

Original Research

Comparison of esomeprazole containing levofloxacin versus clarithromycin in patients with *Helicobacter pylori* infection

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ABSTRACT:

Background: *Helicobacter pylori* (*H. pylori*) is a type of bacteria that infects the stomach lining. It is a common bacterial infection worldwide, with a significant prevalence in developing countries. The present study was conducted to compare esomeprazole containing levofloxacin versus clarithromycin in patients with *Helicobacter pylori* infection. **Materials & Methods:** 84 patients with gastro-duodenal ulcer of both genders were divided into 2 groups of 42 each. Patients in group I were treated with esomeprazole 40 mg and amoxicillin 1 g bid during the early half of treatment, and continued the same dose of esomeprazole with levofloxacin 500 mg and tinidazole 500 mg bid during the second half of treatment and group II patients were treated with the identical treatment excepting clarithromycin 500 mg bid as a substitute of levofloxacin. **Results:** Gastrointestinal bleeding was seen in 5 and 8, NSAID consumption in 7 and 6, gastric ulcers in 16 and 12, ulcer size (>10 mm) in 8 and 9, duodenal ulcer in 20 and 22, ulcer size (>10 mm) in 4 and 3, and gastric/duodenal erosion in 6 and 8 patients in group I and II respectively. The difference was non-significant ($P > 0.05$). The success rate found to be 84% in group I and 82% in group II by intention-to-treat analysis (ITT analysis). The success rate was 94% in group I and 91% in group II as per Preprotocol (PP analysis). The difference was non-significant ($P > 0.05$). **Conclusion:** Despite significant disparities in the incidence of antibiotic resistance, esomeprazole-containing sequential regimens incorporating levofloxacin and/or clarithromycin had high eradication rates.

Keywords: Gastrointestinal bleeding, Gastric ulcer, *Helicobacter pylori*

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INTRODUCTION

Helicobacter pylori (*H. pylori*) is a type of bacteria that infects the stomach lining. It is a common bacterial infection worldwide, with a significant prevalence in developing countries.¹ *H. pylori* infection is usually acquired during childhood, and it can persist for many years if left untreated. The exact route of transmission of *H. pylori* is not fully understood, but it is believed to primarily occur through oral-oral or fecal-oral routes.² Factors such as poor sanitation, crowded living conditions, and socioeconomic status may increase the risk of transmission.³ *H. pylori* infection can lead to various gastrointestinal conditions, including gastritis (inflammation of the stomach lining), peptic ulcer disease (ulcers in the stomach or duodenum), and in some cases, stomach cancer. The bacterium produces

enzymes and toxins that can damage the protective mucus layer of the stomach, allowing acid to irritate the underlying tissues and leading to inflammation and ulceration.⁴

The main cause of therapy failure for *H. pylori* is patterns of primary antibiotic resistance. The effectiveness of *H. pylori* treatment may be influenced by a number of additional variables in addition to antibiotic resistance, including patient adherence to treatment, gastric acidity, CYP2C19 polymorphism, high bacterial counts, and pathogenicity of microorganisms.⁵ When the resistance to fluoroquinolones is less than 10% and the resistance to clarithromycin is greater than 20%, fluoroquinolones may be considered as an alternative for first-line therapy.⁶ However, esomeprazole suppresses stomach acid better than other proton

pump inhibitors (PPIs), especially at larger doses.⁷The present study was conducted to compareesomeprazole containing levofloxacin versus clarithromycin in patients with Helicobacter pylori infection.

MATERIALS & METHODS

The present study consisted of 84 patients with gastro-duodenal ulcerof both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 42 each. Patients in group I were treated with esomeprazole 40

mg and amoxicillin 1 g bid during the early half of treatment, and continued the same dose of esomeprazole with levofloxacin 500 mg and tinidazole 500 mg bid during the second half of treatment and group IIpatients were treated with the identical treatment excepting clarithromycin 500 mg bid as a substitute of levofloxacin. To assess eradication, C14-urea breath test was implemented 8 weeks afterward treatment.Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Clinical characteristics

Parameters	Group I	Group II	P value
Gastrointestinal bleeding	5	8	0.92
NSAID consumption	7	6	0.96
Gastric ulcer	16	12	0.71
Ulcer size (>10 mm)	8	9	0.95
Duodenal ulcer	20	22	0.82
Ulcer size (>10 mm)	4	3	0.25
Gastric/duodenal erosion	6	8	0.17

Table I shows that gastrointestinal bleeding was seen in 5 and 8, NSAID consumption in 7 and 6, gastric ulcers in 16 and 12, ulcer size (>10 mm) in 8 and 9, duodenal ulcer in 20 and 22, ulcer size (>10 mm) in 4 and 3, and gastric/duodenal erosion in 6 and 8 patients in group I and II respectively. The difference was non- significant (P> 0.05).

Table II Comparison of success rate

Parameters	Group I	Group II	P value
ITT analysis	84%	82%	0.95
PP analysis	94%	91%	0.87

Table II, graph I shows that success rate found to be 84% in group I and 82% in group II by intention-to-treat analysis (ITT analysis). The success rate was 94% in group I and 91% in group II as per Preprotocol (PP analysis). The difference was non- significant (P> 0.05).

DISCUSSION

The standard treatment for H. pylori infection involves a combination of antibiotics and acid-suppressing medications, known as triple therapy or quadruple therapy.^{8,9} Commonly used antibiotics include clarithromycin, amoxicillin, metronidazole, and tetracycline, often combined with a proton pump inhibitor (PPI) or bismuth subsalicylate.¹⁰ Treatment regimens may vary depending on factors such as antibiotic resistance patterns and patient tolerance.^{11,12}The present study was conducted to compare esomeprazole containing levofloxacin versus clarithromycin in patients with Helicobacter pylori infection.

We found that gastrointestinal bleeding was seen in 5 and 8, NSAID consumption in 7 and 6, gastric ulcers in 16 and 12, ulcer size (>10 mm) in 8 and 9, duodenal ulcer in 20 and 22, ulcer size (>10 mm) in 4 and 3, and gastric/duodenal erosion in 6 and 8 patients in group I and II respectively. Mokhtare et al¹³estimated the effect of two 10-day esomeprazole containing clarithromycin and levofloxacin sequential therapies on H. pylori treatment.Totally, 186 H. pylori-infected patients with gastro-duodenal ulcer

were randomly designated patients to group A (N = 94) who treated with esomeprazole 40 mg and amoxicillin 1 g bid during the early half of treatment, and continued the same dose of esomeprazole with levofloxacin 500 mg and tinidazole 500 mg bid during the second half of treatment and Group B (N = 92) who treated with the identical treatment excepting clarithromycin 500 mg bid as a substitute of levofloxacin. To assess eradication, C14-urea breath test was implemented 8 weeks afterward treatment. The success rate was 85.1% (95% confidence interval [CI] = 77.9–92.3) and 83.7% (95% CI = 76.2–91.2) eradication intention-to-treat analysis (P = 0.302) and so, 93.0% (95% CI = 87.6–98.4) and 90.0% (95% CI = 83.6–96.3) eradication by per-protocol analysis (P = 0.420) for Group A and B, respectively. No significant difference was seen among regimens. Drug adverse reactions were not significantly different between regimens. Group A had a 97.8% adherence rate to treatment and Group B had 98.9%.

We found that success rate found to be 84% in group I and 82% in group II by intention-to-treat analysis (ITT analysis). The success rate was 94% in group I and 91% in group II as per Preprotocol (PP analysis).

Moradniani et al¹⁴ aimed to evaluating the efficacy of levofloxacin based sequential therapy vs clarithromycin based sequential therapy in H.pylori (HP) eradication. 200 HP infected patients randomly divided into two therapeutic groups. 1-Levofloxacin based sequential regimen (group A); omeprazole and amoxicillin for 7days followed by omeprazole, amoxicillin and levofloxacin for 7days. 2-clarithromycin based sequential regimen (group B): omeprazole and amoxicillin for 7days followed by omeprazole, amoxicillin and clarithromycin for 7days. HP eradication was evaluated with urea breath test with carbon 13 (UBT) 6 weeks after the end of treatment. Per protocol eradication rates of group A and B were 87.6% and 76% respectively. By intention to treat analysis, eradication rate of group A and B groups were 85.1% and 73% respectively. Levofloxacin based sequential regimen was more effective than clarithromycin based sequential regimen ($P=0.028$). Adverse events were seen in 19.6% and 15.6% in group A and B respectively. Drug compliance was 97% in group A and 96% in group B. There was no significant difference between two groups in term of adverse events ($p=0.470$) and compliance ($p=0.651$).

The limitation of the study is the small sample size.

CONCLUSION

Authors found that despite significant disparities in the incidence of antibiotic resistance, esomeprazole-containing sequential regimens incorporating levofloxacin and/or clarithromycin had high eradication rates.

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