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To Explore the Clinical Effect of Self-made Shugan Jianzhong Decoction in the Treatment of *Helicobacter Pylori* (Hp)-positive Chronic Atrophic Gastritis (CAG) with Liver and Stomach Stagnation Heat Type

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Abstract: *Objective:* To analyze the effect of self-prepared Shugan Jianzhong Decoction in the treatment of *Helicobacter pylori* (Hp)-positive chronic atrophic gastritis (CAG) caused by liver and stomach stagnation heat. *Methods:* 90 Hp-positive CAG patients with liver and stomach stagnation and heat in the hospital from 2023.3 to 2024.3 were divided into control group and observation group by random number table method. They were treated with quadruple therapy and quadruple therapy plus self-made Shugan Jianzhong Decoction respectively to compare the effects. *Results:* Through different treatment plans, the treatment effectiveness and Hp clearance rate of the observation group were higher than those of the control group; the TCM syndrome scores of the observation group were lower than those of the control group; the levels of gastric function indicators were higher than those of the control group; the levels of inflammatory factors were lower than those of the control group ($p < 0.05$); the incidence of adverse reactions was similar between the two groups ($p > 0.05$). *Conclusion:* The self-prepared Shugan Jianzhong Decoction is effective in treating Hp-positive CAG diseases. It has significant advantages in clearing Hp, promoting symptoms and improving gastric function. It is safe and reliable when used in combination with western medicine and is worthy of promotion.

Keywords: Liver and stomach stagnation heat; *Helicobacter pylori*; Chronic atrophic gastritis; Shugan Jianzhong Decoction

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1. Introduction

Chronic atrophic gastritis (CAG) is an inflammatory lesion that occurs in the gastric mucosa and has obvious chronic disease characteristics, such as long cycle, slow progression, difficulty in curing, and easy recurrence [1]. There are many causes of this disease, including dietary habits, living habits, *Helicobacter pylori* (Hp) infection, etc. The vast majority of patients are positive for Hp after diagnosis, so it is considered to be the main cause [2]. The disease can cause a series of gastrointestinal symptoms, such as nausea, vomiting, abdominal pain, etc. If it persists for a long time, it can progress to gastric cancer through intestinal metaplasia or atypical hyperplasia. Therefore, early detection and early treatment are crucial to improving prognosis and preventing cancer [3]. The main difficulty in the treatment of this disease is Hp infection,

which is difficult to eradicate and easily causes recurrence of the disease. Western medicine mainly uses antibiotics for treatment. For example, quadruple therapy is currently commonly used, but it only has an anti-infective effect, and there are problems such as drug resistance and adverse reactions [4]. In recent years, with the continuous deepening of understanding of traditional Chinese medicine treatment, it has been widely used in the treatment of various chronic diseases, and has shown the advantages of stable and long-lasting effects and high safety. CAG belongs to the categories of "epigastralgia" and "fullness" in traditional Chinese medicine. It is common in liver and stomach stagnation and heat. The pathological basis is stagnation of liver Qi, long-term heat dissipation, and transverse reflux that invades the stomach. Based on this, the pathophysiological state can be improved by soothing the liver and regulating Qi and strengthening the middle and harmonizing the stomach, so as to achieve the therapeutic effect of the disease. In this study, 90 Hp-positive CAG patients were observed in groups to explore the application value of the self-made Shugan Jianzhong Decoction.

2. Materials and methods

2.1. General information

As shown in **Table 1**, the baseline data of the two groups were comparable ($p > 0.05$).

2.1.1. Inclusion criteria

(1) Meet the diagnostic criteria of the "Consensus Opinions on the Diagnosis and Treatment of Chronic Atrophic Gastritis with Traditional Chinese Medicine" [5];
(2) Diagnosis through gastroscopy;
(3) Hp positive;
(4) Sign an informed consent form.

2.1.2. Exclusion criteria

(1) Allergy to drug ingredients;
(2) Combined with peptic tract ulcer;
(3) Digestive system tumor;
(4) Missing data.

Table 1. Baseline data of the two groups

Group	n	Gender		Age range (years)	Average age (years)	Duration of disease (months)	Average disease duration (months)
		Male	Female				
Observation group	45	24 (53.33)	21 (46.67)	32–75	55.26 ± 6.38	2–8	5.35 ± 1.04
Control group	45	26 (57.78)	19 (42.22)	33–74	55.48 ± 7.12	2–9	5.42 ± 1.26
χ^2/t	-	0.180		0.154		0.287	
p	-	0.671		0.878		0.774	

2.2. Method

2.2.1. Control group

Quadruple therapy, levofloxacin capsules (Guangdong Yishu Pharmaceutical Co., Ltd., H20073451) 0.2 g/time, 2 times/d; amoxicillin capsules (Hong Kong Aomei Pharmaceutical Factory, HC20130016) 1 g/time, 2 times/d; Leibei Prazole sodium enteric-coated capsules (Zhuhai Rundu Pharmaceutical Co., Ltd., H20050228) 20 mg/time, once/d; bismuth potassium citrate capsules (Zhejiang China Resources Sanjiu Zhongyi Pharmaceutical Co., Ltd., H10920076) 0.3 g/time, 4

times/d. Continue taking the medication for 2 weeks.

2.2.2. Observation group

Quadruple therapy is the same as above, plus the self-made Shugan Jianzhong Decoction, the formula is: 6 g of Zhigancao; 10 g each of *Pinellia ternata*, *Bletilla striata*, *Coptis chinensis*, and Notoginseng root; 12 g Agarwood; Bupleurum, *Citrus aurantium*, white peony root, *Poria cocos*, fried *Atractylodes rhizome*, *Corydalis Corydalis*, and Dandelion 15 g each; and *Codonopsis pilosula* 20 g. Decoction in water, take 1 dose daily, morning and evening, for 28 days.

2.3. Observation indicators

(1) Efficacy evaluation
The disappearance of symptoms and signs is marked as effective, improvement is effective, no change or worsening is ineffective, and the Hp clearance rate is measured with a carbon 13 breath analyzer;
(2) TCM syndrome score
The main symptoms are evaluated, 1 is mild, 2 is moderate, and 3 is severe;
(3) Gastric function indicators
Enzyme-linked immunoassay Gastrin and gastrin were measured by adsorption method, and gastrin-17 was measured by immunoturbidimetric method;
(4) Inflammatory factors
C-reactive protein (CRP), interleukin-8 (IL-8), and tumor necrosis factor-α (TNF-α) were measured by enzyme-linked immunosorbent method;
(5) Adverse reactions: nausea, constipation, and loss of appetite.

2.4. Statistical processing

SPSS 26.0 statistical software was used for data analysis. Measurement data were expressed as mean ± standard deviation "$\bar{x} \pm s$", and comparisons between two groups were made using *t*-tests. Count data were expressed as rates, and comparisons between groups were made using χ^2 tests. $p < 0.05$ was considered a statistically significant difference.

3. Results

3.1. Efficacy evaluation

The treatment effectiveness and Hp clearance rate of the observation group were higher than those of the control group ($p < 0.05$). See **Table 2**.

Table 2. Comparison of efficacy evaluation between the two groups (n, %)

Group	n	Effective	efficient	Invalid	Always efficient	HP clearance rate
Observation group	45	26 (57.78)	18 (40.00)	1 (2.22)	97.78	40 (88.89)
Control group	45	22 (48.89)	14 (31.11)	9 (20.00)	80.00	32 (71.11)
χ^2	-				7.200	4.444
p	-				0.007	0.035

3.2. Traditional Chinese medicine syndrome score

After treatment, the TCM syndrome scores were compared between the groups ($p < 0.05$). See **Table 3**.

Table 3. Comparison of TCM syndrome scores between the two groups [$\bar{x} \pm s$, points]

Group	n	Abdominal pain and fullness		Acid reflux		Epigastric tightness		Belching	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	45	2.35 ± 0.20	1.05 ± 0.24*	2.06 ± 0.22	0.65 ± 0.14*	2.03 ± 0.24	0.58 ± 0.10*	2.03 ± 0.31	0.68 ± 0.14*
Control group	45	2.40 ± 0.24	1.62 ± 0.21*	2.03 ± 0.16	0.98 ± 0.16*	2.01 ± 0.42	1.05 ± 0.32*	2.05 ± 0.28	1.10 ± 0.34*
t	-	1.074	11.990	0.740	10.412	0.277	9.404	0.321	7.662
P	-	0.286	< 0.001	0.461	< 0.001	0.782	< 0.001	0.749	< 0.001

Note: Compared with the group before treatment, *$p < 0.05$

3.3. Gastric function indicators

After treatment, the levels of gastric function indexes in the group were compared ($p < 0.05$). See **Table 4**.

Table 4. Comparison of gastric function indicators between the two groups ($\bar{x} \pm s$)

Group	n	Gastrin (pg/mL)		Gastrotropin (pg/mL)		Gastrin-17 (pmol/L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	45	16.26 ± 2.04	26.35 ± 2.41*	207.26 ± 26.46	251.48 ± 30.68*	0.62 ± 0.12	1.35 ± 0.15*
Control group	45	16.30 ± 2.68	22.15 ± 2.68*	207.15 ± 20.54	236.26 ± 32.14*	0.60 ± 0.11	0.85 ± 0.12*
t	-	0.080	7.817	0.022	2.298	0.824	17.461
p	-	0.937	< 0.001	0.982	0.024	0.412	< 0.001

Note: Compared with the group before treatment, *$p < 0.05$

3.4. Inflammatory factors

After treatment, the observation group had CRP (3.05 ± 0.57) mg/L, IL-8 (12.35 ± 2.68) μg/L, TNF-α (1.35 ± 0.24) μg/L, they were all lower than those in the control group (5.24 ± 0.41) mg/L, (17.15 ± 2.24) μg/L, and (2.48 ± 0.30) μg/L, compared with the two groups ($p < 0.05$).

3.5. Adverse reactions

The observation group included 2 cases of nausea, 1 case of constipation, and 1 case of loss of appetite, and 1 case in the control group. The incidence rates of the two groups were 8.88% and 6.66%, respectively, and the comparison between the groups ($p > 0.05$).

4. Discussion

CAG generally has no obvious symptoms in the early stage. After the condition recurs or worsens, you may feel abdominal pain. Some patients may lose appetite or even lose weight significantly. If not treated promptly and effectively, delayed recovery may lead to the risk of cancer. Hp infection is the main cause of chronic gastritis and plays an important role in the occurrence, progression, and recurrence of CAG [6]. Hp neutralizes gastric acid through urease in the human stomach and triggers a local inflammatory reaction. It can also contact and combine with gastric mucosal epithelial cells, causing damage to the gastric mucosa, resulting in abdominal pain, nausea and other symptoms [7]. For Hp-positive CAG patients,

eradication of Hp is the key to treatment and will also directly affect the recurrence rate. Antibiotics are the main treatment drugs. Due to the problem of multiple drug resistance, a quadruple antibiotic regimen is currently generally adopted, but there are still a few problems such as drug resistance, insignificant gastric function, and adverse reactions [8]. It is easy to relapse after treatment, and the effect of traditional Chinese medicine treatment is more stable. In recent years, the integration of traditional Chinese and Western medicine has become a trend in the treatment of chronic diseases, providing more options for the treatment of CAG diseases.

Chinese medicine believes that the formation of stomachache, fullness and other diseases is a long-term evolution process. Long-term illness, physical weakness, long-term illness and excessive blood stasis are mixed with deficiency and excess. Among them, yang deficiency is the main pathological basis, which can affect transportation and transformation, resulting in poor blood flow, gastric stasis, and further development, with the risk of hyperplasia and cancer [9]. Liver-stomach heat stagnation type is a TCM classification of CAG. TCM theory believes that the internal organs influence each other. For example, dysfunction of the liver may lead to liver-Qi stagnation and further affect the stomach. Therefore, liver function status may play a certain role in gastric lesions. Huatan Xiaoyu Recipe is more helpful in the treatment of chronic gastritis. Its mechanism is to protect the gastric mucosa, improve gastric mucosal blood circulation, and enhance the regeneration and repair function of mucosal epithelial cells. According to the pathological basis of CAG with liver and stomach heat stagnation, treatment can be carried out from the directions of soothing the liver and regulating Qi, activating blood circulation and removing blood stasis, clearing away heat and detoxifying. Therefore, in this study, patients were given self-made Shugan Jianzhong Decoction.

In the treatment of Hp-positive CAG patients, the efficacy evaluation mainly refers to the changes in symptoms and signs and the Hp clearance rate. This study found that the total effective rate and Hp clearance rate were higher in the observation group; after treatment, the TCM syndrome scores in the group were lower than before treatment, and the observation group was lower than the control group. Xiong Li [10] and others also obtained the same conclusion. Compared with simple quadruple therapy, the Hp clearance rate was significantly improved after adding the traditional Chinese medicine Shuganjianzhong Decoction. This result suggests that simple quadruple therapy can eliminate some Hp and promote disease improvement, but the effect is limited, while combined with the self-made Shugan Jianzhong Decoction can enhance the curative effect. Analysis of the reasons: *Bupleurum* and *Citrus aurantium* are used in this prescription to soothe the liver and regulate Qi, which can relieve the internal and external effects, clear away heat and raise yang, and can alleviate the patient's yang deficiency constitution; *Coptis chinensis* and Dandelion both have the effect of clearing away heat and detoxifying, and the latter can reduce swelling and dissipate stagnation; *Codonopsis pilosula* is used to replenish Qi, strengthen the spleen and stomach, and assist in regulating the constitution; *Corydalis* is used to promote Qi and blood circulation, which can relieve the symptoms of epigastric pain; Zhigancao can harmonize various medicines. The main functions of the whole prescription include soothing the liver and regulating Qi, clearing away heat and detoxifying, strengthening the spleen and stomach, and can effectively reduce symptoms such as belching, abdominal pain and fullness. It can be used on the basis of quadruple therapy to further strengthen the curative effect.

Abnormal gastric function is affected by many factors, of which local inflammatory reaction is one. It is also affected by a variety of environmental factors, such as changes in eating habits, long-term loss of appetite, physical weakness, etc. CAG develops chronically, and both Hp infection and local inflammatory reaction can affect gastric function. Therefore, the disease may be accompanied by abnormal expression of related gastric function indicators. This study found that the observation group had better improvement in gastric function, indicating that the application of traditional Chinese medicine can promote functional recovery. Analysis of reasons: The main functions of quadruple therapy are anti-inflammatory and regulating gastric acid secretion, etc., but it has unsatisfactory effects on gastric function. *Codonopsis Atractylodes* is used in Shuganjianzhong Decoction, which has the function of strengthening the spleen, replenishing the middle and neutralizing the stomach, regulating the functions of the internal organs from the direction of the liver, spleen and stomach, thereby alleviating gastric dysfunction [11].

CAG has chronic inflammatory reaction as the main pathological characteristic. Inhibiting the expression of

inflammatory factors will determine the success rate of treatment. This study found that after treatment, the levels of inflammatory factors in the group decreased, and the observation group was lower than the control group, indicating that the self-prepared Shugan Jianzhong Decoction has a good inhibitory effect on inflammatory reactions. In the study of Song Liying, Shugan Hewei Decoction was used to treat elderly CAG patients and found that this prescription can effectively reduce inflammation in the body [12]. Analysis of the reasons: In addition to being affected by Hp infection, the inflammatory reaction of CAG is also caused by blocked meridians, poor blood circulation, blood stasis, long-term yang deficiency, etc. Shugan Jianzhong Decoction is used for treatment. The whole prescription has the effect of activating blood circulation and removing blood stasis, dredging the veins and stasis, and clearing the veins. Reduce the inflammatory reaction by accelerating blood circulation; the formula contains *Codonopsis pilosula*, *Atractylodes macrocephala*, *Poria cocos*, licorice, etc., which has the effect of promoting blood circulation and removing blood stasis, cooling blood and relieving pain. *Panax notoginseng* can replenish blood, remove blood stasis, remove blood stasis and regenerate, and has direct or indirect anti-inflammatory effects.

Hp-positive CAG is commonly treated with quadruple therapy, which is prone to adverse reactions. Whether the addition of traditional Chinese medicine decoction will affect the toxic and side effects is the key to evaluating its promotion and application value. In this study, drug-related adverse reactions were compared between the two groups, and no differences were found. Nausea, constipation, and loss of appetite in a few patients are all common adverse reactions of antibiotics, indicating that traditional Chinese medicine is safe and feasible in combination with Western medicine. During the treatment, attention should be paid to preventing and controlling potential adverse reactions of Western medicines, especially in combined treatment, where a large number of drugs are used to avoid mutual reactions. Drug compatibility should be scientifically adjusted based on the actual situation of the patient, and the dosage and time of drug use should be carefully controlled. After the condition recovers, the drug should be discontinued in a timely manner to reduce dose-dependent toxic and side effects.

In summary, the self-made Shugan Jianzhong Decoction greatly improves the efficacy of Hp-positive CAG, shows significant advantages in clearing Hp, promoting symptoms and improving gastric function, and is safe and reliable when combined with western medicine.

About the author

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Disclosure statement

The author declares no conflict of interest.

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