antigen Test positivity ($p < 0.01$). A weak correlation was observed between antibody titers and Stool Antigen Test positivity ($r = 0.53$). Cohen's kappa coefficient ($\kappa = 0.22$) indicated a fair agreement between serology and Stool Antigen Test.

Table -I. Demographic distribution of the participants (N=125).

Variable	Category	Frequency	Percentage
Mean age		38.8±10.9	
Age groups	≤18-27 years	34	27.2
	28-37 years	31	24.8
	38-47 years	35	28.0
	48-57 years	23	18.4
	≥58 years	2	1.6
Gender			
	Male	47	37.4
	Female	78	62.6
Occupation			
	Service	26	20.8
	Businessman	14	11.2
	Housewife	43	34.4
	Student	14	11.2
	Drivre	05	4.0
	Garments worker	16	12.8
	Farmer	07	5.6
Education			
	No formal education	6	4.8
	Primary	17	13.6
	Secondary	42	33.6
	Higher Secondary	30	24.0
	Graduation and above	30	24.0
Family income			
	< 20,000tk	30	24.0
	20,000-40,000 tk	57	45.6
	>40,000 tk	38	30.4
Smoker			
	Yes	49	39.2
	No	76	60.8

Participant characteristics showed a mean age of 38.8 ± 10.9 years, predominance of females (62.6%), most were housewives (34.4%) or service holders (20.8%), one-third had secondary education, 45.6% had monthly income 20,000–40,000 taka and 39.2% were smokers (Table -I).

Table -II. Comparison of Stool antigen-positive participants with different groups of Antibody titer.

Antibody titer Groups	Stool Ag Positive (%)	Stool Ag Negative (%)	P Value
A	8 (21.1)	30 (78.9)	0.0003
B	11 (25.6)	32 (74.4)	0.0029
C	14 (73.7)	5 (26.3)	0.0001
D	18 (72.0)	7 (28.0)	0.0001
Total (125)	**51 (40.8)**	**74 (59.2)**	**0.0001**

*Chi-square test

Stool antigen positivity was observed in 40.8% of participants, with significantly higher rates in antibody titer Groups C (73.7%) and D (72.0%) compared to Groups A and B ($p < 0.01$, Chi-square test). (Table-II).

Table -III. Pairwise comparison of Stool Ag positivity between antibody titer Groups.

Comparison of Antibody titer grades	% of Stool Ag +ve	% of Stool Ag -ve	P value
A vs B	21.1	25.6	0.631
A vs C	**21.1**	**73.7**	**0.001**
A vs D	**21.1**	**72.0**	**0.001**
B vs C	**25.6**	**25.6**	**0.004**
B vs D	**25.6**	**72.0**	**0.002**
C vs D	73.7	72.0	0.901

*Chi-square test with Bonferroni correction

Higher antibody titer groups (C and D) were significantly associated with stool antigen positivity compared to lower titer groups (A and B) ($p < 0.05$, Bonferroni-adjusted $p < 0.0083$), indicating a strong link with active H. pylori infection (Table -III)

Table -IV. Correlation between H.Pylori antibody titer with Stool Antigen test.

Correlations of tests	Correlation Values	P Value
Antibody titer vs Stool antigen test	0.53	$P < 0.01$

*Spearman's rank correlation

H. pylori antibody titer showed a moderate but significant correlation with the stool antigen test ($r = 0.53$, $p < 0.01$) (Table- IV).

Table -V. Cross-tabulation and Cohen's Kappa agreement statistics between antibody test and stool antigen positive

Antibody titer	Stool antigen		Total
	Positive	Negative	
Positive (Group B,C,D)	43	44	87
Negative (Group A)	8	30	38
Total	51	74	125
Observed Agreement (Po)			0.584
Expected Agreement (Pe)			0.464
Cohen's Kappa (κ)			0.22

Comparison of antibody and stool antigen tests showed fair agreement ($\kappa = 0.22$, Po = 58.4%), indicating limited reliability of the antibody test alone (Table -V).

Discussion:

This study provides an updated demographic and clinical profile of dyspeptic patients in Bangladesh. The mean age was 38.9 years, with the majority (28%) aged 38–47 years, consistent with prior studies [7,12]. Approximately 45.6% of participants reported a monthly income of 20,000–40,000 BDT, suggesting socioeconomic influences on dietary habits and healthcare access. The high smoking prevalence (39.2%) highlights the role of modifiable lifestyle factors in dyspeptic patients.

Regarding *Helicobacter pylori,* seropositivity was 72%, corresponding to recent regional reports [7,13] and indicating a declining trend from previously reported rates of 92%[6], likely due to improved sanitation and widespread eradication therapy. Stool Antigen Test (SAT) positivity was observed in 40.8% of participants, with higher antibody titer groups (C and D) showing greater concordance with active infection. However, the moderate correlation between antibody titers and stool antigen ($r = 0.53$, $p < 0.01$) and fair agreement by Cohen's kappa ($\kappa = 0.22$), emphasizes the limited diagnostic reliability of serological assays when used in isolation.

Clinical implications:

Commercial serological tests demonstrate inferior performance compared with the Stool Antigen Test. Serology alone is not a reliable marker of *H. pylori* infection, although higher titers show a statistically significant association.

Strengths and Limitations:

This study highlights the diagnostic value of antibody titers against stool antigen test in a Bangladeshi cohort. However, its single-center design, absence of H. pylori culture and restriction to one geographical region may limit generalizability.

Conclusion:

Anti-H. pylori serology alone has limited diagnostic value. High antibody titers may indicate active infection, but confirmatory testing remains essential for accurate diagnosis in clinical practice.

Recommendations:

Multi-center studies are needed to validate serological tests for H. pylori and define population-specific cutoff values. Assays based on indigenous strains may improve diagnostic accuracy. Expanding access to stool antigen and urea breath tests can reduce reliance on endoscopy.

Conflict of Interest: There is no conflict of interest.

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