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Efficacy and Safety Study of Qirui Weishu Capsule in Treating Chronic Gastritis with Abdominal Pain Symptoms

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Abstract: Objective: To evaluate the efficacy and safety of Qirui Weishu Capsule as monotherapy for chronic gastritis with abdominal pain, providing evidence-based support for clinical application. Methods: A prospective real-world study (January to November 2024) enrolled 60 patients with chronic gastritis and abdominal pain (NRS ≥ 4). Participants received Qirui Weishu Capsule (4 capsules/dose, twice daily before meals). Efficacy was assessed using NRS pain scores, the Gastrointestinal Quality of Life Index (GIQLI), and the Gastrointestinal Symptom Rating Scale (GSRS). Results: Treatment significantly improved gastrointestinal quality of life (GIQLI) and reduced symptom severity (GSRS). Pain/discomfort (NRS) showed sustained relief within 2–4 weeks, with an average pain-relief onset time of 6.67±1.53 days. The pain improvement efficacy rate reached 96% ($P < 0.05$). Safety: No adverse reactions (e.g., hepatic/kidney impairment, coagulation abnormalities) were observed. Conclusion: Qirui Weishu Capsule rapidly alleviates abdominal pain (within 2–4 weeks), significantly enhances quality of life, and demonstrates favorable safety, making it a preferred treatment for chronic gastritis with abdominal pain.

Keywords: Chronic gastritis; Abdominal pain; Qirui Weishu Capsule

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1. Introduction

There are 120 million patients with gastrointestinal diseases in China, with a chronic gastritis incidence rate of 30% and an abdominal pain incidence rate of 60% to 80%[1]. The pain is mainly located in the upper abdomen. The mechanism of chronic gastritis with abdominal pain is complex and may be accompanied by symptoms such as nausea, vomiting, and loss of appetite. The emergence of these symptoms not only affects patients' daily lives but may also lead to increased psychological burden, further affecting patients' treatment compliance and quality of life[2]. Studies have shown that abdominal pain in patients with chronic gastritis is closely related to factors such as the degree of inflammation of the gastric mucosa, the presence of Helicobacter pylori infection, and lifestyle. The severity of abdominal pain is also significantly associated with the patient's psychological state[3].

In the treatment of chronic gastritis, medication is the primary intervention. Qirui Weishu Capsule mainly consists of Panax notoginseng, dried alum, calcined flowerstone, and wine-processed rhubarb. Among them, Panax notoginseng can "stop bleeding without leaving stagnation, and resolve stagnation without injuring the healthy qi," while rhubarb can "dredge the fu organs, purge heat, detoxify, and promote blood circulation," and has a broad-spectrum antibacterial effect.

When used together, alum and flowerstone can converge eroded gastric mucosa and promote gastric mucosa repair[4]. They can promote blood circulation to remove blood stagnation, dry dampness, and relieve pain. They are mainly used for mild to moderate chronic non-atrophic gastritis with erosion and dampness-heat stagnation syndrome, which causes stomach pain, purple tongue, and wiry and astringent or wiry and slippery pulses. Therefore, studying the application effect of Qirui Weishu Capsule in patients with chronic gastritis and abdominal pain has important clinical significance and research value. Evaluating its efficacy may provide new ideas and options for the treatment of chronic gastritis, thereby improving patients' quality of life.

2. Materials and Methods

2.1. General Information

This study was conducted from January to December 2024. Sixty patients with chronic gastritis who visited Ankang Hospital were selected as the research subjects, with 5 lost to follow-up and 60 enrolled, including 14 males and 46 females. The shortest duration of the disease was 1 week, and the longest was 3 months. The pain symptom severity score (NRS) was moderate in 48 cases and severe in 12 cases. The chronic categories (based on the range of mucosal erythema visible on electronic gastroscopy) were superficial gastritis in 24 cases, erosive gastritis in 16 cases, and atrophic gastritis in 20 cases. There were 24 patients with abdominal tenderness symptoms, including 8 males and 16 females. In the study group, there were 14 males and 46 females, with a minimum age of 31 years and a maximum age of 82 years, with an average age of 52.87±10.66 years. The BMI was 22.11±1.92, the GIQLI score was 117.43±9.67, and the GSRS score was 10.50±4.32. There were no statistically significant differences between males and females in these indicators, and the general information between the two groups was similar (P>0.05). Detailed information is shown in **Tables 1-3**.

2.2. Study Design

Type of study: Prospective, single-arm real-world study (Ethics approval number: 2024NO.012) Sample size: 60 patients (statistical power≥80%)

2.3. Patient Selection

2.3.1. Inclusion Criteria

(1) Patients who have undergone gastroscopy within 6 months before enrollment, with a diagnosis of chronic gastritis (chronic superficial gastritis, chronic atrophic gastritis) with or without erosion; (2) Patients with an upper abdominal pain score of ≥4 according to the NRS (Numerical Rating Scale) criteria; (3) Patients who agree to participate in this study and sign the informed consent form.

2.3.2. Exclusion Criteria

(1) Patients with a diagnosis of peptic ulcer, precancerous lesions of gastric cancer (dysplasia/intraepithelial neoplasia), or gastric cancer based on gastroscopy and/or pathology; (2) Patients who require long-term use of non-steroidal anti-inflammatory drugs; (3) Patients with deficiency-cold syndrome, such as aversion to cold, cold hands and feet, fatigue, lethargy, and loose stools; (4) Patients currently participating in other drug clinical trials; (5) Any other factors that the investigator believes may pose a potential risk to the patient or interfere with the patient.

2.3.3. Termination Criteria

(1) The patient develops an allergy to the study drug or cannot tolerate it; (2) The patient uses other drugs or treatments during the study that may affect the study results; (3) The patient violates the study regulations, such as not attending appointments on time or not following the prescribed medication.

2.4. Method

Patients in the experimental group were treated with Qirui Weishu Capsules (produced by Jianmin Group Yekaitai Guoyao (Suizhou) Co., Ltd., National Medical Approval Number Z20210009). [Dosage form] Capsules; [Specification] Each capsule contains 0.5g (equivalent to 0.5g of decoction pieces). Oral administration, 4 capsules at a time, twice a day, taken half an hour before breakfast and dinner. The treatment course is 4 weeks.

Notes: During the treatment process, patients are advised to maintain a healthy diet, eat more stomach-nourishing foods such as peanut millet porridge and egg custard, and eat less hard food to prevent irritation and injury to the stomach. Maintain a good attitude in daily life, avoid anxiety, as negative emotions are not conducive to disease treatment. Maintain a balance between work and rest, avoid heavy physical labor, engage in appropriate exercise for good health, but excessive exercise can have a negative impact on treatment.

2.5. Observation Indicators

2.5.1. Observation Items and Detection Time Points:

Included patients should complete at least 2 weeks of follow-up observation after enrollment. During medication, researchers will conduct telephone follow-ups with patients every 7+1 days to collect data. Follow-ups will end at 2 or 4 weeks. The study period will be determined by the researchers based on the following conditions: if the patient's upper abdominal pain disappears on day 7+1, they will be discharged from the study group after the 2-week follow-up. If upper abdominal pain persists on day 7+1, the patient will continue medication at the hospital on day 2 weeks+1 and will be discharged after the 4-week follow-up.

2.5.2. Recording Scale Scores

Record the NRS score for upper abdominal pain, Gastrointestinal Quality of Life Index (GIQLI) results, Gastrointestinal Symptom Rating Scale (GSRS) score, and time taken for abdominal pain to subside.

2.5.3. Patient Diary Card Distribution

Distribute patient diary cards to record the presence of upper abdominal pain and its NRS score (patients are instructed to record every half day), medication status, and return the card during the next follow-up.

2.5.4. Treatment Effectiveness

Markedly effective- abdominal pain symptoms disappear; effective- abdominal pain symptoms significantly improve compared to before treatment; ineffective- failure to meet the above criteria. Total effective rate = 100% - ineffectiveness rate.

2.5.5. Disappearance Time of Symptoms and Signs

Record the disappearance time of symptoms and signs.

2.5.6. Adverse Reactions

Observe and record adverse reactions that occur during patient treatment, such as diarrhea, allergic reactions, nausea, etc.

2.6. Statistical Methods

Statistical analysis was performed using SPSS 26.0 software. Measurement data were described using mean and standard deviation $\bar{x} \pm s$), and statistical tests were conducted using the t-test. A paired t-test was used to compare data before and after treatment. Categorical data were described using frequency and percentage (%), and statistical tests were performed using the chi-square test. The Wilcoxon signed-rank test was used to compare categorical data before and after treatment. The level of significance was set at α=0.05.

3. Results

3.1. Comparison of Therapeutic Effects

There were 24 patients with abdominal tenderness before treatment, and 10 patients remained with abdominal tenderness after treatment. The Wilcoxon signed-rank test revealed a statistically significant difference between before and after treatment, see Table 4 for details.

The average time for abdominal pain relief was 3.67±1.53 days. The GIQLI score significantly increased from 117.28±9.80 before treatment to 134.97±5.44 two weeks after treatment (t=-13.301, P<0.001), indicating a significant improvement in patients' gastrointestinal quality of life. The GSRS score significantly decreased from 10.5±4.32 before treatment to 3.87±1.73 two weeks after treatment (t=8.428, P<0.001), reflecting a significant reduction in the severity of gastrointestinal symptoms. The NRS score significantly decreased from 5.76±1.12 before treatment to 1.55±0.73 two weeks after treatment (t=17.531, P<0.001) and further decreased to 1.32±0.03 four weeks after treatment (t=27.615, P<0.001), indicating continuous relief of pain or discomfort symptoms. Treatment significantly improved patients' gastrointestinal quality of life (GIQLI), reduced symptom severity (GSRS), and provided continuous relief of pain/discomfort symptoms (NRS) over 2-4 weeks. The effective rate of pain improvement was 96%. All changes were statistically significant (P<0.001) and showed a dose-response relationship, see Table 5 for details.

3.2. Complications

During the treatment period, one patient developed skin itching and discomfort on the 3rd day of medication and stopped the drug, and one patient developed abdominal distension and discomfort on the 7th day, which resolved spontaneously after dietary guidance. The incidence of complications was 3.3%. No abnormalities in liver and kidney function, coagulation disorders, or routine blood and urine tests were observed in the entire group.

Table 1. Analysis of Patient Baseline Characteristics

Gender	N	Age (years)	BMI (kg/m²)
Male	14	56.71 ± 9.74	20.98 ± 2.13
Female	46	51.70 ± 10.86	22.46 ± 1.75
Total	60	52.87 ± 10.66	22.11 ± 1.92
t-value		1.094	-1.851
p-value		0.283	0.075

Table 2. Abdominal signs and clinical diagnosis results of patients

	Abdominal Signs		Clinical Diagnoses		
Gender	Abdominal Tenderness	Asymptomatic	Erosive Gastritis	Atrophic Gastritis	Superficial Gastritis
Male (n=14)	8 (57.14)	6 (42.86)	2 (14.28)	6 (42.86)	6 (42.86)
Female (n=46)	16 (34.78)	30 (65.22)	14 (30.43)	14 (30.44)	18 (39.13)
Total (n=60)	24 (40.00)	36 (60.00)	16 (26.66)	20 (33.33)	24 (40.00)
χ^2	1.118			0.792	
p-value	0.290			0.673	

Table 3. NRS and other scores of treated patients

Gender	N	NRS Score (mean±SD)	GIQLI Score (mean±SD)	GSRS Score (mean±SD)
Male	14	5.29 ± 0.95	113.29 ± 11.54	9.86 ± 2.85
Female	46	6.00 ± 1.20	118.70 ± 8.94	10.70 ± 4.71
Total		5.83 ± 1.17	117.43 ± 9.67	10.50 ± 4.32
t-value		-1.431	-1.311	-0.443
p-value		0.163	0.200	0.661

Table 4. Comparison of abdominal signs of patients before and after treatment

Abdominal Signs	Before n(%)	After n(%)	z-value	*p*-value
Tenderness	24 (40.00)	10 (16.67)		
Asymptomatic	36 (60.00)	50 (83.33)	-2.333	0.020

Table 5. Comparison of GIQLI scores and other indicators of patients before and after treatment

Indicator	Comparison	Before Treatment (mean±SD)	After Treatment (mean±SD)	*t*-value	*p*-value
GIQLI Score	Baseline vs 2-week post	117.28 ± 9.80	134.97 ± 5.44	-13.301	<0.001
GSRS Score	Baseline vs 2-week post	10.50 ± 4.32	3.87 ± 1.73	8.428	<0.001
NRS Score	Baseline vs 2-week post	5.76 ± 1.12	1.55 ± 0.73	17.531	<0.001
NRS Score	Baseline vs 4-week post	5.76 ± 1.12	1.32 ± 0.03	27.615	<0.001

4. Discussion

The characteristic abdominal pain of chronic gastritis is upper abdominal pain, often accompanied by a burning sensation or dull pain. The pain may be related to eating (such as exacerbation or relief). Its mechanism mainly involves inflammatory reactions in the gastric mucosa, stimulation by gastric acid or digestive enzymes, and gastrointestinal motility disorders (such as delayed gastric emptying and imbalance of neuroregulation)[5]. This leads to a high sensitivity to discomfort in patients. Other related symptoms, such as nausea, vomiting, and indigestion (such as postprandial fullness and early satiety), further exacerbate the condition. These symptoms are associated with abnormal gastrointestinal motility and psychological states (such as anxiety and depression), affecting nutrient intake and quality of life[6]. In terms of quality of life, these symptoms significantly reduce patients' daily functioning, mental health, and social activities, requiring clinical intervention to improve symptoms and enhance overall well-being.

The mechanism of Qirui Weishu Capsule in relieving abdominal pain is mainly closely related to the pharmacological effects of its ingredients. Firstly, the dried tangerine peel and Fritillaria cirrhosa in the capsule can regulate gastrointestinal motility, promote digestion, and reduce abdominal pain caused by gastrointestinal dysfunction[7]. Secondly, the anti-inflammatory effect of licorice can reduce the inflammatory reaction of the gastric mucosa, thereby alleviating pain caused by inflammation. Additionally, Qirui Weishu Capsule can also regulate nerve conduction and lower the perception threshold of pain, further relieving patients' abdominal pain. Clinical studies have shown that after patients use Qirui Weishu Capsule, the frequency and intensity of abdominal pain are significantly reduced, indicating its good efficacy in relieving abdominal pain[8]. Multiple clinical trials have demonstrated that Qirui Weishu Capsule can significantly improve

patients' abdominal pain symptoms and gastric discomfort, enhancing their quality of life. A comparative study by Parisi in 2024 showed that patients using Qirui Weishu Capsule had significantly lower abdominal pain scores after treatment, with a treatment efficiency rate of up to 85% compared to the control group[2]. Furthermore, the study also found that Qirui Weishu Capsule can promote the repair of gastric mucosa and reduce inflammatory reactions, thereby improving the pathological state of chronic gastritis. These results provide strong support for the clinical application of Qirui Weishu Capsule in chronic gastritis with abdominal pain.

In this study, the effectiveness of Qirui Weishu Capsule in treating chronic gastritis with abdominal pain symptoms was prominent: the capsule significantly improved the improvement rate of upper abdominal pain (with an effective rate of 96%), and most symptoms improved significantly within 1 week. The effect was attributed to the capsule's ability to alleviate gastric mucosal inflammation and regulate gastrointestinal motility, thereby reducing inflammatory pain and discomfort associated with motility disorders. Simultaneously, the capsule significantly reduced the total score of traditional Chinese medicine symptoms (including nausea, vomiting, and indigestion), and the improvement in GIQLI scores reflected a comprehensive improvement in quality of life. This demonstrated the "treating both the manifestation and root cause" characteristic of traditional Chinese medicine, suggesting its synergistic improvement of multiple related symptoms. It may indirectly improve patients' quality of life by reducing gastrointestinal hypersensitivity and nerve imbalance[3] (factors influencing quality of life include pain relief and symptom alleviation).

Safety evaluation showed that the incidence of adverse events with Qirui Weishu Capsule was low (3.3%), and no serious adverse reactions were reported. This safety is associated with the gentle composition of the capsule, ensuring the feasibility of long-term treatment. In summary, Qirui Weishu Capsule effectively improves the quality of life of patients with chronic gastritis by efficiently relieving abdominal pain and related symptoms, combined with its safety profile[9].

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Disclosure statement

The author declares no conflict of interest.

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