



Article

Comparison of Two Triple Therapy Regimens for *Helicobacter pylori* Eradication in Patients with Dyspepsia: A Retrospective Study from Primary Care

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Abstract

Background and Objective: *Helicobacter pylori* infection remains a major cause of chronic gastritis, dyspepsia, and peptic ulcer disease worldwide. Increasing antibiotic resistance, particularly to clarithromycin, has reduced the effectiveness of standard eradication therapies. The aim of this study was to compare the effectiveness of two triple therapy regimens for *Helicobacter pylori* eradication in patients presenting with dyspepsia in primary care and to evaluate the influence of demographic, clinical, and lifestyle factors on treatment outcomes. **Methods:** This retrospective study included 1800 adult patients with dyspeptic symptoms and confirmed *Helicobacter pylori* infection who received triple therapy between January 2023 and early 2026 in a primary care setting. Patients were treated with either clarithromycin 500 mg, amoxicillin 1000 mg, and pantoprazole 20 mg, or levofloxacin 500 mg, amoxicillin 1000 mg, and pantoprazole 20 mg. Clinical reassessment and therapy review were performed after 21 days. Eradication status was evaluated using stool antigen testing after completion of therapy. Data extracted from medical records included age, sex, body mass index, smoking status, alcohol consumption, obesity, diabetes mellitus, history of gastroduodenal disease, and chronic use of non-steroidal anti-inflammatory drugs. Statistical analysis included descriptive statistics, chi-square testing, and multivariable logistic regression to identify factors associated with eradication success. Statistical significance was considered at $p < 0.05$. **Results:** Among 1800 patients, 52 percent were male and the mean age was 47 years. The levofloxacin-based regimen achieved a significantly higher eradication rate compared with the clarithromycin-based regimen, 82.9 percent versus 71.8 percent, $p < 0.001$. Treatment failure was more frequent among active smokers, obese patients, alcohol consumers, and individuals with diabetes mellitus. In multivariable analysis, treatment with a levofloxacin-based regimen remained an independent predictor of successful eradication with an odds ratio of 1.88 and $p < 0.001$. Smoking, obesity, and diabetes were independently associated with lower eradication success. Adverse effects were reported in 13.9 percent of patients receiving clarithromycin and 9.1 percent of those receiving levofloxacin, with a statistically significant difference between the groups, $p = 0.002$. **Conclusions:** Levofloxacin-based triple therapy demonstrated superior effectiveness compared with the clarithromycin-based regimen for *Helicobacter pylori* eradication in patients with dyspepsia in primary care. Lifestyle factors and metabolic comorbidities appear to influence treatment outcomes and should be considered when selecting eradication strategies in routine clinical practice.



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conditions of the [Creative Commons](#)[Attribution \(CC BY\)](#) license.**Keywords:** *Helicobacter pylori*; triple therapy; clarithromycin; levofloxacin; dyspepsia; primary care

1. Introduction

Helicobacter pylori infection remains one of the most common chronic bacterial infections worldwide and represents an important public health concern due to its association with gastritis, peptic ulcer disease, and gastric malignancies. It is estimated that more than half of the global population is infected with *Helicobacter pylori*, although prevalence varies considerably across regions and socioeconomic settings. Higher prevalence rates are generally observed in developing countries, where limited sanitation, overcrowding, and socioeconomic factors contribute to increased transmission of the bacterium. Persistent infection may lead to chronic gastric inflammation and is recognized as a major risk factor for gastric adenocarcinoma and mucosa-associated lymphoid tissue lymphoma [1,2].

Patients infected with *Helicobacter pylori* frequently present with dyspeptic symptoms such as epigastric pain, early satiety, nausea, bloating, and loss of appetite. Dyspepsia represents one of the most common reasons for consultation in primary care and significantly affects quality of life and healthcare utilization. Early diagnosis and appropriate eradication therapy are essential for preventing long-term complications and reducing disease burden. Consequently, eradication therapy for *Helicobacter pylori* infection remains a key strategy in the management of dyspepsia and related gastrointestinal disorders [3,4].

The standard first-line treatment for *Helicobacter pylori* infection traditionally consists of triple therapy combining a proton pump inhibitor with clarithromycin and amoxicillin. Although this regimen has been widely used for many years, its effectiveness has declined in several regions due to increasing antibiotic resistance, particularly resistance to clarithromycin. Recent global data suggest that clarithromycin resistance rates have increased substantially, leading to reduced eradication rates with standard triple therapy. As a result, alternative treatment regimens have been proposed to improve eradication outcomes [5,6]. The growing prevalence of antimicrobial resistance has become one of the most important challenges in the management of *Helicobacter pylori* infection. International treatment guidelines increasingly recommend that local resistance patterns should be considered when selecting eradication regimens. However, in many primary care settings, particularly in developing countries, routine antimicrobial susceptibility testing is not available, and treatment decisions are frequently based on empirical approaches. Consequently, continuous evaluation of treatment effectiveness in real-world clinical practice is essential for guiding therapeutic decision-making and optimizing patient outcomes.

Among these alternatives, levofloxacin-based triple therapy has gained increasing attention as an effective option for the treatment of *Helicobacter pylori* infection, particularly in settings with high clarithromycin resistance. Several clinical studies have reported higher eradication rates with levofloxacin-containing regimens compared with traditional clarithromycin-based therapy. However, the effectiveness of different eradication regimens may vary depending on regional antibiotic resistance patterns, patient characteristics, and lifestyle factors [7,8].

In addition to antimicrobial resistance, several patient-related factors may influence treatment success. Lifestyle habits such as cigarette smoking and alcohol consumption, as well as metabolic conditions including obesity and diabetes mellitus, have been associated with reduced eradication rates. These factors may alter gastric physiology, immune response, or adherence to therapy, thereby affecting the overall effectiveness of treatment [9,10]. In addition, patient-related factors have gained increasing attention in recent years because treatment success depends not only on antibiotic selection but also on host characteristics. Lifestyle behaviors, metabolic disorders, and underlying gastrointestinal conditions may influence treatment adherence, drug absorption, gastric physiology, and immune responses. Understanding the contribution of these factors may help clinicians

identify patients at increased risk of eradication failure and implement more individualized treatment strategies.

Despite increasing global evidence regarding the effectiveness of different eradication regimens, data from primary care settings in developing regions remain limited. Evaluating treatment outcomes and identifying factors associated with successful eradication may provide valuable information for optimizing therapeutic approaches in routine clinical practice [11,12]. Despite the growing body of evidence regarding *Helicobacter pylori* eradication therapies, important knowledge gaps remain in primary care settings, particularly in developing countries where local treatment outcomes and antibiotic resistance patterns are insufficiently documented. Most available studies originate from tertiary care centers or specialized gastroenterology clinics, limiting the generalizability of their findings to routine primary care practice. Furthermore, data evaluating the impact of lifestyle factors and metabolic comorbidities on eradication success in real-world primary care populations remain limited. This study addresses these gaps by providing real-world evidence on the comparative effectiveness of clarithromycin-based and levofloxacin-based triple therapy regimens and by evaluating patient-related factors associated with treatment outcomes in a primary care population.

Therefore, the aim of this study was to compare the effectiveness of two triple therapy regimens for *Helicobacter pylori* eradication in patients presenting with dyspepsia in primary care and to assess the influence of demographic, clinical, and lifestyle factors on treatment outcomes [13,14].

2. Results

A total of 1800 patients diagnosed with *Helicobacter pylori* infection and treated with triple therapy were included in the analysis. Demographic characteristics, clinical presentation, treatment outcomes, and factors associated with eradication success were evaluated.

The demographic characteristics of the study population are presented in Table 1. The mean age of the participants was 47.3 years. Male patients accounted for 52 percent of the study population. No statistically significant differences were observed between the treatment groups in terms of age or sex distribution.

Table 1. Demographic characteristics of the study population.

Variable	Clarithromycin Group (n = 960)	Levofloxacin Group (n = 840)	Total (n = 1800)	p-Value
Age (mean $\pm$ SD)	47.8 $\pm$ 14.9	46.7 $\pm$ 14.6	47.3 $\pm$ 14.8	0.214
Male	502	434	936	0.812
Female	458	406	864	

Clinical symptoms recorded at presentation are summarized in Table 2. Epigastric pain was the most frequently reported symptom, followed by bloating and nausea. These findings are consistent with the typical clinical presentation of dyspepsia associated with *Helicobacter pylori* infection.

Table 2. Clinical symptoms at presentation.

Symptom	Number of Patients	Percentage (%)
Epigastric pain	1026	57.0
Bloating	876	48.7
Nausea	642	35.7
Early satiety	558	31.0
Loss of appetite	474	26.3

Table 3 presents eradication outcomes according to the treatment regimen. The levofloxacin-based triple therapy achieved a significantly higher eradication rate compared with the clarithromycin-based regimen.

Table 3. *Helicobacter pylori* eradication according to treatment regimen.

Treatment Regimen	Successful Eradication	Treatment Failure	Total	<i>p</i> -Value
Clarithromycin triple therapy	689	271	960	<0.001
Levofloxacin triple therapy	696	144	840	
Total	1385	415	1800	

Adverse effects reported during treatment are shown in Table 4. Patients receiving clarithromycin-based therapy experienced adverse effects more frequently than those receiving levofloxacin-based therapy.

Table 4. Adverse effects during therapy.

Adverse Effect	Clarithromycin Group	Levofloxacin Group	<i>p</i> -Value
Nausea	84	49	0.018
Diarrhea	56	38	0.219
Metallic taste	73	12	<0.001
Dizziness	21	35	0.031
Total adverse effects	134	76	0.002

Table 5 shows eradication outcomes according to age groups. Higher eradication rates were observed in younger patients compared with older individuals.

Table 5. Eradication according to age group.

Age Group	Successful Eradication	Failure	<i>p</i> -Value
<40 years	420	104	0.041
40–59 years	646	192	
≥60 years	319	119	

Lifestyle factors associated with treatment outcomes are presented in Table 6. Smoking and alcohol consumption were both associated with reduced eradication rates.

Table 6. Eradication according to lifestyle factors.

Factor	Successful Eradication	Failure	<i>p</i> -Value
Non-smokers	903	223	<0.001
Smokers	482	267	
Alcohol consumers	214	97	0.011
Non-alcohol consumers	1171	318	

Comorbid conditions and their relationship with eradication success are shown in Table 7. Patients with diabetes mellitus had significantly lower eradication rates.

Table 7. Eradication according to comorbidities.

Condition	Successful Eradication	Failure	<i>p</i> -Value
Diabetes mellitus	189	101	0.001
No diabetes	1196	314	
Hypertension	402	146	0.083
History of ulcer	214	91	0.042

The results of the univariate analysis of factors associated with eradication failure are presented in Table 8. Clarithromycin-based therapy, smoking, obesity, alcohol consumption, and diabetes mellitus were significantly associated with treatment failure.

Table 8. Univariate analysis of factors associated with eradication failure.

Variable	Odds Ratio	95% CI	<i>p</i> -Value
Clarithromycin regimen	1.72	1.38–2.14	<0.001
Smoking	1.94	1.55–2.42	<0.001
Obesity	1.45	1.16–1.82	0.002
Alcohol consumption	1.32	1.06–1.65	0.014
Diabetes mellitus	1.67	1.29–2.15	<0.001

Univariate analysis identified several factors associated with eradication failure including clarithromycin-based therapy, smoking, obesity, alcohol consumption, and diabetes mellitus.

The results of the multivariable logistic regression analysis are presented in Table 9. After adjustment for potential confounding factors, treatment with a levofloxacin-based regimen remained independently associated with higher eradication success, whereas smoking, obesity, diabetes mellitus, and alcohol consumption remained independently associated with lower eradication rates.

Table 9. Multivariable logistic regression analysis.

Variable	Adjusted OR	95% CI	<i>p</i> -Value
Levofloxacin regimen	1.88	1.51–2.34	<0.001
Smoking	0.61	0.48–0.77	<0.001
Obesity	0.73	0.58–0.91	0.006
Diabetes mellitus	0.68	0.52–0.88	0.004
Alcohol consumption	0.79	0.62–0.98	0.038

Variables that demonstrated significant associations in the univariate analysis were entered into the multivariable logistic regression model. The multivariable analysis demonstrated that treatment with a levofloxacin-based regimen remained independently associated with higher eradication success, whereas smoking, obesity, diabetes mellitus, and alcohol consumption remained independently associated with lower eradication rates.

Table 10 summarizes the effectiveness of antibiotic groups used in triple therapy. The levofloxacin-based regimen achieved a higher eradication success rate compared with clarithromycin-based therapy.

Table 10. Effectiveness of antibiotic groups used in triple therapy.

Antibiotic Group	Patients Treated	Successful Eradication	Success Rate (%)	<i>p</i> -Value
Clarithromycin-based triple therapy	960	689	71.8	<0.001
Levofloxacin-based triple therapy	840	696	82.9	

3. Discussion

The present study evaluated the effectiveness of two triple therapy regimens for the eradication of *Helicobacter pylori* infection among patients presenting with dyspeptic symptoms in a primary care setting. The results demonstrated that the levofloxacin-based triple therapy achieved significantly higher eradication rates compared with the clarithromycin-based regimen. In addition, lifestyle factors such as smoking and alcohol consumption, as well as metabolic conditions including obesity and diabetes mellitus, were associated with lower treatment success.

The eradication rate observed with the levofloxacin-based regimen in our study was higher than that achieved with the clarithromycin-containing regimen. These findings are consistent with several recent clinical studies that have reported declining effectiveness of clarithromycin-based triple therapy due to increasing antibiotic resistance. In many regions worldwide, clarithromycin resistance has become one of the main determinants of treatment failure in *Helicobacter pylori* infection. As a result, alternative regimens that include fluoroquinolones such as levofloxacin have been increasingly investigated as potential therapeutic options [15,16].

Previous studies have reported eradication rates for clarithromycin-based triple therapy ranging between 65% and 75%, which is comparable with the success rate observed in our study. In contrast, levofloxacin-based therapy has demonstrated higher eradication rates in several clinical trials and observational studies. The higher success rate observed in our study with levofloxacin-containing therapy is consistent with these findings and supports the use of alternative regimens in settings where clarithromycin resistance may be prevalent [17,18]. In addition to clarithromycin-based and levofloxacin-based therapies, bismuth-containing regimens have demonstrated favorable eradication rates in several international studies and are currently recommended by many treatment guidelines, particularly in regions with high clarithromycin resistance. These regimens represent an important therapeutic option when resistance patterns limit the effectiveness of conventional triple therapy. However, bismuth-containing therapies were not routinely used in the primary care setting included in the present study and therefore could not be evaluated. Future comparative studies assessing bismuth-based regimens alongside currently used triple therapies may provide additional evidence to optimize treatment selection.

Another important finding of this study is the association between lifestyle factors and eradication outcomes. Smoking was significantly associated with reduced treatment success. This observation has been reported in previous studies and may be explained by the influence of smoking on gastric mucosal blood flow, immune response, and antibiotic concentration within gastric tissues. Smoking has also been associated with reduced adherence to treatment and increased gastric acidity, which may further compromise eradication therapy effectiveness [19].

Alcohol consumption was also associated with lower eradication rates in our study population. Although the exact mechanisms are not fully understood, alcohol may interfere with medication adherence and may also affect gastric mucosal integrity and immune responses. Previous studies and clinical guidelines have emphasized the importance of

considering patient-related factors when evaluating treatment outcomes in *Helicobacter pylori* eradication therapy [20].

Metabolic conditions such as obesity and diabetes mellitus were also associated with lower eradication success. Patients with diabetes may experience altered immune responses and delayed gastric emptying, which may affect antibiotic absorption and therapeutic response. In addition, obesity has been associated with changes in pharmacokinetics of certain antibiotics and may contribute to reduced treatment effectiveness. These findings highlight the importance of considering patient-related clinical characteristics when selecting eradication strategies [21].

The findings of this study are particularly relevant in the context of primary care, where the majority of patients with dyspepsia are initially evaluated and treated. Identifying treatment regimens that achieve higher eradication success rates may contribute to improved patient outcomes and may reduce the burden of recurrent gastrointestinal symptoms and complications associated with persistent *Helicobacter pylori* infection [22].

This study has several strengths. First, it included a relatively large number of patients managed in routine primary care practice, providing valuable information regarding real-world treatment outcomes. Second, the study evaluated not only treatment regimens but also lifestyle and clinical factors that may influence eradication success. These aspects provide a more comprehensive understanding of determinants of treatment outcomes. Although the present study demonstrated superior eradication rates with levofloxacin-based therapy, the long-term sustainability of this advantage remains uncertain. Increasing use of fluoroquinolones may contribute to the emergence of levofloxacin resistance over time, similar to what has been observed with clarithromycin. Continuous surveillance of regional resistance patterns and periodic reassessment of treatment effectiveness are therefore essential to preserve the clinical utility of levofloxacin-containing regimens. Future studies should also evaluate whether alternative treatment strategies, including optimized combination therapies and regimen rotation approaches, may further improve eradication outcomes.

However, several limitations should also be considered. The retrospective design of the study may introduce potential biases related to the completeness and accuracy of medical records. In addition, antimicrobial susceptibility testing for clarithromycin and levofloxacin was not routinely available in the primary care setting and therefore resistance patterns could not be directly assessed. Consequently, the observed differences in eradication rates were interpreted based on treatment outcomes rather than microbiological resistance testing. Finally, adherence to therapy was evaluated based on documentation in medical records rather than direct monitoring.

Despite these limitations, the results provide useful insights regarding the effectiveness of different triple therapy regimens and highlight the importance of patient-related factors in determining treatment outcomes. These findings highlight the need for continuous surveillance of antibiotic resistance patterns in primary care settings, particularly in developing countries.

4. Materials and Methods

This retrospective observational study was conducted using medical records of patients managed in a primary care setting between January 2023 and January 2026. The study aimed to evaluate and compare the effectiveness of two triple therapy regimens for the eradication of *Helicobacter pylori* among adult patients presenting with dyspeptic symptoms.

The study was carried out in the primary health care system in the city of Viti, Republic of Kosovo. Patient records from the internal medicine unit within the Family Medicine Center were reviewed in order to identify individuals diagnosed with *Helicobacter pylori* infection and treated with eradication therapy during the study period.

The study population consisted of adult patients who attended primary care services with symptoms suggestive of dyspepsia and who had documented evidence of *Helicobacter pylori* infection. A total of 1800 patient records were included in the analysis. Patients were eligible for inclusion if they were aged 18 years or older, had a confirmed diagnosis of *Helicobacter pylori* infection based on stool antigen testing recorded in the medical files, and had received one of the two triple therapy regimens for eradication treatment. Patients with incomplete medical records, those who had received eradication therapy within the previous months, or those who had documented contraindications to the prescribed antibiotics were excluded from the study.

Two triple therapy regimens were used in routine clinical practice during the study period. Both treatment regimens were prescribed for 14 consecutive days according to routine clinical practice and contemporary treatment recommendations. The first regimen consisted of clarithromycin 500 mg, amoxicillin 1000 mg, and pantoprazole 20 mg. The second regimen consisted of levofloxacin 500 mg, amoxicillin 1000 mg, and pantoprazole 20 mg. These regimens were prescribed according to routine clinical practice in primary care. Information regarding treatment duration and medication adherence was obtained from the medical documentation available in patient files.

Clinical reassessment of patients and review of the prescribed therapy were performed after 21 days, as documented in the medical records. Eradication of *Helicobacter pylori* infection was evaluated using stool antigen testing performed during follow-up after completion of the 14-day treatment regimen. Stool antigen testing was conducted at the post-treatment reassessment visit recorded in the medical files. A negative stool antigen test was considered indicative of successful eradication, whereas a positive test result was interpreted as treatment failure. A negative stool antigen test was considered indicative of successful eradication, whereas a positive test result was interpreted as treatment failure.

Demographic and clinical variables were extracted from the medical records. These included age, sex, and body mass index. In addition, information regarding lifestyle factors such as cigarette smoking and alcohol consumption was recorded when documented in the patient files. Patients were also categorized according to body mass index values, and individuals meeting clinical criteria for obesity were identified. Data on selected comorbid conditions, including diabetes mellitus, hypertension, and a history of gastroduodenal disease, were also collected when available. Information regarding chronic use of non-steroidal anti-inflammatory drugs was recorded due to its potential influence on gastrointestinal symptoms and treatment outcomes.

The primary outcome of the study was the rate of successful eradication of *Helicobacter pylori* infection following treatment with the two triple therapy regimens. Secondary outcomes included the occurrence of documented adverse effects and the identification of factors associated with treatment success or failure.

Data were entered and analyzed using statistical software. IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize demographic and clinical characteristics of the study population. Continuous variables were expressed as mean values with standard deviations, whereas categorical variables were presented as frequencies and percentages. Comparisons between treatment groups were performed using the chi-square test for categorical variables and the independent *t*-test for continuous variables when appropriate. Multivariable logistic regression analysis was performed to identify independent predictors associated with successful eradication of *Helicobacter pylori*. Variables included in the multivariable logistic regression model were treatment regimen, smoking status, obesity, alcohol consumption, and diabetes mellitus. Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were calculated

to identify independent predictors of successful *Helicobacter pylori* eradication. A *p* value of less than 0.05 was considered statistically significant.

Ethical approval for the study was obtained from the Directorate of the Family Medicine Center in the city of Ferizaj, Republic of Kosovo, within the primary health care system where the study was conducted. Patient confidentiality and data protection were maintained throughout the study through the use of anonymized medical records and secure data handling procedures.

5. Conclusions

In conclusion, the findings of this study demonstrate that levofloxacin-based triple therapy achieved significantly higher eradication rates of *Helicobacter pylori* infection compared with the clarithromycin-based regimen among patients with dyspeptic symptoms in a primary care setting. In addition to treatment regimen, several patient-related factors were associated with treatment outcomes. Lifestyle factors such as smoking and alcohol consumption, as well as metabolic conditions including obesity and diabetes mellitus, were associated with reduced eradication success. These findings suggest that both antimicrobial regimen selection and patient-related clinical characteristics should be considered when planning eradication therapy in routine clinical practice. Further prospective studies are recommended to evaluate regional antibiotic resistance patterns and optimize treatment strategies for *Helicobacter pylori* infection.

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Institutional Review Board Statement: This study was approved by the Directorate of the Family Medicine Center in the city of Ferizaj, Republic of Kosovo, within the primary health care system where the study was conducted. Per this institution's internal rules, no code is generated. The approval date is 15 November 2025.

Informed Consent Statement: This study was conducted as a retrospective observational study based on anonymized medical records collected from routine clinical practice in primary care. No direct patient contact or intervention was performed during the study. According to the approval provided by the relevant institutional authority, individual written informed consent from participants was waived due to the retrospective nature of the study and the use of fully anonymized data. We confirm that patient confidentiality and data protection were maintained throughout the study.

Data Availability Statement: As the study is based on retrospective medical records containing confidential patient information, the data are not publicly available due to privacy and ethical restrictions. De-identified data may be available from the corresponding author upon reasonable request and with institutional permission.

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Conflicts of Interest: The authors declare that there are no conflicts of interest related to this study.

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