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Original article

To evaluate of the effect of adding licorice to the standard treatment regimen of *Helicobacter pylori*

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ABSTRACT

Objective: The aim of this study was to evaluate the effect of licorice in *H. pylori* eradication in patients suffering from dyspepsia either with peptic ulcer disease (PUD) or non-ulcer dyspepsia (NUD) in comparison to the clarithromycin-based standard triple regimen.

Methods: In this randomized controlled clinical trial, 120 patients who had positive rapid urease test were included and assigned to two treatment groups: control group that received a clarithromycin-based triple regimen, and study group that received licorice in addition to the clarithromycin-based regimen for two weeks. *H. pylori* eradication was assessed six weeks after therapy. Data was analyzed by chi-square and t-test with SPSS 16 software.

Results: Mean ages and SD were 38.8 ± 10.9 and 40.1 ± 10.4 for the study and control groups, respectively, statistically similar. Peptic ulcer was found in 30% of both groups. Response to treatment was 83.3% and 62.5% in the study and control groups, respectively. This difference was statistically significant.

Conclusion: Addition of licorice to the triple clarithromycin-based regimen increases *H. pylori* eradication, especially in the presence of peptic ulcer disease.

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Introduction

Helicobacter pylori (*H. pylori*) is a Gram negative S shaped flagellated bacteria infecting half of mankind with a very variable prevalence depending on different factors such as race, age, and socioeconomic status ranging from a low prevalence in developed countries to a prevalence as high as 80% in developing countries like Iran.¹ *H. pylori* is a successful pathogen

which can persistently survive in the stomach of infected persons throughout his/her life and if it results in chronic inflammation serious digestive diseases may ensue such as chronic gastritis, peptic ulcer disease (PUD), gastric cancer, and gastric MALT-oma (mucosa associated lymphoid tissue lymphoma).²

Peptic ulcer disease is one of the consequences of *H. pylori* infection and is one of the most common treatable diseases worldwide. The commonest cause of peptic ulcer is *H. pylori*

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and if not eradicated it will result in 50–80% relapse in 6–12 months after treatment interruption,³ but if successfully treated its recurrence will drop to 6–20%, as reported by two separate meta-analyses.^{4,5}

Relation between dyspepsia and *H. pylori* is unclear, but eradication leads to symptoms improvement in 7.1% of patients.⁶

American College of Gastroenterology (ACG) recommends the treatment of *H. pylori* in all infected patients irrespective of the presence of ulcer. Recommended first line standard regimen by ACG for the treating *H. pylori* is a triple regimen containing clarithromycin, amoxicillin or metronidazole, and proton pump inhibitor (PPI) for 10–14 days. Quadruple regimen is recommended in areas where the prevalence and resistance to clarithromycin or metronidazole is more than 20%, or if the first choice has been tried recently or repeatedly.⁷

Antibiotic resistance to *H. pylori* has increased in recent past years. Compared to 2010 the resistance rate to clarithromycin and amoxicillin in 2012 has raised significantly.⁸ The effectiveness of the present therapeutic regimen is still not satisfactory and despite several studies the best treatment regimen for treating *H. pylori* remains a challenging clinical dilemma.⁹ Antibiotic resistance and adverse effects in addition to poor patient compliance have limited the efficacy of *H. pylori* treatment. Therefore, the role of herbal medicine has been evaluated in the treatment of *H. pylori*, including licorice (liquorice).¹⁰

Licorice herb (*Glycyrrhiza glabra* - *G. glabra*) has routinely been used for centuries in traditional Chinese.¹¹ Roots and rhizomes of this herb has been reported to be antioxidant, antimicrobial, and antiviral.^{12,13} Furthermore, *G. glabra* has anti-inflammatory, anticancer, and anti-ulcer activity.^{14–16} Licorice is extracted from the root of *G. glabra* herb and one of its active ingredient is glycyrrhizin acid, which due to its affinity to mineralocorticoid receptors may result in edema and hypertension. Therefore, it should be used with caution in patients suffering from cardiovascular disease and/or hypertension.¹⁷ (Fig. 1).



Fig. 1 – Photograph of *Glycyrrhiza glabra* herb.

There two types of action of licorice in PUD and against *H. pylori*: (1) a repairing effect in PUD: protective mucosal effect by secreting a material named as secretin¹⁸; and (2) antibacterial and anti-adhesive effect against *H. pylori* by inhibiting DNA gyrase (a crucial enzyme for bacterial replication and transcription) and dihydrofolate reductase enzyme blockage.¹⁹ In addition, the polysaccharide released from the root of licorice plays an inhibiting role in *H. pylori* adhesion to gastric mucosa.²⁰ Besides, treatment with licorice for patients suffering from dyspepsia improves their clinical complaints.²¹

Owing to the rise of *H. pylori* resistance against antibiotics and the effectiveness of licorice for treating *H. pylori*, this study was designed to compare the efficacy of adding licorice to the standard clarithromycin-based triple regimen in the treatment of *H. pylori*.

Material and methods

This randomized controlled clinical trial was conducted in Velayat teaching hospital in Qazvin (northwest of Iran). A total of 120 patients over 16 years of age referred for esophagogastroduodenoscopy (EGD) at the digestive disease outpatient department due to gastrointestinal complains entered this study from May to December of 2015. Biopsy was performed when indicated by the endoscopist.

Patients with a positive rapid urease test were included in this study if none of the following conditions were present: pregnancy, use of proton pump inhibitor (PPI), bismuth or antibiotic in the past two weeks, gastrointestinal (GI) bleeding or any complication of PUD, giant ulcer, gastric ulcer, ethanol consumption or substance abuse, chronic underlying disease like diabetes mellitus, hypertension, cirrhosis, cerebrovascular attack, coronary artery disease, and gastric cancer. Patients who were reluctant to continue the treatment or complete the follow-up or suffering from a comorbidity needing non-steroidal anti-inflammatory drugs (NSAIDs) or antibiotic to be continued during the period of study were excluded. Informed consent was obtained from all eligible. Sixty patients were randomly assigned to receive one of two treatment regimens: triple regimen consisting of clarithromycin (500 mg BID) + Amoxicillin (1 gr qd) + 20 mg BID of Omeprazole (control group) or the same regimen supplemented by licorice [D-Reglis (380 mg BID) made by Iran daruc Pharmacy Company] for two weeks (LR group). Both groups received at least four weeks of treatment with omeprazole 20 mg daily subsequently. Two weeks after completing the treatment, *H. pylori* eradication was assessed with *H. pylori* stool antigen (HPSA) test by Ag ACON Biotech (Hang Zhou) Co., Ltd.

This study is registered at Iran Registration Clinical Trial Center and was approved with the Irct registration number: IRCT2014061718124N1.

The outcome of this study was *H. pylori* eradication. Data were stored at SPSS 16 software and analyzed by using of t-test, chi-square test. A *p*-value <0.05 was considered significant.

Results

Out of 120 eligible patients, 110 patients completed the study complying with the prescribed medications and follow-up;

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