



Diagnostic Accuracy of Rapid Urease Test (RUT) for *Helicobacter pylori* Infection in Patients with Acid Peptic Disease and Dyspepsia

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Abstract

Helicobacter pylori (*H.pylori*) is a bacterial species that resides in a specific region of the stomach lining known as the gastric antrum. It exists in a layer between the outer surface and slimy layer on top of the inner lining, where the level of acidity is around seven. The present study was conducted among 170 patients at Krishna Hospital and Medical Research Centre, Karad with symptoms suggestive of Acid Peptic Disease (APD) and Dyspepsia. In this study, majority of the patients, i.e., 123 (72.4%) diagnosed with the symptoms suggestive of APD out of which 98 (79.6%) *H. pylori* infections were reported to be positive on Histopathology, and 96 of them were correctly identified by Rapid Urease Test (RUT). The remaining 47 (27.6%) patients presented with symptoms suggestive of dyspepsia out of which 34 (72.34%) came positive on Histopathology and all of them were correctly diagnosed by RUT. Also 69 (40.6%) patients had features suggestive of diffuse gastritis out of which 59 (85.5%) were positive for disease on Histopathology, out of which 58 of them were correctly diagnosed by RUT. And 15 (8.8%) patients had features of antral gastritis out of which 12 (80%) had the disease on Histopathology. Statistical analysis of the data was performed on SPSS and MS Excel 2019. Furthermore, sensitivity of RUT to correctly diagnose patients suffering from *H pylori* infection was 90.91%, and Specificity of the test for predictive value for the same was 73.68% with a Positive (PPV) of 92.31% as well as Negative (NPV) of 70% and Diagnostic accuracy of it was 87.06%.

Keywords: *Helicobacter Pylori*, Antral gastritis, RUT, Endoscopic biopsy, Gastric ulcer, Dyspepsia, Histopathology.

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1 Introduction

Helicobacter pylori is a type of bacteria that lives in the stomach. *H.pylori* infection is a very common and long-lasting bacterial infection that affects about 4.4 billion people all over the world. *H.pylori* is a type of bacteria that is shaped like a spiral. It needs a certain amount of oxygen to survive and is very picky about its surroundings. It can move around and has tiny hairs called flagella. It is a type of bacteria that stains pink when tested. It is known to be the most common reason for long-term bacterial infections in humans and it affects around half of the world's population.



Figure 1: Helicobacter Pylori (Tatiana Shepeleva / Shutterstock)

Once inhabited or populated by a specific species called H.pylori causes long-lasting, but not deep, swelling which leads to ulcers in the intestines and stomach. H.pylori is a microorganism that causes stomach problems like gastritis, duodenal and gastric ulcers, and stomach cancer. MALT lymphoma and gastric cancer are diseases that affect the lining of the stomach.

The most likely way the disease spreads is from person to person, but it can also spread through the mouth-to-mouth and fecal-oral routes. For role of H. pylori in the peptic ulcers development, it is important to highlight the need for effective treatment and eradication of the bacteria in order to prevent and manage these ulcers. Microbiologists and clinicians are trying to find the best way to diagnose H. pylori in duodenal ulcers and gastric cancer.

However, in order to have the most effective management of H. pylori. To effectively address diseases related to H. pylori bacteria, it is imperative to have a specific and precise diagnosis, particularly when determining the appropriate treatment approach. This study is being conducted to find proof of H. pylori. In our surroundings, we have a stomach infection called H. We can find out if someone has this infection by testing for H. pylori. We will check for H. pylori in a stomach tissue sample by using a test that gives quick results and looking at it under a microscope. In this study, we want to determine how well the Rapid Urease Test can detect the presence of H. pylori. We will look at the Positive Predictive Value (PPV), Sensitivity, Specificity, as well as Negative Predictive Value (NPV) of the test for the bacterial infection in the stomach, found by testing a small tissue sample.

In 1982, the first explanation came from John Robin Warren and Barry James Marshall, both Australian scientists. Warren was a pathologist and Marshall was a microbiologist. At that time, experts believed that no tiny germ could survive in the acidic conditions of the stomach. In 1982, Marshall and Warren discovered and grew a bacteria called Campylobacter pyloridis in the stomach. It was later renamed Helicobacter pylori.

2 Literature Review

H. pylori is a very common type of bacteria that can cause long-term infection in humans. It affects a large number of people worldwide, with different populations having a varying percentage of infection. The chances of getting H. pylori infection are connected to how much money a person has and the living conditions they have when they are young. People who are poorer and have lower incomes are often more likely to get sick than those who are richer and have higher incomes. Most people catch infections when they are young. Infections can spread

from one person to another, especially when sanitation is not good and there are too many people in a small space.

There are many substances made by *H. pylori* that can be harmful. Urease dehydrogenase, vacuolizing cytotoxin-Vac A exotoxin, Cag A (cytotoxin-associated gene A), endopeptidase, and haemolysin are names of different substances or enzymes. *pylori* grows best at 37°C in conditions with low levels of oxygen. Different types of media are used such as Skirrow's medium and chocolate medium. The main diseases caused by *H. pylori*'s virulence factors are a toxin called Vac A, as well as a group of genes called CagPal.

In simple terms, *H.pylori* makes a strong substance called urease that can break down urea into ammonia and bicarbonate. This creates an environment that is less acidic and more alkaline in the stomach. But, the enzyme helps us find the organism. *pylori* organisms need a specific kind of environment to survive. They can only live in the lining of the stomach because the stomach lining has special receptors that the organisms can stick to. Therefore, The bacteria *H. pylori* can also be found in abnormal tissue in different parts of the stomach and intestines such as the esophagus, duodenum, Meckel's diverticulum, and rectum.

H. pylori infection is usually found in people who have ongoing stomach inflammation, and it is also found in most patients with ulcers in the stomach or the upper part of the small intestine. People who don't have an infection and have stomach ulcers often use NSAIDs. Non-ulcer dyspepsia exhibits a less strong association. Most people with stomach cancer have or had *H. pylori* infection at certain time.

In certain hospitals, especially in poorer countries, doctors may ask patients to keep a test tube for 1-2 days. They then ask the hospital staff to record the results of the test to see if it is positive or not. *pylori*, the bacteria attach to the cells that line the stomach and create a biofilm, which protects them from being destroyed by stomach acid. This colonization can lead to the development of gastric ulcers and other digestive problems. The test showed a positive result, but it may cause problems with determining if it is truly positive or negative for the actual *H. pylori* infection. In most scenarios, the positive urease reaction does not typically necessitate a larger quantity of *H. heilmannii* or an extended period of time.

3 Method

The research was done on 170 patients who were treated at the Surgery Department in Krishna Institute of Medical Sciences, Karad. Referrals for these patients had been made by other departments in the institute. The study took place from December 2018 to July 2020. A sample was obtained from all the individuals with Acid Peptic Disorder and Dyspepsia during an Endoscopy procedure to check for the presence of H-Pylori bacteria. We then performed a quick test and examined the sample under a microscope to confirm the presence of the bacteria. A written informed consent was signed by all the patients prior to the beginning of study.

Inclusion Criteria: All patients of Acid Peptic Disorder and Dyspepsia of Age Group (1875 Years).

We chose patients who met certain criteria for the study in a consecutive manner. We talked to patients to get information about their age, gender, reasons for coming in, and any other health problems they have had in the past. These patients had a medical check-up, and the doctors took notes on their overall health and vital signs. They used a special tool to look inside the stomach and then took a sample of tissue from two different parts of the stomach. A small sample of tissue was tested quickly to check for a bacteria called urease. Another small sample of tissue was looked at under a microscope after being stained with special dyes.

The researchers looked at the slides and considered these features:

- a) Foveolar hyperplasia: an increase in cells in a small part of the stomach lining. Features of degeneration refer to signs of damage and deterioration. Severe cases may include erosion, where the stomach lining wears away, haemorrhage, which is bleeding, and mucosal necrosis, which is death of the stomach lining.
- b) Chronic active gastritis with lots of inflammation caused by lymphoplasmacytic cells and neutrophils.
- c) The living things look like slightly curved, seagull wing-shaped sticks. They are mostly found in the stomach's slimy substance and the surface that covers it.
- d) The stomach has a condition called pititis, where there is inflammation in the gastric pits. This inflammation is often active or neutrophilic.
- e) Large clusters of immune cells.

The information about foveolar epithelium and gastric pits was written down on a form that was made and tested in advance.

All the characteristics were described in simple terms. For numbers that can take on any value, we used the average plus or minus the spread to describe them. For categories of information, we used numbers and percentages in summarizing the data and presenting it in diagrams. A Chi-square test was used to see if there was a connection between two groups of non-numerical information.

The chi-square statistic formula used in the test is:

$$X_e^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

where, "c" represents the number of choices or options (degree of freedom), and "O" represents the value actually observed and "E" is expected value.

$$C = (\text{number of rows} - 1) \times (\text{number of columns} - 1)$$

Sensitivity: Specificity analysis was done to check relative efficiency.

Sensitivity and the true positive rate (TPR) can be used interchangeably to express the same idea. With hit rate:

$$TPR = \frac{TP}{P} = \frac{TP}{(TP + FN)}$$

specificity (SPC) or true negative rate:

$$SPC = \frac{TN}{N} = \frac{TN}{(FP + TN)}$$

precision or positive predictive value (PPV)

$$PPV = \frac{TP}{(TP + FP)}$$

negative predictive value (NPV)

$$NPV = \frac{TN}{(TN + FN)}$$

Upon the conclusion of the study conducted and in terms of p-value being 0.05, the results were evaluated as being of considerable importance, with scientific significance being a key factor; without it, they were deemed not in statistical terms significant. Microsoft Excel 2019

along with SPSS software version 23 (IBM Statistics, Chicago, USA) were used to analyze the data.

4 Results

We evaluated the age distribution among the individuals who participated in the current study. In accordance to our analysis, the majority of patients, or 22.4%, were among the ages of 31 and 40, followed by 20.6% of patients over the age of 60, 19.4% of patients within the ages of 21 and 30, 18.8% of patients among the ages of 41 and 50, 15.9% of patients between the ages of fifty-one and sixty, and 2.9% of patients under the age of 20.

47 (27.5%) of the 170 patients who were included in the study had signs and symptoms of dyspepsia, whereas 123 (72.4%) of the patients had acid peptic disease (APD) (see Table 1).

Table 1: Clinical Diagnosis

Clinical Dx	N	Percent
Dyspepsia	47	27.6
APD	123	72.4
Total	170	100

Out of 170 patients, 86 (50.6%) had normal results from the endoscopy test, 69 (40.6%) of them had features suggestive of Diffuse gastritis, whereas 15 (8.8%) patients had features of Antral Gastritis (Table 2).

Table 2: Oesophago-gastroduodeno (OGD)- Scopy Diagnosis

OGD Dx	N	Percent
WNL	86	50.6%
Diffuse Gastritis	69	40.6%
Antral Gastritis	15	8.8%
Total	170	100%

There were 130 (76.5%) patients with positive result on Rapid Urease Test (RUT), whereas 40 (23.5%) patients had negative result on Rapid Urease Test (Figure 2).

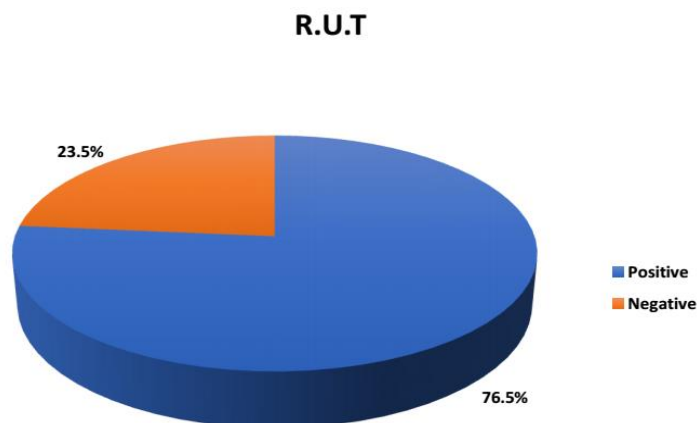


Figure 2: Findings of Rapid Urease Test (RUT)

There were 132 (77.6%) patients who had features of H Pylori infection on Histopathological examination and 38 (22.4%) patients showed no relevant features.

Histopathology report

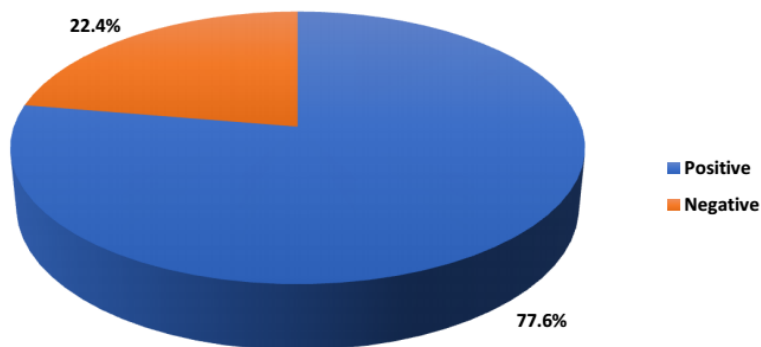


Figure 3: Histopathology Report

Out of 123 individuals with APD, 56 (45.5%) had normal endoscopic results, 54 (43.9%) had diffuse gastritis-related symptoms, and 13 (10.6%) had antral gastritis. The remainder of the 47 dyspepsia patients were divided into 30 (63.8%) with acceptable endoscopic results, 15 (31.9%) with diffuse gastritis characteristics, and 2 (4.3%) with antral gastritis observations.

Table 3: Comparison of Clinical Diagnosis with OGD Diagnosis

OGD Dx	Dyspepsia		APD		Total	p-value
	N	%	N	%		
WNL	30	63.8%	56	45.5%	86	
Diffuse Gastritis	15	31.9%	54	43.9%	69	
Antral Gastritis	2	4.3%	13	10.6%	15	0.082
Total	170		123	47		

Note: * significant at 5% level of significance (p<0.05).

Comparison of OGD Diagnosis With R.U.T. Results

Out of 86 patients who had a normal endoscopy, 58 (67.4%) of them had a positive finding on a different test called RUT, while the negative finding was observed in only 28 (32.6%) of patients. Out of 69 patients who were diagnosed with Diffuse Gastritis during an endoscopy, 58 patients (84.1%) showed positive results on the RUT test and 11 patients (15.9%) showed negative results. Out of 15 patients who had a condition called Antral Gastritis when examined with a flexible tube, 14 (which is about 93.3% of them) had a positive result on a special test called RUT. Only 1 patient (around 6.7%) had a negative result.

Comparison of OGD Diagnosis with R.U.T. Results

OGD Dx	RUT-ve		RUT+ve		Total	p-value
	N	%	N	%		
WNL	28	32.6%	58	67.4%	86	
Diffuse Gastritis	11	15.9%	58	84.1%	69	0.014*
Antral Gastritis	1	6.7%	14	93.3%	15	
Total	170		130	40		

Note: * significant at 5% level of significance (p<0.05).

Figure 5 illustrates that among the 86 patients with a normal endoscopy, a total of 61 (70.9%) individuals had positive outcomes.9%) of them had a positive finding on

histopathology and 25 (29.1%) patients had a negative finding. Out of 69 patients with Diffuse Gastritis, 59 patients (85.5%) had positive findings on Histopathology, while 10 patients (14.5%) had negative findings. Positive Histopathology findings were observed in 80% of the 15 patients who underwent endoscopy for Antral Gastritis, while the remaining 20% had negative results.

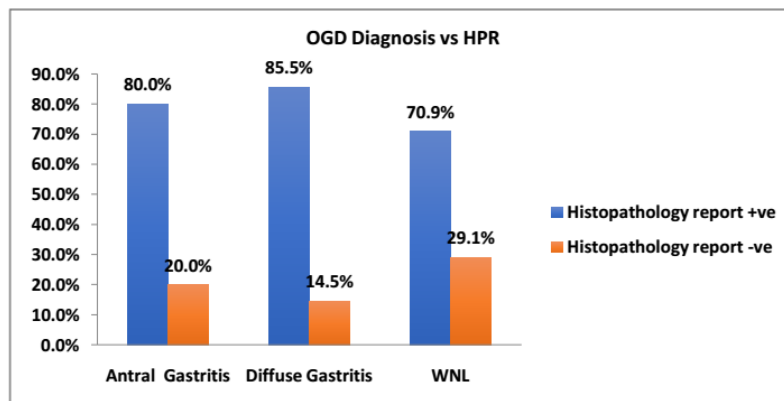


Figure 4: Comparison of OGD Diagnosis with Histopathology Report.

Calculating the data from the figure using statistical analysis formulas, we observe that the RUT has a good ability to correctly diagnose patients with *H. pylori* infection. It is sensitive in detecting true positive cases and can correctly identify 90.91% of infected patients. It also has a specificity of 73.68%, meaning it can accurately identify true negative cases. The PPV is 92.31%, indicating that if the RUT result is positive, there is a high chance the patient is truly infected. The NPV is 70%, meaning if the result is negative, there is a 70% chance the patient is truly not infected. So, the RUT can correctly detect *H. pylori* infection in patients 87.06% of the time.

Table 4: Sensitivity Analysis of R.U.T. Result Compared to Histopathology Report

Parameter	HPR	RUT	Total
FN (False Negative)	HPR +ve	RUT -ve	12
FP (False Positive)	HPR -ve	RUT +ve	10
TN (True Negative)	HPR -ve	RUT -ve	2
TP (True Positive)	HPR +ve	RUT +ve	120

From a group of 170 patients that were looked at, 15 patients were found to have Antral Gastritis. Out of 15 patients with Antral Gastritis, 14 had a positive result on the RUT test and 1 had a negative result. Out of 14 patients with RUT positive, 12 patients showed positive results on HPR while 2 patients had negative results. The last patient with negative RUT also had a negative result on HPR. Out of 170 people who were examined, 69 of them had Diffuse Gastritis. Out of 69 people with Diffuse Gastritis, 58 tested positive on RUT and 11 tested negative. In total, 55 patients with a positive case of RUT also showed a positive result on HPR, and only 3 patients demonstrated a negative result. Out of 11 patients with RUT negative results, 4 patients were found to have positive results on HPR, while 7 patients had negative results.

Normal results were found in 86 patients out of a total of 170 who underwent the endoscopy test. Out of the total 86 patients, 58 patients had positive results on RUT (rapid urease test) while 28 patients had negative results. Out of 58 patients who tested positive for RUT, 53 patients had a positive result on HPR, while 5 patients had a negative result. Out of 28 patients who did not have RUT, 8 patients tested positive for HPR and 20 patients tested negative.

Table 5: Sensitivity Analysis

Sensitivity	90.91%
Accuracy	87.06%
NPV	70.00%
Specificity	73.68%
PPV	92.31%

The occurrence of APD was found in 123 individuals among the total of 170 patients. Out of 123 patients with APD, 13 patients were found to have Antral Gastritis during their endoscopy. Out of 123 people with APD, 54 had Diffuse Gastritis when their stomachs were examined. Out of the 54 patients with Diffuse Gastritis, 44 patients showed positive results on a test called RUT, while 10 patients showed negative results. Out of 170 patients that were looked at, there were still 47 patients who had Dyspepsia. Out of 47 patients with stomach problems, 15 patients had a type of stomach inflammation called diffuse gastritis when examined with a tool called endoscopy. Out of the 15 people with Diffuse Gastritis, 14 tested positive for RUT and 1 tested negative. Out of 47 people with stomach problems, 30 of them had normal results from an endoscopy. Out of the 30 patients with normal results, 18 tested positive on the RUT and 12 tested negative. Out of the 18 patients who tested positive for RUT, 16 patients showed positive results on the histopathology test, while 2 patients had negative results.

5 Discussion

In our study comprising of 170 patients, 123 (72.4%) patients came with the symptoms suggestive of acid peptic disease (APD). Out of those 123 APD patients, 98 (79.6%) were positive for H-pylori infection on Histopathology and 96 were positive on RUT. Out of the remaining patients 47 (27.6%) presented with symptoms suggestive of dyspepsia. Out of those 47 patients, 34 (72.34%) came positive on Histopathology and 32 of them were positive on Rapid Urease Test. comparable findings were seen in research investigations conducted by [9-154, where they found that the majority of patients had chronic gastritis and dyspepsia. Due to the widespread presence of H. pylori in the population, Virendra S. Athavale et al.'s study included individuals who reported abdominal discomfort as a symptom, which led to a greater rate of RUT detection.

Out of 170 patients, 69 (40.6%) of them had features suggestive of diffuse gastritis out of which 59 (85.5%) were positive on Histopathology and 58 of them were positive on Rapid Urease Test. Out of 170 patients, 15 (8.8%) patients had features of antral gastritis out of which 12 (80%) had positive finding on Histopathology and 14 were detected on Rapid Urease Test. Similar results were seen in study done by Shiwani Sharma et al(77), where she got gastritis as the majority finding and also with the study done by Nanivadekar et al(84), where he showed gastritis as the predominant finding.

Most of the patients with positive RUT had features suggestive of H pylori infection on Histopathology, thus suggesting a positive correlation between the two. Comparing the result of RUT and Histopathological examination we found in our study that The RUT is able to correctly diagnose 90.91% of patients with H. pylori infection. It has a specificity of 73.68%, which means it correctly identifies patients without the infection. The +ve Predictive Value is 92.31%, meaning that if the test shows a positive result, there is a high likelihood that the patient has the infection. The -ve Predictive Value is 70%, indicating that if the test shows a negative result, there is a good chance the patient does not have the infection. Overall, the test has a diagnostic accuracy of 87.06% in correctly diagnosing H pylori infection. The same results were discovered in other studies. In a study, Virendra et al., found that the RUT had a

high ability to detect something, with 96.83%. It also had a moderate ability to rule out something, with 74.47%. In terms of predicting whether something is present or not, it had a PPV of 95.24% and a NPV of 81.25%. As per Shiwani Sharma and her colleagues, This test is really good at accurately detecting the condition it is testing for (sensitivity 100%). However, it is not very good at ruling out the condition when it's not present (specificity 59%). Out of all the positive results from this test, only 55.7% truly have the condition (positive predictive value).

On the other hand, if the test result is negative, it is highly reliable in showing that the person does not have the condition (negative predictive value 100%). Based on S. Redeen and his co-authors' research, In 1982, the test was found to be 90% accurate in detecting the condition (sensitivity), 98% accurate in ruling out the condition (specificity), 96% accurate in predicting that someone has the condition when they actually do (positive predictive value-PPV), and 95% accurate in predicting that someone does not have the condition when they actually don't (negative predictive value-NPV). JavedYakoob and others found that the test correctly identified 71.9% of positive cases and 80% of negative cases. The test correctly predicted the presence of a condition 82.1% of the time and correctly predicted the absence of a condition 69% of the time.

In our research, we used a paper-based test for RUT. The RUT had a sensitivity of 90.91%, meaning it was able to accurately detect positive results 90.91% of the time. The specificity of the test was 73.68%, indicating that it correctly identified negative results 73.68% of the time. A trustworthy method to search for and recognize *H. pylori* is important to treat people who have an infection and to eliminate the bacterial strains.

6 Conclusion

Symptoms pointing to acid peptic disease (APD) were observed in the majority of patients in our research (72.4%). Out of these patients, 98% had an *H. pylori* infection as confirmed by examining tissue under a microscope, and 96 of them were also correctly identified by a quick test called the Rapid Urease Test. The remaining 47 (27.6%) patients presented with symptoms suggestive of dyspepsia out of which 34 (72.34%) came positive on Histopathology and all of them were correctly diagnosed by Rapid Urease Test. In conclusion, our study shows that the Rapid Urease Test is a reliable approach to diagnose *H. pylori*. When addressing Acid Peptic Disease and Dyspepsia in patients, it can offer a beneficial replacement for Histopathology. In our study we observed, there were 86 patients who had normal endoscopy findings. Out of 86 patients, 58 patients had positive result on RUT and 28 negative. So, we conclude, normal OGD finding does not exclude *H. pylori* infection. Gastric mucosal biopsy is must even though gastric mucosa is normal on endoscopy for diagnosis of *H. pylori*. Moreover, all patients undergoing OGD should have mucosal biopsy taken from antrum and body of the stomach irrespective of endoscopic diagnosis for the confirmation of *H. pylori* infection.

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