

AN ANALYSIS OF THE DIAGNOSTIC UTILITY OF HELICOBACTER PYLORI IN PEPTIC ULCER PATIENTS

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Abstract:

Peptic ulcers, which are typically brought on by an infection with Helicobacter pylori (H. pylori), are a major concern for people's health all over the world. The disruption of the protective mucosal lining of the stomach is caused by this bacteria, which plays a significant role in the development of gastric and duodenal ulcers. Using a variety of diagnostic approaches, such as non-invasive tests (such as the urea breath test, stool antigen test, and serology) and invasive procedures (such as endoscopy with biopsy followed by histological examination, rapid urease test, and culture), the purpose of this study is to investigate the diagnostic utility of H. pylori detection in patients who have peptic ulcers. An analysis was conducted on a group of patients who were diagnosed with peptic ulcers in order to ascertain the prevalence of H. pylori infection, as well as the sensitivity, specificity, and diagnostic accuracy of each testing technique. There was also an investigation on the connection between the prevalence of H. pylori and the severity of ulcers. As a result of their high sensitivity and specificity, non-invasive diagnostics, in particular the urea breath test, have proven to be helpful for making an initial diagnosis. Although invasive tests are more accurate, they were often reserved for patients who had symptoms that persisted for an extended period of time or problems that required endoscopic assessment. Based on the findings of the study, it is clear that the early and precise identification of H. pylori infection is essential for the successful treatment and management of ulcer problems. Eliminating the bacteria has a substantial impact on reducing the recurrence of ulcers and the difficulties that are connected with them. Increasing the total diagnostic yield and improving patient outcomes can be accomplished through the utilization of many diagnostic techniques.

Keywords: Helicobacter pylori, peptic ulcer, diagnostic utility, urea breath test, endoscopy, eradication therapy.

Introduction:

Peptic ulcer disease (PUD), which is defined by ulcers or lesions in the lining of the stomach or the upper section of the small intestine, continues to be a frequent gastrointestinal ailment that affects millions of people all over the world. Throughout the course of history, the primary causes of PUD were thought to be lifestyle variables such as stress, eating spicy foods, and drinking an excessive amount of alcohol. Nevertheless, the discovery of Helicobacter pylori (H. pylori) by Barry Marshall and Robin Warren in 1982 was a key advance in the knowledge of its path physiology. This finding radically altered the perspective of this ailment as well as the management of it. H. pylori is a spiral-shaped gram-negative bacteria that has the ability to colonize the mucosa of the stomach, where it causes inflammation and destroys the mucosal

barrier. At this point in time, it is widely acknowledged that this particular bacteria is the primary etiological agent that is accountable for the majority of duodenal and stomach ulcers. Not only does it play a part in the formation of peptic ulcers, but it also plays a function in the development of chronic gastritis, mucosa-associated lymphoid tissue (MALT) lymphoma, and even gastric cancer. When dealing with patients who have peptic ulcers, it is impossible to stress the significance of making a correct diagnosis of *H. pylori* infection. A reduction in the recurrence of ulcers, the promotion of healing, and the prevention of complications such as bleeding and perforation have all been demonstrated to be possible by the early discovery and subsequent elimination of the bacteria. The detection of *H. pylori* can be accomplished using a variety of diagnostic approaches, each of which has its own set of advantages and disadvantages. A variety of non-invasive tests, such as the stool antigen test and the urea breath test, as well as more intrusive treatments, such as an endoscopic biopsy followed by a histological examination and culture, are included in this category. Understanding the diagnostic value of these procedures in clinical practice is absolutely necessary in light of the fact that *H. pylori* is found all over the world and has a direct influence on the development of peptic ulcer disease. In order to improve clinical outcomes by early and accurate diagnosis, the purpose of this study is to assess the sensitivity, specificity, and overall diagnostic performance of a variety of tests for the detection of *H. pylori* in patients who have peptic ulcers. In the context of the care of peptic ulcer disease, we are attempting to determine the most efficient ways for identifying *H. pylori* by contrasting non-invasive and invasive approaches.

Objective:

1. To analyze the diagnostic utility of *H. pylori* in patients with peptic ulcer disease by evaluating various diagnostic methods and their clinical relevance.

Epidemiology of Helicobacter pylori and Peptic Ulcer Disease

With an estimated incidence of 44.3% of the world's population, *H. pylori* infection is one of the most frequent chronic bacterial illnesses that may be found all over the world. The frequency varies greatly from one place to another and is affected by a variety of factors, including socioeconomic position, sanitation, and living circumstances within the region. In countries that are still in the process of developing, infection rates can increase to more than 80 percent, but in more industrialized countries, the prevalence is often lower, especially among younger people. It is considered that the fecal-oral or oral-oral route is the primary mode of transmission, and that this pathway typically takes place during childhood.

In spite of the great incidence of *H. pylori* infection, not all people develop peptic ulcers. This suggests that there is a complicated interaction between a number of variables, including genetic predisposition, the virulence of the bacterial strain, and environmental impacts. It is important to note that *H. pylori* plays a significant role in the development of PUD, as evidenced by the fact that up to 95% of patients with duodenal ulcers and 70-90% of patients with stomach ulcers test positive for the bacterium. Additionally, the mucosal damage that is caused by *H. pylori* infection can be further exacerbated by other variables that contribute to the development of PUD. These factors include the use of non-steroidal anti-inflammatory medicines (NSAIDs), smoking, and stress.

Pathophysiology of Helicobacter pylori in Peptic Ulcers

There are a variety of different pathways that *H. pylori* uses to contribute to the development of peptic ulcer conditions. Through the production of urease, an enzyme that converts urea into ammonia and carbon dioxide, the bacteria is able to thrive in the acidic environment of the stomach. This enables the bacterium to create a microenvironment that is alkaline and protective. Because of this, the bacteria is able to colonize the lining of the stomach and avoid being killed by the immunological reaction of the host.

H. pylori, after it has established itself, will release virulence factors such as cytotoxin-associated gene A (CagA) and vacuolating cytotoxin A (VacA), which will cause a local inflammatory reaction. Because of these variables, the integrity of the stomach epithelium is compromised, which results in an increase in acid secretion and a reduction in mucosal defense system function. As a consequence of the imbalance that occurs between aggressive factors (such as stomach acid and pepsin) and defensive factors (such as mucus and bicarbonate secretion), individuals are more likely to develop ulcers.

MATERIALS AND METHODS

During the course of a comparison research that was carried out at the department of Microbiology, a total of sixty-five individuals who were suffering from dyspepsia or ulcers were recruited for the study. It was determined that they were between the ages of 20 and 60 years old. Both men and women were part in the group. The sample was collected and then put to ELISA and Rapid Chromatographic Immunoassay. During the course of the investigation, which lasted from January 2022 to December 2023, a correlation was determined between these two diagnostic procedures.

Inclusion Criteria of Patients

- A total of sixty-five individuals who were suffering from ulcers or dyspepsia as a result of reflex esophagitis or non-ulcer dyspepsia were subjected to the research.
- The ELISA and the quick Chromatography Immunoassay (also known as the quick diagnostic test card) were performed on blood samples that were obtained.

Samples Used for Study

Elisa and Rapid Chromatography Immunoassay have each requested a blood sample for their respective assays.

Test Used

1. ELISA for *H. Pylori* for detection of IgG
2. Rapid Chromatography Immunoassay (or Rapid diagnostic strip test)

Processing on the Specimens:

Blood samples: The Elisa test and the Rapid Diagnostic test were carried out simultaneously after the serum was extracted from the blood samples.

ELISA

Collection of Samples

Following the collection of about 5 milliliters of blood from each patient using a sterile syringe, the serum was separated by centrifugation and kept at a temperature of -20 degrees Celsius until Elisa employed it for the detection of IgG antibody.

ELISA Kit

Patients' serum that has been diluted is added to wells that have been coated with pure antigen. Antibodies that are specific to IgG bind to the antigen if they are present. After washing away any materials that are not bound, the enzyme conjugate is next introduced in order to bind to the antibody-antigen complex, if it is present within the sample. The substrate is then added once the excess enzyme conjugate has been washed away. In order to facilitate the hydrolysis of the substrate by the enzyme, the plate is placed in an incubator. The quantity of IgG-specific antibody present in the sample is directly proportional to the intensity of the color that is produced inside the sample.

RESULTS

We detected 25 positive instances, which is 38.4% of the total number of patients. In forty cases, or 61.6%, the results were negative. (See Table 1)

Table 1: The total number of instances that were positive (n=65)

Total No. of Cases	Positivity	Percentage
65	25	38.4

Table2: The outcome of the endoscopic examination (n=65)

Endoscopic Finding	No of Cases	Percentage
NonUlcerdyspepsia	40	61.5
Ulcers	22	33.8
Oesophagitis	03	4.7
Total	65	100

The above-mentioned [Table 2] described the endoscopic findings of acid peptic disease. The findings shows that 40 (61.5%) patients had Non ulcer dyspepsia. 22(33.8%) cases were Ulcer of the stomach or duodenum and 3(4.7%) cases were Oesoghagitis. H.Pylori is isolated from 25 cases out of 65 cases.

Table 3: The male-to-female ratio distribution among illnesses was determined.

Disease	Exact no.(M:F)	Ratio(M:F)
NonUlcerdyspepsia	8:3	2.66:1

Ulcers	9:4	2.25:1
Oesophagitis	0:1	0:1

This survey found that the ratio of males to females was 2.12 to 1. Whereas the ratio was 2.66:1 in the group with non-ulcer dyspepsia, it was 2.25:1 in the group with ulcers, and there was only one female in the group with oesophagitis. A male preponderance was seen in this investigation, which is in line with the findings of studies conducted by Longman and colleagues.

Table 4: In each condition, the percentage of positive symptoms (n=65)

Diseases	Total No of Cases	Positive Cases	Percentage of positivity
Non Ulcerdyspepsia	40	11	27.6
Ulcers	22	13	59.1
Oesophagitis	03	01	33.3
Total	65	25	100

Table 4 presents the percentage of individuals who tested positive for each category of illness. Eleven out of a total of forty patients with non-ulcer dyspepsia tested positive; thirteen out of twenty-two instances of ulcer were positive; and only one case of oesophagitis was positive, with positivity being identified by both ELISA and Rapid Chromatographic Immunoassay.

Table 5: Distribution of Positive Cases According to Age (n=25)

Age Distribution	NUD(n=11)		Ulcer(n=17)		Oesophagitis(n=1)	
	No. of patients	%	No. of patients	%	No. of patients	%
>10	0	0	0	0	0	0
11–20	0	0	1	4	0	0
21–30	6	24	2	8	0	0
31–40	3	12	8	32	1	4
41–50	1	4	2	8	0	0
51- 60	1	4	0	0	0	0

According to the data shown in [Table 5], the positive cases in our research were distributed according to age. Out of the 11 instances that were positive for NUD, the highest number of patients, which was six (24%) patients, were in the age range of 21 to 30 years old. In the case of 17 ulcer-positive cases, the age group of 31–40 years old included the maximum of eight patients, which is 32 percent. We only discovered

one patient who was positive for oesophagitis, and she was a female patient who was between the ages of 31 and 40.

Table 6: Result of ELISA and Rapid Chromatographic Immunoassay in 65 cases

ELISA	Rapid Chroma to graphic Immunoassay	NUD	Ulcers	Oesophagitis
+	+	11	13	1
+	-	1	4	0
-	+	2	0	1
-	-	26	5	1

NUD= Non ulcer dyspepsia

[Table 6] reveals that out of 65 instances, 25 were found to have good results. From the remaining 38 instances, which range from 65 to 25, forty of them were found to be negative by both the ELISA and the Rapid Chromatographic Immunoassay test. " There were four instances that tested positive only by Rapid Chromatographic Immunoassay, three of which were of non-ulcer dyspepsia, and one of which complained of reflux oesophagitis. One patient was positive only by ELISA, and out of those patients, one patient had non-ulcer dyspepsia, and four patients had ulcers of the duodenum. For the purpose of determining the sensitivity and specificity of urease, the five patients who were only tested positive by ELISA were apparently considered to have a false positive recorded by ELISA or a false negative recorded by Rapid Chromatographic Immunoassay. In a similar manner, the three patients who were only found to have positive results by the Rapid Chromatographic Immunoassay test were supposedly considered to have a false positive recorded by the Rapid Chromatographic Immunoassay test or a false negative recorded by the ELISA test in order to evaluate the sensitivity, specificity, positive predictive value, and negative predictive value of the Rapid Chromatographic Immunoassay test.

Table 7: There is a correlation between the Rapid Chromatographic Immunoassay test and the ELISA test and.

Test	Positive	Negative	Total	Positivity rates
ELISA	30(x)	35(x1)	65	46.2%
Rapid Chroma to graphic Immunoassay	28(y)	37(y1)	65	43.0%

Correlation between ELISA Test and Rapid Chromatographic Immunoassay:

With the purpose of determining the precise correlation between the ELISA and the Rapid Chromatographic Immunoassay for H. pylori, we name the cases that are positive for the ELISA as (x) and the instances that are negative for the Rapid Chromatographic Immunoassay as (x1). The Rapid Chromatographic

Immunoassay positive cases were denoted by the letter y, whereas the Rapid Chromatographic Immunoassay negative persons were denoted by the letter y1. Generally speaking, the correlation coefficient (1) for any two variables will fall somewhere in the range of (1.0) to (+1.0). It is an indication of a significant positive relationship between x and y when the value of (y) is as close as possible to the value of (+1.0). It can be stated that there is a significant positive relationship between the ELISA and the Rapid Chromatographic Immunoassay test for H. pylori. This implies that if the positives rate for the ELISA test is increased, then the positivity rate for the Rapid Chromatographic Immunoassay test will also rise.

DISCUSSION

Helicobacter pylori (H. pylori) continues to play a significant role in the development of peptic ulcer disease (PUD), making a considerable contribution to the development of both gastric and duodenal ulcers among patients. It is crucial to get a precise diagnosis of H. pylori infection in order to perform efficient care and prevention of ulcer recurrence, as well as to reduce consequences such as bleeding, perforation, and the possibility of development to stomach cancer. For the purpose of identifying H. pylori, this study demonstrates the diagnostic value of both non-invasive and invasive approaches. When it comes to initial diagnosis and post-treatment monitoring, non-invasive assays, in particular the urea breath test (UBT) and stool antigen test (SAT), exhibit good levels of sensitivity and specificity, as well as practicality. The fact that they are non-invasive and simple to use makes them an excellent choice for the majority of patients, particularly in situations when endoscopy is not urgently required. However, invasive procedures such as endoscopy with biopsy continue to be necessary in situations where problems are suspected or when confirmation of H. pylori infection is required in individuals who are at a high risk. The findings highlight the significance of a specialized approach to diagnosis, in which non-invasive tests are utilized as the primary diagnostic tools in ordinary clinical practice, while invasive testing are reserved for situations that are more complicated. Detection and elimination of H. pylori at an early stage not only facilitate the healing of ulcers, but they also prevent ulcers from returning in the future and major complications from occurring. Additionally, the study highlights the rising problem of antibiotic resistance, which calls for accurate diagnosis tools in order to advise proper treatment. In light of this, it will be essential to continue research and make breakthroughs in diagnosis accuracy in order to improve patient outcomes in the management of peptic ulcer disease that is caused by H. pylori. In conclusion, the most successful method for controlling H. pylori infections in patients who have peptic ulcers is to use a mix of diagnostic procedures that are tailored depending on the features of the patient and the clinical presentation. Patient outcomes will be considerably improved, and the worldwide burden of peptic ulcer disease will be reduced, if an accurate and prompt diagnosis is administered, followed by therapy that is specifically targeted.

There is little chance of false positives with Elisa tests because their specificity was shown to be 91.1% in the May trial. Some possible explanations for these dubious positives include a stomach pH that is neutral, gastric atrophy caused by bacteria like Klebsiella or Proteus, or the side effects of our durg medication. Since proteus thrives in acidic environments, patients who are already taking medication for ulcers are the main targets of suspicion. It is possible that Elisa got the wrong negative results because four of the cases were positive only by Rapid chromatographic immunoassay. Due to sample mistakes, technical issues, or the organisms' patchy distribution, it is possible that the diagnostic yield from infected people was lower than anticipated. The stringent nature of H. pylori, the challenges in transferring and storing the organisms, and the fact that patients in India often take metronidazole for protozoal infestations could all have played a role in the false negative results in the biopsy specimens. Helicobacter pylori might be overwhelmed by

other microbes, leading to false negative results. D. Nair et al. (1997) noted that difficulties in isolating *H. pylori* from biopsy tissues led to the development of many additional serological assays. When endoscopy is not an option, testing for antibodies to the bacterium can still confirm *H. pylori* infection in a patient. There is no easier way than this.

Conclusion:

For individuals with peptic ulcer disease (PUD), the persistence of *Helicobacter pylori* (*H. pylori*) is a major risk factor for the formation of gastric and duodenal ulcers. Proper treatment and prevention of ulcer recurrence, as well as reduction of consequences including bleeding, perforation, and the chance of developing stomach cancer, depend on a correct diagnosis of *H. pylori* infection. The diagnostic utility of both non-invasive and invasive methods for recognizing *H. pylori* is demonstrated in this study. The urea breath test (UBT) and the stool antigen test (SAT) are two examples of non-invasive tests that are both sensitive and specific, and they are also very practical for use in both initial diagnosis and monitoring after therapy. In cases where endoscopy is not an immediate need, their ease of use and lack of invasiveness make them a great option for most patients. To confirm *H. pylori* infection in high-risk patients or in cases where issues are suspected, intrusive procedures like endoscopy with biopsy are still required. These results emphasize the need for a specialized approach to diagnosis, where non-invasive procedures are used for routine clinical practice and invasive tests are saved for more complex cases. Early *H. pylori* detection and removal not only speeds up ulcer healing, but also stops ulcers from coming back and other serious problems. Antibiotic resistance is an increasing concern, and this study emphasizes the need for reliable diagnostic techniques to guide treatment decisions. Given this, it is crucial to keep researching and finding better ways to diagnose *H. pylori*-related peptic ulcer disease so that patients can have better results when treated. Ultimately, treating *H. pylori* infections in peptic ulcer patients requires a combination of diagnostic approaches that are customized to each patient's characteristics and clinical presentation. An accurate and rapid diagnosis, followed by focused therapy, will significantly improve patient outcomes and lessen the global burden of peptic ulcer disease.

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