



## A STUDY OF PREVALENCE OF HELICOBACTER PYLORI INFECTION IN URBAN TERTIARY CARE HOSPITAL

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**ABSTRACT** The study is aimed at documenting the prevalence of H. Pylori infection in patients attending a tertiary care teaching hospital, with a large catchment area can be very useful in understanding the burden of this illness. The aim of the study was to determine the prevalence of H. Pylori infection and the use of serological test in diagnosis of Helicobacter Pylori infection in gastritis patients. To study the Helicobacter Pylori infection prevalence in gastritis patients and to evaluate the use of serological test as a screening investigation for H. Pylori infection. The study was a prospective observational study. The study was done in the department of General Surgery, Dhanalakshmi Srinivasan Medical College and hospital, Perambalur, which is a urban tertiary care teaching hospital. Study duration: The data collection for the study was conducted between March 2017 to August 2018. The prevalence of H. Pylori infection was high in the study population. There was no association between the age and H. Pylori infection in study population. The proportion of H. Pylori infection was higher in females. Urea breath test had shown complete concordance with gold standard test with 100 % sensitivity, specificity and predictive values. Serum IgG has displayed High, sensitivity, specificity and predictive values in the study population.

**KEYWORDS :** H.Pylori,urea breath test,gastritis,serological test

### INTRODUCTION

Helicobacter pylori, a gram-negative bacterium which colonizes the mucosa of stomach is present in more than half of the world's population. H. Pylori has been reported to be an important cause of gastro duodenal disorders like peptic ulcer and a major risk factor in the development of gastric carcinoma (GC) and primary gastric lymphoma (PGL). Evidences supporting the etiological role of H pylori in GC and PGL include higher frequency of isolation of H pylori in patients with GC and PGL. Several meta-analyses studies revealed a strong association between H pylori and GC and PGL. (1)

Frequency of H pylori infection varies in various countries. In the developing countries like Bangladesh, India, Pakistan and Thailand, H. pylori is common among general population and is acquired at an early age. There are several studies from India that showed that H. pylori is acquired by most people in early childhood. (2-5) Studies from India showed that the prevalence of IgA and IgG antibodies to H pylori was 56% and 22% respectively and 87% in 0-4, 5-9 and 10-19 years age groups, respectively. (5, 6) In contrast, in more industrialized countries like China, Japan and Singapore prevalence of H pylori infection is somewhat lower. As H pylori is transmitted by faeco-oral route, lower socioeconomic status, poor sanitation, overcrowding and poor water supply are some of the important factors in the development of H.Pylori infection in higher frequency and acquiring the infection in lower age in under developed Asian countries.(7)

Since the discovery of the organism by Marshall and Warren in 1982 various invasive and noninvasive diagnostic tests were developed. Each test has its own advantages and disadvantages which will make it more or less appropriate depending on the clinical situation.(8)The invasive biopsy-based tests which include histology, culture and rapid urease test are important in the diagnosis of H. pylori, as endoscopy allows assessment of treatment indications.(9) Various noninvasive test like serological tests, like stool antigen test,urea breath test etc are also in practice for long period of time. Even though these tests offer an advantage of simplicity and less discomfort to the patient, ease of carrying out by minimally trained paramedical staff, their validity and reliability is relatively inferior compared to the invasive methods.The specificity, sensitivity and positive and negative predictive value of these tools is quite heterogeneous across different settings. (10-15).So, it is advised by many researchers to exercise some caution while prescribing these tests and making clinical decisions based on these test results. We also have to look carefully at the clinical situation, including the pretest probability of the infection in our population, the age of the patient, patients' present complaints and past medical histories, socio-economic status. They identify, measure, and compare the costs and consequences of the alternative strategies to diagnose and/or treat H. pylori infection. These analyses are useful because, despite their complexity, they provide clear picture about the effectiveness of a given tool/strategy in a particular clinical scenario and the cost of each approach.(8)

The present study, which is aimed at documenting the prevalence of H. Pylori infection in patients attending a tertiary care teaching hospital, with a large catchment area can be very useful in understanding the burden of this illness. Also the attempt to estimate the validity and reliability of noninvasive screening methods on these subjects will provide key inputs necessary for clinicians to make appropriate decisions by strengthening the existing evidence on the subject.

### AIMS & OBJECTIVES

#### AIM:

The aim of the study was to determine the prevalence of H. Pylori infection and the use of serological test in diagnosis of Helicobacter Pylori infection in gastritis patients.

#### OBJECTIVES:

1. To study the Helicobacter Pylori infection prevalence in gastritis patients.
2. To evaluate the use of serological test as a screening investigation for H. Pylori infection.

### MATERIALS AND METHODS

**Study Setting:** The study was done in the department of General Surgery, Dhanalakshmi Srinivasan Medical college and hospital, Perambalur, which is a urban tertiary care teaching hospital.

**Study design:** The study was a prospective observational study

**Study population:** The study subjects were patients with symptoms of gastritis and dyspepsia seeking treatment from general surgery outpatient department in the study setting

**Study duration:** The data collection for the study was conducted between March 2017 to August 2018

#### INCLUSION CRITERIA:

- 1) All patients with gastritis and dyspeptic symptoms
- 2) Age group 15 – 50 years
- 3) Both genders

#### Exclusion criteria:

- 1) Patients who are contraindicated for Upper Gastro Intestinal endoscopy.

**Sample size:** Considering the minimum sensitivity and specificity combination to be detected as 85% each, with an alpha error of 0.05 and 80% power of study, a total of 27 participants were required. To account for an attrition rate of 10%, it was decided to include 30 subjects in the final study. Sample size was calculated using stata IC software version 13.

**SAMPLING METHOD:** All the eligible subjects who gave consent to participate in the study were sequentially recruited by convenient sampling, till the required sample size is reached.

**Study procedure:**

Any participant presenting to the OPD with the following symptoms of dyspepsia were analysed for eligibility to be included in the study.

1. Abdominal bloating.
2. Abdominal pain.
3. Nausea
4. Vomiting.
5. Heartburn
6. Indigestion.
7. Loss of appetite

Participants, who satisfied the inclusion and exclusion criteria were explained about the study and consent was obtained from them. Subjects who had signed the informed written consent were evaluated initially by thorough clinical history and physical examination.

Patients were asked to come to outpatient department on the next day morning with empty stomach and with reports of viral markers. Serum IgG antibody against Helicobacter Pylori were assessed by quantitative ELISA by taking 2 ml of blood from the patient and sent to microbiology laboratory where it is centrifuged and serum sample is prepared and stored in optimal condition as up to 60 samples can be run in a single ELISA kit. Urea breath test was done for those patients using Infrared Spectrometer results of which were obtained immediately. Patient is then advised about the endoscopy procedure and 10% lignocaine is sprayed in the posterior pharyngeal wall and patient is positioned in left lateral position. Upper gastro intestinal endoscopy is done which is recorded and biopsy was taken from mucosa of the antrum of the stomach from each participant. Biopsy specimen is stored in formalin and sent to pathology laboratory where the specimen was stained using Giemsa stain and assessed for presence of bacteria. The biopsy specimen sent, were reported after five days. Hence patients were asked to come after collecting the biopsy report to outpatient department. Results obtained were tabulated in the masterchart.

**STATISTICALMETHODS:**

The diagnosis of Pylori by the Giemsa staining was considered as the gold standard investigation in the study. The diagnosis by Serum markers and urea breath test were considered as the explanatory variables. Initially descriptive analysis of all the variables was done by frequency and percentages for categorical variables, mean and standard deviation for quantitative variables. Serum markers and urea breath test validity (sensitivity & Specificity) and predictive values in diagnosing H.Pylori infection were calculated along with their 95% CI. The Serum markers and urea breath test reliability in diagnosing H.Pylori infection were assessed by calculating kappa statistic and p value. Statistical significance of the association was assessed by Chi square test. Statistical analysis was done using IBM SPSS statistical software version 22.

**RESULTS**

80 participants were included in the study for final analysis.

**TABLE1: Descriptive analysis of Age Group in study group (N=80)**

Age Group	Frequency	Percentages
20-29	25	31.25%
30-39	19	23.75%
40-49	36	45.00%

Out of the 80 subjects, the proportion of participants, between 40 to 49 years was 45.00%, which was the most common age group in study population. The proportion of subjects who were aged between 30 to 39 years and 20 to 49 years was 23.75% and 31.25% respectively in study population.(table 1)

**TABLE2:** Descriptive analysis of SEX in study group (N=80) Males constituted 60% of the study population and females constituted the remaining 40% of the study population. (Table 2)

SEX	Frequency	Percent
Female	32	40.00%
Male	48	60.00%
Total	80	100.00%

**TABLE3:** Descriptive analysis of UREA BREATH TEST in study group (N=80)

UREA BREATH TEST	Frequency	Percent
Positive	59	73.8%
Negative	21	26.3%
Total	80	100.00%

The urea breath test has given 59(73.8%) positive results in study population. The remaining participants 21 (26.3%) showed negative results.(table 3)

**TABLE 4:** Descriptive analysis of SERUM IgG in study group (N=80)

SERUM IgG	Frequency	Percent
Positive	61	76.25%
Negative	19	23.75%
Total	80	100.00%

Serum IgG has given 61 (76.25%) positive results, and the remaining 19 (23.75%) were reported negative by serum Ig G. (table 4)

**TABLE 5:** Descriptive analysis of ANTRAL MUCOSAL BIOPSY in study group (N=80)

ANTRAL MUCOSAL BIOPSY	Frequency	Percent
Positive	59	73.80 %
Negative	21	26.30%
Total	80	100.00%

The Antral mucosal biopsy has given 59(73.8%) positive results in study population. The remaining 21 (26.3%) participants were negative for H.Pylori by Antral mucosal biopsy.( table 5)

**TABLE6:** Association of ANTRAL MUCOSAL BIOPSY with Age Groups of study population (N=80)

Age groups	ANTRAL MUCOSAL BIOPSY		Chi square value	P-value
	Positive	Negative		
20-29	19	6	.373	0.829
	76.00%	24.00%		
30-39	13	6		
	68.42%	31.58%		
40-49	27	9		
	75.00%	25.00%		

The prevalence of H.Pylori infection in 20 to 29 years age group (76%) was the highest, followed by 40 to 49 years (75%) and in 30 to 39 years (68.42%) was the least in the study population. No significant P value 0.829 (table 6) association between age and H.Pylori infection was proven in the study.

**TABLE7:** Association of ANTRAL MUCOSAL BIOPSY with SEX of study population (N=80)

SEX	ANTRAL MUCOSAL BIOPSY		Chi square	P-value
	Positive	Negative		
Female	28	4	5.298	0.02
	87.50%	12.50%		
Male	31	17		
	64.58%	35.42%		

The prevalence of H.pylori infection was 87.5% in females and 64.58% in males. The difference in the proportion of H.pylori infection between the two genders was statistically significant. (P value 0.02). (Table 7)

**TABLE8:** Association between urea breath test and antral mucosal biopsy (N=80)

UREA BREATH TEST	ANTRAL MUCOSAL BIOPSY		Chi square	P value
	Positive	Negative		
Positive	59	0	80.000	0.00
	100.00%	0.00%		
Negative	0	21		
	0.00 %	100.00 %		

Table8: Association between urea breath test and antral mucosal biopsy (N=80)

There was strong positive association between the urea breath test and antral mucosal biopsy in study population, which was statistically significant (P value < 0.01). (Table 8)

**TABLE 9:** validity and predictive values of urea breath test in study population (N=80)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	100.00%	100%	100%
Specificity	100.00%	100%	100%
False positive rate	0.00%	0%	0%
False negative rate	0.00%	0%	0%
Positive predictive value	100.00%	100%	100%
Negative predictive value	100.00%	100%	100%
Diagnostic accuracy	100%	100%	100%

The urea breath test has yielded 100% sensitivity, specificity, positive and negative predictive values in the study, with no false positive or false negative results. (Table 9)

**TABLE 10:** association between serum IgG and antral mucosal biopsy findings in study population

SERUM IgG	ANTRAL MUCOSAL BIOPSY		Chi square	P value
	Positive	Negative		
Positive	57	4	51.450	<0.001
	96.61%	19.05%		
Negative	2	17		
	3.39%	80.95%		

There was strong positive association between the serum IgG and antral mucosal biopsy in study population, which was statistically significant (P value < 0.01). (Table 10)

**TABLE 11:** validity and predictive values of serum IgG in study population (N=80)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	96.61%	91.99%	101.2%
Specificity	80.95%	64.15%	97.74%
False positive rate	19.05%	2.252%	35.84%
False negative rate	3.39%	-1.22%	8.007%
Positive predictive value	93.44%	87.23%	99.65%
Negative predictive value	89.47%	75.67%	103.2%
Diagnostic accuracy	93%	86.72%	98.27%

Serum IgG had 96.61% sensitivity (95% CI 91.99 to 101.2%), 80.95% specificity (64.15% to 97.74%) in study population. The positive predictive value was 93.44% (87.23% to 99.65%) and the negative predictive value was 89.47% (75.67% to 103.2%) in study population. The overall diagnostic accuracy was 93% (86.72% to 98.27%) in study population (table 11).

**TABLE 12:** Reliability of serum marker and urea breath test in study population

Test	Kappa statistic	Standard error	P value
Urea breath test	1.00	0.00	<0.001
Serum IgG	0.8	0.078	<0.001

The reliability of the urea breath test and serum IgG as calculated by kappa statistic were 1.00 and 0.8 were respectively (P value < 0.001) indicating very high reliability (table 12).

**TABLE 13:** Comparative analysis of the serum IgG findings of current study findings with the published studies

Study reference	Study population	Screening test	Validity
Current study	People between 15 to 50 years, of both genders, suffering from dyspepsia	Serum IgG By ELISA	Sensitivity: 96.61% Specificity: 80.95% PPV: 93.44% NPV: 89.47%
Kazemi, S., et al. (2011).(38)	94 patients who had indication of endoscopy included in the study.	Serum IgG VIDAS-method	sensitivity, specificity, PPV, NPV and Diagnostic accuracy of 96%, 83%, 98%, 96% and 91% respectively

Peng, N. J., et al. (2009).(40)	One hundred patients, undergoing upper GI endoscopy for dyspepsia	Serum IgG	sensitivity, specificity, PPV, NPV and Diagnostic accuracy 90.6, 85.1, 82.7 and 88.9% and 88% respectively
Redeen, S., et al. (2011).(47)	304 volunteers from the general population was screened for H. pylori infection by serum igG	Serum IgG	Sensitivity 99%, specificity 82% DA: 86%
Locatelli, A., et al. (2004).(46)	A study including 93 patients undergoing upper digestive endoscopy due to dyspeptic symptoms	serum IgG by ELISA	Sensitivity of 64.0%, specificity of 83.7%, positive predictive value of 82.0%, negative predictive value of 66.6% and accuracy of 73.1%
Garcia-Diaz, E., et al. (2002).(44)	214 patients (164 men and 50 women) with an average age of 58 +/- 15 years, who were admitted for upper gastro-intestinal bleeding due to gastroduodenal peptic ulcer.	Serum IgG by ELISA	Sensitivity, specificity, PPV, NPV of 87.5, 54.5, 94.3 and 33.3%, respectively

Even though the current study has given completely matching results with gold standard, there are many studies in the literature which have reported lower validity and reliability of urea breath test. The study by Kazemi, S., et al. (2011) et al has reported sensitivity, specificity, PPV, NPV and Diagnostic accuracy of 89%, 73%, 92%, 90% and 82% respectively. Another study by Peng, N. J., et al. (2009) have reported sensitivity, specificity, PPV, NPV and Diagnostic accuracy of 100, 85.1, 88.3 and 100% and DA of 93%. The range of sensitivity reported by various other studies by Redeen, S., et al. (2011), Jonaitis, L. V., et al. (2007). and Perri, F., et al. (2005) was ranging from 90 to 100%

But the differences between the current study and various other studies were generally lower. The gold standard test, against which the study results were compared was also one of the important reason for this variation, as many studies have taken, culture and immunohistochemistry methods as gold standard, which are likely to yield higher positive results, the simple staining method, which has been used in the current study.

**DISCUSSION**

Considering the increasing number of studies across the globe, reporting strong link between H. Pylori and various benign and malignant conditions of stomach and limited volume of evidence on validity of screening tests on Indian subjects, the current study was conducted on 80 subjects, attending a tertiary care teaching hospital with dyspepsia. The key sociodemographic characteristics of the study population included almost even distribution across the different decadal age groups ranging from 20 to 49 years, with slightly higher proportion in the age group i.e. 40 to 49 years (table 1). Majority of the study subjects were males, as they constituted 60% of the study population and females constituted only 40% of the study population (table 2).

All the study participants have been evaluated by two different noninvasive screening tests, i.e. urea breath test and serum IgG for H. Pylori (table 3 and 4). The findings of antral mucosal biopsy based tests were considered as gold standard technique in the current study and the screening results of both non invasive tests were compared against the gold standard. In the current study, H. Pylori infection prevalence, as diagnosed by antral mucosal biopsy was 73.8% (table 5). The prevalence of H. Pylori infection in 20 to 29 years age group



was the highest (76%), followed by 40 to 49 years (75%) and the least in 30 to 39 years (68.42%) in the study population. No significant (P value 0.829) association between age and H.Pylori infection was proven in the study(table 6). The prevalence of H.pylori infection was 87.5% in females and it was 64.58% in males. The difference in the proportion of H.pylori infection between the two genders was statistically significant. (P value 0.02)(table 7). The urea breath test has given 59(73.8%) positive results in study population. The remaining participants 21 (26.3%) were negative for H. Pylori by urea breath test(table 8). The urea breath test has yielded 100% sensitivity, specificity, positive and negative predictive values in the study, with 0% false positive or false negative results(table 9). The reliability of the urea breath test and serum IgG as calculated by kappa statistic was 1.00(table 12).

The H. Pylori infection prevalence, reported by different studies published across the globe was quite variable. In study by Ahmad, M. M., et al. (1997)(16) the reported prevalence was quite high, compared to the current study. The study population characteristics were similar to the current study and the finding of no association with age was also confirmed by the study, but the authors have used serum Ig G level as the diagnostic test in this study. Another study conducted in India by Bhasin, D. K., et al. (1999)(17), which has assessed the prevalence among gastric cancer patients, reporting to a tertiary care hospital in India, has reported only 36.25% prevalence. Few other studies conducted in India and other South East Asian countries like studies by Pandey, R., et al. (2014).(18)Mujawar, P., et al. (2015).(19) have reported similar lower prevalence, as compared to the current study. Another study from India by Misra, V., et al. (2007).(20) have reported H. pylori prevalence in normal population as 80% and in gastric cancer cases as 78%. A study by Muller, L. B., et al. (2007)(21) had reported a prevalence of 76%. The reported prevalence in these two studies was similar to current study. The population characteristics in various studies were ranging from, normal subjects, patients with dyspepsia, patients presenting with upper GI bleed to patients with suspected or confirmed gastric carcinoma. The diagnostic test and the quality of performance of the diagnostic test was also an important source of variability in prevalence.

In the current study, the Serum IgG had 96.61% sensitivity (95% CI 91.99 to 101.2%), 80.95% specificity (64.15% to 97.74%) in study population. The positive predictive value was 93.44%(87.23% to 99.65%) and the negative predictive value was 89.47% (75.67% to 103.2%) in study population. The overall diagnostic accuracy was 93% (86.72% to 98.27%) in study population(table 11). The reliability of Serum IgG, as assessed by the kappa statistic was 0.8(table 12). The reported ranges of sensitivity, specificity and predictive values in the current study are in agreement with majority of the published studies. The reported values of sensitivity, specificity, PPV, NPV and Diagnostic accuracy by Kazemi, S., et al. (2011) were 96%, 83%, 98%, 96% and 91% respectively. Another study by Peng, N. J., et al. (2009) has reported sensitivity, specificity, PPV, NPV and Diagnostic accuracy 0.6, 85.1, 82.7 and 88.9% and 88% respectively in their study of 100 patients who were undergoing upper GI endoscopy for dyspepsia. But Locatelli, A., et al. (2004) in a similar study have reported a lower sensitivity of 64.0%, specificity of 83.7%, positive predictive value of 82.0%, negative predictive value of 66.6% and accuracy of 73.1% compared to the current study(table 13). In summary, it can be concluded that serum H.Pylori markers sensitivity, specificity and predictive values are generally high and there are only minor variations in the current study.

## CONCLUSION

1. The prevalence of H. Pylori infection was high in the study population, as almost three fourth of the study population were positive for H. Pylori in the study population, as confirmed by staining of the biopsy specimens
2. There was no association between the age and H. Pylori infection in study population
3. The proportion of H. Pylori infection was higher in females, compared to males in study population
4. Urea breath test had shown complete concordance with gold standard with 100 % sensitivity, specificity and predictive values
5. Serum Ig G has displayed High, sensitivity, specificity and predictive values in the study population. But all the parameters were lower compared to urea breath test
6. The reliability of both urea breath test and serum Ig G were very high in the study

## LIMITATIONS:

1. The role of other factors, like socio economic status, eating habits, substance abuse on prevalence of H. Pylori could not be evaluated in the study, considering it's relatively lesser sample size
2. The findings of the study shall be generalized with caution, as the study was limited to a single treatment center and the sample size was relatively small

## RECOMEDATIONS:

1. Large scale prospective studies on the subject are need of the hour to document the exact burden in the community and to understand the validity and reliability of the screening tests, when applied in large scale.

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