Comparison between the effectiveness of Furazolidone and Clarithromycin on eradication of helicobacter pylori among patients with peptic ulcer

Asghar Rahmani[1], Ali Jafari Haidarloo[2], Hoda Mabrokzadeh[1], Khairollah Asadollahi[3, 4], Ghobad Abangah[2], Koroush Sayehmiri[3, 4], Ahmad Naser[5]

1. Student Research Committee, Faculty of Medicine, Ilam University of Medical Sciences, Ilam, Iran
2. Department of Gastroenterology, Faculty of Medicine, Ilam University of Medical Sciences, Ilam, Iran
3. Department of Social Medicine, Faculty of Medicine, Ilam University of Medical Sciences, Ilam, Iran
4. Psychosocial Injuries Research Center, Ilam University of Medical Sciences, Faculty of Medicine, Ilam University of Medical Sciences, Ilam, Iran
5. Clinical Microbiology Research Centre, Faculty of Medicine, Ilam University of Medical Sciences, Ilam, Iran

***Corresponding author:** Tel: +98 8432238460 Fax: +98 8432238461
Address: Department of Social Medicine, Faculty of Medicine, Ilam University of Medical Sciences
E-mail: masoud_1241@yahoo.co.uk
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Abstract

Introduction: Helicobacter pylori (H. pylori) infections occur in about 50% of the world population and have a main role in the creation of peptic ulcer and gastric cancers. We aimed to evaluate the effectiveness of two treatment regimens on the eradication of H. pylori and its complications among peptic ulcer patients.

Materials and methods: By a clinical trial, patients with peptic ulcer showing an infection compliance of more than 80%, confirmed by biopsy, were entered into the study and were randomly divided in two groups. Group A was treated by medical regimen of Amoxicilline, Bismot, Omeperasol and Furazolidone (ABOF) and group B by medical regimen of Amoxicilline, Bismot, Omeperasol and Clarithromycin (ABOC) for two weeks. In the next step, both groups were treated by only Omeperasol for two weeks and finally, the infection rate of H. pylori was investigated by urea breath testing among both groups.

Results: Among the 137 registered patients, 17 were unable to continue. The mean age of patients in group A, was 36.1 years and for group B, was 40.1 years. The rate of infection eradication in group A was 38.3% and in group B was 53.3% (P= 0.07). The most common symptoms among patients in group A were a bad taste mouth (80%) and headache (70%) and in the group B were headache (62%) and a bad taste mouth (60%) respectively.

Conclusion: ABOF regimen compared to ABOC, showed a lower rate of infection eradication and also more complications for patients and the ABOC was considered as the preferred regimen.

Keywords: Peptic ulcer, Helicobacter pylori, Eradication, Furazolidone, Clarithromycin

Introduction

The usefulness of Helicobacter pylori (H. pylori) eradication for the treatment of peptic ulcer is widely recognized, and short-term concomitant triple therapy using a proton pump inhibitor (ppi) and two types of antibiotic is the most popular treatment regimen. H. pylori are the important cause of gastritis, peptic ulcer

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disease and a major risk factor of gastric cancer (1). The global eradication success of standard triple regimen used for H. pylori infection has declined in recent years (2). The rate of re-infection after one year of treatment in Iran is about 16.4% which spot to the sub-optimal treatment regimens (3). Dependable extirpation of H. pylori infection significantly helps to manage these diseases. Any success on the infection eradication depends on many factors including compliance, antibiotic resistance, and adequate dosing of proton pump inhibitor (PPI) that provides adequate acid suppression. The standard therapeutic regimen currently available consists of a 3 antibiotics (amoxicillin, clarithromycin, and metronidazole), and an acid suppressive medication (4). However; bacterial resistance to metronidazole and increasing resistance to clarithromycin have prompted a search for alternative therapies (5-7). A useful regimen in one geographical area may not be effective in another area. The subject of cost is another complicated choice, especially in developing and underdeveloped countries. In addition, the high cost of many drugs such as quinolones and clarithromycin, are deterrent factors for their use in developing countries (8). Furazolidone is a relatively new medication with a low intestinal absorption rate which is widely available and inexpensive in developing countries. Furazolidone is a synthetic nitrofuran with a broad spectrum of antimicrobial activities used in the treatment of bacterial infections in humans (9). Furazolidone has been used more than 20 years in China for the treatment of peptic ulcer as the single therapeutic agent (10). In recent years, a number of clinical trials have demonstrated furazolidone as a suitable drug for the treatment of H. pylori. There are some limited reports of resistance to furazolidone (11, 12). Clarithromycin is another medication which accompanied with other drugs as the first line regimen for the treatment of H. pylori, particularly when the resistance to this drug is less than 15 to 20% (13). Clarithromycin is an important antibiotic used for the treatment of H. pylori infections, and the main factor of treatment failure is drug resistance. Clarithromycin acts by binding to the peptidyltransferase region of 23S rRNA and inhibits protein synthesis (14) and is recognized as the key antibiotic for H. pylori treatment since it has showed the most powerful bactericidal effect in vitro compared to the effects of other available antibacterial agents (15). Unfortunately, the rate of resistance to clarithromycin is increasing world-wide, and the level of this resistance varies between different geographical regions (16). The concurrent presence of H. pylori and non-steroidal or anti-inflammatory drugs has been considered as a damaging factor to the gastro duodenal mucosa (17). Low socio-economic and educational levels, poor socioeconomic conditions, living in a family with a high number of siblings, and use of external water have been identified as risk factors for infection onset. The infection persists virtually long-life if not opportunely treated. Therapy failure depends on several factors that can be divided into bacterial and host origin. Treatment-specific descriptions including manufacturer advices such as doses, duration of use as well as methods to detect the infection are the effective factor in the treatment of infection (18).

Materials and methods

By a clinical trial, all peptic ulcer patients attending to Ilam gastroenterology clinics and having an infection compliance of more than 80%, confirmed by biopsy, were entered into the study. Excluding criteria were; age less than 18years, involving with other concurrent severe diseases, previous history of H. pylori , stomach surgery, antibiotic sensitivity, application of proton pomp inhibitors or NSAID during past month, stomach cancer and any report of previous non completion treatment period. 137 patients with confirmed H .pylori were entered into the

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study and were randomly divided in two groups of A and B .

Group A was treated by medical regimen of Amoxicilline (1 gr BD), Bismot sub citrate (240mg BD), Omeperasol (20mg BD) and Furazolidone (200mg BD) for two weeks and group B was also treated by the same regimen except for Furazolidone which was substituted by Clarithromycin (500my BD). In the next step, both groups were treated by only Omeperasol for two weeks and finally, the infection rate of H. pylori was investigated by urea breath testing (UBT) among both groups. Before UBT, all patients were NPO for 6 hours and negative UBT was considered if 14Co2 <50dpm was reported during 10 minutes (eradication of H. pylori) and any report of 14Co2 more than 200dpm was considered as positive UBT (existence of H. pylori).

Statistical analysis

Using SPSS 16 both qualitative and quantitative variables were analyzed. Quantitative variables were expressed as mean ± standard deviation (SD) and qualitative variables were described by percentage. Chi-squared or Fisher exact tests were used to compare the effects of treatment in groups A and B, appropriately. Independent T-test was used for comparison of quantitative variables. A p-value <0.05 was considered as significant.

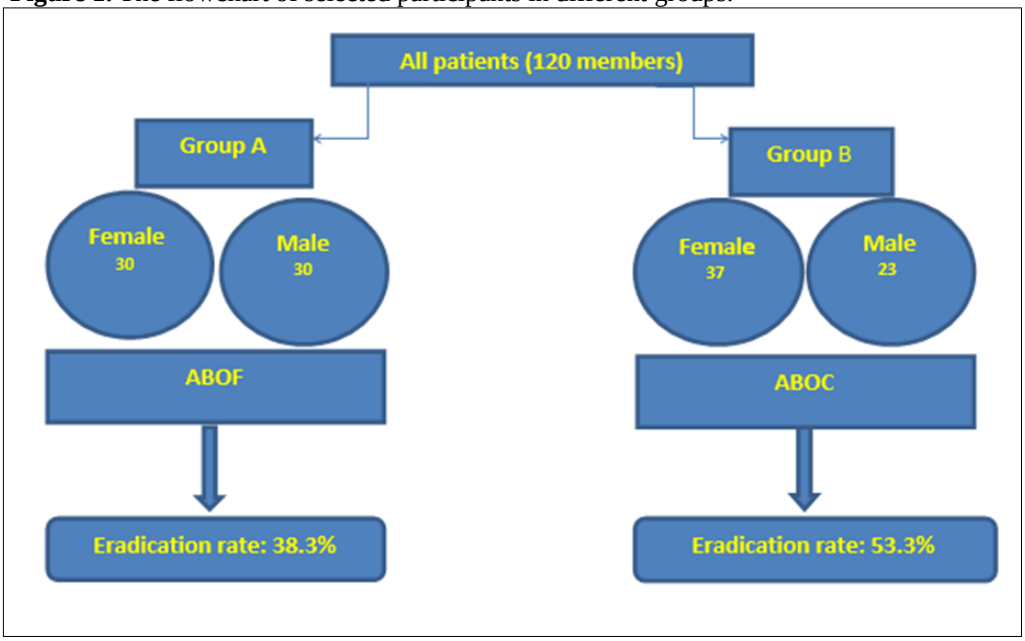
This study was confirmed by the research ethics committee of Ilam University of medical sciences, conform to the last update of Helsinki Declaration and all patients completed a consent form for entering into the study. Patients were also able to exit freely from the study.

Results

Totally 137 patients had the criteria to enter in the study and due to noncompliance, 17 patients (5 from group A and 12 from group B) were exited from the study. Finally, 120 patients (each group 60) who completed the treatment regimen were analyzed (Figure 1). Both medical complications and response to drug regimens were investigated.

Group A included 30 male and 30 female and group B included 23 male and 37 female with a mean age of 36.1 yrs for group A and 40.1 yrs for group B. Negative urea breath test (UBT) was reported for 32 patients (53%) in group B (ABOC) and for 23 patients (38%) in group A (ABOF) (P=0.07) (Tables 1-2).

Figure 1. The flowchart of selected participants in different groups.



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Table 1. Frequency rate of infected participants after 1 month in different groups according to the UBT results.

Variable	Eradicated	Non eradicated	Total
Group A	23 (38.3)	37 (61.7)	60 (50)
Group B	32 (53.3)	28 (46.7)	60 (50)
Total	55(45.8)	65 (54.2)	120 (100)

Data are shown as number or percent.

Table 2. Frequency rate of side effects reported by participants among both group.

Variable	Group A	Group B	P value
Headache	42 (70)	37 (61.7)	0.22
Vomiting	37 (61.7)	28 (50)	0.07
Diarrhea	29(48.3)	32(53.3)	0.35
Abdominal pain	40 (66.7)	35 (58.3)	0.22
Stool colour change	36 (60)	32 (53.3)	0.29
Skin sensitivity	15 (25)	10 (16.7)	0.18
Bad taste mouth	48 (80)	36 (60)	0.01
Nausea	6 (10)	9 (15)	0.29

Data are shown as number or percent.

Headache (61.7%), nausea (46.7%), vomiting (15%), diarrhoea (53.3%),abdominal pain (58.3%), melena (53.3%) and dermal sensitivity (16.7%) were reported among patients in group B and the rates of involved patients in group A for the above mentioned medical complications were 70%, 61.7%, 10%, 48.3%, 66.7%, 60% and 25% respectively, all statistically non-significant. There was a significant difference between patients in the group B (60%) compared to those in the group A (80%) for bad flavor of the mouth as a medical complication ($p<0.01$). The prevalence of side effects due to treatment regimen was generally 37.5% among patients in group A and 22.1% among those in group B. The total treatment expenditure for group B was 2.3 times more than that for group A.

Discussion

The discovery of H. pylori as the promoting factor of many diseases caused a high attempt by the researchers to find a comprehensive method of therapy for this agent. Many people still attribute symptoms of dyspepsia to an ulcer, and believe that ulcers are caused by diet, stress, and lifestyle factors; however, it is now clear that eradication of H. pylori is very effective on the treatment of this illness. It has been accepted that H. pylori infection is the major cause of peptic ulcer, MALT lymphoma and gastroesophageal reflux disease (GERD), and the number of suggested regimens for its treatment and eradication are increasing. In the recent studies, triple therapy with omeprazole, amoxycillin and clarithromycin has been reported as an effective regimen. Most international guidelines for H. pylori eradication point to the standard triple therapy including the combination of two antibiotics and a proton-pomp inhibitor (PPI) for at least 7 days, but the success rates using these triple therapies have fallen to 75%(19). To overcome H. pylori treatment limitations, furazolidone-based treatments have been suggested in developing countries by the World Gastroenterology Organization guidelines (8). Furazolidone-based regimens usually achieve low eradication rates. Only a high-dose regimen improves the cure rate, but increases the incidence of severe side effects simultaneously (20). Although the current study did not show a significant difference between the two medical regimens of ABOF and ABOC, but the ABOF showed a lower rate of eradication as well as higher complications for patients. According to these results, the ABOC was considered as the preferred regimen.

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