ORIGINAL ARTICLE

Clarithromycin Versus Levofloxacin-Based Triple Regime in Stool Antigen-Positive Helicobacter Pylori Patients: A Quasi-Experimental Study in Islamabad

Tayyab Mahmood[1*], Rizwan Ahmed[1], Muhammad Naeem Jan[1], Aqsa Aslam[2], Hina Azeez[1], Tehseen Tanvir[3]

ABSTRACT

Objective: To compare the eradication rate and adverse effects of clarithromycin versus levofloxacin-based triple regimen in patients with positive stool antigen test for Helicobacter pylori.

Study Design: Quasi-experimental study.

Place and Duration of Study: This study was conducted at the Medicine Department of Federal Government Polyclinic Hospital, Islamabad, Pakistan, from 1st January 2024 to 30th December 2024.

Methods: A total of 270 patients with positive stool antigen tests for H. pylori were included using non-probability convenience sampling. Patients were allocated into two groups with 135 patients each: Group I received clarithromycin, omeprazole, and amoxicillin, whereas Group II received levofloxacin, omeprazole, and amoxicillin. In each group, 70 patients completed the regimen for 14 days, and 65 patients took it for 10 days. A repeat stool antigen test was performed 4 weeks after completion of the regimen. Data was analyzed using the Statistical Package for the Social Sciences (SPSS) version 26.

Results: Helicobacter pylori were eradicated in 117 (86.7%) and 99 (73.3%) patients with levofloxacin- and clarithromycin-based regimens, respectively (*P*-value=0.006). Significant eradication was achieved in 53 (81.5%) with levofloxacin versus 43 (66.2%) with a clarithromycin-based regimen, with a 10-day regimen. The eradication rates were significantly higher with levofloxacin than with a clarithromycin-based regimen (91.4% versus 80%) with a 14-day regimen. The adverse effects occurred in 61 (22.6%) patients, 36 (13.3%) occurring in Group I, and 25(9.3%) in Group II (*P*-value=0.05). The adverse effects occurred in 3% with a 10-day regime and 6.3% with a 14-day regime, with no statistical significance.

Conclusion: The levofloxacin-based triple regimen is highly effective, eradicating Helicobacter pylori in 86.7% of patients, and is relatively safer, with fewer adverse effects. The best eradication rate is achieved with a 14-day levofloxacin regimen followed by a 14-day clarithromycin regimen and then a 10-day levofloxacin regimen.

Keywords: *Clarithromycin, Disease Eradication, Helicobacter Pylori, Levofloxacin.*

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[1]*Department of Medicine*
Federal Government Polyclinic Hospital, Islamabad, Pakistan
[2]*Department of Pathology*
Rawal Institute of Medical Sciences, Islamabad, Pakistan
[3]*Department of Medicine*
KRL Hospital, Islamabad, Pakistan
Correspondence:
Dr. Tayyab Mahmood
Federal Government Polyclinic Hospital, Islamabad, Pakistan
E-mail: tayyabmahmoodkhokhar@gmail.com
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Introduction

Infections caused by Helicobacter pylori are prevalent, affecting nearly 4.4 million people, making almost 50% of the global population. According to the World Health Organization (WHO), it is the most common cause of peptic ulcer and gastric cancer. It ranks among the top causes of cancer-related deaths worldwide. In developing countries, the rate of infection is very high (85–95%) as compared to the developed nations, with the prevalence of 30-50%.[1] The increasing concern regarding H. pylori is attributed not only to its

increased prevalence but also to its relation with gastric cancer.[2] Another alarming situation is the emergence of antibiotic-resistant H. pylori, including clarithromycin and metronidazole-resistant strains, which have made the treatment more challenging and can lead to treatment failure.[3] In addition, H. pylori infections also contribute to huge financial losses to healthcare systems worldwide.[4]

Helicobacter pylori is a microaerophilic, curved, gram-negative rod that resides in the human stomach. The bacterium causes chronic gastritis, which leads to peptic ulcer, gastric cancer, and gastric mucosa-associated lymphoid tissue lymphoma (MALToma).[2] The prevalence of H. pylori infections varies greatly among various geographical areas and is associated with advanced age, poor hygiene, lower socioeconomic status, overcrowding and drinking untreated water.[5] Many patients with H. pylori infection are asymptomatic and serve as the source of infection for others. Symptomatic cases present with epigastric pain, nausea, vomiting and bloating. Helicobacter pylori infection also causes iron deficiency anemia, vitamin B12 deficiency and thrombocytopenia. The transmission route of H. pylori is not well-known. It has been documented that the organism is transmitted through the fecal-oral or oral-to-oral route.[3] Helicobacter pylori possesses various virulence factors, and its pathogenesis is linked to the ability of the organism to withstand the acidic environment of the stomach.[2,6]

The diagnostic tests include isolation of the organism from a gastric biopsy, a urea breath test, and a stool antigen test. Gastric biopsy has a sensitivity and specificity of 100% and 98%, whereas urea breath test and stool antigen have sensitivities and specificities of 97% and 100% versus 70% and 94%, respectively.[5] As gastric biopsy is an invasive procedure, culture and antibiotic susceptibility testing to determine the treatment of choice cannot be performed in most cases. The treatment options available are triple and quadruple therapy. Triple therapy consists of proton pump inhibitor (PPI), amoxicillin, and clarithromycin, whereas quadruple therapy includes bismuth, PPI, tetracycline, and metronidazole. As resistance to clarithromycin and metronidazole is rising, another combination consisting of amoxicillin, a PPI, and a fluoroquinolone is now being introduced as a second-line regimen.[7] The reported efficacy of this regimen in eradicating H. pylori is 75 to 90%. However, with the emergence of levofloxacin-resistant H. pylori, the efficacy of this regimen is decreasing.[8] Early detection and treatment of H. pylori infection is important to minimize gastric damage and the chances of gastric cancer. If the infection is not treated properly, the organism can persist for life. This study compared the eradication rates and adverse effects of clarithromycin versus levofloxacin-based triple therapy in patients with positive H. pylori stool antigen test results in our setting. This would help combat the disease and reduce disease recurrence, the risk of gastric cancer, associated deaths, and economic losses. In addition, the duration of regimes was also compared, as a 10-day regime has been documented to be associated with fewer side effects.

Methods

This quasi-experimental study was conducted at the Medicine Department of Federal Government Polyclinic Hospital, Islamabad, from 1st January 2024 to 30th December 2024, after obtaining ethical approval from the hospital's Ethical Review Committee vide letter no: FGPC.1/12/2022/ E.committee dated 3rd June 2022. After obtaining informed consent, patients aged 18 years or older with a positive H. pylori stool antigen test were included using a nonprobability convenience sampling technique. Patients already taking eradication therapy for H. pylori or any other antibiotic, having gastrointestinal malignancies except MALToma, patients who have penicillin allergy or who did not take the full course of therapy or were lost for follow-up were excluded. The sample size of 270 was calculated using an eradication rate of 80.4% with levofloxacin and 57.4% with clarithromycin-based therapy, a 5% level of significance, and 80% power.[9] Patients with suggestive symptoms of gastritis or peptic ulcer were asked to give their stool samples at the hospital laboratory for the H. pylori stool antigen test. Those with positive test met the inclusion exclusion criteria and were allocated into two groups with 135 patients each: Group I received clarithromycin (500 mg BD),

omeprazole (20 mg BD) and amoxicillin (1g BD), whereas, Group II received levofloxacin (500 mg OD), omeprazole (20 mg BD) and amoxicillin (1g BD). In each group (N = 135), 70 patients completed the regimen for 14 days, and 65 patients took it for 10 days. Repeat stool antigen test was done 4 weeks after completion of regimen. A negative stool antigen test ensures that H. pylori has been eradicated. The patient demographics, eradication rate of H. pylori, and adverse effects with each regimen were noted on the Proforma.

Data was analyzed using the Statistical Package for the Social Sciences (SPSS) version 26. Frequencies and percentages were calculated for categorical variables. Mean and standard deviation were used for numeric variables. Independent t-test and Chi-Square tests were used to compare numeric variables and categorical variables, respectively. A *P*-value ≤0.05 was considered significant.

Results

The patients had an average age of 45.94±17.32 years, with a minimum and maximum age of 18 and 70 years, respectively. Out of 270 patients, 144 (53.3%) were male, and 126 (46.7%) were female. The two groups did not differ in age and gender. Eighty-five (31.5%) patients presented with burning pain in abdomen, 65 (24.1%) with empty stomach pain, 79 (29.3%) had nausea, 57 (21.1%) had frequent burping, 36 (13.3%) had bloody vomits, 55 (20.4%) had bloody/black tarry stools, 244 (90.4%) had loss of appetite, and 39 (14.4%) patients had documented weight loss.

Table 1: Comparison of Demographics, Eradication Rate, and Adverse Effects between Two Groups

Variables	Group I	Group II	Total	*Chi-Square* statistic	*P*-value
Age (Years)	46.06±17.70	45.82±16.99	-	0.114	0.911
Age Groups					
<45 years	65 (48.1%)	59 (43.7%)	124 (45.9%)		
>45 years	70 (51.9%)	76 (56.3%)	146 (54.1%)	0.536	0.46
Total	135 (100%)	135 (100%)	270 (100%)		
Gender					
Male	75 (55.6%)	69 (51.1%)	144 (53.3%)		
Female	60 (44.4%)	66 (48.9%)	126 (46.7%)	0.535	0.47
Total	135(100%)	135 (100%)	270 (100%)		
Overall Eradication Rate					
Eradicated	99 (73.3%)	117 (86.7%)	216 (80%)		
Not Eradicated	36 (26.7%)	18 (13.3%)	54 (20%)	7.5	0.006*
Total	135 (100%)	135 (100%)	270 (100%)		
Eradication Rate with 10 Days Regime					
Eradicated	43 (66.2%)	53 (81.5%)	96 (73.8%)		
Not Eradicated	22 (33.8%)	12 (18.5%)	34 (26.2%)	3.982	0.04*
Total	65 (100%)	65 (100%)	130 (100%)		
Eradication Rate with 14 Days Regime					
Eradicated	56 (80%)	64 (91.4%)	120 (85.7%)		
Not Eradicated	14 (20%)	6 (8.6%)	20 (14.3%)	3.733	0.05*
Total	70 (100%)	70 (100%)	140 (100%)		
Adverse Effects					
Metallic taste	14 (5.2%)	4 (1.5%)	18 (6.7%)		
Nausea & Vomiting	8 (3%)	5 (1.9%)	13 (4.9%)		
Diarrhea	10 (3.7%)	5 (1.9%)	15 (5.6%)	9.690	0.05*
Dizziness	2 (0.7%)	7 (2.5%)	9 (3.2%)		
Palpitations	2 (0.7%)	4 (1.5%)	6 (2.2%)		
Total	36 (13.3%)	25 (9.3%)	61 (22.6%)		

**Statistically Significant*

Helicobacter pylori was eradicated in 117 (86.7%) of the patients with a levofloxacin-based regimen, 99 (73.3%) patients with a clarithromycin-based regimen, and 99 (73.3%) patients with a levofloxacin-based regimen, with a significant difference. The eradication rates were highest with levofloxacin than with a clarithromycin-based regimen (91.4% versus 80%) with a 14-day regimen. The adverse effects occurred in 61 (22.6%) of the patients, 36 (13.3%) occurring in Group I and 25 (9.3%) in Group II (*P*-value=0.05) (Table 1).

The 14-day treatment of levofloxacin and clarithromycin-based regimes was superior to their 10-day regimes, with higher eradication rates achieved with 14 days. However, the *P*-value was not significant. The adverse effects occurred in 3% with a 10-day regimen and 6.3% in a 14-day regimen, but the difference was not significant. These results are shown in Table 2.

Table 2: Comparison of Eradication Rates and Adverse Effects with Duration of Regimes

Regime	10 Days	14 Days	Total	*Chi-Square* statistic	*P*-value
Clarithromycin Eradication Rate					
Eradicated	43(66.2%)	56 (80%)	99 (73.3%)		
Not Eradicated	22(33.8%)	14 (20%)	36 (26.7%)	3.304	0.06
Total	65 (135)	70 (100%)	135 (100%)		
Adverse Effects					
Metallic taste	5 (1.9%)	9 (3.2%)	14 (5.2%)		
Nausea & Vomiting	3 (1.1%)	5 (1.9%)	8 (3%)		
Diarrhea	4 (1.5%)	6 (2.2%)	10 (3.7%)		
Dizziness	1 (0.4%)	1 (0.4%)	2 (0.7%)	0.278	0.99
Palpitations	1 (0.4%)	1 (0.4%)	2 (0.7%)		
Total	14 (5.2%)	22 (8.1%)	36 (13.3%)		
Levofloxacin Eradication Rate					
Eradicated	53 (81.5%)	64 (91.4%)	117 (86.7%)		
Not Eradicated	12 (18.5%)	6 (8.6%)	18 (13.3%)	2.852	0.09
Total	65 (100%)	70 (100%)	135 (100%)		
Adverse Effects					
Metallic taste	1 (0.4%)	3 (1.1%)	4 (1.5%)		
Nausea & Vomiting	2 (0.7%)	3 (1.1%)	5 (1.9%)		
Diarrhea	2 (0.7%)	3 (1.1%)	5 (1.9%)		
Dizziness	2 (0.7%)	5 (1.9%)	7 (2.5%)	0.512	0.97
Palpitations	1 (0.4%)	3 (1.1%)	4 (1.5%)		
Total	8 (3%)	17 (6.3%)	25 (9.3%)		

Discussion

The proper treatment of H. pylori infections is challenging for several reasons. First, H. pylori is protected by the stomach's mucosal lining, making antibiotic penetration difficult. Second, the therapy's adverse effects lead to patient noncompliance. Third, reinfection or relapse can occur, and when patients are treated with the same drugs, antibiotic resistance can develop. Resistance against clarithromycin has been reported, which is the main drug of the treatment regimen. Metronidazole resistance is also common. In addition to these first-line drugs, levofloxacin-resistant strains are also found. At present, the global resistance rate of H. pylori to clarithromycin is 27.2%, metronidazole is 39.7%, and levofloxacin is 22.5%. The resistance rate is anticipated to increase further in the coming years. Resistance rates to various

antibiotics differ markedly across geographical regions.[10,11]

In our study, the average patient age was 45.94±17.32 years, with 53.3% males. Similarly, the average age was 45.2±13.4 in another study, but 60.7% were female.[12] The average age of the patients was 54.5+11 years in a study by Gashi Z et al. and 50% were males.[13]

Our results revealed that Helicobacter pylori was eradicated in 86.7% of patients with a levofloxacin-based regimen and 73.3% with a clarithromycin-based regimen, with statistical significance. Similarly, in another study, the levofloxacin regimen resulted in H. pylori eradication in 74.5% of the cases as compared to the clarithromycin regimen with 62% eradication rate. The results were significant.[12] In another Iranian study, the researchers compared quadruple therapy of two types: levofloxacin in one group and clarithromycin in the other. The study showed that levofloxacin gave better results (89.7%) in H. pylori eradication as compared to the clarithromycin group (69.6%), with a *P*-value of 0.01.[14] A study conducted at Shaikh Zayed Hospital, Lahore, reported H. pylori eradication in 81.7% and 65.0% of the patients taking levofloxacin and clarithromycin, respectively, which is significant.[15] Contrary to our results, a study conducted in China found no significant difference in H. pylori eradication rates between the two regimens (85% with levofloxacin versus 80.8% with clarithromycin).[13] Another study showed no statistical difference between eradication rates of clarithromycin (43.7%) and levofloxacin (50.8%) regimes, but the efficacy of both regimes was very low.[16] In another study, the eradication rate of clarithromycin and levofloxacin was 64.66% and 74.36%. The results showed that eradication rates for clarithromycin and levofloxacin were not significantly different.[17]

Our findings revealed that adverse effects occurred in 61 (22.6%) of the patients, significantly more common (13.3%) in the clarithromycin group and 9.3% in patients taking levofloxacin. Another study also showed that the adverse effects were higher in patients taking clarithromycin as compared to levofloxacin.[14] In contrast, according to another study, there was no difference in side effects between the two regimes. The treatment was given for 10 days, and only minor side effects occurred in 6.6% of patients, including nausea, vomiting, diarrhea, and a metallic taste.[13] The adverse effects were seen in 30.4% and 26.7% of the patients taking clarithromycin and levofloxacin regimes, respectively, in a study by Aung WP et al.[16]

In our study, the most common adverse effects in patients taking clarithromycin were metallic taste and diarrhea, whereas dizziness was most frequent in the levofloxacin group. Similarly, the most common adverse effects were diarrhea & metallic taste with clarithromycin and palpitations & dizziness with levofloxacin in another study.[16]

In our study comparing treatment duration, eradication was achieved in 81.5% of patients with levofloxacin versus 66.2% with a clarithromycin-based regimen, with a 10-day regimen. The eradication rates were highest with levofloxacin than with the clarithromycin-based regimen (91.4% versus 80%) with a 14-day regimen. All these results were statistically significant. In a study conducted in Saudi Arabia, a significantly higher eradication rate was observed in patients who received therapy for 14 days (80.9% with levofloxacin and 66.3% with clarithromycin). In contrast, the eradication rates were 62.7% with levofloxacin and 41.2% with clarithromycin with 10 days' regimen, but this difference was not significant.[12] Another study revealed lower eradication rates of levofloxacin triple therapy for 7 to 10 days. The rate improved to 80% with 14 days' regime.[18] A study from Peshawar reported the eradication rate of 68.4% with clarithromycin and 82.4% with levofloxacin, with 14 days of treatment, and 64.6% versus 42.4% for levofloxacin and clarithromycin, respectively, at 10 days. Only the results of the 14-day regimen were significant.[19]

In our study, the 14-day treatment with levofloxacin and clarithromycin-based regimens was superior to the 10-day regimens, with higher eradication rates achieved with 14 days. However, the p-value was not significant. Adverse effects occurred in 3% with a 10-day regimen and 6.3% with a 14-day regimen. But the difference was not significant. In a study conducted in Canada, significant eradication was achieved in 91.5% of patients taking a 14-day clarithromycin

regimen compared to 63.6% with a 10-day regimen. In addition, no difference in side effects was seen between the two groups.[20] In another study, the eradication rate of 75.6% was reported in patients taking levofloxacin for 10 days as compared to 92.5% on 14 days' treatment, with statistical significance. Adverse effects occurred in 11% and 16% of patients at 10 and 14 days of treatment, respectively, but the difference was not significant (*P*-value = 0.12).[21]

The study only compared the levofloxacin-based triple regimen with the clarithromycin regimen. Further research should be conducted to compare multiple available regimes for H. pylori.

Conclusion

The 14-day levofloxacin-based triple regimen is preferred for eradicating H. pylori compared to the clarithromycin regimen, with fewer adverse effects.

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Author Contributions

TM: Conception and design of the work
RA: Manuscript writing for methodology design and investigation
MNJ: Data acquisition, curation, and statistical analysis
AA: Writing the original draft, proofreading, and approval for final submission
HA: Validation of data, interpretation, and write-up of results
TT: Revising, editing, and supervising for intellectual content