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Clinical Study on the Therapeutic Effect of Yiqi Huoxue Formula on Unstable Angina Pectoris with Qi Deficiency and Blood Stasis Syndrome

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Abstract: *Objective*: To analyze and evaluate the therapeutic effect of Yiqi Huoxue Formula on patients with unstable angina pectoris of Qi deficiency and blood stasis syndrome. *Methods*: A total of 95 patients with unstable angina pectoris admitted to our hospital from January to December 2025 were selected for the study. They were randomly divided into a control group (47 cases) and an observation group (48 cases) using a random number table. The control group received conventional Western medicine intervention, while the observation group was additionally treated with Yiqi Huoxue Formula. The changes in traditional Chinese medicine (TCM) syndrome scores, clinical efficacy, angina symptom scores, inflammatory markers, cardiac troponin I (cTnI), and the discontinuation or reduction rate of nitroglycerin tablets were compared between the two groups. *Results*: Compared with the control group, the TCM syndrome scores in the observation group significantly decreased after treatment ($p < 0.05$). The total effective rates in the observation and control groups were 93.75% and 76.60%, respectively ($p < 0.05$). Compared with before treatment, the angina symptom scores in both groups decreased after treatment, with a greater reduction observed in the observation group ($p < 0.05$). Compared with the control group, the observation group had lower levels of IL-6, hs-CRP, and cTnI after treatment ($p < 0.05$). The total discontinuation or reduction rates of nitroglycerin in the observation and control groups were 79.17% and 53.19%, respectively ($p < 0.05$). *Conclusion*: For patients with unstable angina pectoris of Qi deficiency and blood stasis syndrome, the addition of Yiqi Huoxue Formula to Western medicine treatment can effectively alleviate their clinical symptoms and reduce TCM syndromes, reduce inflammatory responses and myocardial injury levels, enhance clinical efficacy, and help reduce nitroglycerin usage, demonstrating good clinical application value.

Keywords: Yiqi Huoxue formula; Unstable angina pectoris; Qi deficiency and blood stasis syndrome; Clinical efficacy

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1. Introduction

Unstable angina pectoris is a common type of coronary heart disease, lying between stable angina pectoris and acute myocardial infarction. Its frequency and severity of attacks often progress or are difficult to predict, with relatively challenging symptom relief and a higher likelihood of progressing to myocardial infarction

or experiencing severe adverse cardiovascular events [1]. According to epidemiological data, the prevalence of coronary heart disease among individuals aged ≥ 18 in China was 758 per 100,000 from 2020 to 2022, with a continuous rise in mortality rates in recent years. In 2021, the mortality rate was 135.08 per 100,000 among urban residents and 148.19 per 100,000 among rural residents [2,3]. Currently, nitrate esters, β-blockers, and statins are commonly used clinically to treat unstable angina pectoris, aiming to improve coronary blood flow, regulate lipid metabolism, and enhance the stability of atherosclerotic plaques, thereby helping to control disease progression and alleviate symptoms [4]. Traditional Chinese medicine classifies unstable angina pectoris under the categories of "chest obstruction" and "heart pain", primarily caused by factors such as aging, dietary irregularities, and emotional imbalances. The disease is located in the heart and closely related to the dysfunction of the liver, spleen, and kidney. Pathologically, it is characterized by a combination of deficiency in the root and excess in the manifestation, with deficiency often involving insufficient heart, spleen, and kidney functions, and excess commonly presenting as blood stasis, phlegm turbidity, Qi stagnation, and cold pathogens obstructing the heart vessels [5]. Yiqi Huoxue Formula is derived from modifications of two classic formulas, Danggui Buxue Decoction and Buyang Huanwu Decoction, and is an empirical formula of Professor Guo Shuwen, a mentor in the seventh batch of national academic experience inheritance projects for senior traditional Chinese medicine experts. The formula combines multiple herbs, including *Astragalus membranaceus*, Ginseng, *Angelica sinensis*, and *Ligusticum chuanxiong*, to achieve the effects of replenishing Qi, activating blood, and unblocking meridians to relieve pain. Studies have indicated that the combination of Yiqi Huoxue Formula with conventional treatment can further reduce angina symptom scores, decrease angina attacks, reduce nitroglycerin tablet usage, and lower inflammatory levels in patients with unstable angina pectoris of Qi and Yin deficiency syndrome [6]. However, there are few studies on the application of Yiqi Huoxue Formula in unstable angina pectoris of Qi deficiency and blood stasis syndrome. Therefore, this study added Yiqi Huoxue Formula to conventional Western medicine treatment to observe its effects on TCM syndrome scores, angina symptom scores, inflammatory markers, and other aspects.

2. Materials and methods

2.1. General information

A total of 95 patients with unstable angina pectoris admitted to our hospital from January to December 2025 were included in the study and divided into a control group (47 cases) and an observation group (48 cases). There was no statistically significant difference in baseline data between the two groups ($p > 0.05$), as shown in **Table 1**.

Table 1. Comparison of baseline data [($\overline{x} \pm s$), cases (n)]

Group	n	Male/Female	Age (years)	NYHA cardiac function classification		
				Class I	Class II	Class III
Observation group	48	29/19	58.72 ± 8.83	23 (47.92)	21 (43.75)	4 (8.33)
Control group	47	25/22	59.26 ± 7.20	26 (55.32)	19 (40.43)	2 (4.26)
t/χ^2		0.505	0.326		0.940	
p		0.477	0.745		0.625	

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Meeting the diagnostic criteria for unstable angina [7];

(2) Conforming to the criteria for traditional Chinese medicine (TCM) diagnosis of chest pain due to Qi deficiency and blood stasis, with primary symptoms including chest pain or chest tightness; secondary symptoms including palpitations, shortness of breath, fatigue, insomnia, and spontaneous sweating; tongue appearance often showing pale purple tongue, and pulse condition characterized by weakness and astringency [8].

(3) Experiencing at least two episodes of angina within 15 days prior to enrollment, including episodes triggered by rest or mild activity;

(4) Having signed an informed consent form.

2.2.2. Exclusion criteria

(1) Patients with acute ST-segment elevation myocardial infarction or those already diagnosed with acute myocardial infarction;

(2) Patients with severe heart failure or severe arrhythmia;

(3) Patients with severe liver or renal dysfunction or failure of vital organs;

(4) Patients with coexisting malignant tumors or autoimmune diseases;

(5) Patients allergic to the components of the medications used in the study.

2.3. Methods

The control group received conventional Western medicine treatment, specifically: Isosorbide Mononitrate Sustained-Release Tablets (Qilu Pharmaceutical Co., Ltd., National Medical Products Administration Approval Number H20065685, 40 mg/tablet) 40 mg orally once daily; Atorvastatin Calcium Tablets (Qilu Pharmaceutical Co., Ltd., National Medical Products Administration Approval Number H20193143, 10 mg/tablet) 20 mg once daily; Aspirin Enteric-Coated Tablets (Bayer HealthCare Co., Ltd., National Medical Products Administration Approval Number J20130078, 100 mg/tablet) 100 mg once daily; Metoprolol Tartrate Tablets (AstraZeneca Pharmaceutical Co., Ltd., National Medical Products Administration Approval Number H32025391, 25 mg/tablet) 12.5 mg twice daily, for a treatment duration of 4 weeks.

The observation group received additional treatment with a Qi-tonifying and blood-activating formula, consisting of: Raw *Astragalus* 30 g, *Angelica Sinensis* 15 g, Ginseng 10 g, Notoginseng Powder 6 g (dissolved in water before administration), *Ligusticum Chuanxiong* 15 g. The herbs were soaked in water and then decocted, with the dregs removed to obtain approximately 400 mL of medicinal liquid. This was taken warmly in two divided doses, morning and evening, 200 mL each time, one dose per day, for a continuous treatment duration of 4 weeks.

2.4. Observation indicators

(1) The TCM syndrome score was composed of five symptoms: chest pain (tightness), palpitations, shortness of breath, fatigue, and pale complexion. The scoring method is detailed in **Table 2**.

Table 2. TCM symptom scoring scale

Symptom	0 points	2 points	4 points	6 points
Chest pain (tightness)	Asymptomatic	Typical angina pectoris episodes, each lasting several minutes, occurring ≥ 2–3 times per week or 1–3 times per day, mild in severity, requiring occasional oral nitroglycerin.	Typical angina episodes several times daily, lasting from a few minutes up to about 10 minutes, with obvious pain, often requiring sublingual nitroglycerin.	Episodes multiple times daily, affecting daily activities (e.g., defecation, dressing), lasting longer, requiring repeated sublingual nitroglycerin.
Palpitations	Asymptomatic	Occasional palpitations, mild, with little impact on daily life.	Palpitations occur from time to time, last longer, and are accompanied by some discomfort.	Frequent palpitations, uneasy sensation, difficult to relieve, even interfering with daily life.
Shortness of breath	Asymptomatic	Shortness of breath after general activity.	Shortness of breath upon mild activity.	Shortness of breath or tachypnea even at rest.
Fatigue and weakness	Asymptomatic	Fatigue and weakness after exertion, reluctance to speak much.	Fatigue and weakness upon any movement, disinclination to talk.	Fatigue and weakness even at rest, no desire to speak.
Dull and dark complexion	Asymptomatic	Complexion slightly dark.	Complexion dull and dark.	Complexion markedly dull and dark.

(2) Clinical efficacy assessment

Marked effectiveness is defined as a significant improvement in clinical symptoms and signs, with a decrease in syndrome score of ≥ 70%. Effectiveness is indicated by an improvement in symptoms and signs compared to the previous state, with a reduction in syndrome score ranging from 30% to < 70%. Ineffectiveness is characterized by no significant improvement or worsening of symptoms and signs, with a decrease in syndrome score of < 30% and ≥ 0%. Aggravation is denoted by a deterioration in symptoms and signs compared to the previous state, with a decrease in syndrome score of < 0%. The overall effective rate is calculated as (marked effectiveness + effectiveness) / total number of cases × 100%.

(3) Angina symptom score

A comprehensive score is assigned based on the frequency of episodes, duration, and intensity of pain. Specific scoring criteria are detailed in **Table 3**.

Table 3. Evaluation method for angina symptom score

Angina pectoris	0 points	2 points	4 points	6 points
Attack frequency	None	About 2–6 times per week, on average less than once per day	About 1–3 times per day	Frequent daily attacks, ≥ 6 times per day
Duration	None	Each attack lasts a short time, no more than 5 minutes	Each attack lasts about 5–10 minutes	Each attack lasts a long time, ≥ 10 minutes
Pain intensity	None	Angina occurs only during high-intensity activities (e.g., brisk walking, jogging, or carrying heavy loads upstairs); daily activities are unaffected	Angina is induced by ordinary daily activities (e.g., normal walking or climbing stairs); mild reduction in exercise capacity	Angina occurs with minimal activity (e.g., short-distance walking or mild uphill walking); daily life is significantly limited

(4) Inflammatory markers and cardiac troponin I (cTnI)

Inflammatory markers include Interleukin-6 (IL-6) and high-sensitivity C-reactive protein (hs-CRP). For patients, 5 mL of elbow venous blood was collected in a fasting state in the early morning, placed

in an anticoagulant-free vacuum blood collection tube, allowed to stand at room temperature for 30 minutes, and then centrifuged at 3000 r/min for 10 minutes to separate the serum. IL-6 was detected using the enzyme-linked immunosorbent assay, hs-CRP was detected using the immunoturbidimetric assay, and cTnI was measured using the chemiluminescence immunoassay.

(5) Discontinuation and reduction of nitroglycerin

Compare the changes in nitroglycerin use before and after treatment in patients and calculate the discontinuation and reduction rate. Discontinuation and reduction rate = (number of patients who discontinued use after treatment + number of patients with reduced dosage) / total number of patients using the drug before treatment × 100%.

2.5. Statistical analysis

The study data were processed using SPSS 26.0 software. Count data were presented as the number of cases and percentages, and compared using the χ^2 test. Measurement data were expressed as ($\overline{x} \pm s$) after normality testing, and differences between groups were analyzed using the *t*-test. A difference was considered statistically significant when $p < 0.05$.

3. Results

3.1. Traditional Chinese medicine (TCM) syndrome scores

The TCM syndrome scores in the observation group were lower than those in the control group after treatment ($p < 0.05$). See **Table 4**.

Table 4. Comparison of TCM syndrome scores ($\overline{x} \pm s$, points)

Group	n	Before treatment	After treatment	*t*	*p*
Observation group	48	18.76 ± 1.28	9.42 ± 1.61	31.461	< 0.001
Control group	47	19.12 ± 1.47	13.01 ± 1.17	22.295	< 0.001
t		1.274	12.411		
p		0.206	< 0.001		

3.2. Clinical efficacy

The overall effective rates in the observation group and the control group were 93.75% and 76.60%, respectively ($p < 0.05$). See **Table 5**.

Table 5. Comparison of clinical efficacy [cases (%)]

Group	n	Markedly effective	Effective	Ineffective	Worsened	Effective rate
Observation group	48	28 (58.33)	17 (35.42)	3 (6.25)	0 (0.00)	45 (93.75)
Control group	47	16 (34.04)	20 (42.55)	10 (21.28)	1 (2.13)	36 (76.60)
χ^2						8.276
p						0.041

3.3. Angina pectoris symptom scores

Compared with before treatment, the angina pectoris symptom scores in both groups decreased after

treatment, with a greater reduction observed in the observation group ($p < 0.05$). See **Table 6**.

Table 6. Comparison of angina pectoris symptom scores ($\overline{x} \pm s$, points)

Group	n	Before treatment	After treatment	*t*	*p*
Observation group	48	11.03 ± 1.62	5.48 ± 1.05	19.918	< 0.001
Control group	47	10.75 ± 1.35	6.86 ± 0.88	16.549	< 0.001
t		0.914	6.935		
p		0.363	< 0.001		

3.4. Inflammatory indicators and cTnI

Compared with the control group, the observation group exhibited significantly lower levels of IL-6, hs-CRP, and cTnI after treatment ($p < 0.05$). See **Table 7**.

Table 7. Comparison of inflammatory indicators and cTnI ($\overline{x} \pm s$, points)

Group	n	IL-6 (pg/mL)		hs-CRP (mg/L)		cTnI (μg/L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	48	16.15 ± 2.04	8.93 ± 1.53*	6.26 ± 0.82	3.73 ± 0.61*	0.058 ± 0.016	0.035 ± 0.014*
Control group	47	16.41 ± 2.37	11.19 ± 1.28*	6.07 ± 0.77	4.25 ± 0.34*	0.054 ± 0.020	0.041 ± 0.008*
t		0.573	7.800	1.164	5.117	1.078	2.557
p		0.568	< 0.001	0.248	< 0.001	0.284	0.012

Note: Compared with the pre-treatment within the same group, *$p < 0.05$.

3.5. Discontinuation and reduction of nitroglycerin

The total discontinuation and reduction rates of nitroglycerin in the observation group and the control group were 79.17% and 53.19%, respectively ($p < 0.05$). See **Table 8**.

Table 8. Discontinuation and Reduction of nitroglycerin [case (%)]

Group	n	Discontinued	Reduced	Unchanged	Increased	Total discontinued/reduced
Observation group	48	20 (41.67)	18 (37.50)	10 (20.83)	0 (0.00)	38 (79.17)
Control group	47	11 (23.40)	14 (29.79)	19 (40.43)	3 (6.38)	25 (53.19)
χ^2						8.897
p						0.031

4. Discussion

The occurrence of unstable angina is predominantly associated with the rupture or erosion of coronary atherosclerotic plaques, which subsequently triggers platelet aggregation and thrombus formation. This process may be accompanied by coronary artery spasm, leading to narrowing or even occlusion of the coronary lumen, resulting in acute myocardial ischemia and hypoxia. Clinically, unstable angina is characterized by unstable chest pain episodes, prolonged duration, and a higher risk of spontaneous onset, influenced by a combination of traditional cardiovascular risk factors. In traditional Chinese medicine (TCM), angina falls under the category of "chest impediment", a term first recorded in the Huangdi Neijing

(The Yellow Emperor's Classic of Internal Medicine). TCM posits that the occurrence of unstable angina is fundamentally rooted in deficiency of vital Qi, with dietary irregularities, emotional disturbances, or invasion by cold pathogens serving as predisposing factors. These factors lead to the obstruction of the heart vessels by pathogenic factors such as cold coagulation, Qi stagnation, and phlegm turbidity, resulting in impaired blood circulation and the onset of the disease [9]. The pathogenesis is characterized by a combination of deficiency in the root and excess in the manifestations, with various pathogenic factors intermingling. Therefore, treatment should focus on promoting blood circulation to remove blood stasis, unblocking the collaterals to alleviate pain, while also nourishing Qi to strengthen the body's resistance.

The results of this study indicate that, compared to the control group, the observation group exhibited lower scores in TCM syndrome and angina pectoris after treatment, along with a higher overall clinical response rate and nitroglycerin discontinuation/reduction rate ($p < 0.05$). This suggests that the Yiqi Huoxue Decoction can further alleviate the symptom burden in patients with Qi deficiency and blood stasis-type unstable angina, enhance clinical efficacy, and promote a reduction in nitroglycerin usage. Research by Li Zhengyu et al. also pointed out that the Yiqi Huoxue Decoction can effectively improve TCM syndrome manifestations in patients, particularly providing notable relief for symptoms such as chest pain, palpitations, and spontaneous sweating [10]. The analysis suggests that the raw astragalus and ginseng in the formula are both key herbs for replenishing Qi, nourishing and strengthening the heart and spleen, and promoting Qi circulation to enhance blood flow. *Angelica sinensis* nourishes and invigorates the blood, aiding Qi while promoting blood circulation to remove stasis. *Ligusticum chuanxiong* promotes Qi circulation and invigorates the blood, acting as a "blood-invigorating Qi medicine" that facilitates Qi movement to enhance blood flow. *Panax notoginseng* can both remove blood stasis to alleviate pain and stop bleeding without leaving stasis, possessing both blood-activating and vascular-protective effects. When combined, these herbs work synergistically to nourish Qi and strengthen the body, promote blood circulation to unblock the vessels, and remove blood stasis to alleviate pain. This results in improved blood flow to the heart vessels, alleviating chest pain, and replenishing Qi and blood, thereby improving symptoms such as palpitations, shortness of breath, and fatigue. Consequently, this is manifested as a decrease in TCM syndrome and angina symptom scores, an improvement in clinical efficacy, and a reduced need for nitroglycerin. Modern pharmacological studies have shown that *astragalus* primarily contains *astragalus* polysaccharides and astragalosides. The former possesses immunomodulatory and antioxidant effects, inhibiting platelet adhesion and reducing myocardial ischemic injury, while the latter participates in regulating calcium ion homeostasis, contributing to improved myocardial contraction and perfusion. Ginseng contains ginsenosides that can regulate myocardial energy metabolism and improve cardiac function. *Panax notoginseng* contains *Panax notoginseng* saponins, which inhibit platelet aggregation, improve blood rheology, and protect myocardial cells. *Ligusticum chuanxiong* contains ligustrazine, which dilates the coronary arteries and improves coronary blood flow. Angelica sinensis contains ferulic acid, which possesses antioxidant and microcirculation-improving effects. The synergistic action of these components helps inhibit inflammatory responses, improve blood viscosity and microcirculation perfusion, and reduce the severity of myocardial ischemia, thereby decreasing the frequency and duration of angina attacks and enhancing overall treatment efficacy. From the perspective of inflammatory responses, when coronary atherosclerotic plaques are in an unstable state, macrophages and vascular endothelial cells are activated, releasing pro-inflammatory factors such as IL-6. This promotes the synthesis of acute-phase reactant proteins like hs-CRP, enhances endothelial cell inflammatory responses

and platelet adhesion/aggregation, exacerbates local vascular inflammation and thrombotic tendencies, and further reduces myocardial blood supply. Under sustained ischemic conditions, some myocardial cells sustain minor damage, releasing cTnI into the bloodstream. Changes in cTnI levels can reflect the degree of myocardial injury and the risk of disease progression. This study showed that, compared to the control group, the observation group had lower levels of IL-6, hs-CRP, and cTnI after treatment ($p < 0.05$), indicating that the Yiqi Huoxue Decoction can effectively inhibit inflammatory responses and reduce myocardial injury, thereby improving the pathological state in patients with Qi deficiency and blood stasis-type unstable angina. An animal study indicated that *Panax notoginseng* saponins can regulate the cGAS/STING/NF-κB signaling pathway and downregulate the expression of inflammatory factors such as IL-6 and TNF-α, thereby exerting anti-inflammatory effects [11]. Research by Li Zhengyu et al. showed that *Astragalus* can improve myocardial cell ion homeostasis by regulating β-receptor expression in myocardial cells and inhibiting the activity of Na^+-K^+-ATPase and Ca^{2+}-ATPase, thereby reducing myocardial injury caused by ischemia and improving cardiac function [10].

5. Conclusion

In conclusion, the addition of the Yiqi Huoxue Decoction to conventional Western medicine treatment can further improve TCM syndromes and angina symptoms in patients with Qi deficiency and blood stasis-type unstable angina, enhance overall clinical efficacy, inhibit inflammatory responses, reduce myocardial injury, and promote a decrease in nitroglycerin usage, demonstrating good comprehensive therapeutic value.

Disclosure statement

The authors declare no conflict of interest.

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