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Research Article

A Comparative Study of Invasive Endoscopic Biopsies Vs Noninvasive Antibody Test Kit Method for Detection of H. Pylori

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ABSTRACT

Helicobacter pylori infection affects approximately half of the global population and represents a significant public health concern due to its established role in gastric pathology including chronic gastritis, peptic ulcers, and gastric cancer. Accurate detection is crucial for effective management and prevention of complications.

Objective: To compare the diagnostic performance of invasive histopathological methods versus non-invasive serological testing for H. pylori detection and to assess gastric mucosal changes using the Sydney grading system.

Methods: A prospective cross-sectional study was conducted on 40 patients presenting with dyspeptic symptoms at MGM Medical College, Navi Mumbai from July 2023 to January 2025. Gastric biopsies were subjected to three histopathological staining methods: Hematoxylin and Eosin (H&E), Giemsa, and Warthin-Starry stains. Gastric mucosal changes were graded according to the Sydney system. Serum antibody testing was performed as the non-invasive method. Diagnostic performance parameters including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated.

Results: Among invasive methods, Warthin-Starry stain demonstrated the highest detection rate (90.0%), followed by Giemsa stain (82.5%) and H&E stain (75.0%). All patients (100%) tested positive by at least one invasive method. Serum antibody testing showed remarkably poor performance with only 7.5% positive results, demonstrating 100% specificity but extremely low sensitivity (10%) when compared to H&E staining. Agreement between invasive and non-invasive methods was only 7.5%. Sydney grading revealed moderate to marked chronic inflammation in 72.5% of cases, with intestinal metaplasia present in all cases.

Conclusion: Invasive histopathological methods, particularly Warthin-Starry staining, demonstrated superior diagnostic performance compared to non-invasive serological testing for H. pylori detection in this population. The poor correlation highlights the limitations of serology and supports the use of invasive diagnostic approaches when accurate H. pylori detection is crucial for patient management.

Keywords*: Helicobacter pylori, histopathology, Giemsa stain, Warthin-Starry stain, serology, Sydney grading system, chronic gastritis, intestinal metaplasia, diagnostic accuracy.*

INTRODUCTION

Helicobacter pylori is the leading cause of chronic gastritis and can lead to a range of serious gastroduodenal conditions in some individuals, including gastric and duodenal peptic ulcers, gastric cancer, and gastric mucosa-associated lymphoid tissue (MALT) lymphoma. These varied outcomes result from complex interactions among bacterial virulence factors, host genetic predispositions, and environmental influences.[1] This typically chronic infection is believed to play a critical role

in the development of peptic ulcer disease and gastric adenocarcinoma. Helicobacter pylori, the most prevalent and well-recognized bacterium of its kind, is carried by over half of the global population.[2]

As reported by the World Gastroenterology Organization (2021), Helicobacter pylori infection affects around half of the world's population. Its prevalence varies significantly based on geographic location, ethnicity, race, age, and socioeconomic status, with higher rates observed in developing nations. Notably, substantial variation exists not only between countries but also within countries, cities, and even among different subpopulations.[3] A wide range of invasive and noninvasive techniques have been developed for the diagnosis of H. pylori, many of which are now routinely used in clinical practice.[4]

For individuals not undergoing gastroscopy, serological testing offers a convenient method for detecting H. pylori infection by identifying circulating antibodies. However, this method cannot differentiate between an active infection, harmless colonization, or previous exposure to H. pylori.[5] Additionally, PCR is crucial for detecting point mutations linked to antibiotic resistance in H. pylori, as well as identifying important virulence factors like CagA and VacA.[6] The accurate detection of H. pylori is essential for appropriate clinical management and represents a significant diagnostic challenge in contemporary gastroenterology practice.

METHODOLOGY

This prospective cross-sectional study was conducted at the Department of Pathology, MGM Medical College and Hospital, Navi Mumbai, from July 2023 to January 2025. The study included 40 patients aged 18-75 years presenting with clinically suspected gastritis symptoms. Patients with inadequate biopsy specimens or those unwilling to provide consent were excluded from the study.

Inclusion criteria -

1. Age group 18-75 years
2. Gender - Male and female
3. Suspected H.pylori

Exclusion criteria -

1. Patients with inadequate, improper, unpreserved biopsies.
2. Patients not willing to give consent.

Procedure

All endoscopic gastric mucosal biopsies were collected from various sites and submitted to the histopathology laboratory in 10% buffered formalin. The specimens were properly oriented and embedded, then processed through graded alcohol for dehydration, cleared in xylene, and embedded in paraffin. Thin sections of 3 μm thickness were cut using a rotary microtome and stained with three different methods: Haematoxylin and Eosin (H&E), Warthin-Starry, and Giemsa stains. Each biopsy was examined for morphological changes with particular attention to chronic inflammation, activity, atrophy, and intestinal metaplasia, along with identification of Helicobacter pylori using the Sydney grading system.

For the non-invasive method, serum samples were collected and tested using the H. pylori Ab Combo Rapid Test, a lateral flow chromatographic immunoassay for qualitative detection of antibodies (IgG, IgM, and IgA) against Helicobacter pylori. The test was performed according to manufacturer instructions, with results read at 15 minutes for positive cases and confirmed at 20 minutes for negative cases. Statistical analysis was performed using SPSS version 24, with sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) calculated for different detection methods. Chi-square test was used for categorical variables, with $p<0.05$ considered statistically significant.

ETHICAL CLEARANCE

The study protocol was approved by the Institutional Ethics Committee (IEC), MGM Medical College, Kamothe Navi Mumbai (Approval No. DHR-EC/SC/ 2023/06/119). Patient confidentiality was maintained throughout the study.

RESULTS

The study population was analyzed for demographic characteristics, clinical presentation, and diagnostic performance of various H. pylori detection methods. Invasive methods included three histopathological staining techniques (H&E, Giemsa, and Warthin-Starry), while the non-invasive method involved serum antibody testing. Gastric mucosal changes were systematically graded using the Sydney classification system. Diagnostic performance parameters were calculated using H&E stain as the reference standard for comparison with other methods.

Table 1: Demographic and Clinical Characteristics

Parameter	Category	Number (n)	Percentage (%)
Age Distribution	18-30 years	12	30.0
	31-50 years	14	35.0
	51-75 years	14	35.0
Gender	Male	15	37.5
	Female	25	62.5
Presenting Symptoms	Epigastric pain	8	20.0
	Nausea	9	22.5
	Vomiting	10	25.0
	Heartburn	5	12.5
	Bloating	8	20.0

Table 2: H. pylori Detection Rates by Different Methods

Detection Method	Positive n (%)	Negative n (%)	Total
H&E Stain	30 (75.0)	10 (25.0)	40
Giemsa Stain	33 (82.5)	7 (17.5)	40
Warthin-Starry Stain	36 (90.0)	4 (10.0)	40
Any Invasive Method	40 (100.0)	0 (0.0)	40
Serum Antibody Test	3 (7.5)	37 (92.5)	40

Table 3: Sydney Grading System Results

Parameter	Grade	Number (n)	Percentage (%)
Chronic Inflammation	Mild	11	27.5
	Moderate	15	37.5
	Marked	14	35.0
H. pylori Colonization	Mild	12	30.0
	Moderate	13	32.5
	Marked	15	37.5
Intestinal Metaplasia	Mild	9	22.5
	Moderate	16	40.0
	Marked	15	37.5
Atrophy	Mild	22	55.0
	Moderate	11	27.5
	Marked	7	17.5

Table 4: Diagnostic Performance Analysis Using H&E as Reference Standard

Test Method	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Agreement with H&E (%)
Giemsa Stain	93.3	50.0	84.8	71.4	82.5
Warthin-Starry Stain	96.7	30.0	80.5	75.0	80.0
Serum Antibody Test	10.0	100.0	100.0	27.0	32.5

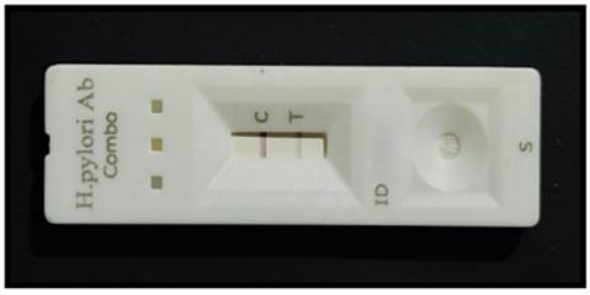

FIGURE1: RAPID ANTIBODY TEST–POSITIVE.

FIGURE2: RAPID ANTIBODY TEST–NEGATIVE

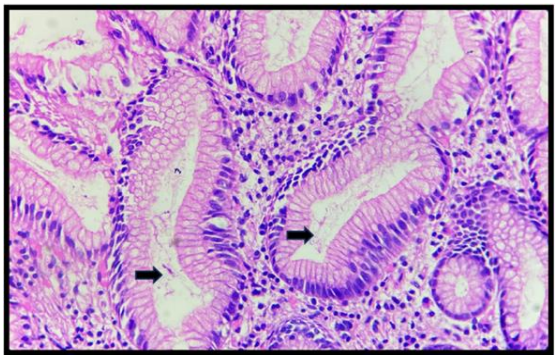
FIGURE3: H&E STAIN–H.pylori gastritis

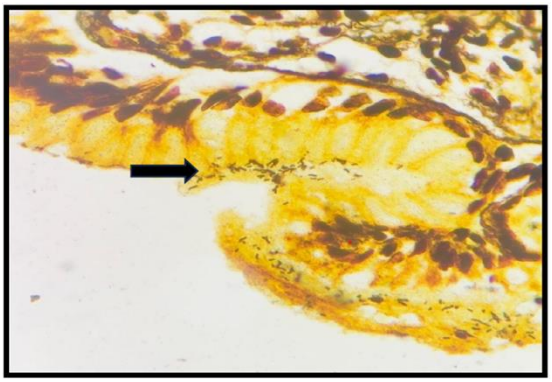
FIGURE4: WARTHIN STARRY STAIN–H.pylori gastritis

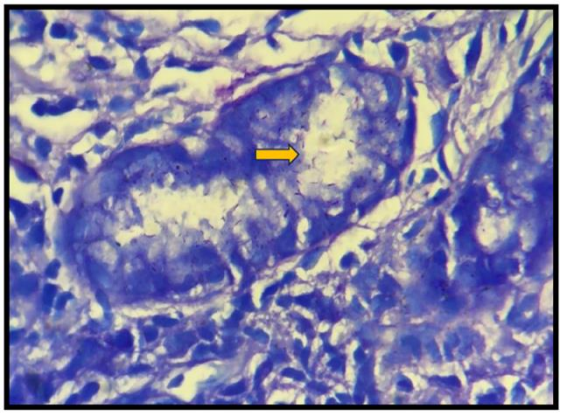
FIGURE5: GIEMSA STAIN–H.PYLORI POSITIVE (OIL IMMERSION)

The demographic analysis revealed a relatively even age distribution with female predominance (62.5%). Vomiting was the most common presenting symptom (25%), followed by nausea (22.5%). Among invasive methods, Warthin-Starry stain achieved the highest detection rate (90%), while serum antibody testing showed remarkably poor performance with only 7.5% positive results. The Sydney grading system revealed significant gastric pathology with 72.5% showing moderate to marked chronic inflammation and all patients demonstrating some degree of intestinal metaplasia. Agreement between

invasive and non-invasive methods was extremely poor at only 7.5%, highlighting the inadequacy of serological testing in this population.

DISCUSSION

The findings of this study demonstrate clear superiority of invasive histological methods over non-invasive serology for accurate H. pylori detection, with important implications for clinical practice and diagnostic strategy formulation. The superior performance of Warthin-Starry stain observed in our study (90% detection rate) aligns with previous research demonstrating its reliability for H. pylori detection. Cutler AF et al.[7] reported that Warthin-Starry stain provides excellent sensitivity and specificity for H. pylori detection, while Lee and Kim[8] found that H&E stain sensitivity ranges from 69-93% with specificity of 87-90%, which closely matches our H&E results of 75% sensitivity. The relatively poor performance of H&E stain in our study is consistent with findings from multiple studies, where a multi-pathologist evaluation study reported very poor sensitivity (66%) and suboptimal specificity (88%) for H&E stain in H. pylori identification.[9] This reduced sensitivity is particularly problematic in cases with low bacterial density or when atrophic mucosal changes are present, conditions where specialized stains become essential for accurate diagnosis.

The serum antibody test demonstrated remarkably poor performance in our study, with only 7.5% positive results compared to 100% positivity using invasive methods, which is consistent with several recent studies questioning the reliability of serology for H. pylori diagnosis. Omar et al.[10] in their systematic review and meta-analysis of non-invasive tests in elderly patients reported that serology showed the lowest diagnostic odds ratio (14.2) compared to urea breath test (94.5) and stool antigen test (47.9). The poor specificity of serology (73.3%) in their study aligns with our findings of inadequate performance. Hussein RA et al.[6] examined various methods in Iraqi patients and found that the 14C-UBT displayed the best overall performance with sensitivity of 97.5%, specificity of 97%, and total accuracy of 97.3%, followed by stool antigen test, rapid urease test, CagA-IgG, and culture methodologies. Several factors may contribute to the poor serological performance in our population, including the timing of antibody response, cross-reactivity with other bacterial antigens, and population-specific variations in immune response.

The application of the Sydney grading system in our study provided comprehensive evaluation of gastric mucosal changes associated with H. pylori infection, revealing significant inflammatory response in the majority of cases with 72.5% showing moderate to marked chronic inflammation. The high percentage of moderate to marked intestinal metaplasia (77.5%) is concerning, as this represents an advanced premalignant lesion in the gastric carcinogenesis cascade. Studies have shown that intestinal metaplasia significantly increases the risk of gastric adenocarcinoma development.[11] The clinical implications of our findings support the recommendation for routine use of specialized stains in H. pylori diagnosis, particularly in populations with high prevalence of advanced gastric pathology. The poor performance of serology in our population raises questions about the applicability of test-and-treat strategies that rely on non-invasive testing, suggesting that endoscopic diagnosis may be necessary for reliable detection in certain populations, which has cost implications but may be justified by improved diagnostic accuracy.

CONCLUSION

This comparative study demonstrates the clear superiority of invasive histological methods over non-invasive serology for accurate Helicobacter pylori detection. Warthin-Starry stain emerged as the most effective diagnostic method with 90% detection rate, followed by Giemsa stain (82.5%) and H&E stain (75%). The serum antibody test showed significant limitations with only 7.5% positive results and 10% sensitivity, indicating inadequacy as a standalone diagnostic tool in this population. The 92.5% disagreement rate between invasive and non-invasive approaches represents a critical diagnostic gap that could lead to missed diagnoses and inappropriate treatment decisions. The Sydney grading system revealed significant gastric pathology with high prevalence of advanced premalignant lesions, emphasizing the importance of comprehensive histopathological assessment. These findings support the use of invasive diagnostic approaches, particularly Warthin-Starry staining, when accurate H. pylori detection is crucial for patient management and highlight the need for population-specific validation of diagnostic methods in clinical practice.

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