MEDS Clinical Medicine (2024)
Clausius Scientific Press, Canada

DOI: 10.23977/medsc.2024.050422
ISSN 2616-1907 Vol. 5 Num. 4

Clinical Efficacy of Modified Huangqi Jianzhong Tang in the Treatment of Spleen-Stomach Deficiency Cold Pattern Gastric Ulcers

Sun Kexin

First Clinical Hospital of Zhejiang University of Traditional Chinese Medicine, Hangzhou City, Zhejiang Province, China

Keywords: Spleen-Stomach Deficiency Cold Pattern Gastric Ulcers; Huangqi Jianzhong Tang; Gastrin; Helicobacter pylori Eradication Rate

Abstract: This study investigates the clinical efficacy of modified Huangqi Jianzhong Tang in treating spleen-stomach deficiency cold pattern gastric ulcers, comparing its effects with conventional Western medical treatments. Ninety-six patients diagnosed with this pattern at our hospital from July 2022 to July 2023 were randomly assigned to either the treatment group or the control group, with 48 patients in each. The treatment group received the modified Huangqi Jianzhong Tang, while the control group underwent standard Western medical therapy. The treatment lasted for 8 weeks. Primary outcome measures included Traditional Chinese Medicine (TCM) symptom scores, gastrin levels, serum markers (such as IL-10, TGF-β1, IL-17), and Helicobacter pylori eradication rates. Results indicated that both groups experienced a reduction in TCM symptom scores such as epigastric pain, acid reflux, bloating, and fullness, with the treatment group showing a significantly greater reduction ($P<0.05$). Reductions in gastrin levels were also more pronounced in the treatment group ($P<0.05$). Decreases in IL-10, TGF-β1, and IL-17 levels were observed in both groups, with larger decreases in the treatment group ($P<0.05$). Additionally, the H. pylori eradication rate and the overall clinical effectiveness were significantly higher in the treatment group ($x^2=4.36$, $p=0.037$ and $X2=4.02$, $p=0.045$, respectively). These findings suggest that the modified Huangqi Jianzhong Tang not only effectively alleviates symptoms of spleen-stomach deficiency cold pattern gastric ulcers but also modulates immune responses and promotes gastric function recovery.

1. Introduction

Gastric ulcers, a common gastrointestinal disorder, are characterized by localized defects in the gastric mucosa that may extend into the muscular layer or deeper tissue layers. Globally, the incidence of gastric ulcers is associated with several factors, including Helicobacter pylori infection and prolonged use of non-steroidal anti-inflammatory drugs (NSAIDs)[1]. Despite significant advancements in modern medical treatments for gastric ulcers, pharmacotherapy often leads to adverse reactions and a high recurrence rate[2].

Traditional Chinese Medicine (TCM), an integral part of Chinese medical heritage, maintains

unique theoretical perspectives and therapeutic approaches for treating gastric ulcers. According to TCM principles, gastric ulcers fall under categories such as "stomach pain" and "mass in the stomach." Spleen-stomach deficiency cold pattern gastric ulcers are particularly prevalent, characterized by insufficient yang energy of the spleen and stomach, leading to impaired digestive function and stagnation of cold within the stomach [3].

Huangqi Jianzhong Tang, a classical TCM formula composed of ingredients like Astragalus membranaceus, Codonopsis pilosula, and Atractylodes macrocephala, is known for its efficacy in strengthening the spleen, augmenting qi, warming the middle, and alleviating pain. This formula is commonly applied in clinical settings to treat conditions caused by spleen and stomach weakness, such as chronic gastritis and gastric ulcers [4]. Individualized modification of this formula based on syndrome differentiation, a hallmark of TCM treatment, allows for more precise and symptom-oriented therapy [5].

In recent years, the integration of TCM with Western medicine in treating gastric ulcers has garnered increasing attention within the international medical community [1]. This study, leveraging the traditional Huangqi Jianzhong Tang with tailored modifications, aims to treat spleen-stomach deficiency cold pattern gastric ulcers, evaluating its clinical efficacy and safety to support more comprehensive therapeutic strategies for gastric ulcers.

2. Materials and Methods

2.1 General Information

This study employed a prospective, randomized controlled clinical trial design. The subjects were patients diagnosed with spleen-stomach deficiency cold pattern gastric ulcers at our hospital from July 2022 to July 2023.

(1) Inclusion criteria were as follows: ages between 18 and 75 years, meeting the diagnostic criteria for spleen-stomach deficiency cold pattern gastric ulcers according to the " Guidelines for Primary Care of Chronic Gastritis (Practical Version 2019)[6]" and confirmation of gastric ulcers by endoscopic examination. All patients provided informed consent to participate in the study.

(2) Exclusion criteria included: 1) use of any anti-ulcer medications, both traditional Chinese and Western, within the last month; 2) presence of severe cardiovascular or cerebrovascular diseases, liver or kidney dysfunction, psychiatric disorders, or other serious chronic illnesses; 3) women who were pregnant or breastfeeding; 4) patients with allergies to any of the study medications.

Based on the inclusion and exclusion criteria, 96 patients with spleen-stomach deficiency cold pattern gastric ulcers were enrolled and randomly divided into a control group and an observation group, with 48 patients in each. The control group received conventional treatment, while the observation group received conventional treatment supplemented with modified Huangqi Jianzhong Tang. Randomization was performed using a sealed envelope method to ensure the randomness and blinding of the group assignments.

Baseline characteristics such as gender, age, and duration of illness were as follows: the control group included 28 males and 20 females, aged 30-75 years, with an average age of (56.21±5.33) years, and disease duration ranging from 1 to 10 years, with an average duration of(6.42±1.27)years. The observation gro [up consisted of 27 males and 21 females, aged 32-74 years, with an average age of(55.81±4.90)years, and disease duration ranging from 2 to 9 years, with an average duration of(6.55±1.37)years. Statistical tests confirmed that there were no significant differences in the baseline data between the two groups, indicating good comparability.

2.2 Treatment Methods

2.2.1 Observation Group

In addition to conventional Western medical treatment, patients in the observation group received a modified Huangqi Jianzhong Tang. The base formula consisted of the following ingredients: Astragalus membranaceus 30g, Codonopsis pilosula 20g, Atractylodes macrocephala 20g, Poria cocos 15g, Glycyrrhiza uralensis 10g, Pinellia ternata 15g, Paeonia lactiflora 15g, and Citrus reticulata 10g. Modifications were made based on specific symptoms: for notable abdominal pain, 10g of Corydalis yanhusuo was added to enhance analgesic effects; for poor appetite, 15g of Crataegus pinnatifida and 15g of Hordeum vulgare were added to aid digestion and improve appetite; for nausea and vomiting, 10g of Zingiber officinale and 10g of Pinellia ternata were added to reduce nausea and prevent vomiting; for constipation, 10g of Rheum palmatum was added to regulate bowel function and relieve constipation; for epigastric and abdominal distension, the amount of Glycyrrhiza uralensis was reduced to 5g and 10g of Aucklandia lappa and 10g of Amomum villosum were added to soothe the liver and reduce distension.

The formula was prepared by decocting the above ingredients twice, each time for 1.5 hours, combining the decoctions and administering them warm on an empty stomach in the morning and evening.

2.2.2 Control Group

Patients in the control group received conventional Western medical treatment, which primarily included:

(1) Acid-suppressing medication: Omeprazole enteric-coated tablets (produced by Sinopharm Group Co. Ltd.), 20mg, once daily, orally.

(2) Gastric mucosal protectant: Bismuth potassium citrate capsules (produced by Jeju Pharmaceutical Group Co. Ltd.), four times a day, one capsule each time, taken with water half an hour before meals and at bedtime. Do not drink milk or take antacids or other alkaline medications within half an hour before or after taking the medication.

The treatment lasted for 8 weeks, aiming to suppress gastric acid secretion, protect the gastric mucosa, and promote ulcer healing.

2.3 Observation Indicators

To comprehensively assess the therapeutic effects of the modified Huangqi Jianzhong Tang on patients with spleen-stomach deficiency cold pattern gastric ulcers and to explore its potential biological mechanisms, the following specific observation indicators were set:

2.3.1 Traditional Chinese Medicine (TCM) Symptom Score Assessment

The TCM symptom score is used to evaluate changes in TCM clinical symptoms, including epigastric pain, acid reflux, stuffiness, and bloating. Each symptom is scored on a scale from 0 to 3, where 0 indicates no symptoms, 1 indicates mild, 2 indicates moderate, and 3 indicates severe symptoms. The total symptom score is calculated by summing the scores of all symptoms, with higher scores indicating more severe TCM symptoms.

2.3.2 Gastrin Level Measurement

Gastrin is a crucial hormone for gastric acid secretion, and its level reflects the status of gastric

acid production. Fasting venous blood samples from patients are used to measure serum gastrin levels using the Enzyme-Linked Immunosorbent Assay (ELISA) method. The results are reported in pg/mL, and a reduction in gastrin levels is typically associated with improvement in gastric ulcer symptoms.

2.3.3 Serum Marker Measurements

The study measures serum markers including the anti-inflammatory cytokines IL-10 and TGF-β1, as well as the pro-inflammatory cytokine IL-17, which reflect the state of inflammation and immune regulation in the body. These cytokines are also measured using the ELISA method from fasting venous blood samples, with results reported in pg/mL. Decreased levels of IL-17 and increased levels of IL-10 and TGF-β1 typically indicate controlled inflammatory responses and improved immune regulation.

2.3.4 Helicobacter pylori Eradication Rate Testing

Helicobacter pylori is one of the primary causes of gastric ulcers, and its eradication rate is an important indicator of treatment efficacy. Eradication is determined through gastric biopsy and subsequent bacterial culture or urea breath test. The eradication rate is expressed as a percentage, with an increase in the eradication rate usually correlating with an improved ulcer healing rate.

3. Research Results

3.1 Comparison of TCM Symptom Scores

Between Groups Before treatment, there was no statistical difference in TCM symptom scores between the two groups ($p>0.05$). After treatment, the TCM symptom scores for epigastric pain, acid reflux, stuffiness, and bloating decreased in both groups, with the observation group showing a greater reduction compared to the control group ($P<0.05$).(Table 1)

Table 1: Comparison of TCM Symptom Scores between Groups (Mean ± SD, points)

Group	Number of Cases	Epigastric Pain		Acid Reflux		Stuffiness and Bloating	
		Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
Control	48	3.16±0.18	1.80±0.14	2.99±0.30	1.92±0.18	3.23±0.32	1.77±0.17
Observation	48	3.14±0.14	1.40±0.09	3.03±0.32	1.29±0.21	3.13±0.28	1.11±0.09
t		0.60	16.74	-0.62	15.58	1.71	21.41
p		0.553	<0.001	0.550	<0.001	0.091	<0.001

3.2 Comparison of Gastrin Levels between Groups

Before treatment, there was no statistical difference in gastrin levels between the two groups ($p>0.05$). After treatment, gastrin levels decreased in both groups, with the observation group experiencing a greater reduction compared to the control group ($P<0.05$). (Table 2)

Table 2: Comparison of Gastrin Levels Between Groups (Mean ± SD, ng/L)

Group	Number of Cases	Before Treatment	After Treatment
Control	48	153.03±9.67	101.12±8.74
Observation	48	152.87±9.29	90.77±8.34
t	/	0.12	5.32
p	/	0.910	0.001

3.3 Comparison of Serum Markers between Groups

Before treatment, there was no statistical difference in serum markers between the two groups ($p>0.05$). After treatment, the levels of IL-10, TGF-β1, and IL-17 decreased in both groups, with the observation group showing a greater reduction compared to the control group ($P<0.05$). (Table 3)

Table 3: Comparison of Serum Markers between Groups (Mean ± SD, ng/L)

Group	Number of Cases	IL-10		TGF-β1		IL-17	
		Before	After	Before	After	Before	After
Control	48	104.45±8.67	88.70±6.15	1320.12±36.22	1075.12±32.33	117.45±7.64	96.91±5.21
Observation	48	105.10±7.99	64.79±6.10	1323.45±36.52	894.93±24.45	118.90±7.40	79.45±5.43
t	-	0.34	19.01	0.44	51.20	0.99	15.95
p	-	0.738	0.001	0.657	0.001	0.322	0.001

3.4 Comparison of Helicobacter pylori Eradication Rates between Groups

The observation group demonstrated a higher Helicobacter pylori eradication rate compared to the control group ($x^2=4.360$, $p=0.037$). (Table 4).

Table 4: Comparison of Helicobacter pylori Eradication Rates between Groups (n, %)

Group	Number of Cases	Positive (Eradicated)	Negative (Not Eradicated)	Eradication Rate (%)
Control	48	12(25.00)	36(75.00)	36(75.00)
Observation	48	5(10.42)	43(89.58)	43(89.58)
x^2	-	-	-	4.36
p	-	-	-	0.037

3.5 Comparison of Clinical Efficacy between Groups

The clinical efficacy rate of the observation group was higher than that of the control group ($x^2=4.019$, $p=0.045$), (Table 5).

Table 5: Comparison of Clinical Efficacy between Groups (n, %)

Group	Number of Cases	Markedly Effective	Effective	Ineffective	Efficacy Rate (%)
Control	48	18(37.50)	20(41.67)	10(20.83)	38(79.17)
Observation	48	27(56.25)	18(37.50)	3(6.25)	45(93.75)
x^2	-	-	-	-	4.02
p	-	-	-	-	0.045

4. Discussion

This randomized controlled trial investigated the clinical efficacy of the modified Huangqi Jianzhong Tang in the treatment of spleen-stomach deficiency cold pattern gastric ulcers. Huangqi Jianzhong Tang, a classical Traditional Chinese Medicine (TCM) formula, is renowned for its capabilities to warm the interior, supplement deficiency, and harmonize the spleen and stomach [7]. The findings demonstrated that Huangqi Jianzhong Tang surpasses conventional Western treatments in alleviating epigastric pain, improving digestive functions, reducing inflammatory markers, and enhancing Helicobacter pylori eradication rates [8].

Significant reductions in TCM symptom scores post-treatment, particularly in epigastric pain, acid

reflux, stuffiness, and bloating, not only underscored the efficacy of this traditional herbal formula but also highlighted its pharmacological synergy with ingredients such as Codonopsis pilosula and Atractylodes macrocephala. Codonopsis, characterized by its sweet taste and neutral properties, has been traditionally used to strengthen the spleen and nourish the blood, with modern pharmacological studies validating its role in enhancing immunity, protecting gastrointestinal mucosa, and combating ulcers [5].

Atractylodes, a staple in TCM, has been celebrated since the Shennong Bencao Jing for its spleen-strengthening and damp-resolving properties. Its incorporation in the study markedly enhanced splenic and gastric functions, thereby effectively mitigating ulcer symptoms, aligning with its historical uses [9]. Dioscorea, another crucial component, known for its spleen and stomach fortifying attributes, proved significantly effective for patients with weak digestion and related symptoms, augmenting the overall therapeutic impact of the formula.

Moreover, the roles of Glycyrrhiza (Licorice) and Citrus peel were pivotal. Licorice, known for its harmonizing capabilities, not only enhanced the formula's overall effectiveness but also contributed anti-inflammatory and anti-ulcer properties crucial for treating gastric ulcers [10]. Citrus peel, through its qi-regulating effects, improved symptoms like stomach distension and facilitated digestion.

Personalized adjustments to the formula were made based on specific symptoms, exemplifying the tailored approach of TCM. For instance, intense abdominal pain was addressed by adding Corydalis, known for its potent analgesic properties. Appetite loss was managed with Crataegus and malt, enhancing digestion and ameliorating dyspeptic symptoms [11]. Zingiber and Pinellia were included for their roles in warming the middle and stopping vomiting, effectively alleviating nausea.

The significant decreases in serum levels of IL-10, TGF-β1, and IL-17 post-treatment highlighted an immune-modulatory mechanism potentially influenced by Codonopsis and Atractylodes. The reduction of these cytokines suggested alleviation of systemic inflammation, underscoring the formula's capacity to modulate immune responses [12].

An increased Helicobacter pylori eradication rate is a critical index in ulcer treatment. The higher eradication rate observed in the study group might relate to the antibacterial and anti-inflammatory properties of the Huangqi Jianzhong Tang components, which enhance antimicrobial actions both directly and through immunological pathways [13].

In summary, this study demonstrated that the modified Huangqi Jianzhong Tang not only effectively improved clinical symptoms in patients with spleen-stomach deficiency cold pattern gastric ulcers but also enhanced Helicobacter pylori eradication rates and modulated immune responses. These results accentuate the pivotal role of TCM in contemporary medical practices, offering effective strategies for the comprehensive management of gastric ulcers and illustrating the potential of integrating traditional and modern medical approaches for broader therapeutic possibilities.

References

[1] Kamada T, Satoh K, Itoh T, et al. Evidence-based clinical practice guidelines for peptic ulcer disease 2020[J]. Journal of gastroenterology, 2021, 56: 303-322.

[2] Malfertheiner P, Megraud F, Rokkas T, et al. Management of Helicobacter pylori infection: the Maastricht VI/Florence consensus report [J]. Gut, 2022, 71(9): 1724-1762.

[3] Huang J Q, Sridhar S, Hunt R H. Role of Helicobacter pylori infection and non-steroidal anti-inflammatory drugs in peptic-ulcer disease: a meta-analysis [J]. The Lancet, 2002, 359(9300): 14-22.

[4] Kuna L, Jakab J, Smolic R, et al. Peptic ulcer disease: a brief review of conventional therapy and herbal treatment options [J]. Journal of clinical medicine, 2019, 8(2): 179.

[5] Lanas A, Chan F K L. Peptic ulcer disease [J]. The Lancet, 2017, 390(10094): 613-624.

[6] L üBin, Chen Weichang, Kou Yi, et al. Guidelines for Primary Care of Chronic Gastritis (Practical Version 2019) [J]. Chinese Journal of General Practitioners, 2020, 19(9): 776-782.

[7] Lei M Y. Research progress of traditional Chinese medicine in the prevention and treatment of dyspepsia following spleen stomach weakness [J]. Med Data Min, 2022, 5(1): 5.
[8] Hu J, He T, Liu J, et al. Pharmacological and molecular analysis of the effects of Huangqi Jianzhong decoction on proliferation and apoptosis in GES-1 cells infected with H. pylori [J]. Frontiers in Pharmacology, 2022, 13: 1009705.
[9] Liu Y, Xu W, Wang G H, et al. Material basis research for Huangqi Jianzhong Tang against chronic atrophic gastritis rats through integration of urinary metabonomics and SystemsDock[J]. Journal of ethnopharmacology, 2018, 223: 1-9.
[10] Sun Y, Zhang J, Chen Y. Efficacy and safety of Jianzhong decoction in treating peptic ulcers: a meta-analysis of 58 randomised controlled trials with 5192 patients [J]. BMC complementary and alternative medicine, 2017, 17: 1-16.
[11] Nie B, Luo R, Chen X, et al. Clinical Study on Moxibustion Therapy for Gastric Pain of Deficiency-Cold Type [J]. Journal of Acupuncture and Tuina Science, 2011, 9: 98-100.
[12] Jia L, Qin X, Liu Y. Integrated pharmacokinetics of Huangqi Jianzhong Tang in normal and chronic atrophic gastritis rats [J]. Biomedical Chromatography, 2022, 36(12): e5492.
[13] Wei Y, Ma L X, Yin S J, et al. Huangqi Jianzhong Tang for treatment of chronic gastritis: a systematic review of randomized clinical trials[J]. Evidence-Based Complementary and Alternative Medicine, 2015, 2015(1): 878164.