

Comparative Evaluation of Stool Antigen Test and Serology (Ig^M) For *Helicobacter Pylori* Infection Among Symptomatic and Asymptomatic Population in India¹

*Saroj Kumar Thakur, **Dr. Potsangbam Kumar Singh

*Research Scholar, **Professor, CMJ University, Shillong, Meghalaya

DOI:10.37648/ijrmst.v15i01.003

Received: 25 November 2022; Accepted: 28 December 2022; Published:27 January 2023

ABSTRACT

Introduction: *Helicobacter pylori* is an important bacterial agent that mediates a range of gastrointestinal illnesses ranging from gastritis to stomach cancer. These problems can be caused by a variety of factors, including but not limited to: Eliminating the *Helicobacter pylori* bacteria is a viable option for treating or preventing the disorders listed above. Despite the fact that living in the harsh conditions of the stomach's acidic environment was not something that was anticipated in the past. The bacteria known as *H. pylori* have been shown to have a significant role in the formation of peptic ulcers, as a recent discovery has shown. It manifests as a constant pain or discomfort in the upper abdomen, which is frequently associated with eating or feeling hungry, belching, bloating, nausea, vomiting, early satiety, and heartburn. Other symptoms that may be experienced include early satiety and early satiety, bloating, nausea, and vomiting. In some instances, the pain and suffering come and go at random intervals.

Objective: The aim of this study is to compare the *H. pylori* stool antigen (HpSAg) and Immunoglobulin (Ig^M) serology tests in symptomatic and Asymptomatic population in India, and determine their usefulness.

Materials & Methods: The tertiary care center's department of microbiology served as the site for the cross-sectional study, which was carried out there between September 2019 and August 2021. The study was hosted by the department. Participants in the research ranged in age from 18 to 70 years old and might either have symptoms or not. Symptomatic and asymptomatic individuals were both included. 46 individuals had samples of their blood and faeces obtained and analysed for *H. pylori* infection using the enzyme-linked immunosorbent test (ELISA), Ig^M serology, and HpSAg, respectively. The results showed that all of the patients were infected with *H. pylori*.

Results: Out of forty-six samples, controls had more reliable serology results compared to the subjects, with 42 (91.3%), as opposed to 31, which had 67.4%, and this difference was significantly significant ($p=0.001$). The faeces antigen test for *H. pylori* (HpSAg) was more reliable in the controls (36 out of 78.3%) than it was in the subjects (31 out of 67.4%), with only one instance (2.2%) of an unclear result in the two groups. In any event, this did not constitute a statistically significant finding ($p = 0.48$).

¹ How to cite the article:

Thakur S.K., Singh P.K., Comparative Evaluation of Stool Antigen Test and Serology (Ig^M) For *Helicobacter Pylori* Infection Among Symptomatic and Asymptomatic Population in India, IJRMST, Jan-Jun 2023, Vol 15, 16-23, DOI: <http://doi.org/10.37648/ijrmst.v15i01.003>

Conclusion: The HpSAg and Ig^M test is a non-invasive, straight forward, and accurate method for determining whether *H. pylori* is present in a stool & blood sample respectively; nonetheless, its utilization for determination has to be investigated.

Keywords: HpSAg, Ig^M, symptomatic and asymptomatic, *H. pylori*, ELISA

INTRODUCTION

Helicobacter pylori is an important bacterial agent that mediates a range of gastrointestinal illnesses ranging from gastritis to stomach cancer. These problems can be caused by a variety of factors, including but not limited to: Eliminating the Helicobacter pylori bacteria is a viable option for treating or preventing the disorders listed above. Despite the fact that living in the harsh conditions of the stomach's acidic environment was not something that was anticipated in the past. ¹⁻³ Peptic ulcers have been linked to the bacteria *H. pylori*, which has been demonstrated to have a significant role in the development of peptic ulcers. ^{4,5} It manifests as a constant pain or discomfort in the upper abdomen, which is frequently associated with eating or feeling hungry, belching, bloating, nausea, vomiting, early satiety, and heartburn. Other symptoms that may be experienced include early satiety and early satiety, bloating, nausea, and vomiting. In some instances, the pain and suffering come and go at random intervals. ⁶ The pervasiveness of *H. pylori* infection has been accounted for to be higher in non-industrial nations comparative with created nations. Various methods of transmission have been proposed by logical literary works and these incorporate, oro-oral, faeco-oral, gastro-oral, gastro-gastric and individual to individual transmissions. ^{7,8} They are financially accessible, simple to perform and reasonable, yet answered to be temperamental for the determination of *H. pylori* since they can't separate among dynamic and asymptomatic colonization and past and current *H. pylori* infection. ⁹ The stool antigen test is utilized to distinguish hints of *H. pylori* antigens in the excrement. It is a dependable and precise test for analysis of the *H. pylori* infection and affirmation of its fix after treatment, since it maintains a strategic distance from recognition of past *H. pylori* infection. It is helpful to the patients and can be effortlessly performed even in little research centers. ¹⁰ However its precision in various clinical circumstances and outside of controlled investigations involves concern. There is scarcity of studies pointed toward deciding *H. pylori* symptomatic tests exactness among asymptomatic grown-up population in India. There is the requirement for fundamental examinations on exactness of financially savvy and accessible painless analytic strategies. ¹¹ In this study, we looked at the *H. pylori* infection between the stool antigen test and a blood antibody test strategy (Ig^M) to figure out which technique is a more proficient and trustworthy painless test for recognition of *H. pylori* infection in asymptomatic and symptomatic grown-up patients' population in India. What's more, the current study decided the exactness, responsiveness, explicitness, positive and negative probability proportions of the stool antigen and Ig^M serology tests just as sex, age and geological region varieties with the pace of *H. pylori* infection.

MATERIALS & METHODS

The cross-sectional study was carried out in Department of Microbiology from September 2019 to August 2021 at Tertiary Care Center. A total 46 Blood and Stool samples from both symptomatic subject and asymptomatic control are taken respectively. 89 patients both (subject and control) with age group between 18 to 70 years are included in the study.

Inclusion and Exclusion Criteria for Subjects

Inclusion Criteria

1. Subjects with side effects of dyspepsia.
2. Side effects more likely than not endured for at least 3 months or intermittent in nature over a similar period.

3. Subjects who gave informed agree to take part in the review.

Exclusion Criteria

1. Participants who had symptoms of dyspepsia for a period of fewer than ninety days before to the study.
2. Participants who were resistant to the therapy for *H. pylori* eradication.
3. Participants who had used an inhibitor of the proton pump (PPI) or another medicine known to limit secretion within the previous month before to the test.
4. Participants who were given an anti-toxin therapy during the previous month, prior to taking the test.
5. Test subjects who had consumed bismuth compounds within the previous month prior to the examination.
6. Participants who had clinical manifestations of an illness caused by gastroesophageal reflux disease (GORD).

Inclusion and Exclusion Criteria for Controls

Inclusion Criteria

1. People that were age and sex coordinated with subjects selected into the review.
2. Clearly solid people.
3. People who gave informed assent

Exclusion Criteria

1. Individuals with previous history of chronic or recurrent symptoms of dyspepsia.
2. Individuals in whom a clinical or laboratory diagnosis of peptic ulcer disease had been made in the past.

Sample Collection

○ Blood Sample for Serological Evaluation

A plain vial devoid of any anticoagulant was used to collect approximately 5 milliliters of venous blood from each patient.⁹The patient's name, together "with the patient number and the date of collection, was written on the vial". The vial was heated in a water bath at 37⁰c for half an hour, or blood had been clotted. After the blood had been clotted, it was centrifuged, and the serum was aspirated into a few (200μl) Eppendorf tubes. These tubes were then stored at -70⁰c until they were analyzed.

○ Stool Sample for Antigen Detection

About 20 grams of stool were collected into a sterile container. All stool samples were frozen at -70⁰c until tested for *H. pylori* antigen.

○ Test Performed

Detection of *Helicobacter pylori* Antigen in Stool Specimens by ELISA

ELISA for the *H. pylori* antigen (monoclonal) in stool specimens was performed using a commercial test kit

(Premier Platinum HpSAg Plus®, Meridian Bioscience Europe, Italy). The manufacturer's instructions were followed during the procedure.

Detection of Anti-*H. pylori* Ig^M in the Serum by ELISA

ELISA for the anti-*H. pylori* Ig^M antibody was performed using a commercial test kit (SERION ELISA® Classic *Helicobacter pylori* Ig^M, Serion, Germany). The manufacturer's instructions were followed during the procedure.

○ Statistical Analysis

The results of the study were recorded systematically, and the statistical analysis of the data was performed using SPSS 20.0 for Windows 7. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy of serum ELISA were calculated manually using a standard formula. The level of significance was set at $P < 0.05$.

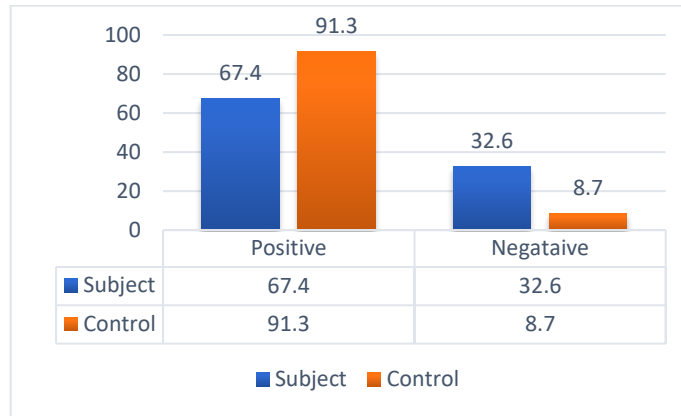
RESULTS

The study included both 46 individuals (20 males and 26 females) and 46 controls (20 males and 26 females). In all, there were 46 participants. The average age of the patients was found to be 40.87 ± 13.31 years, whereas the average age of the controls was found to be 40.83 ± 13.20 years. The ages of the two test participants and the controls ranged from 18 to 70 years, with 18 years serving as the base age.

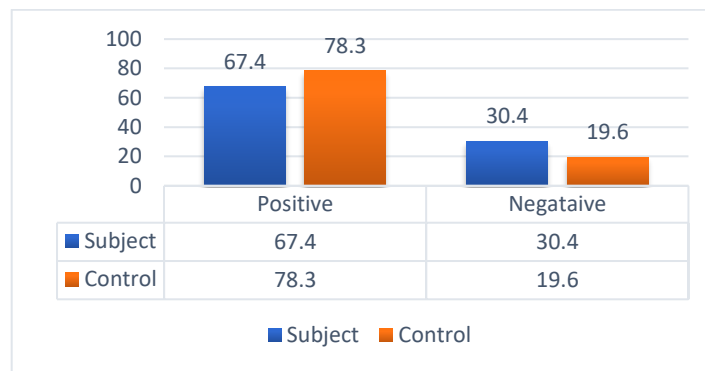
The results of the serology (Ig^M) and *H. pylori* stool antigen (HpSAg) tests for the two groups are outlined in **Table No.1**. The controls had more reliable serology results compared to the subjects, with 42 (91.3%), as opposed to 31, which had 67.4%, and this difference was significantly significant ($p = 0.001$). The feces antigen test for *H. pylori* (HpSAg) was more reliable in the controls (36 out of 78.3%) than it was in the subjects (31 out of 67.4%), with only one instance (2.2%) of an unclear result in the two groups. In any event, this did not constitute a statistically significant finding ($p = 0.48$). **Graph No.1, 2**

Table No.1: Serology and stool antigen test in subjects and controls

Variable	Subjects(n=46)	Control(n=46)	Total(n=92)	χ^2	P-Value
<i>H.pylori</i> Ig ^M				8.03	0.001
Positive	31(67.4%)	42(91.3%)	73(79.3%)		
Negative	15 (32.6%)	4(8.7%)	19(20.7%)		
Stool antigen test for <i>H. pylori</i> (HpSAg)				1.46	0.48
Positive	31(67.4%)	36(78.3%)	67(72.8%)		
Negative	14(30.4%)	9(19.6%)	23(25.0%)		
Equivocal	1(2.2%)	1(2.2%)	2(2.2%)		



Graph No.1: *H. pylori* Ig^M test in subjects & Control



Graph No.2: *H. pylori*(HpSAg) test in subjects & Control

Table No.2 illustrates the correlation between the stool antigen test and the serology performed on both the subjects and the controls. 77.4% of the individuals tested positive for both HpSAg and *H. pylori* Ig^M, with a P-value of 0.07. Despite the fact that 35 (83.3%) of the controls tested positive for HpSAg and *H. pylori* Ig^M, which was very important.

Table No.2: Comparison of stool antigen test and serology in subjects and controls

Group			<i>H. pylori</i> Ig ^M		Total	χ ²	P-value
			Positive	Negative			
Subjects	HpSAg	Positive	24(77.4%)	7(46.7%)	31(67.4%)	5.41	0.07
		Negative	7(22.6%)	7(46.7%)	14(30.4%)		
		Equivocal		1(6.7%)	1(2.2%)		
Controls	HpSAg	Positive	35(83.3%)	1(25.0%)	36(78.3%)	8.56	0.014
		Negative	6(14.3%)	3(75.0%)	9(19.6%)		
		Equivocal	1(2.4%)		1(2.2%)		

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DISCUSSION

This study showed that females are more prone to *H. pylori* infection than males that is 56.52% is female and 43.47% is males. There is 13.05% of female is more than male with *H. pylori* infection in dyspeptic patients in contrast to the pattern observed by Jones in the British population. In the British study, the researchers saw that older people complained of dyspepsia more frequently than younger people. This led them to hypothesise that older people were probably more concerned about their health or were afraid of more serious underlying disorders.¹³

The prevalence of was found to be 67.4% among the symptomatic (dyspeptic) subjects in this study when using both serology (IgM) and the *H. pylori* stool antigen (HpSAg) test, whereas the prevalence of was found to be 91.3% and 78.3% among the asymptomatic control subjects when using both serology (IgM) and the *H. pylori* stool antigen (HpSAg) test respectively.

The serology results of the controls were more trustworthy than those of the patients, and the difference between the two groups was statistically significant ($p = 0.001$). The *H. pylori* facial antigen test (HpSAg) was more trustworthy in the controls than it was in the patients, with just one occasion (2.2% of total cases) of an ambiguous result in each group. In any case, this did not constitute a finding that could be considered statistically significant ($p = 0.48$). The majority of the research that looked at the effectiveness of the stool antigen test in the diagnosis of *H. pylori* infection focused on defining the sensitivity and specificity of the test. As a result, the real prevalence has not been the focus of serious research and close inspection in populations that have been investigated.¹⁴ Instead, the positives and negatives were evaluated in relation to a gold standard that had been established beforehand.¹⁵ However, research conducted by Buyukbaba-Boral et al. demonstrates that a prevalence of 36.6% was found in *H. pylori* stool antigen (HpSAg) tests conducted on 445 patients in Turkey ranging in age from 2 to 78 years. After taking into account participants' ages, the researchers found that the frequency of among people with ages ranging from 16 to 78 was 42.4% in the same study. The population that was examined in this study was far smaller than the one that was investigated in Turkey. It is possible that the results of a study with a much bigger population might have been different. It is also essential to emphasise that despite the fact that a kit very comparable to this one was utilised in the research conducted in Turkey.¹⁶

In the examination of the faeco prevalence performed by many researchers on the symptomatic population, there is a shortage of case control studies. This should not come as a surprise given that a number of studies conducted in both young and adult populations represent good sensitivity and specificity. Furthermore, in general, the prevalence of (as evaluated by a number of different diagnostic methods) has frequently been reported as being higher in the dyspeptic group than in the asymptomatic controls.^{17,18,19} The seroprevalence in the dyspeptic participants is comparable to the faecoprevalence, but in the control subjects, the seroprevalence is significantly greater than the faecoprevalence. When one takes into account the fact that an individual may contain antibodies to *H. pylori* as a result of earlier exposure, even if he may not be actively infected with the organism, one sees that this is not an unexpected finding at all. The seroprevalence of 91.3% among the controls is close to the 89.19% that Ding Zet al. obtained.²⁰ Abuse of antibiotics is a frequent practice in this region of the globe, which may be the reason for the comparatively lower seroprevalence among dyspeptic patients in our study that was conducted in the same region of the nation. It is also important to take into account the fact that patients who have functional dyspepsia typically make up a larger percentage of dyspeptic cases. Furthermore, it is common knowledge that patients who have functional dyspepsia have a greater number of psychosomatic-emotional complaints and, as a result, make more frequent trips to the hospital. According to the findings of past studies that were carried out in this region of the world, in addition to the high frequency of among controls, it is possible that the cause of dyspepsia in this region is the result of a combination of many factors.²¹ In this study correlation between the stool antigen test and the serology performed on both the subjects and the controls. 77.4% of the individuals tested positive for both HpSAg and *H. pylori* Ig^M, with a P-value of 0.07. Despite the fact that 35 (83.3%) of the controls tested positive for HpSAg and *H. pylori* Ig^M, which was very important. There is statistically significant

difference between type of abdominal pain, use of herbal medicine, alcohol ingestion, & NSAID intake.

CONCLUSION

The HpSAg and Ig^M test is a non-invasive, straightforward, and accurate method for determining whether *H. pylori* is present in a stool & blood sample respectively; nonetheless, its utilization for determination has to be investigated. According to the findings of this study, factors such as type abdominal pain, use of herbal medicine, alcohol ingestion, & NSAID intake considered to be risk factors for *H. pylori* infection.

ACKNOWLEDGEMENT

We thank Education and Research Deputies of CMJ University supporting this work. We particularly thank faculties of microbiology department for supporting the work and providing all of the kits used in this work.

Financial support and sponsorship: Nil

Conflict of Interest: None

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