EFFECTIVENESS OF TRADITIONAL MEDICINE REGIMES IN TREATING DUODENAL ULCER WITH HELICOBACTER PYLORI

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ABSTRACT

Objectives: This randomized controlled trial was performed to examine the effectiveness of Helicobacter pylori max regime, a traditional medicine preparation, among duodenal ulcer patients with Helicobacter pylori infection.

Material & Methods: The intervention group (n = 42) used Helicobacter pylori max regimen and the control group (n = 43) used Omeprazole, Amoxicillin and Clarithromycin (OAC) regimen.

Results: The number of patients having type A pain relief in intervention group (33.3%) was higher than that in control group (23.3%) (p> 0.05). There were 59.5% patients in the intervention group not having Helicobacter Pylori after treatment, which was lower than that of control group (69.8%) (p> 0.05). The rate of complete healing in the HP max group reached 68.2%, equivalent to the rate of complete healing in the patients using OAC (71.1%) (p> 0.05). No serious adverse effects were observed in these two groups.

Conclusion: These findings depicted the potential of HP max in clinical settings in order to reduce the burden of duodenal ulcers with H. pylori infection.

Key words: duodenal ulcer, helicobacter pylori, HP max

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INTRODUCTION

Duodenal ulcer is a common disease in the world and in Vietnam[1-3]. This disease is caused by an imbalance between ulcers (acid-pepsin, Helicobacter pylori, etc.) and protective factors (mucilage, mucosa barrier, etc.)[4,5]. Treating duodenal ulceration should be based on the pathophysiology of this disease. To date, three allopathic medication regimes are mostly used to treat duodenal ulcer including Omeprazole, Amoxicillin and Clarithromycin (OAC)[6,7]. In Vietnam, along with western medicine, traditional medicine has been encouraged and paid special attention by the Ministry of Health to treat duodenal ulcer[8]. In traditional medicine, herbs such as Ampelopsis cantoniensis, Ardisia silvestris, and Oldenlandia eapitellata Kuntze are shown to be effective in gastric-duodenal ulcer treatment[9,10]. In this study, we produced a medicine entitled HP max which included all these three herbs as ingredients. This product has been tested for toxicity and pharmacological effects such as anti-inflammatory, pain relief, acids neutralization, wound healing and eradication of HP on experimental animals, which indicated that HP max products had high safety and good therapeutic effects[11-13]. To demonstrate the effectiveness of HP max in the clinical setting, this study aims to evaluate the pain relief, ulceration healing and eradication of H. pylori (Helicobacter pylori) in patients with duodenal ulcer treated with HP max regimes.

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MATERIALS AND METHODS

This randomized controlled trial was performed at the Department of Internal Gastroenterology - 108 Central Military Hospital and the Hospital of Traditional Medicine - Ministry of Public Security. Patients were eligible for this study if they 1) were confirmedly diagnosed with duodenal ulcer via clinical examination and endoscopic procedure, and 2) had H. pylori (+). They were randomly divided into 2 groups: the intervention group (n = 42) received HP max drug, and the control group (n = 43) received OAC regimes. Patients were diagnosed by using EVIS 160 and 180 endoscopes (Olympus - Japan) at the Department of Internal Medicine - Central Hospital 108 or Endoscopic Room - Hospital of Traditional Medicine - Ministry of Public Security. Histopathological procedures were performed at the Department of Disease Surgery - Central Hospital 108. The protocol of this study was approved by the institutional review board of Hospital of Traditional Medicine - Ministry of Public Security.

HP max medications: The intervention group received HPmax capsules. This drug (including 280mg Ampelopsis cantoniensis, 170mg Ardisia silvestris, and 110mg Oldenlandia eapitellata Kuntze per capsule) was manufactured by Vietnam Natural Products Joint Stock Company VINACOM on modern technology lines, which met basic standards certified by Drug Administration

of Vietnam. One package contained 24 capsules. Patients took twice daily 3 capsules each after meal in 30 days.

The OAC regimen: The control group received Omeprazole 20 mg: 2 tablets / day (01 tablet at 9.00 a.m and 01 tablet at 21.00) x 30 days; Amoxycillin 500 mg: 2 capsules/ time x 2 times/ day x 14 days; and Clarithromycin 500 mg: 1 tablet/ time x 2 times / day x 14 days.

Subjective symptoms (pain, belch, pyrosis) were evaluated before treatment (T0), after first week (T1), second week (T2), third week (T3), and 4th week (T4). Patients having pain relief at T1 were classified "Type A", while those relieving pain at T2, T3 were categorized as "Type B", and "Type C" at T4. Conditions of ulcers were evaluated after four weeks of treatment, including ulcer healing (type A); miniature ulcers (type B); and ulcer retention (type C). The eradication rate of HP after treatment was assessed including: H. pylori (-) and H.pylori (+).

Stata 12.0 was used to analyze data. Chi-squared test was used to examine the difference between intervention and control groups in the effectiveness of each regime. P-value of less than 0.05 was considered statistically significant.

RESULTS

Among 85 patients, most of them showed pain during hunger (60.0%). The proportion of heartburn, nausea and vomiting and slow digestion were 100%, 16.5% and 69.4%, respectively. The differences in these clinical symptoms between both arms were not statistically significant (p>0.05).

Results of endoscopic procedure are shown in Table 2. Most of ulcers position was frontside of duodenum (89.4%). The majority of patients had one ulcer (95.3%). Most of ulcer had 0.5-1.0 cm of diameter (82.0%). The differences between both arms were not statistically significant (p>0.05).

After treatment, Table 3 reveals that no difference between both arms was found regarding time of pain relief, ulcer conditions and H.pylori positivity (p>0.05).

Table 4 shows that in both groups, minority of patients suffered adverse effects such as nausea, anorexia, diarrhea or headache. The differences between both arms were not statistically significant (p>0.05).

Table 1: Clinical symptoms of patients before treatment

Clinical symptoms	Intervention	Control	Total	p-value
	(Using HP max) n=42	(Using OAC) n=43	n=85	
	n (%)	n (%)	n (%)	
Epigastric pain	42 (100.0)	43 (100.0)	85 (100.0)	>0.05
Pain in hunger	25 (59.5)	26 (60.5)	51 (60.0)	
Pain on a full stomach	2 (4.8)	2 (4.6)	4 (4.8)	
Pain on a full stomach and in hunger	15 (35.7)	15 (34.9)	30 (35.2)	
Heartburn	42 (100.0)	43 (100.0)	85 (100.0)	>0.05
Nausea and vomiting	7 (16.7)	7 (16.3)	14 (16.5)	>0.05
Slow digestion	28 (66.7)	31 (72.0)	59 (69.4)	>0.05

Table 2: Endoscopic characteristics in patients before treatment

Characteristics of endoscopy	Intervention	Control	Total	p-value
	(Using HPmax) n=42	(Using OAC) n=43	n=85	
	n (%)	n (%)	n (%)	
Position of ulcers	42 (100.0)	43 (100.0)	85 (100.0)	>0.05
Frontside of duodenum	38 (90.4)	38 (88.4)	76 (89.4)	
Backside of duodenum	2 (4.8)	3 (6.9)	5 (5.9)	
Both sides	2 (4.8)	2 (4.7)	4 (4.7)	
Number of ulcers				
One	40 (95.2)	41 (95.3)	81 (95.3)	>0.05
Two	2(4.8)	2 (4.7)	4 (4.7)	
Size of ulcer (Diameter)				
0.5 – 1.0 cm	36 (81.8)	37 (82.2)	73 (82.0)	>0.05
1.1 -1.5 cm	7 (15.9)	7 (15.6)	14 (15.7)	
> 1.5 cm	1 (2.3)	1 (2.2)	2 (2.3)	

Table 3: Effectiveness of treatment between both groups after treatment.

Characteristics	Intervention	Control	p-value
	(Using HP-max) n=42	(Using OAC) n=43	
	n (%)	n (%)	
Time of pain relief			> 0.05
Type A (= < 7 days)	14 (33.3)	10 (23.3)	
Type B (8 – 21 days)	26 (61.9)	26 (60.4)	
Type C (> 21 days)	2 (4.8)	7 (16.3)	
Ulcer conditions			
Type A (scar healing)	30 (68.2)	32 (71.1)	> 0.05
Type B (miniature)	12 (27.3)	11 (24.4)	
Type C (intact keeping)	2 (4.5)	2 (4.5)	
H.pylori positive			
Negative	25 (59.5)	30 (69.8)	> 0.05
Positive	17 (40.5)	13 (30.2)	

Table 4: Unexpected side effects after treatment in 2 groups.

Characteristics	Intervention	Control	p-value
	(Using HPmax) n=42	(Using OAC) n=43	
	n (%)	n (%)	
Nausea	2 (4.8)	2 (4.6)	>0.05
Anorexia	1 (2.4)	1 (2.3)	>0.05
Diarrhea	1 (2.4)	1 (2.3)	>0.05
Headache	1 (2.4)	1 (2.3)	>0.05

DISCUSSION

The position of duodenal ulcer can be in anterior wall, posterior wall or both walls. In our study, the duodenal ulcer in anterior wall accounts for the highest percentage for both groups. Results of the study also showed that there was no difference in the image characteristics of endoscopy between both groups, which was consistent with research results of other domestic and foreign researchers[14,15]. Acid and H.pylori are two important factors that cause gastric-duodenal ulcers[16,17]. Studies have shown that H. pylori is a major cause of changing the internal stable balance between somatostatin, gastrin and acid[18]. In our study, over 85 patients had duodenal ulcers of H.pylori (+) and there were no significant differences in the level of H. pylori infection between two groups. These findings suggested similarity of both groups regarding clinical and paraclinical characteristics. In this study, the goal of treating ulcers was to reduce ulcer factors, enhancing mucosal protection and eradicating H. pylori. Therefore, treatment of duodenal ulcers should be based on the pathophysiology of gastric-duodenal ulcers. Studies worldwide recommended that patients with duodenal ulcers with infected H. pylori should use 3-drug regimens including a proton pump inhibitor (PPI) and two antibiotics. The common regime used was OAC regimen (Omeprazole + Amoxiciliin + Clarithromycin: OAC)[1-15].

After treatment, findings of this study indicated that the number of patients with "Type A" pain relief (33.3%) in the intervention group was higher than the control group but the difference was not statistically significant. This result suggested that HP max was an effective drug that reduces pain symptoms, which was equivalent to OAC regimen in treating duodenal ulcers. This is consistent with other studies in Vietnam. For example, a prior study showed that ampelope regimen also had a rapid analgesic effect for patients with duodenal ulcers compared to other western medicine regimens[19]. Results also indicated that there was no difference in the rate of scar healing between two groups. Moreover, the rate of H. pylori eradication in intervention and control groups were 59.5% and 69.8%, respectively but the difference was not significant (with p> 0.05). HP max medicine was shown to be effective in eradicating H. pylori in vitro, but the rate of eradication depends on the concentration of drug used[20]. Regarding adverse effects, both HP max and OAC regimens had some manifestations: nausea, loss of appetite, fluid loss and headache; but without serious complications, no patient had to stop taking the drug. Unwanted manifestations occur briefly and do not need any treatment. These findings depicted the potential of HP max in clinical settings in order to reduce the burden of duodenal ulcers with H. pylori infection.

Limitations of this study included the small sample size and short period of follow-up. Moreover, information about acceptability of patients is lacking, requiring further studies to understand this issue.

CONCLUSION

These findings depicted the potential of HP max in clinical settings in order to reduce the burden of duodenal ulcers with H.pylori infection. Further studies should be conducted to measure the acceptability of this regime in patients with duodenal ulcers.

REFERENCES

1. Papadakis MA, McPhee SJ. Current medical diagnosis and treatment 2019: McGraw-Hill; 2019: 925-38.
2. Hoang TT, Bengtsson C, Phung DC, Sörberg M, Granström M. Seroprevalence of Helicobacter pylori infection in urban and rural Vietnam. CDLI. 2005;12(1):81-5.
3. Quach DT, Luu MN, Hiyama T, To T-H, Bui QN, Tran TA, et al. Early Diagnosis of Helicobacter pylori Infection in Vietnamese Patients with Acute Peptic Ulcer Bleeding: A Prospective Study. Gastroent Res Pract. 2017;2017:3845067.
4. Ahmed S, Belayneh YM. Helicobacter pylori And Duodenal Ulcer: Systematic Review of controversies in Causation. Clin Exp Gastroenterol. 2019;12:441-7.
5. Kirsner JB. Peptic Ulcer: A Review of the Recent Literature on Various Clinical Aspects: Part II. Gastroenterology. 1968;54(5):945-75.

6. Wong BCY, Chang FY, Abid S, Abbas Z, Lin BR, Van Rensburg C, et al. Triple therapy with clarithromycin, omeprazole, and amoxicillin for eradication of Helicobacter pylori in duodenal ulcer patients in Asia and Africa. Aliment Pharmacol Ther.2000;14(11):1529-35.

7. Habu Y, Mizuno S, Hirano S, Kiyota K, Inokuchi H, Kimoto K, et al. Triple Therapy with Omeprazole, Amoxicillin and Clarithromycin Is Effective against Helicobacter Pylori Infection in Gastric Ulcer Patients as well as in Duodenal Ulcer Patients. Digestion. 1998;59(4):321-5.

8. Thuy T. Gastric-duodenal ulcers. Lecture of traditional medicine (volume II). Hanoi Medical University, Hanoi, Vietnam: Medical Publishing House; 2011: 87-91.

9. Van Thu N, Cuong TD, Hung TM, Van Luong H, Woo MH, Choi JS, et al. Anti-inflammatory compounds from Ampelopsis cantoniensis. Nat Prod Commun. 2015;10(3):383-5.

10. Gerrits M, van Vliet A, Kuipers E, Kusters J. Helicobacter pylori and antimicrobial resistance: Molecular mechanisms and clinical implications. Lancet Infect Dis. 2006;6: 699-709.

11. Tuyen PB, Thong NT, Phuong DT, Thanh VTN. The study on the effect of HPmax on general condition and functions of blood creation of experimental rabbits. Pharma J (Vietnamese). 2012;436:28-32.

12. Tuyen PB, Thong NT, Phuong DT, Thanh VTN. The study on the effect of HPmax on structures and functions of a liver and kidney of experimental rabbit. J Med Res (Vietnamese). 2011;5:6-12.

13. Tuyen PB, Thong NT, Phuong DT, Thanh VTN. The study on the analgesic and acid neutralizing effect of HPmax on the experiment. Journal of 108 - Clinical Medicine and Pharmacy (Vietnamese). 2014;2:27-32.

14. Hoan PQ. The study on infection status and some biological characteristics of H. pylori in patients with duodenal ulcers before and after internal medical treatment [Doctoral thesis in Medicine]. Hanoi, Vietnam: Vietnam Military Medical University; 2002.

15. Lai KC, Lau CS, Ip WY, Wong BCY, Hui WM, Hu WHC, et al. Effect of treatment of Helicobacter pylori on the prevention of gastroduodenal ulcers in patients receiving long-term NSAIDs: a double-blind, placebo-controlled trial. Aliment Pharm Ther. 2003;17(6):799-805.

16. Go MF, Graham DY. How does Helicobacter pylori cause duodenal ulcer disease: the bug, the host, or both? J Gastroenterol Hepatol. 1994;9: S8-10.

17. Olbe L, Fandriks L, Hamlet A, Svennerholm AM, Thoreson AC. Mechanisms involved in Helicobacter pylori induced duodenal ulcer disease:an overview. World J Gastroenterol. 2000;6(5):619-23.

18. Trung TT. Gastric-duodenal disease and Helicobacter pylori infection. Hanoi, Vietnam: Medical Publishing House; 2008.

19. Nam V. Contributing to study the effect of che day in the treatment of duodenal ulcer [Doctoral thesis in Medicine]. Hanoi, Vietnam: Hanoi Medical University; 1995.

20. Tuyen PB, Thong NT, Phuong DT, Thanh VTN. HP max resistance against Helicobacter Pylori and anti-duodenal ulcers on experiment. J Med Internet Res.(Vietnamese). 2012;3C(80):109-15.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under

Tuyen PB: Concept, supervision, data collection, Statistical analysis and manuscript writing

Hoa PT: Concept, data collection and manuscript writing

Huyen TT: Statistical analysis, data collection and manuscript writing.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.