



**A CROSS-SECTIONAL STUDY TO DETERMINE THE PREVALENCE OF HELICOBACTER PYLORI AMONG PATIENTS WITH DYSPEPSIA RESIDING AT KELAMBAKKAM, CHENNAI. AND TO COMPARE THE EFFICACY OF BIOPSY TAKEN FROM FUNDUS AND PYLORUS ON PATIENTS WITH LONG TERM PPI USAGE.**

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**ABSTRACT:**

Helicobacter Pylori (H. Pylori) is one of the common bacterial infectious diseases predominately affecting the gastrointestinal tract. India being a prototypical developing country, there are about 20 million Indians who are estimated to suffer from peptic ulcer disease, due to H. Pylori infection. However, many people consume Proton pump inhibitor (PPI) with or without being prescribed. The objective of the study was to determine the prevalence of H. Pylori infection in patients with long term dyspepsia at Kelambakkam, Chennai and to compare the efficacy of H. Pylori detection via Esophagogastroduodenoscopy (EGD scopy) biopsy technique at gastric fundus and pylorus.

**Keywords:** Helicobacter Pylori, Gastrointestinal tract, Dyspepsia, Proton pump inhibitor, Esophagogastroduodenoscopy, Double biopsy technique, Gastric adenocarcinoma

## 1. METHODS

It is a Cross-sectional diagnostic study conducted from December 2023 to March 2024, carried out at Chettinad Hospital and Research Institute a tertiary care center, at Kelambakkam. A total of 100 patients with dyspepsia lasting for 2 months and above were randomly selected from the outpatient department of General Surgery. They were divided into three groups based on their age. They were given a course of 8 weeks of Omeprazole 20mg twice a day. Followingly, EGD scopy was performed to rule out H. Pylori infestation. All the patients underwent double biopsy technique, from fundus and pylorus and P value was calculated.

## OUTCOME

From the total sample size of 100 patients (50 male and 50 female), H. Pylori was detected in 74 patients (74 %). Females (59.4%) were predominately higher when compared to males (40.6%) with a significant P valve (0.001). Among all three age groups, maximum patients with H. Pylori detected were under 25-35 years (40.5%). However, among the 74 detected cases, 62 patients were fundal positive for H. Pylori and just 12 patients were pylorus positive (p<0.001)

## 2. CONCLUSION

H. Pylori infection is one of the treatable causes of chronic dyspepsia and the use of proton pump inhibitors would remarkably reduce the gastric symptoms. Moreover, detecting H. Pylori in patients with long term PPI usage is also crucial and, in such instance, it is always advised to take a double biopsy technique via EGD scopy to lower the false negativity.

## 3. INTRODUCTION

*Helicobacter pylori* (*H. pylori*) is a gram-negative bacterium and it colonises in the mucosal lining of the human digestive tract especially in stomach and duodenum<sup>1</sup>. Right from its discovery by Warren and Hastings in the early eighties; research on *H. pylori* is substantial<sup>2,3</sup>. It is considered to be one of the most common chronic bacterial infections which affect almost two thirds of the worldwide population<sup>4</sup> ranging from 10% in developed western countries to 80% in developing countries. The transmission of this bacteria is from person to person and through contaminated water. It causes inflammation in the gut especially in the stomach and duodenum<sup>1</sup>. Most of these inflammatory changes are silent and clinical manifestations occur in around one-fifth of the patients after a long latent period<sup>5</sup>. This urease producing bacteria synthesis ammonia with results in release of biochemical substances such as proteases, vacuolating cytotoxin A and phospholipases contributing significantly to its inflammatory and carcinogenic potential<sup>6</sup>. The manifestations of *H. pylori* infection include gastritis, gastric atrophy, duodenal ulcer disease, gastric ulcer disease, primary gastric B-cell lymphoma, gastric adenocarcinoma, iron deficiency anemia, and vitamin B12 deficiency<sup>7,8</sup>. Several techniques exist for diagnosing *H. pylori* infection, and include non-invasive methods such as urea breath testing, faecal antigen testing and serological tests. Tissue samples may

also be obtained during endoscopy and can be evaluated by microscopy, culture or rapid urease test.<sup>9</sup> The regimens recommended by National institute of Clinical Excellence for *H. pylori* eradication are omeprazole, amoxicillin, and clarithromycin (OAC) for 10 days; bismuth subsalicylate, metronidazole, and tetracycline (BMT) for 14 days; and lansoprazole, amoxicillin, and clarithromycin (LAC) for 10–14 days of treatment. However, many people are just empirically treated with PPIs alone, with or without being prescribed which increases the mortality of patients<sup>10</sup>. The objective of the study was to determine the prevalence of *H. Pylori* infection in patients with long term dyspepsia and to compare the efficacy of *H. Pylori* detection via Esophagogastroduodenoscopy (EGD scopy) biopsy technique at gastric fundus and pylorus.

### STUDY OBJECTIVE

- To determine the prevalence of *Helicobacter Pylori* infection in patients with dyspepsia presenting to a tertiary care centre at Kelambakkam.
- To determine whether double biopsy technique (from both Pylorus and Gastric fundus) is more conclusive than traditional biopsy technique (from pylorus alone), via EGD scopy, in patients with long term PPI usage.

### 4. METHODS

This was a cross-sectional diagnostic study conducted at Chettinad Hospital and Research Institute, a tertiary care unit at Kelambakkam over a period of 4 months from December 2023 to March 2024. Patients with dyspepsia coming to outpatient department of General Surgery were selected based on the inclusion criteria. All patients who met the inclusion criteria were recruited consecutively upon signing a written informed consent and were categorized based on their age group. Dyspepsia symptoms included: one or more of the following symptoms; Epigastric pain, burning sensation in epigastrium, postprandial fullness, regurgitation and early satiation

The inclusion criteria are: both male and female patients in the age group 25 to 55 years, patients with dyspepsia for 2 or more months and patients who were already diagnosed with gastroesophageal reflux disease (GERD), peptic ulcer disease (PUD). The exclusion criteria are: patients not confirming to the above age group, patients with history of alcoholic gastritis, corrosive gastritis, pre-existing GI malignancies, Inflammatory Bowel Disease, patients with past history of tuberculosis and patient with uncontrolled Diabetes Mellitus / immuno-compromised.

All the 100 patients were advised to take C. Omeprazole 20mg twice a day for 8 weeks and was planned for EGD scopy. All the patients were prepared prior to the procedure with 8 hours of fasting. Before the procedure patients were sprayed with 10% Lignocaine topical anesthetic agent. Endoscopic evaluation of patients was carried out using a fibre optic gastro-duodenoscope Olympus and following standard procedures. Instrument sterilization was done using a routine technique of cleaning the instrument with cetrimide, 70% alcohol, glutaraldehyde (Cidex®) and later running equipment in distilled water for up to 30 min in between endoscopic sessions. Patients were placed in the left lateral position with pulse oximetry monitoring and I.V line for maintenance fluid. All anatomic regions of the

esophagus, OG junction, stomach, first and second parts of the duodenum were examined and endoscopic impressions were noted. Pinch biopsies from pylorus and fundus were obtained and sent for histopathological diagnoses and *H. pylori* detection.

#### Study variables

The social demographic factors were: age, sex, occupation, marital status, home address, and level of education. Other variables include: alcohol consumption, cigarette smoking, self-harm attempt by consuming corrosive substances, use of non-steroidal anti-inflammatory drugs, proton pump inhibitors, and antibiotics. Clinical variables: epigastric pain or burning sensation regurgitation, postprandial fullness and early satiety. The dependent variable: microscopic diagnoses (histologically confirmed *H. pylori* associated gastritis)

#### Data analysis

Data was analysed using R software version 4.1.1. R Core Team (2021). Chi square test was used and significance was defined as a P value < 0.05. The prevalence of *H. pylori* associated gastritis was calculated as total number of patients with *H. pylori* associated gastritis divided by the total number of study subjects and expressed as a percentage.

#### Ethical considerations

Ethical committee approval was obtained from the Institutional Human Ethics Committee (IHEC) of Chettinad Hospital and Research Institute. Written informed consent was obtained from all the participants. All the major ethical issues will be addressed by the primary investigator. The study will protect the rights of research participants. Voluntary participation of all the individuals is considered. All the participants are free to opt in or out of the study at any point of time without feeling an obligation to continue. Study will maintain scientific integrity

## 5. RESULTS

Among 100 patients with dyspepsia (50 males and 50 females) the mean age was 42 years  $\pm$  12 SD. The patient distribution across the age group from Table 1: 34% in both 25-35 and 36-45 age groups and 32% in 46-55 age group. Patients detected with *H. Pylori* was 74, with female predominance of 44 (59.4%) and males with 30 (40.6%) (Table 2 & Fig. 1). Majority of the *H. Pylori* positive patients were under the age group of 25-35 ( $p = <0.012$ ) with 10 males and 20 females (Table 3 & 4). From the Figure 2, there was equal number of male patients across all the age group, who are *H. Pylori* positive. whereas in females, majority of the detected patients were under 25-35 age group. However, after 8 weeks of PPI intake, among the total *H. Pylori* detected cases, 62 patients were Fundal positive and just 12 patients were pylorus positive (Table 5). Table 6: The table shows patient distribution across the age groups with *H. Pylori*- fundal positive, pylorus positive and non-detected patients. There was a significant p value of 0.005 among male patients with *H. Pylori* detection.

Table 1: The tabular column represents the distribution of patients among the age groups.

AGE GROUP (Both Gender)		
	Frequency	Percent

Age Group (years)	25-35	34	34.0
	36-45	34	34.0
	46-55	32	32.0
	Total	100	100.0

Table 2: The table represents H. Pylori detected and non-detected among both male and female

	H. PYLORI INFECTION		TOTAL	P-VALUE
	DETECTED	NOT DETECTED		
MALE	30	20	50	0.001
FEMALE	44	6	50	
TOTAL	74	26	100	

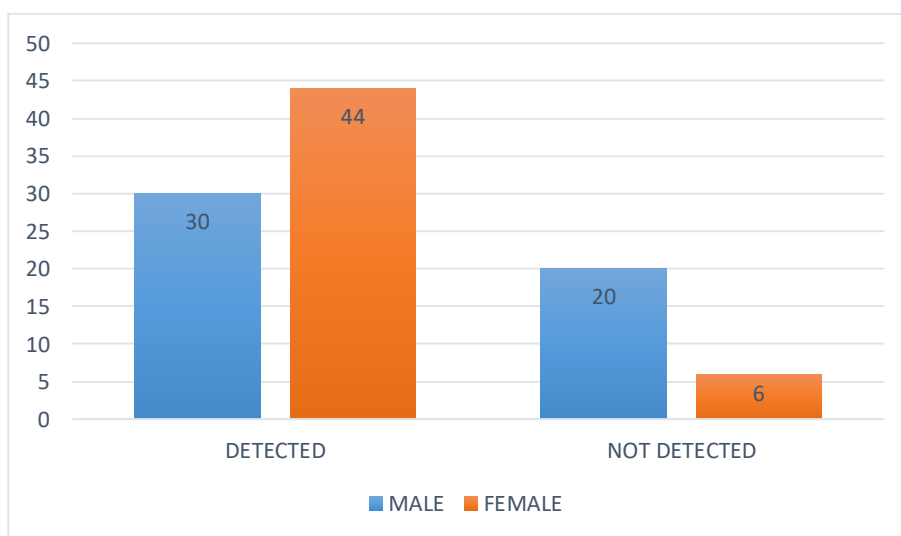


Fig 1: The bar graph depicts a significant number of H. Pylori detected cases among females with a p value of 0.001.

GENDER	AGE GROUP	DETECTED	NOT DETECTED	TOTAL	P value
BOTH SEX	25-35	30	4	34	<0.012
	36-45	26	8	34	
	46-55	18	14	32	
	TOTAL	74	26	100	

Table 3: Data represents maximum strength seen in the age group of 25-35 with 30 H. Pylori positive patients.

AGE GROUP	H. PYLORI DETECTED		TOTAL	P-VALUE
	MALE	FEMALE		
25-35	10	20	30	0.305
36-45	10	16	26	
46-55	10	8	18	
TOTAL	30	44	74	

Table 4: H.Pylori detected patients across various age groups and gender

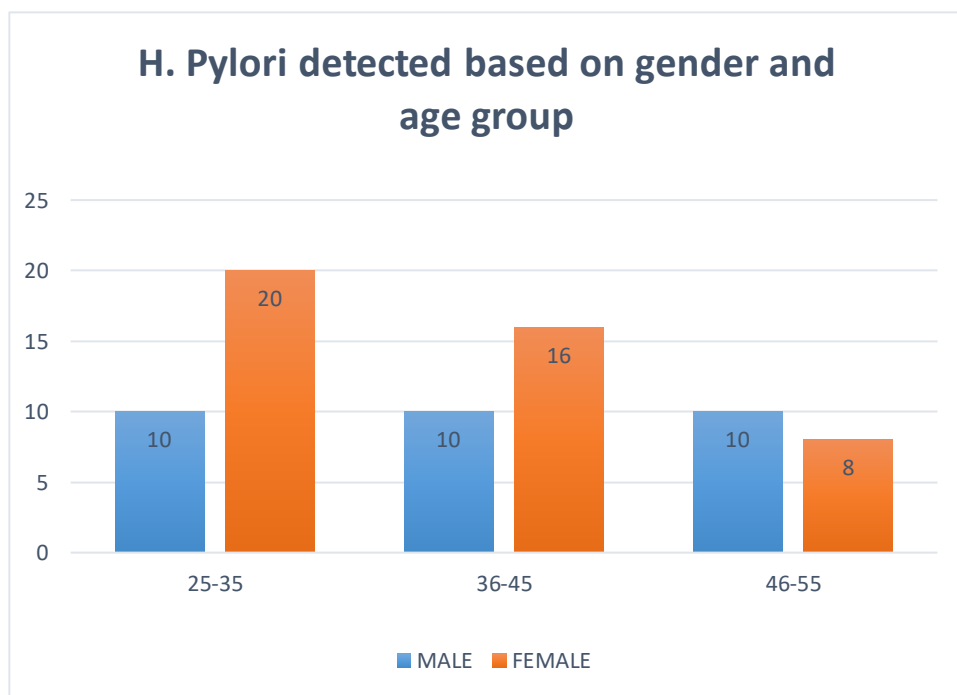


Fig 2: The chart represents an equal number of male patients across all the age group, who are H. Pylori positive. Whereas in females, majority of the detected patients were under 25-35 age group.

	H. PYLORI DETEDEDTED		TOTAL	P-VALUE
	PYLORUS	FUNDUS		
MALE	6	24	30	0.466
FEMALE	6	38	44	
TOTAL	12	62	74	

Table 5: Cases detected with H. Pylori at pylorus and fundus among both male and female

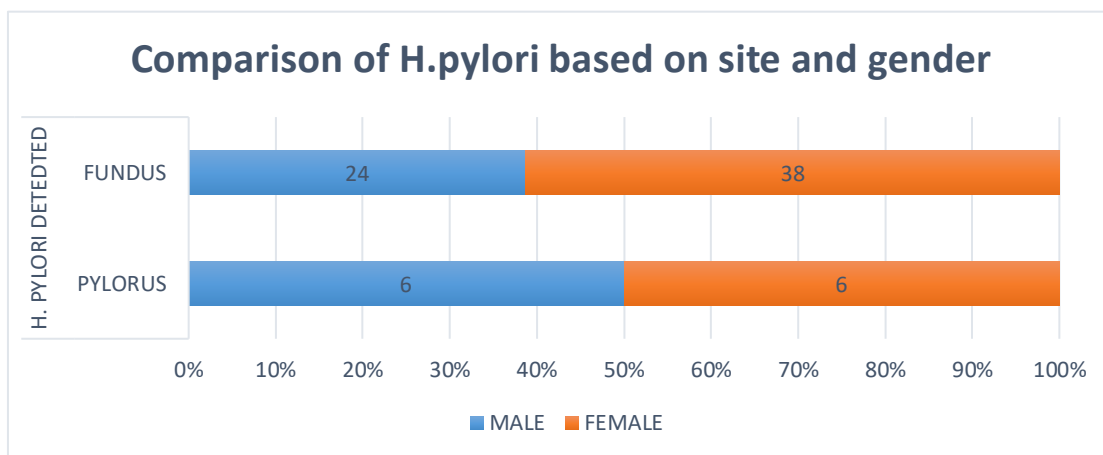


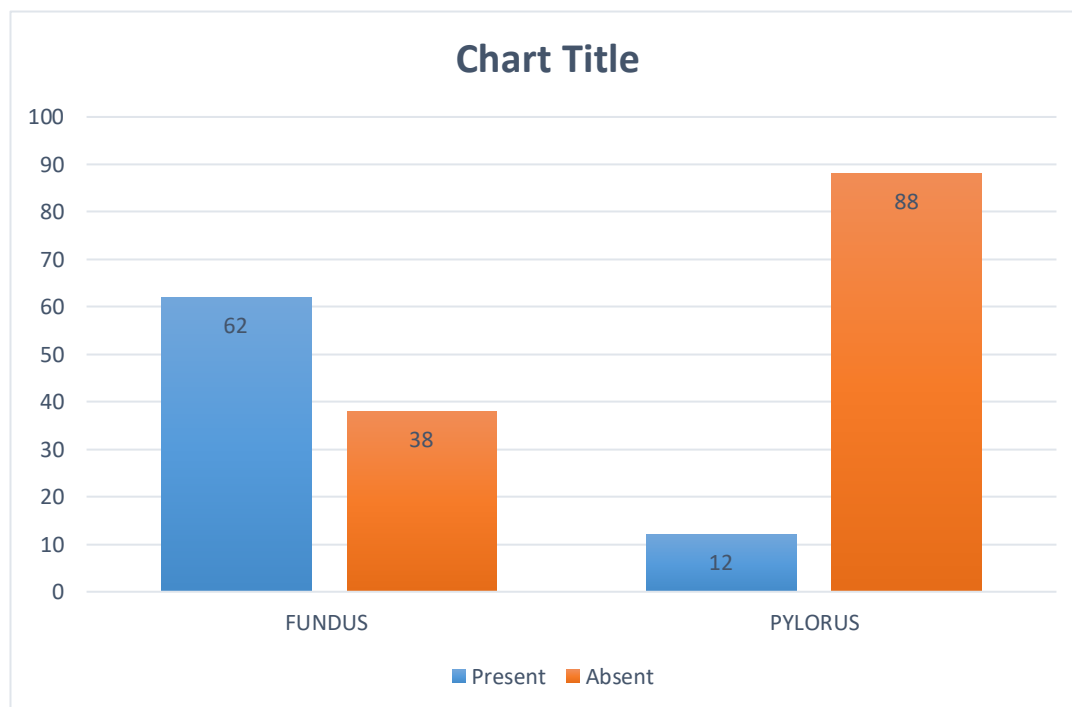
Fig 3: The bar graph denotes maximum patients were fundal positive for H. Pylori (62 cases with 24 males and 38 females) and just 12 patients were pylorus positive. However, among the fundal positive cases females were majority.

GENDER	AGE GROUP	FUNDUS	PYLORUS	NOT DETECTED	TOTAL	P-VALUE
MALE	25-35	10	0	0	10	0.005
	36-45	8	2	8	18	
	46-55	6	4	12	22	
	TOTAL	24	6	20	50	
FEMALE	25-35	16	4	4	24	0.277
	36-45	14	2	0	16	
	46-55	8	0	2	10	
	TOTAL	38	6	6	50	

Table 6: The table shows patient distribution across the age groups with H. Pylori- fundal positive, pylorus positive and non-detected patients. There was a significant p value of 0.005 among male patients with H. Pylori detection.

	FUNDUS	PYLORUS
Present	62	12
Absent	38	88
Total	100	100

Fig 4: The graph represents that, just 12 patients were H. Pylori positive at pylorus and an additional biopsy sampling from the fundus resulted in 62 more patients who were H. Pylori positive.



## 6. DISCUSSION

The overall prevalence of H. Pylori associated gastritis may be an under estimated, as majority of them would be on empirical treatment with antibiotics. However, this value is similar to one found by Wabinga et al.<sup>11</sup> in his retrospective study in 2002. In contrast, a study in Kenya in 2012 reported 52% prevalence of H. Pylori in adults<sup>12,13</sup>.

According the study, 82% of the patients had epigastric pain and burning sensation. Post prandial fullness was noted among 52% of patients and regurgitation among 36% of patients. Patients who were already diagnosed with peptic ulcer disease (PUD) were 28%. During endoscopic study it was found that 68% of them had pan gastritis and among them 37% had bile reflex. Bleeding ulcers at antrum were noted in 17% of patients and 6 patients had hiatus hernia.

Several studies have proven that the prevalence of H. Pylori is considerable high in developing countries, and is also associated with low educational level, low socio-economic status and poor sanitation<sup>14,15</sup>.

### STUDY LIMITATION

The major limitation of the study, this is a single centered study with a small sample size. If this study had been a multi centered, the sample size would be larger and the conclusion drawn would be more precise. Ultrasonography of abdomen was not done for patients who were H. Pylori negative to rule out other causes of dyspepsia like pancreatitis, hepatobiliary disease, etc. Probability of recall bias could be there as the patients forget the onset of their symptoms.



## 7. CONCLUSION

H. Pylori being one of the most potent causative agent to cause dyspepsia and its always advised to treat the causative agent. However, many patients never undergo a proper diagnostic technique and would consuming PPI with or without being prescribed. On evaluating the cause for dyspepsia in such patients who are on long term PPI, there is a higher predisposition of false negativity in detecting H. Pylori via traditional endoscopic biopsy technique from pylorus. Meanwhile, if biopsies are taken from both fundus and pylorus (double biopsy technique), it would increase the detection rate and would help in treating patients with dyspepsia. Moreover, according to the current study, younger people residing at Kelambakkam, are more pre-disposed for H. Pylori infection.

### PARTICIPANT INFORMED CONSENT FORM

#### IHEC Proposal No: IHEC-II/0658/24

**Title of Study:** A cross-sectional study to determine the prevalence of helicobacter pylori among patients with dyspepsia residing at Kelambakkam, Chennai. And to compare the efficacy of biopsy taken from fundus and pylorus on patients with long term PPI usage.

Name of Principal Investigator: Dr. Ansu Samuel

Mobile No: 7306490939

I have carefully read the contents of the information sheet provided and it has been explained to me in detail and it has been explained to me in a language I understand and I understand it fully. I confirm that I have been given an opportunity to ask questions.

The nature and purpose of the study and its possible risks benefits and expected duration of the study and other relevant details of the study have been explained to me in detail.

I understand that my participation is voluntary and that I may withdraw at any time without giving any reasons.

I understand that the information collected about me through my participation in this research and sections of any of my medical notes may be viewed by responsible persons from CARE. I wholeheartedly consent to access of my records by these persons.

I therefore consent to participate in the above study.

Handwriting / Left thumb recording

Date

Place

Participant Name

This is to certify that the above consent has been obtained in my presence.

Signature of Principal Investigator

the witness

the witness

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