



A Comparative Study between Rapid Urease Test and Histopathology for Helicobacter pylori in Acid Peptic Disease Patients at a Tertiary Care Hospital.

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Abstract

Background: Gastritis, peptic ulcer disease, and stomach malignancies are often associated with the gram-negative bacterium *Helicobacter pylori*. Accurate diagnosis is essential for effective management and prevention of complications. The RUT (Rapid Urease Test) is widely used because of its rapidity and cost-effectiveness, whereas histopathology is considered the gold standard. The purpose of this study was to assess the diagnostic precision of histopathology and RUT in identifying *H. pylori* infection in acid reflux disease patients. **Methods:** A prospective observational study was carried out on 100 individuals over the age of 18 who had upper gastrointestinal endoscopy-diagnosed gastritis and symptoms suggestive of acid reflux illness. Gastric biopsy specimens were obtained from the antro-pyloric region and subjected to both RUT and histopathological examination. Histopathology was considered the reference standard. Statistical analysis included calculation of sensitivity, specificity, PPV (Positive Predictive Value), NPV (Negative Predictive Value), and diagnostic accuracy. **Results:** Among the 100 patients studied, 58 were RUT positive and 42 were RUT negative. Histopathology detected *H. pylori* infection in 68 patients. RUT demonstrated 58 true positives, 32 true negatives, 10 false negatives, and no false positives. The sensitivity, specificity, PPV, NPV, and diagnostic accuracy of RUT were 85.3%, 100%, 100%, 76.2%, and 90%, respectively. A statistically significant association was observed between RUT and histopathology results ($p < 0.0001$). **Conclusion:** Rapid urease test is a simple, rapid, and economical screening method for detecting *Helicobacter pylori* infection in patients with acid peptic disease. However, due to its moderate sensitivity and lower negative predictive value, histopathology remains the gold standard for definitive diagnosis.

Keywords: *Helicobacter Pylori*, Rapid Urease Test, Histopathology, Acid Peptic Disease, Gastritis.



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INTRODUCTION

Gram-negative, microaerophilic, spiral-shaped *Helicobacter pylori* (*H. pylori*) frequently colonises the gastric mucosa, especially the antral area of the stomach. It can survive in the acidic stomach environment because it produces a lot of the enzyme urease. A number of gastrointestinal disorders, such as chronic gastritis, duodenal ulcers, gastric ulcers, MALT (Mucosa-Associated Lymphoid Tissue) lymphoma, and gastric adenocarcinoma, are thought to be significantly influenced by *H. pylori*. [1] Although some people may not have any symptoms, burning epigastric pain, pain that gets worse when the stomach is empty, nausea, appetite loss, frequent burping, bloating, and inadvertent weight loss are all signs of an *H. pylori* infection. Cytotoxin-associated gene A (CagA), vacuolating cytotoxin gene (VacA), urease synthesis, and bacterial motility are some of the mechanisms that contribute to *H. pylori*'s virulence. These factors compromise the integrity of the stomach mucosa, causing inflammation and ulceration.

Globally, the prevalence of *H. pylori* infection varies; rates have been reported to be 40–50% in wealthy countries and 80–90% in impoverished countries. [2,3] Oral-oral and fecal-oral pathways are frequently used for transmission. Overcrowding, poor sanitation, tainted water sources, and low socioeconomic position are all linked to higher illness rates. [4,5] Proper treatment and long-term monitoring of afflicted individuals depend on an accurate diagnosis of *H. pylori* infection.

H. pylori infection can be detected and tracked using both invasive and non-invasive diagnostic techniques. Endoscopic biopsy samples are needed for invasive tests such as PCR (Polymerase Chain Reaction), RUT (Rapid Urease Test),

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histopathology with specific stains, and culture. The urea breath test, stool antigen testing, and serology are examples of non-invasive techniques.[6,7] Histopathology is still the gold standard diagnostic technique, although the rapid urease test is frequently utilised during endoscopy due to its ease of use, speed, and affordability.[6,8] The effectiveness of the rapid urease test and histopathology in identifying *H. pylori* infection is compared in this study.

AIMS AND OBJECTIVES

The goal of the current study was to assess and contrast the diagnostic efficacy of histopathology and the RUT in identifying *Helicobacter pylori* infection in individuals with acid reflux illness. Using histopathology as the reference standard, the study also sought to evaluate the rapid urease test's sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy.

MATERIALS AND METHODS

Study Design

This prospective observational study was conducted in the Department of General Surgery at ACS Medical College and Hospital during the period 2023–2025. The study included 100 patients presenting to the surgical outpatient department with symptoms suggestive of acid peptic disease who subsequently underwent upper gastrointestinal endoscopy. All patients provided written informed permission after being informed of the operation and receiving approval from the institutional ethical committee. Each patient underwent a comprehensive physical examination and a full clinical history before undergoing an upper gastrointestinal endoscopy, the results of which were methodically documented.

Inclusion and Exclusion Criteria

The study included patients aged 18 years and above who presented with symptoms suggestive of acid peptic disease and were diagnosed with acute gastritis on upper gastrointestinal endoscopy, including patients with calculous or acalculous cholecystitis. Patients below 18 years of age, those with a history of previous *H. pylori* eradication therapy, recent use of antibiotics or proton pump inhibitors within the preceding two weeks, severe systemic illness, and pregnant women were excluded from the study.

Data Collection Procedure

After obtaining written informed consent, all patients were admitted and underwent detailed clinical history taking, physical examination, and routine blood investigations. Upper gastrointestinal endoscopy was performed under local anesthesia using 10% lignocaine (lox) spray, and the endoscopic findings were documented. Gastric biopsy samples were obtained from the antro-pyloric region and divided into two separate containers, one containing 10% buffered formalin for HPE (Histopathological Examination) and the other containing distilled water for RUT (Rapid Urease Testing). The biopsy specimen for RUT was placed in a rapid urease kit containing urea medium, where the presence of *H. pylori* urease enzyme hydrolyzed urea into ammonia, resulting in a color change of the medium from yellow (negative) to red (positive).[3] The formalin-fixed specimens were sent to the pathology laboratory for histopathological examination using hematoxylin and eosin staining, with additional special stains such as Giemsa, Warthin-Starry silver, Genta, and immunohistochemical stains used when required to improve specificity. All procedures were carried out by experienced specialists following standardized protocols to ensure reliability and minimize inter-observer variation.

Statistical Analysis

Using histopathology as the reference standard, statistical analysis was carried out to assess the RUT's diagnostic performance. Sensitivity, specificity, PPV, NPV, and total diagnostic accuracy were among the parameters that were computed. The rapid urease test showed 90.0% overall diagnostic accuracy, 85.3% sensitivity, 100% specificity, 100% positive predictive value, and 76.2% negative predictive value. RUT and histology results were statistically significantly correlated ($p < 0.0001$) according to chi-square analysis, suggesting a robust relationship between the two diagnostic techniques.

RESULTS

Table 1: Distribution of Endoscopic Findings

Endoscopic Findings	Number/Percentage (%)
Pangastritis	39.6%
Antral Gastritis	26.4%
Reflux Esophagitis	13.7%
Duodenitis	10.69%
Esophageal Varices	4.31%
Malignancy	4.2%
Esophageal Candidiasis	3.72%

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Table 1 illustrates the distribution of endoscopic findings among patients with acid peptic disease. Pangastritis was the most common finding, observed in 39.6% of patients, followed by antral gastritis in 26.4% of cases. Reflux esophagitis and duodenitis were identified in 13.7% and 10.69% of patients, respectively. Less common findings included esophageal varices, malignancy, and esophageal candidiasis. These findings indicate that inflammatory gastric conditions constituted the major burden among the study population.

Table 2: Gender Distribution of Study Population

Gender	Number	Percentage
Male	69	69%
Female	31	31%
Total	100	100%

Table 2 shows the gender distribution of the study population. Male patients constituted the majority with 69% of cases, while females accounted for 31%. This observation suggests that acid peptic disease and *Helicobacter pylori* infection were more commonly observed among males in the present study.

Table 3: Age Distribution of Patients

Age Group (in years)	Frequency	Percentage
18–30 years	15	15%
30–40 years	27	27%
40–50 years	33	33%
50–60 years	14	14%
>60 years	11	11%
Total	100	100%

Table 3 illustrates the age-wise distribution of patients included in the study. The highest proportion of patients belonged to the 40–50 years age group (33%), followed by the 30–40 years age group (27%). Patients above 60 years constituted the least proportion at 11%. The findings indicate that middle-aged individuals were more commonly affected by acid peptic disease and *H. pylori* infection.

Table 4: Duration of Symptoms

Duration of Symptoms	Number	Percentage
<1 month	11	11%
1–6 months	33	33%
6 months–1 year	24	24%
>1 year	23	23%
Total	100	100%

Table 4 demonstrates the duration of symptoms among study participants. The majority of patients (33%) had symptoms lasting between 1 and 6 months. Approximately 24% had symptoms for 6 months to 1 year, while 23% reported symptoms persisting for more than one year. Only 11% presented within one month of symptom onset. This suggests that most patients had chronic or prolonged dyspeptic symptoms before seeking medical evaluation.

Table 5: Comparison between Rapid Urease Test and Histopathology

RUT Result	Histopathology Positive	Histopathology Negative	Total
RUT Positive	58 (True Positive)	0 (False Positive)	58
RUT Negative	10 (False Negative)	32 (True Negative)	42
Total	68	32	100

Table 5 compares the results of RUT with histopathology findings for the diagnosis of *Helicobacter pylori* infection. Among the 100 patients studied, 58 cases were true positives and 32 cases were true negatives. Ten patients were false negatives, while no false positive cases were identified. The absence of false positives indicates high specificity of RUT, whereas the presence of false negatives suggests moderate sensitivity.

Table 6: Diagnostic Performance of Rapid Urease Test

Parameter	Formula	Value
Sensitivity	$TP / (TP + FN)$	85.3%
Specificity	$TN / (TN + FP)$	100%
Positive Predictive Value (PPV)	$TP / (TP + FP)$	100%
Negative Predictive Value (NPV)	$TN / (TN + FN)$	76.2%
Diagnostic Accuracy	$(TP + TN) / \text{Total}$	90%

Table 6 illustrates the diagnostic performance of the Rapid Urease Test in detecting *Helicobacter pylori* infection. The test demonstrated high specificity and positive predictive value of 100%, indicating that positive RUT results strongly correlated with histopathological confirmation. Sensitivity was found to be 85.3%, while the negative predictive value was comparatively lower at 76.2%, suggesting that negative RUT results should be interpreted cautiously. Overall diagnostic accuracy of the test was 90%.

Table 7: Statistical Association between RUT and Histopathology

Statistical Test	Result
Chi-square Test	Significant Association
p-value	<0.0001

Table 7 shows the statistical association between RUT and histopathology findings. Chi-square analysis demonstrated a statistically significant association between the two diagnostic methods with a p-value less than 0.0001. This indicates a strong correlation between RUT and histopathological diagnosis of *Helicobacter pylori* infection.

DISCUSSION

Helicobacter pylori infection is still a major global health concern and is closely linked to mucosa-associated lymphoid tissue lymphoma, gastric cancer, peptic ulcer disease, and chronic gastritis. Therefore, early treatment and the avoidance of problems depend on an accurate identification of *H. pylori*. The RUT and histopathology were used in this investigation to diagnose *H. pylori* infection in patients with acid reflux disease.

The majority of patients in the current study were between the ages of 40 and 50 (33%), followed by those between the ages of 30 and 40 (27%). Similar results were reported by Abd El-latif et al.[2] who found that middle-aged people had a greater prevalence of *H. pylori* infection. Chronic stomach mucosal inflammation, dietary practices, and extended exposure to environmental risk factors may all contribute to this age preponderance.

Males made up 69% of the study population, indicating a male predominance. Comparable observations were reported by Njoroge et al.[3] where males constituted the majority of patients undergoing endoscopic evaluation for *H. pylori* infection. The increased prevalence among males may be related to smoking, alcohol consumption, occupational stress, and lifestyle-related factors.

Among endoscopic findings, pangastritis (39.6%) and antral gastritis (26.4%) were the most common abnormalities detected in this study. Similar findings were described by Lee and Kim[9] who reported gastritis as the most frequent endoscopic manifestation associated with *H. pylori* infection. The affinity of *H. pylori* for the antral mucosa explains the high incidence of gastritis in affected individuals.

Histopathology detected *H. pylori* infection in 68% of patients, whereas RUT detected positivity in 58% of patients. The sensitivity and specificity of RUT in the present study were 85.3% and 100% respectively. These findings are comparable to the study conducted by Abd El-latif et al.[2] who reported sensitivity ranging between 80 and 90% and specificity above 95% for invasive diagnostic tests. Similarly, Njoroge et al.,[3] demonstrated that s possess high specificity and acceptable sensitivity when compared with histopathology.

The PPV of RUT in the present study was 100%, indicating that all patients with positive RUT results were confirmed positive on histopathology. Similar observations were documented by Konakliet al.,[10] who reported very high PPV values for RUT, suggesting that a positive RUT result strongly correlates with active *H. pylori* infection.

However, the NPV in the present study was comparatively lower (76.2%). This indicates that a negative RUT result does not reliably exclude *H. pylori* infection. Similar conclusions were reached by Cosgunet al.,[11] who emphasized that false negative RUT results may occur due to patchy bacterial colonization, low bacterial density, recent proton pump inhibitor therapy, or sampling errors during biopsy collection.

In the present study, no false positive results were observed, whereas 10 false negative cases were identified. False negative results have also been described by Khalifehgholi et al.,[6] who compared multiple diagnostic methods and concluded that histopathology remains more reliable because it allows direct visualization of the organism and assessment of mucosal inflammatory changes simultaneously.

The overall diagnostic accuracy of RUT in the current study was 90%, which is consistent with previously published studies. Urgessa et al.[4] in their systematic review comparing histology and rapid urease tests, reported that RUT demonstrates good diagnostic accuracy and remains a valuable bedside screening test during upper gastrointestinal endoscopy.

Chi-square analysis in the present study showed a statistically significant association between RUT and histopathology ($p < 0.0001$), indicating strong agreement between both diagnostic modalities. Similar statistically significant correlations have been reported in several earlier studies evaluating invasive methods for *H. pylori* diagnosis.[2,3,11]

Although histopathology remains the gold standard due to its superior diagnostic reliability and ability to detect mucosal pathology, RUT offers several practical advantages. It is rapid, inexpensive, easy to perform, and provides results during endoscopy itself. Marshall and Warren[8] who first described *H. pylori* in gastric biopsies, highlighted the importance of rapid diagnostic methods for early initiation of therapy.

The present study also highlights the importance of using histopathology confirmation in clinically suspected patients with negative RUT results. Lee and Kim[9] emphasized that histopathology not only confirms infection but also helps identify premalignant and malignant gastric lesions, which may be missed by rapid diagnostic methods alone.

The findings of the current study support the use of RUT as an effective initial screening tool, especially in resource-limited and remote healthcare settings where immediate diagnosis is beneficial. However, histopathological examination should be considered for confirmation in doubtful or clinically suspicious cases to improve diagnostic accuracy and reduce missed infections.

Limitations

The present study demonstrated that the RUT has good sensitivity and a high positive predictive value, making it a useful and rapid diagnostic tool during endoscopy for the detection of *Helicobacter pylori* infection. However, the negative predictive value of 76.2% indicates that a negative RUT result cannot reliably exclude infection, and confirmation with histopathological examination may be necessary when clinical suspicion remains high.

Histopathology also offers the additional advantage of detecting incidental malignancies and evaluating gastric mucosal changes. The study was conducted in a single tertiary care center with a sample size of 100 patients, which may limit the generalizability of the findings to larger populations. Furthermore, patchy distribution of *H. pylori* within gastric mucosa and biopsy sampling errors may influence the accuracy of both RUT and histopathology. Therefore, larger multicentric studies are recommended to validate these findings and further improve diagnostic strategies for *H. pylori* infection.

CONCLUSION

A quick, easy, and affordable diagnostic technique for identifying *Helicobacter pylori* infection in individuals with acid reflux illness is the rapid urease test. Although the test demonstrates good diagnostic utility, its moderate sensitivity and comparatively low negative predictive value indicate that a negative result may not reliably exclude infection. Therefore, histopathology continues to remain the gold standard diagnostic modality due to its higher accuracy and ability to directly visualize the organism and associated mucosal changes. Nevertheless, RUT serves as an effective alternative screening tool, particularly in remote and primary healthcare settings, where it can facilitate early diagnosis and appropriate treatment, thereby helping to reduce unnecessary antibiotic usage and antimicrobial resistance.

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