# Response rate of commonly practiced anti *H. pylori* therapy among people suffering from *H. pylori* associated peptic ulcer disease in Bangladesh

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# **ABSTRACT**

**Background:** H. pylori, a microaerophilic, Gram-negative bacterium in the alimentary canal, causes chronic gastritis and gastric ulcers and is the most important cause of duodenal ulcers and stomach cancer. Infection by H. pylori carries a 10-20% risk of peptic ulcers and 1-2% risk of stomach cancer over lifetime. Prevalence of H. pylori infection varies from country to country depending on food hygiene, sanitation status and living condition. One study showed 92% of populations are seropositive of H. pylori infection in Bangladesh. Eradication of the infection by using antimicrobial has been reported to lower complications. Recently variable resistance to many antimicrobial have raised the question of selecting appropriate combinations to improve the outcome. The objective of the study was to find out the response rate of anti-H. pylori therapies among H. pylori associated peptic ulcer disease in Bangladesh.

**Methods:** This was a prospective comparative study was done in BIRDEM General Hospital between April 2023 to March 2024. Patients who attended at OPD and indoor of Department of GHPD with symptoms of dyspepsia investigated with endoscopy. Dyspeptic patients, on endoscopy showing features of peptic ulcer disease or erosive gastritis, positive Rapid Urease Test (RUT) test on biopsy and positive H. pylori antigen (Ag) test in stool were included in the study. Their demographic parameters were recorded. Then the study populations were randomly distributed into three groups, each group received different anti-H. pylori therapies namely amoxicillin, clarithromycin and proton pump inhibitor (PPI) combinations (Group A), amoxicillin, levofloxacin and PPI combinations (Group B) and amoxicillin, metronidazole and PPI combinations (Group C) for two weeks followed by PPI for another 6 weeks. Two weeks after treatment cessation, stool samples were collected and evaluated to assess H. pylori eradication rate among different groups.

**Results:** Total 114 patients were enrolled for the study, among them 90 were attended for follow up. These 90 subjects were divided into 3 groups. 33 individuals received Amoxicillin and Clarithromycin, they were termed as Group A, 30 individuals Amoxicillin and Levofloxacin termed as Group B and 27 individuals received Amoxicillin & Metronidazole combination termed as Group C. We found response rate of Group A, Group B and Group C were 66.67%, 63.33% and 55.56% respectively.

**Conclusions:** The study demonstrates varying response rates among commonly prescribed Anti H. Pylori therapies with Amoxicillin, Clarithromycin & PPI combinations had highest response rate than other therapies we used & none could achieve optimum response (>80%) indicates a high rate of failure of commonly prescribed Anti H. Pylori therapies.

**Key words:** H. pylori eradication, peptic ulcer disease, anti-H. pylori therapy, rapid urease test, H. pylori stool Ag test, outcome.

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# INTRODUCTION

Peptic ulcer disease (PUD) has been one of the major causes of morbidity for more than a century. The prevalence of gastric ulcer and duodenal ulcer were estimated to be 3.28% and 7.4% respectively in a multicenter study in Bangladesh. Helicobacter pylori is the most important etiology of PUD all over the world. The prevalence of *H. pylori* infection varies widely among countries. In a series reported between 2009 and 2011, the prevalence of infection ranged from 7% to 90%, depending on the methods of diagnosis and the population that was sampled. In developing countries, 70%–90% of the population is *H. pylori* positive; almost all of them get infected early in life. One study in Bangladesh showed about 92% adults have been found seropositive for *H. pylori* infection.

American and European Helicobacter study group recommends, treatment regimens should be simple, well tolerated and should achieve an eradication rate over 80% in community. The first-line choice of treatment for *H. pylori* infection in the United States and Europe consists of a conventional triple therapy administered for 7-14 days. In Bangladesh, different anti H. pylori therapies are practiced based on physician choice. Previous studies in Bangladesh have shown a low eradication rates (30-64%) using clarithromycin based H. pylori eradication regimen and higher rate of persistence of infection.<sup>8</sup> H. pylori showed high rates of resistance to clarithromycin and metronidazole (39.3% and 94.6%, respectively). Moreover, levofloxacin showed an emerging antimicrobial resistance pattern (66.1%) in a study. As a result, there is possibility of failure of H. pylori eradication in Bangladesh which may result in persistence of H. pylori infection and eventual development of H. pylori associated complications. The aim of the study was to find out the response rate of different anti-H. pylori therapies among H. pylori associated peptic ulcer disease.

### **METHODS**

This prospective comparative study was conducted in the Department of Gastrointestinal, Hepatobiliary and Pancreatic Disorder (GHPD), BIRDEM General Hospital, Shahbagh, Dhaka, between April 2023 to March 2024. Patients who presented with symptoms of dyspepsia in in-patient department (IPD) and out-patient department (OPD) and diagnosed as *H. pylori* associated PUD after further investigation, were included in the study. The total sample size was 90. Study populations were

distributed into 3 different groups, Group A,B and C. Group A received Amoxicillin and Clarithromycin, Group B received Amoxicillin and Levofloxacin and Group C received Amoxicillin and Metronidazole combination. Total duration of treatment was 2 weeks. Every individual was retested for H. Pylori infection by Fecal Ag test after 8 weeks from the onset of treatment. All information was recorded and the efficacy of different anti *H. pylori* regimen was calculated from the data. Pregnant women, patients with gastrointestinal malignancy and who took prior antibiotics within 1 month were excluded from the study.

# **RESULTS**

A total of 90 patients were selected as study population on the basis clinical features (dyspepsia), endoscopic findings (PUD and gastric erosion), biochemical test Rapid Urease test (RUT) and fecal antigen (Ag) test for *H. pylori*. Mean age was 40.15 years. Base-line characteristics are shown in Table I.

**Table I.** Socio-demographic characteristics of the study population (N=90)

Variables	Frequency	Percentage	
Age (in years)			
18-35	33	36.7	
36-53	40	44.4	
54-70	17	18.9	
Mean±SD	$40.15\pm11.73$		
Gender			
Male	58	64.4	
Female	32	35.6	
Occupation			
Service	36	40	
Housewife	23	25.6	
Business	13	14.4	
Student	7	7.8	
Retired	6	6.7	
Others	5	5.6	
Education			
Illiterate	4	4.4	
Primary school certificate(PSC	) 3	3.3	
Junior school certificate (JSC)	1	1.1	
Secondary schhol Certificate (SS	SC) 23	25.6	
Higher Secondary school	25	27.8	
certificate (HSC)			
Graduate	31	34.4	
Masters	3	3.3	

Data presented as frequency and percentage over the columns

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Diabetes mellitus was the most common comorbidity (52.2%) followed by hypertension (31.1%), ischemic heart disease (IHD) (7.8%) and chronic kidney disease (CKD) (5.6%). Twenty four (26.7%) patients had multiple comorbidities. Ongoing medication pattern is presented in Table II.

**Table II.** Drug history related information of the study participants (N=90)

Variables	Frequency	Percentage
Anti-diabetic		
Oral	33	36.7
Insulin	14	15.6
Antihypertensive	29	32.2
Lipid lowering drugs	14	15.6
Non steroidal anti inflammator	y 1	1.1
drugs (NSAIDs)		
Antiplatelet drugs	6	6.7

Data presented as frequency and percentage over the columns

Endoscopic examination of dyspeptic patients revealed 51.1% patients had (PUD) and remaining 48.9% had erosive changes.

One third (33.3%) of Group A patients tested positive for the stool antigen, while 66.7% tested negative; 36.7% of Group B tested positive and 63.3% tested negative and 44.4% of Group C tested positive with 55.6% being negative. There was no statistically significant difference (Table III).

**Table III.** Stool Ag test after 8 weeks of the study participants (N=90)

Stool	Group A	Group B	Group C	p-
Ag test	Frequency	Frequency	Frequency	value
	(%)	(%)	(%)	
Positive	11 (33.3)	11 (36.7)	12 (44.4)	
Negative	22 (66.7)	19 (63.3)	15 (55.6) c	0.669 <sup>ns</sup>

Data presented as frequency and percentage over the columns

c = chi-square test

ns = non-significant

Efficacy rate of different antibiotic combinations calculated statistically. Group A demonstrated the highest efficacy rate, with 66.67% of individuals were became negative of *H. Pylori* infection. Group B showed an efficacy rate of 63.33% while Group C exhibited 55.56% achieving successful treatment outcomes (Table IV).

**Table IV.** Efficacy rate of different drug regimens (N=90)

Efficacy	Frequency	Percentage
Group A	22	66.67
Group B	19	63.33
Group C	15	55.56

Data presented as frequency and percentage over the columns

#### **DISCUSSION**

The introduction of PPI-based triple therapies (PPI-TT) marked a turning point in the treatment of *H. pylori* infection owing to their superior efficacy compared with previous approaches. <sup>10</sup> The three components of PPI-TT include a PPI, clarithromycin and amoxicillin or alternatively, metronidazole as a substitute for either levofloxacin or clarithromycin were mostly recommended first-line therapy globally. <sup>10</sup>

In our study 36.7% of individuals who were prescribed amoxicillin paired with clarithromycin, came for follow up, following 33.3% who were prescribed amoxicillin with levofloxacin. 30% of individuals who were prescribed combination of amoxicillin with metronidazole came for follow up. This picture reflects that people tend to discontinue metronidazole more than other two drugs.

Among the antibiotic combinations assessed, amoxicillin paired with clarithromycin demonstrates the highest efficacy rate, with 66.67% of individuals experiencing successful treatment. Following closely behind is the combination of amoxicillin with levofloxacin, which shows an efficacy rate of 63.33%. The combination of amoxicillin with metronidazole exhibits a lower efficacy rate, with 55.56% of individuals achieving successful treatment outcomes. Out of these regimens efficacy of metronidazole had the lowest efficacy which indicates high rate of resistance of *H*.

*pylori* against metronidazole. Discontinuation of metronidazole due to side effects may also be an important cause of high failure rate of metronidazole based triple therapy.

In our country, we practice different anti H. pylori regimens based on physician choice. Successful treatment of H. pylori associated PUD mainly depends on not only drug adherence and duration of treatment but also development of antimicrobial resistance. So, follow up of eradication of H. pylori infection after treatment completion is very important in our perspective. We found that commonly practiced anti H. pylori regimens have a very high failure rate. None of these regimens could achieve an eradication rate of more than 80% which is international standard. As a result, persistence of *H. pylori* infection and later development of H. pylori associated complications are common in our country. Recent American College of Gastroenterology Guidelines highly recommend bismuth based quadruple therapy as a first line treatment of H. pylori infection. 11 We need further study to find out resistance of individual antimicrobial agents and effectiveness of other therapies including bismuth based therapies and should introduce local guidelines for management of H. pylori infection

# Conclusion

The study demonstrates varying response rates among commonly prescribed anti *H. pylori* therapies with amoxicillin, clarithromycin and PPI combinations had highest response rate than other therapies we used but none of this regimen could achieve optimum response (>80%), indicating a high rate of failure of commonly prescribed anti *H. pylori* therapies in our country. We recommend further large multi-center study with large sample size and integration of antimicrobial resistance patterns into treatment selection to tailor therapies effectively and combat resistance. Eventually we need to establish alternate regimens to increase the efficacy of anti *H. pylori* therapy based on the individual antibiotic sensitivity pattern.

**Authors' contribution:** AM, SA planned the research, collected data, analyzed data and drafted manuscript. NN, MMK did literature search. All authors read and approved final version for submission.

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