A Comparative Study of Serological and Stool Antigen Tests for \textit{Helicobacter pylori} Infection Diagnosis

Shler Ali Khorsheed $^1$

Abstract

Background: \textit{Helicobacter pylori} infection is prevalent worldwide and linked to gastrointestinal disorders, including gastritis, ulcers, and stomach cancer. Accurate diagnosis is crucial for effective treatment and monitoring. Non-invasive tests like serology and stool antigen testing are commonly used for diagnosis, but their comparative efficacy needs evaluation, especially in regions with varying prevalence rates. Methods: This comparative study included 120 participants from northern Iraq, comprising 60 with gastrointestinal disorders (mainly dyspepsia) and 60 healthy controls. Stool and serum samples were collected, and stool antigen tests and serological analysis (IgM) were performed. Results: The prevalence of \textit{H. pylori} infection was higher in patients than controls, with 41.7% positive for stool antigen tests compared to 28.3% in controls (p = 0.003), and 37.5% positive for serology compared to 25.8% in controls (p = 0.001). Stool antigen testing demonstrated higher sensitivity in detecting active infection. Discussion: Non-invasive diagnostic methods like stool antigen tests offer advantages such as ease of implementation and unaffectedness by medications. In this study, stool antigen testing showed superior efficacy in detecting active \textit{H. pylori} infection compared to serology, which may retain antibodies post-treatment, potentially leading to false positives. Conclusion: Both serological and stool antigen tests are valuable for diagnosing \textit{H. pylori} infection, with stool antigen testing exhibiting higher sensitivity, especially in identifying active infections. The study recommends the use of stool antigen tests, particularly in dyspepsia patients, to determine active infection before initiating treatment, considering its superiority over serology. However, factors like sample handling and environmental conditions may affect stool antigen test results.

Keywords: \textit{Helicobacter pylori}, Serology, Stool antigen test, Gastrointestinal disorders, Diagnosis.

1. Introduction

\textit{Helicobacter pylori}, a chronic bacterial infection, affects nearly half of the world's population. This highly mobile, spiral-shaped, or curved Gram-negative bacterium, characterized by multiple flagella, selectively colonizes the gastric epithelium. The \textit{Helicobacter pylori} IgM Test, a blood analysis, is utilized to detect the presence of IgM antibodies, indicating an infection. This infection can significantly impact the digestive system, potentially leading to disorders such as gastritis, digestive ulcers, and, in severe cases, stomach cancer (Rostami and Haddadi, 2012; Awuku et al., 2017; V et al., 2022).

Most individuals infected with \textit{H. pylori} remain asymptomatic.

Significance: Accurate diagnosis of \textit{Helicobacter pylori} infection is crucial due to its association with gastrointestinal diseases, including ulcers and cancer.

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Editor Md Asaduzzaman Shishir, And accepted by the Editorial Board Apr 06, 2024 (received for review Mar 05, 2024)

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Please cite this article.


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2. Materials and Methods

Study Design and Participants:
This comparative study included a total of 120 participants, with 60 individuals suffering from gastrointestinal disorders, particularly dyspepsia, and 60 healthy controls. Participants were recruited from Azadi Teaching Hospital and various private clinics in Kirkuk Governorate, northern Iraq, from April 2021 to March 2022. The study was conducted following the fundamental approvals of the local ethical committee of the Health Directorate.

Inclusion and Exclusion Criteria:
Both male and female participants aged 18 years and older were included in the study. Informed consent was obtained from each participant. The control group consisted of individuals with no history of gastrointestinal disease. For the patient group, inclusion criteria required the persistence of dyspeptic symptoms for at least three months. Exclusion criteria included pregnancy, severe liver and kidney problems, and recent (within one month) use of antibiotics, proton pump inhibitors, or H2 receptor blockers.

Sample Collection and Storage:
Stool and serum samples were collected from all participants and stored at −20 °C until further analysis.

Laboratory Analysis:
Stool Sample Analysis: Stool samples were analyzed for antigens using an enzyme immunoassay kit (HpSA) TM, following the manufacturer’s instructions.

Serum Sample Analysis: Serum samples were analyzed for IgM antibodies using a commercial Premier EIA kit (HpIgM).

Statistical Analysis:
Data were analyzed using IBM SPSS Statistics version 26. Results were expressed in frequencies and percentages. Comparisons between the patient and control groups were made using the chi-square test, with a P-value considered significant at less than 0.05.

3. Results

Participant Demographics
The study included a total of 120 participants, comprising 60 individuals with dyspepsia symptoms (patient group) and 60 healthy controls (control group).

Gender Distribution: The gender distribution indicated a higher prevalence of dyspepsia among males than females. Specifically, there were 36 males (30.0%) in the patient group and 33 males (27.5%) in the control group, making a total of 69 males (52.5%). In comparison, there were 23 females (22.5%) in the patient group and 24 females (20.0%) in the control group, totaling 47 females (47.5%). The percentage of affected males was higher than that of females in both the patient and control groups.

Age Distribution: Participants were categorized into different age groups. The age group with the lowest incidence of dyspepsia was...
Table 1. The baseline characteristics of the individuals participating (N=120).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Controls N=60</th>
<th></th>
<th>Patients N=60</th>
<th></th>
<th>Total N=120</th>
<th></th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>33(27.5%)</td>
<td>36(30.0%)</td>
<td>69(52.7%)</td>
<td>0.96</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Female</td>
<td>23(22.5%)</td>
<td>24(20.0%)</td>
<td>47(37.5%)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>21-30</td>
<td>4(3.3%)</td>
<td>9(7.5%)</td>
<td>13(10.8%)</td>
<td>0.37</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>31-40</td>
<td>18(15.0%)</td>
<td>19(15.8%)</td>
<td>37(31.7%)</td>
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</tr>
<tr>
<td>41-50</td>
<td>19(15.8%)</td>
<td>25(20.8%)</td>
<td>44(36.7%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51-60</td>
<td>11(9.2%)</td>
<td>13(10.8%)</td>
<td>24(20.0%)</td>
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</tr>
</tbody>
</table>

Table 2. Comparison of positive results SAT versus serology tests among participants

<table>
<thead>
<tr>
<th>Tests</th>
<th>Patients N=60 (50%)</th>
<th>Controls N=60 (50%)</th>
<th>Total N=120 (100%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>50 (41.7%)</td>
<td>34 (28.3%)</td>
<td>84 (70.0%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Negative</td>
<td>10 (8.3%)</td>
<td>16 (12.7%)</td>
<td>26 (10.7%)</td>
<td></td>
</tr>
<tr>
<td>Serology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>45 (37.5%)</td>
<td>31 (25.8%)</td>
<td>76 (61.7%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Negative</td>
<td>15 (12.5%)</td>
<td>14 (12.5%)</td>
<td>29 (24.2%)</td>
<td></td>
</tr>
</tbody>
</table>

Note: The result is negative if it is less than 30 milligrams/dl. The possibility of infection increases if the result ranges between 30.01-39.99 milligrams/dl. The result is positive if it is more than or equal to 40 milligrams/dl.
21-30 years, with 9 patients (7.5%) and 4 controls (3.3%), totaling 13 individuals (10.8%). The next least affected age group was 51-60 years, comprising 13 patients (10.8%) and 11 controls (9.2%), totaling 24 individuals (20.0%). The 31-40 age group included 19 patients (15.8%) and 18 controls (15.0%), totaling 37 individuals (32.5%). The 41-50 age group had the highest rates of dyspepsia, with 25 patients (20.8%) and 21 controls (17.5%), totaling 46 individuals (36.7%).

Diagnostic Test Results

Stool Antigen Test (SAT): The SAT results revealed a significantly higher incidence of H. pylori infection among patients compared to the control group. Specifically, 50 dyspepsia patients (41.7%) tested positive for H. pylori, compared to 34 controls (28.3%). This difference was statistically significant (p = 0.003).

Serological Test (IgM): Similarly, the serological test for IgM antibodies indicated a higher prevalence of H. pylori infection in the patient group. In this test, 45 patients (37.5%) tested positive, compared to 31 controls (25.8%). This result also showed statistical significance (p = 0.001).

The results of this study underscore a higher prevalence of H. pylori infection among individuals with dyspepsia symptoms compared to healthy controls. The diagnostic tests, both the stool antigen test and the serological test for IgM, confirmed this higher incidence, with statistically significant differences observed between the patient and control groups. These findings are presented in detail in Table 1 and Table 2, and visually illustrated in Figure 1.

3. Discussion

*Helicobacter pylori* (H. pylori) is a significant bacterial pathogen known to infect the stomach lining, leading to conditions such as ulcers and gastritis. Accurate diagnosis of H. pylori is essential for effective treatment and management of related gastrointestinal disorders. Among the diagnostic methods, blood tests and stool tests are commonly used to detect the presence of the bacteria or the body's immune response to it. Blood tests measure levels of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies. IgM indicates a recent infection, whereas IgG suggests a current or past infection. Stool tests detect H. pylori antigens, providing direct evidence of the bacteria's presence.

Gender and Age Disparities in Infection Rates

Our study revealed a higher prevalence of H. pylori infection among males compared to females. Specifically, 36 males (30.0%) in the patient group and 33 males (27.5%) in the control group tested positive, whereas only 23 females (22.5%) in the patient group and 24 females (20.0%) in the control group were affected. This disparity might be attributed to lifestyle factors, such as dietary habits, longer periods without food, and a higher likelihood of consuming meals outside the home. Additionally, biological differences, such as variations in immune responses between genders, could play a role.

Age also significantly influenced H. pylori infection rates. Participants aged 41-50 exhibited the highest infection rates, with 25 patients (20.8%) and 21 controls (17.5%) testing positive. This age group often leads a demanding lifestyle, which can contribute to irregular eating patterns, higher stress levels, and a potentially weakened immune system, making them more susceptible to infection. Furthermore, genetic predispositions might also influence susceptibility to H. pylori, necessitating further research to understand these underlying factors better.

Diagnostic Methods and Their Efficacy

Non-invasive tests, such as the Stool Antigen Test (SAT) and serological tests, are generally preferred for diagnosing H. pylori due to their convenience and cost-effectiveness. The SAT, in particular, has several advantages, including its simplicity, resistance to drug interference, and ability to monitor post-treatment infection status. It is effective across all age groups and during pregnancy, making it a versatile diagnostic tool.

In our study, the SAT identified a higher incidence of H. pylori infection among dyspepsia patients (41.7%) compared to the control group (28.3%), with a statistically significant difference (p = 0.003). Similarly, the serological test showed a higher positivity rate among patients (37.5%) compared to controls (25.8%), with statistical significance (p = 0.001). These findings underscore the importance of using multiple diagnostic methods to ensure accurate detection of H. pylori.

Comparative Studies and Recommendations

Our results align with previous studies, such as those conducted by Hussein et al. (2021) and Negash et al. (2018), which also found higher infection rates using SAT compared to serological tests. Hussein et al. emphasized the necessity of combining non-invasive and invasive diagnostic methods to accurately diagnose H. pylori and guide treatment. Similarly, Negash et al. recommended the SAT as a superior method for identifying active H. pylori infections in dyspepsia patients.

Given the higher infection rates observed in males and the 41-50 age group, targeted prevention and treatment strategies are essential. Lifestyle modifications, such as healthier eating habits and stress management, could help reduce infection rates. Additionally, the implementation of routine SAT screening in at-risk populations could facilitate early detection and treatment, improving patient outcomes.

The findings of our study highlight the critical role of accurate diagnostic methods in managing H. pylori infections. The SAT proved to be a reliable tool for detecting active infections, showing higher infection rates in patients compared to controls. The observed gender and age disparities in infection rates necessitate targeted interventions and lifestyle modifications to mitigate the
risk of H. pylori infection. Further research is needed to fully understand the underlying factors contributing to these disparities and to develop effective prevention and treatment strategies.

4. Conclusions
Serological tests and the Stool Antigen Test (SAT) are both effective methods for diagnosing Helicobacter pylori infections. Serological tests, which detect IgM antibodies, are useful for identifying recent infections and evaluating treatment effectiveness. However, they can yield false positives due to the persistence of antibodies after the infection has cleared. In contrast, the SAT is preferred for diagnosing active H. pylori infections, particularly in dyspepsia patients, due to its ability to detect active infections directly. Despite its sensitivity to timing and environmental conditions, the SAT is recommended as the most reliable method for confirming active H. pylori infections prior to initiating treatment. Our study underscores the importance of accurate diagnostic methods and highlights the necessity for targeted prevention and treatment strategies, particularly for high-risk groups such as males and individuals aged 41-50. Further research is essential to enhance understanding and improve intervention strategies for H. pylori infections.

Author contributions
S.A.K. conceptualized, analyzed data, edited and reviewed the manuscript. All authors read and approved the final version of the manuscript.

Acknowledgment
The authors thanked the Department.

Competing financial interests
The authors have no conflict of interest.

References


