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ORIGINAL ARTICLE

Levofloxacin versus Clarithromycin-based Therapy for Eradication of Helicobacter Pylori Infection: A Comparative Study

Neveen George Elantouny[1], Ashraf Ahmed Abo Bakr[2], Rehab Hosny EL-Sokkary[3], Yousif Elsayed Elshahat[2]

[1]*Internal Medicine Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt*
[2]*Internal Medicine Department, Maadi Military Hospital (MD, FRCP), Cairo, Egypt*
[3]*Medical Microbiology and Immunology Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt*

Corresponding Author:
Yousif Elsayed Elshahat
Internal Medicine Department, Maadi Military Hospital (MD, FRCP), Cairo, Egypt.

E-mail:
yusifyusif524@gmail.com

ABSTRACT

Background: Helicobacter pylori (H.pylori) infection causes multiple upper gastrointestinal diseases but optimal therapeutic regimen which can eradicate infection in all the cases has not yet been defined. Antimicrobial resistance has decreased eradication rates for H.pylori infection worldwide. The aim of the present study was to compare between the efficacy and tolerability of levofloxacin versus Clarithromycin based triple therapy in eradication of H.pylori infection.

Subjects and Methods: In this comparative cross sectional study, 142 patients with epigastric pain and dyspepsia and positive stool antigen test and only 35 of them were further confirmed by Rapid Urease Test during upper endoscopy (endoscopy was indicated) were enrolled. They were divided into 2 groups The first group (levofloxacin group) was treated with levofloxacin (500 mg daily) plus amoxicillin (1 gm twice a day) plus pantoprazol (40 mg twice daily) for 2 weeks. The second group (clarithromycin group) was treated with clarithromycin (500 mg twice a day) plus pantoprazol (40 mg twice daily) plus amoxicillin (1 gm twice a day) for 2 weeks. For treatment evaluation Stool antigen test was performed after four weeks after cessation of therapy.

Results: H.pylori eradication was successful in 84.5% of the levofloxacin group and 69% of the clarithromycin group (P=0.001). The adverse effects were less frequent in levofloxacin-based than clarithromycin-based Ttiple therapy.

Conclusion: Triple therapy with levofloxacin-based regimen has better efficacy than clarithromycin-based regimen.

Keywords: Helicobacter pylori; Rapid urease test; Stool antigen test

INTRODUCTION

H.pylori is a spiral shaped gram negative bacilli that infects approximately 50% of the human population worldwide and could reach more than 70% in developing countries [1,2].It is adapted to live in the harsh acidic medium of the stomach [3]. Previous studies showed that the seropositivity for anti-H.pylori antibodies among Egyptian population was 91.7%; the rate of infection differs among age groups, with higher rates in older ages [4].

H.pylori has several virulence factors that is associated with the severity of the clinical symptoms [5]. H. pylori is one of the main causes of the upper gastrointestinal disorders, which include peptic ulcer disease (gastric and duodenal), chronic gastritis, gastric mucosal-associated lymphoid tissue lymphoma, and gastric cancers [6]. In the latest years, it has been suggested the

possible role of H. pylori infection with numerous extragastric disorders, which includes neurodegenerative, cardiovascular problems and metabolic, as well as hepatobiliary, pancreatic, and colorectal illnesses. Furthermore, researchers suggested that this bacterium may be related to the development of skin disorders, which includes urticaria in addition to rheumatic diseases [7].

A "test-and-treat strategy" has long been advocated for detecting and eradicating *H. pylori* in patients with dyspepsia with low gastric cancer risk [8]. The most recent version of this strategy targets patients younger than 60 years with chronic or frequently recurring epigastric pain or discomfort in the absence of alarm symptoms, such as unexplained weight loss, progressive dysphagia, odynophagia, recurrent vomiting, family history of gastrointestinal cancer, and iron deficiency anemia [9]**.** Moreover, if a patient with dyspepsia undergoes endoscopy, *H. pylori* presence should be evaluated in gastric biopsies, with the intention of treating if present [9]**.**

Triple therapy with a proton pump inhibitor (PPI), amoxicillin and clarithromycin is the most commonly used regimen for first line treatment of H.pylori infection and defined as standard protocol [10]**.**However, resistant types of H.pylori to this regimen had emerged [11]. levofloxacin-based triple therapy which consists of Levofloxacin 500mg once daily, PPI twice daily and amoxicillin 1gm twice daily for 14 days was a second line option[12]. According to Maastricht v consensus reported levofloxacin containing triple therapies can be used as second line therapies in H.pylori treatment in countries with more than 15% clarithromycin resistance rate [13]. Furthermore, in some studies, metronidazole- and clarithromycin-resistant H. pylori infection has been successfully treated with levofloxacin containing triple therapy [14]**.** The aim of the present study was to compare between the efficacy and tolerability of levofloxacin versus Clarithromycin based triple therapy in eradication of H.pylori infection.

SUBJECTS AND METHODS

This is a prospective study carried out on patients attending the outpatient clinic of the Gastroenterology Department and Endoscopy Unit of El-Maadi Military Hospital from February 2018 to December 2018.Those were complaining of abdominal pain and dyspepsia .A total number of 142 patients out of more than 250 patients were examined and found to be have positive Helicobacter pylori infection ,hence they were selected for this study .All patients (total number 142) were positive for Stool antigen test for H.pylori infection .Only 35 of them were further confirmed by Rapid Urease Test during upper endoscopy (endoscopy was indicated) .They were divided into 2 groups(71 patients in each groups) .The first group (levofloxacin group) was given levofloxacin (500 mg daily) plus amoxicillin (1 gm twice a day) plus pantoprazole (40 mg twice daily) for 2 weeks. The second group (clarithromycin group) was given clarithromycin (500 mg twice a day) plus amoxicillin (1 gm twice a day) plus pantoprazole (40 mg twice daily) for 2 weeks.

The Inclusion Criteria are: Patients with any history of ulcer related dyspepsia, all patients with recent active peptic ulcer diseases (PUD), past history of PUD unless previous cure of H. pylori infection has been documented, MALT lymphoma, all patients underwent upper endoscopic procedure with positive rapid urease test. The Exclusion Criteria are Patients who were less than 18 years old or older than 60 years old, previous allergic reaction to antibiotics (amoxicillin, Clarithromycin, Levofloxacin)

and PPI, contraindication to treatment drugs and pregnant or lactating women.

All study patients were subjected to detailed medical history and clinical examination. Written informed consent was obtained from all participants and the study was approved by the research ethical committee of El-Maadi Military Hospital. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

The H.pylori Antigen Rapid Test Cassette (feces) is a rapid chromatographic Immunoassay for qualitative detection of H.pylori Antigen in human feces specimens, providing results in 10 minutes.

Interpretation of results:

Positive: Two lines appear. One colored line should be in the control line region and another apparent colored line should be in the test line region. **Negative:** One colored line appears in the control line region. No line appears in the test line region. **Invalid:** Colored line failes to appear. Insufficient specimen volume or incorrect procedural techniques are the most like reasons for control line failure.

Rapid urease test (CLO test; Kimberly-Clark Ltd., Draper, Utah, USA) was done to 35 of patients who underwent upper endoscopy with examination of the oesophagus, stomach, and duodenum to the second part using Olympus CV-150 or Pentax EPM-3500. We obtained biopsy specimens from the antrum and from the corpus of the stomach. When the test showed red-violet colour within 24 Hour at room temperature, the diagnosis of H. pylori infection was made.

During treatment; interviewed patients to investigate their compliance to treatment and the adverse effects of the drugs, including abdominal bloating, abdominal pain, bitter taste, constipation, dizziness, epigastric pain, general weakness, halitosis, headache, diarrhoea, loss of appetites, nausea, oral ulcer, skin eruption, sleeping tendency, and vomiting.

The response to treatment was evaluated 4 weeks after cessation of therapy. Instructions were given to patients not to receive any antibiotics or PPI for two weeks before retesting there stool for H.pylori antigen.

STATISTICAL ANALYSIS

Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analysed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) **(**Statistical Package for the Social Sciences) software for analysis.

RESULTS

One hundred and forty two (142) patients were enrolled for this study. There was a statistically non-significant difference between patients who took levofloxacin triple therapy and those who took clarithromycin triple therapy regarding demographic features: age, sex and also clinical presentation (Table 1, 2).

The endoscopic features of the patient underwent upper endoscopy is presented in (Table 3). After completing treatment regimen in both groups; the response was evaluated as shown in (Table 4). Eighty four and half percent (84.5%) of patient were recovered from infection in levofloxacin group versus (69%) of patients in clarithromycin group and eradication of H. pylori was found to be significantly higher in individuals who underwent levofloxacin triple therapy when compared with those who underwent clarithromycin triple therapy ($P<0.05$).

The adverse effects for the treatment were evident 7(9.9%) cases only in levofloxacin group while 10 cases (14%) in clarithromycin group had adverse effect for the regimen (Table 5).

Table (1): Demographic features of the enrolled patients (n=142)

parameter	Levofloxacin group(71)	Clarithromycin group(71)	t	P value
age	45.98±12.27	42.01±11.9	1.957	0.052
Sex(%) M F	 31(43.7%) 40(56.3 %	 35(49.3%) 36(50.7%)	 0.45	 0.53

Table (2): Clinical presentation of the studied groups (n=142)

parameter	Levofloxacin group(71)	Clarithromycin group(71)	Total (142)	Fisher's exact	P
Abdominal pain	0 (0.0%)	5 (7.0%)	5(3.52%)	**3.2**	**0.07**
Epigastric pain	35(49.3%)	23(32.5%)	58(40.8%)	**2.12**	**0.14**
Dyspepsia	36(50.7%)	38(53.5%)	74(52.1%)	**0.013**	**0.9**
Vomiting	0(0%)	3(4.2%)	3(2.11%)	**1.4**	**0.19**
nausea	0(0%)	1(1.4%)	1(0.7%)	**0.9**	**0.31**
Hematemesis and melena	0(0%)	1(1.4%)	1(0.7%)	**0.9**	**0.31**
total	71(100%)	71(100%)	142(100%)		

Table (3): Endoscopic features of the patients underwent upper endoscopy (n=35)

parameter	Levofloxacin group(19)	Clarithromycin group(16)	Total(35)
Antral Gastritis	5	1	6(17.1%)
Duodenal erosion	2	0	2(5.7%)
Duodenitis	0	2	2(5.7%)
Gastric erosion	2	1	3(8.6%)
Gastric ulcer	2	3	5(14.3%)
Gastritis	3	4	7(20%)
H.Hernia	1	0	1(2.9%)
Nodular Gastritis	2	2	4(11.4%)
PanGastritis	1	2	3(8.6%)
Sever Gastritis	1	1	2(5.7%)
total	19	16	100%

Table (4): Response to treatment of H.pylori infection by stool antigen of the studied patients

Result of eradication	Levofloxacin group(71)	Clarithromycin group(71)	Total(142)	X^2	P
Negative stool antigen	60 (84.5%)	49(69%)	109(76.8%)		
Positive stool antigen	11(15.5%)	22 (31%)	33 (32.2%)		
Total	71(100%)	71(100%)	142(100%)	11.38	0.001**

Table (5): Adverse effects of the treatment of the studied groups (n=142)

parameter		Levofloxacin group(71)	Clarithromycin group(71)	Total (142)	Fisher's exact	P
Side effect for two groups	Abdominal pain	1(1.4%)	1(1.4%)	2(1.4%)	6.79	0.34
	Taste disturbances	0(0.0%)	2(2.8%)	2(1.4%)		
	Bloating	2(2.8%)	1(1.4%)	3(2.1%)		
	Diarrhea	1(1.4%)	3(4.2%)	4(2.8%)		
	nausea	3(4.2%)	3(4.2%)	6(4.2%)		
Total number of side effect		7(9.9%)	10(14%)	17 (12%)		

DISCUSSION

Helicobacter pylori is a Class I carcinogen and the predominant bacterium that colonizes the stomach mostly during childhood [15, 16]. Approximately 10% of infected individuals develop overt clinical disease while 90% remain subclinical and the infection can persist throughout life if untreated [17].

Treatment failure of H. pylori infection has been linked to bacterial resistance and poor patient compliance [18, 19].

The current study showed the mean age of infected patients was 45.9±12.2 years old in levofloxacin triple therapy group and 42.01±11.9 years old in clarithromycin triple therapy group which no significant differences between both two groups. Three studies conducted in the USA provided data on the prevalence of H. pylori infection according to different age groups. In all of these studies, the prevalence of H. pylori infection was higher in older than in younger individuals. There were insufficient data available to assess trends in H. Pylori infection over time for different age groups [20-22]. The most common presenting symptoms in our study were dyspepsia 74 patients (52.1.5%) as well as epigastric pain 58 patients (40.8%).

This result was similar to the study done by Karthick et al. [23] which was conducted on 100 patients with epigastric pain of gastric origin; 83 of them had dyspepsia, and of them, 61 were H. pylori positive (73.4%).

Our study showed that gastritis is the most common endoscopic features in studied patients underwent upper endoscopy; the most common finding was gastritis 22 patients from 35patients (62.9%), followed by peptic ulcer. Also Diab et al [24] found a strong association between H. pylori infection and patients with gastritis, with existence of H. pylori infection in 63 (82.9%) of 74 patients with gastritis.

Our study showed that the adverse effects to drugs were seen in 9.9% of the patients on levofloxacin-based triple therapy and 14% of patients on clarithromycin based therapy. Levofloxacin-based therapy was associated with a significant reduction in the incidence of taste disturbance, abdominal pain and diarrhoea compared with clarithromycin triple therapy. No significant difference between both groups in incidence of nausea. These findings are consistent with previous studies [25-27].

Levofloxacin has a good safety profile, thus facilitating its use in clinical practice [28] .This study showed that the incidence of total side

effects in levofloxacin-based regimen had no significant difference compared with clarithromycin triple therapy (9.9%vs 14%), which showed levofloxacin was also generally well tolerated, and most adverse events associated with its use were mild to moderate in severity and transient. However, incidences of taste disturbance (0.0% vs 2.8%), diarrhoea (1.4% vs 4.2%), bloating (2.8% vs 1.4%), and nausea (4.2% vs 4.2%) were lower in levofloxacin group. Results showed levofloxacin group had a positive impact on some H.pylori therapy-related side effects, especially on taste disturbance.

This study showed that the rate of eradication of H.pylori infection is higher in patients who took levofloxacin based triple therapy versus those who took clarithromycin based triple therapy (84.5% versus 69.00%,P value 0.001).This difference indicates that levofloxacin-based triple therapy is more effective than clarithromycin based therapy in the eradication of H.pylori infection.

Similar data were revealed from the study of Gopal et al., [29] on 74 patients with peptic ulcer perforation; H.pylori infection eradication rates were 69% in clarithromycin-based regimen versus 87% in levofloxacin-based regimen on intention to treat analysis.

Comparable results have been reported in study of Chinese population Cheng H ET AL., [30] with eradication rates of 74.5% clarithromycin triple therapy, versus 82.4% in levofloxacin based-triple therapy regimen according to intention to treat analysis.

In another study by Ali Akber Haji-Aghamohammadi et al. [31] , H.pylori infection eradication were 80.4% in levofloxacin triple therapy and 57.4% in clarithromycin triple therapy according to per-protocol analysis.

Maysaa El Sayed Zaki et al. [32] reported in a study done in Mansoura University hospitals, Egypt, that there is a high prevalence of H. pylori resistant strains to clarithromycin (71%), which is thought to be the first-line antibiotic therapy in treatment of H. pylori, whereas resistance patterns were less toward levofloxacin (23.2%).

Although clarithromycin resistance was found in 55.7% of *H.pylori*-positive cases, this percentage could be still underestimated due to the presence of other mutations which were not detected in our study. The eradication of *H. pylori* strains presenting high resistance rates to macrolides, or metronidazole could be reached by the use of approved tetracycline- or amoxicillin-containing regimens replacing the standard triple therapy [33].

Discrepancies across various studies may be explained by overuse of antibiotic particularly flourquinolones Perna et al. [34] Suggest that levofloxacin resistance H.pylori may be associated with prior flourquinolones consumption during the past ten years. The cost of treatment may partly affect in the decision to select treatment regimen. Regarding higher cost of levofloxacin, this issue may prevent the use of levofloxacin as the first line of empiric treatment for H.pylori infection.

In the case of treatment failure with levofloxacin in a clarithromycin-resistant population, the Maastricht III Consensus Report recommended antimicrobial sensitivity tests to select antibiotics for third-line regimens, although it has been reported that the sensitivity of culture is<60% empirical third-line therapies have been proposed to treat refractory H.pylori infection, mainly with furazolidone [35] .

CONCLUSION

This study showed that levofloxacin-based triple therapy is preferable to claritromycin-based regimen in eradication of H.pylori infection, a noteworthy finding especially in countries like Egypt with high clarithromycin resistance. However, the cost of treatment should be considered in the selection of this regimen.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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