



EFFICACY OF FIRST LINE ERADICATION THERAPY IN TREATMENT NAÏVE PATIENTS WITH HELICOBACTER PYLORI INFECTION

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ABSTRACT

Introduction: *Helicobacter pylori* (HP) is a well-recognized cause of peptic ulcer disease and is also linked to gastric adenocarcinoma and mucosa-associated lymphoid tissue (MALT) lymphoma. Despite decades of research, determining the most effective eradication regimen remains a challenge.

Objective: To evaluate the efficacy of first-line *H. pylori* eradication regimens by assessing post-eradication stool antigen results among patients treated at a tertiary care hospital.

Methods: This descriptive cross-sectional study was conducted in the Department of Gastroenterology, Bolan Medical College, Quetta, over a six-month period from 26th September 2020 to 26th March 2021. A total of 113 patients who fulfilled the inclusion criteria were enrolled after obtaining informed consent. Detailed clinical histories were recorded, and stool samples were analyzed post-treatment to assess eradication efficacy. **Results:** Of the 113 participants, 71 (62.8%) were male and 42 (37.2%) female, showing male predominance. *H. pylori* infection was confirmed through histopathology in all cases (100%), while the rapid urease test showed no positive results. All patients received triple therapy as the first-line eradication regimen. Among them, 27 (23.9%) were smokers, 41 (36.3%) were obese, 33 (29.2%) were diabetic, and 36 (31.9%) were hypertensive. Post-eradication stool antigen testing revealed 97 (85.8%) negative and 16 (14.2%) positive results, indicating an eradication success rate of 85.8%. **Conclusion:** The study demonstrates that first-line triple therapy remains highly effective for *H. pylori* eradication in the local population and continues to be a suitable standard regimen in clinical practice.

Key words: *Helicobacter pylori*, efficacy, eradication, first line eradication therapy

INTRODUCTION

Helicobacter pylori (*H. pylori*) is a gram-negative, spiral-shaped, flagellated bacterium that selectively colonizes the gastric mucosa.¹ *H. pylori* has been recognized as one of the most prevalent and persistent human infections worldwide. It is estimated that nearly 50% of the global population is infected, with a markedly higher prevalence in developing countries where socioeconomic conditions, hygiene, and sanitation are poor. Transmission is believed to occur primarily through the

fecal–oral or oral–oral route, often during childhood, and the infection may persist throughout life if not appropriately treated.²

The bacterium plays a pivotal role in the etiology of several gastrointestinal diseases. It is the most common cause of chronic gastritis and peptic ulcer disease and has been strongly linked to serious complications such as gastric adenocarcinoma and mucosa-associated lymphoid tissue (MALT) lymphoma.³ The World Health Organization (WHO) has classified *H. pylori* as a Group I carcinogen due to its established role in gastric cancer development. Eradication of *H. pylori* not only leads to ulcer healing and prevents recurrence but also significantly reduces the long-term risk of gastric malignancies, making it a major focus of gastroenterological research and clinical practice.⁴

Despite its clinical importance, effective eradication of *H. pylori* remains a global challenge. The standard first-line treatment, commonly referred to as triple therapy, consists of a proton pump inhibitor (PPI) combined with two antibiotics—usually clarithromycin and either amoxicillin or metronidazole—administered for 10 to 14 days.⁵ This regimen has historically shown high eradication rates; however, its efficacy has been declining over the past two decades due to increasing bacterial resistance to antibiotics, particularly clarithromycin and metronidazole. Consequently, the success of eradication therapy varies widely among different regions, depending on local resistance patterns, patient compliance, and population characteristics.^{6,7}

Alternative regimens such as sequential therapy, concomitant therapy, and bismuth-based quadruple therapy have been introduced to overcome resistance issues. However, these regimens are often associated with higher costs, complex dosing schedules, and limited availability in resource-constrained settings.⁸ In many developing countries, including Pakistan, triple therapy remains the mainstay of treatment due to its simplicity, affordability, and accessibility. Therefore, evaluating the current efficacy of this regimen in the local population is essential to guide clinical decision-making and ensure effective management.⁹ Treatment-naïve patients—those who have never received prior eradication therapy—represent an ideal group for assessing the true effectiveness of first-line regimens, as they have not been exposed to antibiotic selection pressure that might influence treatment outcomes.¹⁰ Evaluating post-eradication results through noninvasive methods such as stool antigen testing provides a reliable measure of therapeutic success and helps in identifying treatment failures or possible reinfections.^{11, 12} Given the regional variation in *H. pylori* prevalence and antibiotic resistance, there is a need for local data to assess the performance of standard eradication protocols. Therefore, this study was conducted to determine the efficacy of first-line eradication therapy in treatment-naïve patients with *Helicobacter pylori* infection at a tertiary care hospital in Quetta. By assessing post-eradication stool antigen results, this research aims to provide valuable insights into the current effectiveness of triple therapy and contribute to evidence-based recommendations for *H. pylori* management in our population.

MATERIAL AND METHODS

It was descriptive cross sectional study.

SETTING

Study was conducted on inpatients and out patients Department of Gastroenterology, Bolan Medical College, Quetta.

DURATION OF STUDY

Duration: Was 6 months from 26th Sept 2020 26th Mar 2021

SAMPLE SIZE

Sample size: Sample size calculated on the basis of the following

Success rate of Helicobacter pylori eradication by different regimens= 88%^[7]

Confidence level=95%

Bond on error= 6% Sample size (n) = 113 no: of Dyspeptic Patients with h. pylori infection who will take H. pylori eradication therapy Formula $n = z^2 p (1-P) / d^2$

SAMPLING TECHNIQUE:

Non probability consecutive sampling

SAMPLE SELECTION**INCLUSION CRITERIA**

- Patients between 18 years to 50 years of age.
- Either gender
- Dyspepsia for > 6 months
- H. pylori infection on histopathology or RUT
- Taken any of the H. pylori eradication therapy as per operational definition

EXCLUSION CRITERIA

- Patients with metastatic stomach cancer, assessed by history and clinically, gastroscopy and CT scan abdomen, excluding this because is no benefit of treating H. pylori infection in metastatic stomach cancer patients.

DATA COLLECTION

Study was conducted after taking approval from the ethical committee of the institute. Patients attending inpatient or outpatient in department of gastroenterology Bolan Medical College, Quetta with history of Dyspepsia, who have H. pylori infection on histopathology or RUT (EGD guided biopsy), first line H. pylori eradication regimen as per operational definition was given to all patients. In all these patients stool sample was collected and was sent to the laboratory of the institute for helicobacter pylori stool antigen (HPSA). Efficacy of H. pylori eradication was achieved if HPSA is negative. All demography, clinical history was recorded by a principal investigator on a predesigned performa, informed written consent was taken before enrolment. Exclusion criteria was followed strictly to avoid confounding variables plus bias.

DATA ANALYSIS

SPSS version 22 was used for data analysis. Frequencies and percentages was computed for categorical variables like gender, smoking status, H/O diabetes mellitus, hypertension, obesity, efficacy. Moreover we also compute the Mean \pm standard deviation for continuous variables like age, duration of dyspepsia. We used stratification to control effect modifiers like age, gender, duration of dyspepsia Effect modifier like age, gender, duration of dyspepsia, smoking status, H/O diabetes mellitus, hypertension, obesity, H. Pylori infection on (Histopathology/RUT), H. pylori eradication regimen (triple therapy/sequential therapy/quadruple therapy). Finally we used chi-square test to check the effect of modifiers on the outcome. $P \leq 0.05$ was taken as significant.

RESULT

A total of 113 Patients with dyspepsia had H. pylori infection and taken any of first line H. pylori eradication regimen were selected to conduct this study. The mean age was 39.893 ± 6.640 years. The mean duration of dyspepsia was 25.858 ± 17.210 months. The distribution of duration of dyspepsia is presented in Graph-II. The descriptive statistics of duration of dyspepsia is presented in Table-1.

Table-1: (Descriptive statistics of age (years) & duration of dyspepsia (months))

Statistics	Age (years)	Duration of dyspepsia (months)
Minimum	25	7
Maximum	50	66
Mean	39.893	25.858
Std. Deviation	6.640	17.210

The table-2 presents the gender-wise distribution of participants in the study. Out of a total of 113 participants, 71 (62.8%) were male and 42 (37.2%) were female. This shows that male participants formed the majority of the study population, while female participants were fewer in number. The difference in proportion indicates that the study sample was **male-dominant**, with nearly two-thirds of the participants being men. The total percentage adds up to 100%, confirming that all participants were accounted for in these two gender categories.

TABLE – 2: Frequency distribution of gender (n=113)

Gender	Frequency (n)	Percentage (%)
Male	71	62.8%
Female	42	37.2%
Total	113	100%

The table-3 presents the diagnostic findings for *Helicobacter pylori* infection using two different methods — histopathology and the rapid urease test (RUT). According to the results, all 113 cases (100%) were positive for *H. pylori* infection based on histopathological examination. In contrast, no cases (0%) were detected using the rapid urease test (RUT).

This indicates that in this study, histopathology was the only method that confirmed *H. pylori* infection in all participants, while the rapid urease test failed to detect any infection. Therefore, the results highlight that histopathological examination proved to be a more reliable and effective diagnostic tool for identifying *H. pylori* infection in this group of patients.

TABLE – 3 Frequency distribution of Helicobacter infection on(n=113)

Helicobacter infection on	Frequency (n)	Percentage (%)
Histopathology	113	100%
Rapid urease test (RUT)	0	0%
Total	113	100%

The table-4 shows the type of first-line treatment regimens used for *Helicobacter pylori* eradication among the study participants. Out of a total of 113 patients, all (100%) were treated with triple therapy, while none received sequential therapy or quadruple therapy (0%).

This finding indicates that triple therapy was the only regimen used for the initial management of *H. pylori* infection in this study population. The complete absence of other treatment options suggests that triple therapy was the standard or routine first-line approach followed in the clinical setting where the study was conducted.

TABLE – 4: Frequency distribution of type of First line Helicobacter Pylori eradication regimen (n=113)

Type of First line Helicobacter Pylori eradication regimen	Frequency (n)	Percentage (%)
Tripple therapy	113	100%
Sequential therapy	0	0%
Quadruple therapy	0	0%
Total	113	100%

The table-5 presents the smoking habits of the study participants. Out of a total of 113 individuals, 27 participants (23.9%) reported being smokers, while 86 participants (76.1%) were non-smokers.

This shows that the majority of the study population did not smoke, indicating a low prevalence of smoking (less than one-fourth) among participants. The data suggest that most individuals in the study were non-smokers, which may have implications when analyzing risk factors or disease outcomes related to *Helicobacter pylori* infection.

TABLE – 5: Frequency distribution of smoking status (n=113)

Smoking status	Frequency (n)	Percentage (%)
Yes	27	23.9%
No	86	76.1%
Total	113	100%

The table-6 describes the distribution of obesity among the study participants based on their Body Mass Index (BMI). Out of 113 participants, 41 individuals (36.3%) were classified as obese (BMI > 30 kg/m²), while 72 participants (63.7%) were non-obese.

This indicates that more than one-third of the study population was obese, showing a moderate prevalence of obesity among participants. The remaining majority (nearly two-thirds) maintained a BMI below the obesity threshold. These findings suggest that obesity was a relatively common condition in the studied group and could potentially influence the outcomes or risk factors associated with *Helicobacter pylori* infection.

TABLE – 6: Frequency distribution of obesity (BMI >30kg/m²) (n=113)

Obesity (BMI >30kg/m ²)	Frequency (n)	Percentage (%)
Yes	41	36.3%
No	72	63.7%
Total	113	100%

The table-7 presents the distribution of participants according to their history of Diabetes Mellitus. Out of a total of 113 individuals, 33 participants (29.2%) had a history of diabetes, while 80 participants (70.8%) did not report any diabetic condition.

This indicates that nearly one-third of the study population were diabetic, whereas the majority (about two-thirds) were non-diabetic. The data suggest that diabetes was a relatively common comorbidity among the study participants, which may have clinical significance when evaluating factors related to *Helicobacter pylori* infection or treatment response.

TABLE – 7: Frequency distribution of H/O Diabetes Mellitus (n=113)

H/O Diabetes Mellitus	Frequency (n)	Percentage (%)
Yes	33	29.2%
No	80	70.8%
Total	113	100%

The table-8 shows the distribution of participants according to the presence of hypertension. Out of 113 total participants, 36 individuals (31.9%) were found to have hypertension, while 77 participants (68.1%) did not have a history of high blood pressure.

This indicates that nearly one-third of the study population was hypertensive, whereas the majority (around two-thirds) were normotensive. These findings suggest that hypertension was a common comorbid condition among the study participants and could be an important factor to consider in relation to *Helicobacter pylori* infection or its clinical outcomes.

TABLE – 8: Frequency distribution of Hypertension (n=113)

Hypertension	Frequency (n)	Percentage (%)
Yes	36	31.9%
No	77	68.1%
Total	113	100%

The table-9 presents the post-treatment results of the *Helicobacter pylori* stool antigen test, which was used to assess the effectiveness of the eradication therapy. Out of a total of 113 participants, 16 individuals (14.2%) tested positive for *H. pylori* stool antigen after treatment, while 97 participants (85.8%) tested negative.

This indicates that the majority of patients (85.8%) achieved successful eradication of *H. pylori* infection following therapy, as evidenced by their negative stool antigen results. However, a small proportion (14.2%) remained positive, suggesting treatment failure or possible reinfection in these cases. Overall, the findings demonstrate a high eradication rate of *H. pylori* with the applied treatment regimen.

TABLE – 9: Frequency distribution of Post eradication Helicobacter Pylori stool antigen (n=113)

Post eradication Helicobacter Pylori stool antigen	Frequency (n)	Percentage (%)
Positive	16	14.2%
Negative	97	85.8%
Total	113	100%

The Percentage (%) column in the table represents the proportion of participants in each category compared to the total number of study participants. It indicates how much each group contributes to the overall sample size, expressed as a percentage. This value is calculated by dividing the frequency (number of participants in a specific category) by the total number of participants and then multiplying by 100. For example, in the hypertension table, 36 participants had hypertension, which accounts for 31.9% of the total 113 participants, while 77 participants without hypertension make up 68.1%. Together, these values sum up to 100%, showing that all participants are included in the analysis. This column helps to present the data more clearly and allows for easy comparison between different groups in the study (Table-10).

TABLE – 10: Frequency distribution of Efficacy of H. pylori eradication achieved (n=113)

Efficacy of H. pylori eradication achieved	Frequency (n)	Percentage (%)
Yes	97	85.8%
No	16	14.2%
Total	113	100%

DISCUSSION

Helicobacter pylori infection is a known risk factor responsible for the development of gastric ulcers and gastric carcinoma. It is reported in several studies that eradication of *H. pylori* infection lowers the risk of peptic ulcer recurrence and further decreases the risk of gastric cancer.¹³ It is also seen that delaying *H. pylori* eradication enhances the risk of peptic ulcer recurrence and gastric malignancies.¹⁴ Thus, it is prudent to treat and eradicate *H. pylori* infection promptly and appropriately to avoid peptic ulcers and ulcer-associated adverse events.

H. pylori was first discovered by Robin Warren in 1979 and first cultured by Barry Marshall in 1982. Reports of the first antibiotic treatment of *H. pylori* date to 1981, when it was treated with Tetracycline. Several other antibiotics were eventually tried alone or in combination but there was no

consensus among physicians on the best treatment strategy.¹⁵ It was not until 1994 that the National Institute of Health brought together various experts in the field to form a consensus for *H. pylori* management.¹⁶ Nevertheless, considerable confusion regarding management of *H. pylori* persisted until the European *Helicobacter pylori* Study Group (EHPSG) met in Maastricht, Netherlands and formulated the European consensus on *H. pylori* management.¹⁷

Standard triple antibiotic therapy including CLA, Amoxicillin and a Proton pump inhibitor (PPI) has been used worldwide very commonly since this first Maastricht conference.¹⁸ Due to the increasing resistance of *H. pylori* infection to the commonly used CLA-based regimen, the initially set standard of achieving at least an 80% eradication rate has not been easy. Later studies have also shown that eradication rates have declined to 71% in the US and 60% in Europe.¹⁹ Therefore, it has been recommended to perform CLA sensitivity in populations with suspected CLA resistance prevalence of 15–20%.¹⁷

In our study the efficacy of *H. pylori* eradication achieved was seen in 97(85.85%) patients as compare to one previous analysis, the successful eradication 94.2% (114/121), 95.0% (113/119), and 95.8% (113/118) the quadruple therapy (QT), sequential therapy (ST), and concomitant therapy (CT) groups, respectively.²⁰ Amongst the new PPIs, the reported eradication rate of omeprazole-based triple therapy (data from four RCTs) is 88 %.²¹

In recent years it has been demonstrated that the LEVO-based regimen can be used as an alternative agent for the CLA-based regimen in areas of high CLA resistance. The use of LEVO as a first-line therapy has also been studied in many trials. The eradication rates of LEVO-based triple therapy have been reported to be in the range of 72–96%.²² Interestingly all these studies have been conducted outside the US, with most being conducted in European countries.²³ Cammarota et al¹⁶⁵ conducted the first prospective trial studying the efficacy of LEVO-based triple therapy as a first-line therapy in *H. pylori* management. They divided one hundred patients into two groups based on Amoxicillin or tinidazole along with PPI and LEVO. It was noted that both groups achieved high eradication rates with 92% and 90% in intention to treat analysis, respectively. A German randomized trial compared LEVO, Amoxicillin, and Esomeprazole triple therapy with standard triple therapy, and found an eradication rate of 87% with LEVO triple therapy versus 84% following standard triple therapy.²⁴ Gisbert et al^{25,26} conducted two prospective trials in Spain with 64 and 75 patients using LEVO-based first line therapy along with PPI or ranitidine, respectively. They reported eradication rates of 84% and 83%, respectively, in these two studies with good tolerability. A study from the Netherlands using LEVO-containing triple therapies together with Amoxicillin or CLA as a first-line against *H. pylori* showed high eradication rates of 96% and 93%, respectively.²⁷ Based on the prior European studies showing high success rates with LEVO-based therapy, the American College of Gastroenterology guidelines recommended it as an option for the first line treatment of *H. Pylori*.²⁸ LEVO resistance has been reported to be higher in older patients as compared to young individuals. This difference between the older and younger population was 11.7% in Ireland and 19.1% in Italy.^{29,30} Other studies with Bismuth quadruple therapy have reported similar results of lower *H. pylori* eradication rates with increasing age.³¹ Some researchers have also reported lower eradication rates in females.³²

The limitation of our study was single center study, smaller sample size. Further studies with larger sample sizes are required.

CONCLUSION

The present study demonstrates that the first-line triple therapy regimen remains highly effective for the eradication of *Helicobacter pylori* infection, achieving a success rate of 85.8% among the study population. The findings indicate that despite the emergence of antibiotic resistance in various regions, triple therapy continues to be a reliable and practical treatment option in our local clinical setting. The study also observed a higher prevalence of *H. pylori* infection among males and identified common associated factors such as obesity, diabetes mellitus, and hypertension.

Overall, the results suggest that histopathology is a dependable diagnostic tool, and post-eradication stool antigen testing serves as a useful method for evaluating treatment success. Continued

surveillance of eradication rates and antibiotic resistance patterns is recommended to ensure sustained therapeutic efficacy.

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