Section: General Surgery

Original Research Article

COMPARATIVE EVALUATION OF H. PYLORI BY RAPID SEROLOGY TEST AND ANTRAL BIOPSY IN ACID PEPTIC DISEASE

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Received *: 27/05/2025*
Received in revised form *: 08/07/2025*
Accepted *: 30/07/2025*

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DOI: 10.70034/ijmedph.2025.3.237

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (3); 1283-1286

ABSTRACT

Background: The discovery of Helicobacter pylori (H. pylori) significantly changed the understanding of upper gastrointestinal diseases by showing that this Gram-negative, spiral-shaped bacterium can survive in the acidic environment of the human stomach.[1]

Materials and Methods: Study Design and Setting: This prospective diagnostic study was executed in the Department of General Surgery at PES Institute of Medical Sciences and Research (PESIMSR), Kuppam. The research spanned a six-month duration and adhered to institutional protocols and ethical standards. **Study Population and Sample Size:** The study enrolled 100 patients presenting with clinical features suggestive of acid peptic disease (APD). A purposive sampling technique was employed to recruit individuals who fulfilled specific eligibility criteria.

Results: The rapid antibody test demonstrated excellent clinical performance, showing a perfect specificity (100%) and positive predictive value (100%), along with acceptable diagnostic accuracy (84%) and moderate sensitivity (74%).

Conclusion: The research supports rapid serum antibody testing as a beneficial and non-invasive method to detect H. pylori infection which promotes clinical practice. The test demonstrates extraordinary specificity and high positive predictive value which make it a powerful official diagnostic instrument for H. pylori detection within Indian H. pylori hotspots.

Keywords: Helicobacter pylori, Acid peptic disease (APD), Histopathological examination, Rapid serological tests, Diagnostic accuracy.

INTRODUCTION

The discovery of Helicobacter pylori (H. pylori) significantly changed the understanding of upper gastrointestinal diseases by showing that this Gram-negative, spiral-shaped bacterium can survive in the acidic environment of the human stomach.[1] Since then, H. pylori have been firmly established as the main cause of acid peptic disease (APD), including chronic gastritis and peptic ulcer disease (PUD).[2]

Medical research has identified the persistent colonization of Helicobacter pylori as the primary risk factor for the development of gastric mucosa-associated lymphoid tissue (MALT) lymphoma.[3] Furthermore, the International Agency for Research on Cancer has classified H. pylori as a Group I carcinogen, recognizing its well-established role in the pathogenesis of gastric adenocarcinoma.[4] When acquired during childhood, H. pylori infection often leads to lifelong colonization if left untreated, thereby contributing significantly to the burden of chronic gastrointestinal diseases.

Epidemiological studies consistently identify Helicobacter pylori as one of the most widespread and persistent bacterial infections globally, colonizing approximately 50% of the world's population.[5] However, its prevalence exhibits considerable geographic variability, shaped by a complex interplay of socioeconomic conditions, public health infrastructure, sanitation standards, and population demographics, particularly age-related factors.[6,7] While industrialized nations report relatively low prevalence rates, often below 40%,

developing countries continue to experience significantly higher rates, frequently exceeding 70–80%. India represents a notable example, with a substantial national burden of H. pylori infection. Regional studies across the country have documented prevalence rates surpassing 50%, and in some cases exceeding 80%, depending on the diagnostic techniques employed and the characteristics of the study populations.[8,9,10] This substantial local burden necessitates the implementation of context-specific diagnostic and therapeutic strategies to effectively manage and reduce H. pylori-associated morbidity.

Successful treatment and prevention of acid peptic disease (APD) depend on accurate detection and complete eradication of Helicobacter pylori, as this approach promotes ulcer healing, reduces recurrence risk, and lowers the likelihood of gastric cancer development.[3,11] Diagnostic methods for H. pylori are broadly divided into invasive and non-invasive categories. Invasive diagnosis requires the collection of gastric mucosal biopsies via endoscopy, followed by tests such as rapid urease testing (RUT), serological tests, bacterial culture, and histopathological examination.[12] Among these, histology is the most frequently used for confirming infection, as it allows direct visualization of the bacteria and concurrent evaluation of gastric mucosal inflammation and structural changes.[13,14] However, the need for endoscopy limits the application of invasive methods in primary care settings, particularly in resource-limited environments, due to procedural complexity, cost, and lack of specialized equipment.

Rapid immunochromatographic assays that detect Helicobacter pylori–specific IgG and IgA antibodies in serum offer a simple, cost-effective, and time-efficient diagnostic tool, particularly suitable for large-scale screening and resource-limited settings [15]. While these tests are valuable for identifying prior exposure to H. pylori, they are limited by their inability to differentiate active infection from past, resolved cases, as antibodies may persist long after bacterial clearance.[13,15] The diagnostic accuracy of serological assays varies significantly among commercially available kits, largely due to differences in antigenic components, regional genetic variability of H. pylori strains, and host immune response diversity.[16]

Accurate diagnosis of Helicobacter pylori infection requires careful evaluation of both rapid serological assays and histopathological findings, particularly in high-prevalence regions such as India. This study aims to conduct a comparative analysis of rapid serological tests and histopathological examination of antral biopsy specimens in patients clinically diagnosed with acid peptic disease (APD). The primary objective is to assess the diagnostic reliability of rapid serological methods for detecting H. pylori infection, using histopathology as the reference standard.

Clinicians working in resource-constrained settings must adopt diagnostic strategies that balance test performance characteristics—such as sensitivity and specificity—with considerations of feasibility, cost-effectiveness, and clinical applicability. Although histopathological examination offers high diagnostic accuracy for Helicobacter pylori infection, its widespread use is limited by logistical and procedural challenges. Therefore, evaluating the validity of serological methods against histopathology in Indian patients with acid peptic disease (APD) is essential for establishing evidence-based diagnostic protocols. Such validation can support timely, accurate diagnosis and improve treatment outcomes in high-burden populations.

MATERIALS AND METHODS

Study Design and Setting

This prospective diagnostic study was executed in the Department of General Surgery at PES Institute of Medical Sciences and Research (PESIMSR), Kuppam. The research spanned a six-month duration and adhered to institutional protocols and ethical standards.

Study Population and Sample Size

The study enrolled 100 patients presenting with clinical features suggestive of acid peptic disease (APD). A purposive sampling technique was employed to recruit individuals who fulfilled specific eligibility criteria.

Selection Criteria

Inclusion Criteria

- Adults aged 18 to 65 years
- Clinical symptoms indicative of APD, such as heartburn, dyspepsia, or epigastric discomfort
- Patients who underwent both serological and endoscopic diagnostic evaluation for Helicobacter pylori
- Written informed consent obtained prior to participation

Exclusion Criteria

- Prior treatment for H. pylori eradication
- Diagnosis and therapy for H. pylori infection in the previous six months
- Coexisting gastrointestinal disorders likely to confound diagnostic interpretation
- Immunocompromised individuals or those receiving immunosuppressive therapy
- Patients unwilling to provide informed consent

Specimen Collection

- Under sterile conditions, 3 ml of venous blood was collected for rapid serological testing.
- Gastric biopsy specimens were obtained during upper GI endoscopy and sent for histopathological evaluation.

Diagnostic Procedures

1. **Serological Testing:** Blood samples were analyzed using a double antigen sandwich immunoassay to detect *H. pylori*-specific IgG and IgM antibodies.[15,16]
2. **Histopathology**
   Biopsy specimens were processed using

standard histological protocols to identify *H. pylori* organisms and assess gastric mucosal inflammation.[13,14]

Data Management and Statistical Analysis

Upon ethical clearance and informed consent, demographic and clinical data were collected and digitized using Microsoft Excel 2016. Statistical analyses were performed using SPSS v23.0 (SPSS Inc., Chicago, USA).

Descriptive statistics summarized categorical variables as percentages and continuous variables as means ± standard deviations. Inferential analysis used Chi-square and Student's t-tests where appropriate. Sensitivity, specificity, PPV, NPV, diagnostic accuracy, and Cohen's kappa coefficient were calculated to evaluate the concordance between the rapid antigen test and histopathology. Statistical significance was defined as $p < 0.05$.

Ethical Considerations

The Institutional Human Ethics Committee at PESIMSR approved the study protocol. All participants provided written informed consent after a thorough explanation of study objectives and procedures.

RESULTS

Out of 100 enrolled participants, all underwent both endoscopic biopsy and rapid serology testing for H. pylori detection.

Table 1: Age-wise Distribution of H. pylori Detection by Biopsy and Rapid Antibody Test

Age Group	Biopsy Positive	Biopsy Negative	Rapid Antibody Positive	Rapid Antibody Negative
11–20 yrs	3	2	1	4
21–30 yrs	12	11	11	12
31–40 yrs	3	8	3	8
41–50 yrs	20	10	12	18
51–60 yrs	15	3	12	6
61–70 yrs	9	4	7	6

The 41–50 and 51–60-year age groups recorded the highest biopsy positivity, indicating a peak prevalence among middle-aged adults.

Table 2: Frequency of Presenting Symptoms

Chief Complaint	Frequency	Percentage (%)
Epigastric Pain	75	75.0%
Heart Burn	63	63.0%
Bloating	62	62.0%
Nausea/Vomiting	16	16.0%
Dysphagia	3	3.0%
Hematemesis	1	1.0%

Table 3: Diagnostic Concordance Between Biopsy and Rapid Antibody Test

	Biopsy Positive	Biopsy Negative	Total
Antibody Positive	46 (TP)	0 (FP)	46
Antibody Negative	16 (FN)	38 (TN)	54
Total	**62**	**38**	**100**

Diagnostic Indices:

- Sensitivity = 74%
- Specificity = 100%
- PPV = 100%
- NPV ≈ 70%
- Overall Accuracy = 84%
- Cohen's Kappa = 0.686 (substantial agreement)

DISCUSSION

This study evaluated the diagnostic performance of a rapid antibody test for detecting Helicobacter pylori infection by comparing it with histopathological examination of antral biopsy specimens in patients with acid peptic disease (APD). The rapid antibody test demonstrated excellent clinical performance, showing a perfect specificity (100%) and positive predictive value (100%), along with acceptable diagnostic accuracy (84%) and moderate sensitivity (74%). These results support its diagnostic reliability, particularly in identifying true-positive cases.

The highest prevalence of H. pylori infection was observed among individuals in the fourth to sixth decades of life, aligning with both national trends reported in Indian studies,[8,9] and global observations in developing countries.[5,6] In contrast, improved sanitation and better healthcare infrastructure in industrialized nations contribute to significantly lower infection rates.[7]

Consistent with findings by Singh et al,[9] epigastric pain was the most common presenting symptom, occurring in 75% of participants. Belching and bloating were also frequent complaints, while complications such as hematemesis were rare, likely due to the predominance of uncomplicated APD in this cohort. This contrasts with Makaju et al,[10] who reported more severe clinical presentations.

The 74% sensitivity of our rapid antibody test was lower than the pooled sensitivity reported in meta-

analyses (e.g., Gisbert et al,[17]: ~94%), potentially due to regional strain variation or differences in sample processing. To reduce the risk of false negatives, patients with recent antibiotic use were excluded from analysis.[18] Despite the moderate sensitivity, the test's perfect specificity outperforms typical values associated with stool antigen tests,[17,19] suggesting its utility in confirming active infection.

Our findings also highlight the superior specificity of the antibody test when compared to conventional serological assays. Studies by Loy et al,[16] and Chey et al,[21] report serological specificity ranging from 82% to 90%, with limitations in distinguishing active from past infections,[15] As such, the antibody test, while useful for confirming infection, must be interpreted with caution when used to rule out H. pylori.

Histopathological examination confirmed H. pylori infection in 62% of participants, a prevalence consistent with previous Indian data [8, 9]. The study utilized a multi-site biopsy protocol to minimize the risk of sampling errors, thereby enhancing diagnostic accuracy.[14] The Cohen's kappa coefficient for agreement between the two methods was 0.686, indicating substantial agreement and corroborating the findings of Patel et al.[13]

Given its strong specificity and ease of use, the rapid antibody test presents a viable diagnostic option for use in resource-limited settings where endoscopy is not feasible.[22]

Strengths and Limitations

This investigation benefits from using a prospective research method in a genuine clinical practice while employing strict patient selection criteria. The 100% PPV affirms its diagnostic reliability. The moderate detection capability of this test together with a limited study participant number constrains its ability to be widely used. The rate of H. pylori strain prevalence across different regions affects testing accuracy as reported by Garza-González et al.[12]

CONCLUSION

The research supports rapid serum antibody testing as a beneficial and non-invasive method to detect H. pylori infection which promotes clinical practice. The test demonstrates extraordinary specificity and high positive predictive value which make it a powerful official diagnostic instrument for H. pylori detection within Indian H. pylori hotspots. This study develops a practical diagnostic method that utilizes rapid tests first followed by endoscopy only when preliminary screening results are indeterminate or treatment proves ineffective. Research should explore the geographical variations of antigens in addition to developing non-invasive diagnostic methods to achieve fair and accurate timing of acid peptic disease management.[3,12,17,20]

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