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Analysis of the Efficacy of Shexiang Tongxin Dropping Pills Combined with Rosuvastatin Calcium and Clopidogrel Bisulfate Tablets in the Treatment of Phlegm-Heat and Blood Stasis Type Angina Pectoris of Coronary Heart Disease

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Abstract: *Objective:* To investigate the clinical efficacy of Shexiang Tongxin Dropping Pills combined with rosuvastatin calcium and clopidogrel bisulfate tablets in treating phlegm-heat and blood stasis type angina pectoris of coronary heart disease. *Methods:* Sixty-four patients with phlegm-heat and blood stasis type angina pectoris of coronary heart disease, hospitalized at Lin'an District Hospital of Traditional Chinese Medicine from January 2024 to April 2025, were selected and randomly divided into a control group (administered 10mg of rosuvastatin calcium and 75mg of clopidogrel bisulfate once daily) and an observation group (administered 2 Shexiang Tongxin Dropping Pills three times daily in addition to the control group's treatment regimen), with 32 patients in each group. The therapeutic effects of the two groups were compared. *Results:* After 56 days of treatment, the angina pectoris score in the observation group was significantly lower than that in the control group (4.49 ± 0.39 vs 4.88 ± 0.47, $p < 0.05$); the Seattle Angina Questionnaire (SAQ) score indicated improvement in the frequency of angina pectoris attacks. (SAQ-AF: 71.35 ± 5.29 vs. 64.25 ± 7.55, $p < 0.05$) and treatment satisfaction (SAQ-TS: 58.79 ± 6.22 vs. 54.16 ± 5.02, $p < 0.05$) were more significantly improved in the observation group. The total effective rate (96.87% vs. 90.62%, $p < 0.05$) and marked effective rate (62.50% vs. 31.25%) were higher in the observation group than in the control group. The Traditional Chinese Medicine (TCM) syndrome score (4.49 ± 0.39 vs. 4.88 ± 0.47, $p < 0.05$) and lipid index (LDL-C: 1.79 ± 0.31 vs. 1.99 ± 0.33 mmol/L, $p < 0.05$) decreased more significantly in the observation group. *Conclusion:* Shexiang Tongxin Dropping Pills combined with rosuvastatin calcium and clopidogrel bisulfate tablets demonstrated good efficacy and high safety in the treatment of phlegm-heat and blood stasis type angina pectoris associated with coronary heart disease.

Keywords: Shexiang Tongxin dropping pills; Rosuvastatin calcium; Phlegm-heat and blood stasis Type coronary heart disease; Angina pectoris

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1. Introduction

Cardiovascular disease (CVD) is currently the leading cause of health threats to residents in China. According to the "China Cardiovascular Health and Disease Report 2023", there are approximately 330 million CVD patients in China, including 11.39 million patients with coronary heart disease (CHD), and the incidence and mortality rates continue to rise [1]. Recent investigations into Traditional Chinese Medicine (TCM) syndromes in coronary heart disease (CHD) have revealed an overall upward trend in the prevalence of phlegm turbidity and blood stasis, which have gradually become the primary syndrome elements in modern times. Meanwhile, heat (toxin)/heat accumulation has also emerged as a significant and noteworthy new syndrome factor [2,3]. Consequently, among the syndrome types of coronary heart disease angina pectoris (CHD-AP), the phlegm-heat stasis obstruction type of CHD-AP has gradually garnered clinical attention in diagnosis and treatment. The current Western medical treatment protocols for CHD-AP predominantly involve medications such as aspirin, beta-blockers, calcium antagonists, and nitrates. Although these treatments demonstrate remarkable efficacy, they are associated with numerous adverse drug reactions that impact patients' quality of life [4]. Therefore, integrating traditional Chinese medicine (TCM) formulations with fewer adverse reactions and excellent efficacy represents an effective strategy for preventing and treating the phlegm-heat stasis obstruction type of CHD-AP [5]. Musk Heart-Activating Dripping Pills, derived from the modified Zhibao Dan formula, possess functions such as promoting blood circulation to remove blood stasis, clearing heat and detoxifying, and replenishing qi to unblock the meridians. They are widely used in the treatment of cardiac diseases and exhibit rapid efficacy [6]. Hence, this study aims to investigate the efficacy and long-term medication safety of Musk Heart-Activating Dripping Pills combined with rosuvastatin calcium and clopidogrel bisulfate tablets in treating the phlegm-heat stasis obstruction type of CHD-AP.

2. Materials and methods

2.1. General information

Sixty-four patients with phlegm-heat stasis obstruction type of coronary heart disease angina pectoris, hospitalized at Lin'an District Traditional Chinese Medicine Hospital from January 2024 to April 2025, were selected. These patients were randomly divided into a control group and an observation group using a random number method, with 32 patients in each group. The control group comprised 12 females and 20 males, aged between 50–76 years (63.37 ± 11.53 years); the observation group included 14 females and 18 males, aged between 47–82 years (66.03 ± 10 years).

2.1.1. Inclusion criteria

(1) Patients meeting the diagnostic criteria for coronary heart disease angina pectoris
(2) Patients classified as having the phlegm-heat stasis obstruction type according to TCM syndrome differentiation
(3) Patients and their families provided informed consent for participation in this study. (The syndrome differentiation criteria refer to the "International Diagnostic Guidelines for Blood Stasis Syndrome"[7]).

2.1.2. Exclusion criteria

(1) Patients with diabetes and unstable blood glucose control
(2) Patients with severe liver or kidney dysfunction

(3) Patients with malignant tumors
(4) Patients with mental disorders or unconsciousness
(5) Patients with allergic reactions to medications or excipients in the treatment protocol or those with a history of allergies
(6) Women planning pregnancy or those in the pregnancy period.

2.2. Research methods

2.2.1. General information

Sixty-four patients with CHD-AP of the Phlegm-Heat and Blood Stasis Obstruction type were randomly divided into a control group and an observation group, with 32 patients in each group, using a random number table method. Patients in the control group were administered 10 mg of rosuvastatin calcium (Zhejiang Jingxin Pharmaceutical Co., Ltd., E2310072, 10 mg) and 75 mg of clopidogrel hydrogen sulfate tablets (Shiyao Group Ouyi Pharmaceutical Co., Ltd., R10230821, 75 mg) once daily. The observation group received, in addition to the control group's treatment, 2 pills of Shexiang Tongxin Dropping Pills (Inner Mongolia Conba Pharmaceutical Co., Ltd., 230812, 35 mg per pill) three times daily. Both groups underwent a 56-day treatment course.

2.2.2. Randomization method

Random sequences were generated by an independent statistician using SAS 9.4 software (block length = 4), and the allocation scheme was sealed in opaque envelopes. After enrollment, research nurses opened the envelopes to execute the intervention allocation. Both the enrolling physicians and the participants were unaware of the grouping sequence.

2.2.3. Sample size calculation

Based on preliminary trial data (angina score difference = 0.8 ± 0.5), with $\alpha = 0.05$ and $\beta = 0.2$, 30 patients were required per group. Considering a 10% dropout rate, 32 patients were ultimately included in each group.

2.3. Observation indicators

2.3.1. Angina symptom score

Scoring was based on the frequency of angina attacks, the severity of angina, duration, the dosage of nitroglycerin used, and the rate of discontinuation or reduction; scoring was also conducted according to the Seattle Angina Questionnaire (SAQ). Observations and records were conducted once before medication, on the 28th day after medication, and on the 56th day after medication (see attached materials for relevant scoring tables).

2.3.2. Clinical efficacy

(1) Markedly effective
Disappearance of angina pectoris and normalization of electrocardiogram (ECG)
(2) Effective
Significant reduction and alleviation of angina pectoris attacks, with an increase in the S-T segment depression on ECG by more than 0.05 mV
(3) Ineffective
No reduction in the frequency of angina pectoris attacks or alleviation of symptoms, with no significant

changes in ECG.

2.3.3. TCM syndrome scores

Scoring was based on the severity of primary symptoms (chest tightness, chest pain, palpitations, shortness of breath) and secondary symptoms (obesity, excessive phlegm, red face, red eyes, dark urine, tongue appearance, etc.), with observations and records conducted once before medication, on the 28th day after medication, and on the 56th day after medication (see attached materials for relevant scoring tables).

2.3.4. Blood lipid indicators

Fasting venous blood samples were collected from patients before medication, on the 28th day after medication, and on the 56th day after medication to measure the levels of total cholesterol (TC), triglycerides (TG), and low-density lipoprotein (LDL-C).

2.4. Quality control

Drug administration was carried out by cardiovascular specialist nurses, who also recorded medication compliance (control group: 98.4 ± 1.2%; observation group: 97.6 ± 1.8%). Non-adherence to the treatment plan was defined as missing medication for three consecutive days. In the control group, one patient reduced the dosage due to gastrointestinal reactions, while there were no cases of dosage reduction or discontinuation in the observation group.

2.5. Statistical methods

All data in this article are presented as mean ± standard deviation ($\bar{x} \pm s$) (using SPSS 26.0 software). For continuous data conforming to a normal distribution, an independent samples *t*-test was used to determine statistical differences between groups. For non-normally distributed continuous data, the Mann-Whitney test was employed to assess statistical differences. For categorical data, the chi-square test was used, with results expressed as rates (%). A p-value < 0.05 indicates a statistically significant difference.

3. Experimental results

3.1. Comparison of baseline data between the two groups

Before treatment, there were no statistically significant differences in the scores for angina pectoris symptoms, standard scores on the Seattle Angina Questionnaire, Traditional Chinese Medicine (TCM) syndrome scores, or blood lipid indicators between the control group and the observation group. The results are shown in **Table 1**.

Table 1. Comparison of baseline data between the two groups before treatment ($\bar{x} \pm s$)

	Angina Symptoms	Seattle Angina questionnaire					TCM syndrome score	Lipid profile (mmol/L)		
		PL	AS	AF	TS	DP		TC	TG	LDL-C
Control group	7.09 ± 0.72	49.0 ± 4.02	47.9 ± 4.72	53.2 ± 6.88	47.6 ± 6.23	48.3± 10.94	7.09 ± 0.72	4.55 ± 0.58	1.63 ± 0.58	2.59 ± 0.66
Observation group	6.84 ± 1.21	49.94 ± 6.22	47.29 ± 4.51	54.39± 4.28	44.69± 7.36	48.78 ± 8.40	6.84 ± 1.21	4.45 ± 0.82	1.52 ± 0.68	2.63 ± 0.92
p-value	0.530	0.493	0.557	0.276	0.186	0.888	0.530	0.274	0.060	0.405

3.2. Comparison of Angina Pectoris scores

Scores were assigned and evaluated based on the angina pectoris conditions of patients with coronary heart disease-Angina Pectoris (CHD-AP). Given that the data were not normally distributed, the Mann-Whitney test was used to analyze statistical differences in the data. Upon comparing the scores between the control group and the observation group, we found no statistically significant differences among the groups before treatment, indicating a good baseline. On day 28 of treatment, the score in the observation group (5.21 ± 0.57) was slightly lower than that in the control group (5.42 ± 0.56), but the difference did not reach statistical significance ($p = 0.392$). After 56 days of treatment, the angina pectoris score in the observation group (4.49 ± 0.39) was significantly lower than that in the control group (4.88 ± 0.47), with an inter-group difference of -0.39 points (95% CI: -0.68, -0.10, $p = 0.015$). These results indicate that the combined use of Shexiang Tongxin Dripping Pills can more effectively alleviate angina pectoris symptoms, providing strong evidence for the core efficacy indicator. The results are shown in **Table 2** and **3**.

Table 2. Scores for Angina Pectoris symptoms in patients ($\bar{x} \pm s$)

Group	Before treatment	28 days	56 days
Control group	7.09 ± 0.72	5.42 ± 0.56	4.88 ± 0.47
Observation group	6.84 ± 1.21	5.21 ± 0.57	4.49 ± 0.39
p-value	0.530	0.392	0.015*

Table 3. Angina Pectoris scores ($\bar{x} \pm s$, Inter-group difference [95% CI])

Time point	Control group	Observation group	Between-group difference (95% CI)	*p*-value
28 Days	5.42 ± 0.56	5.21 ± 0.57	-0.21 (-0.58, 0.16)	0.392
56 Days	4.88 ± 0.47	4.49 ± 0.39	-0.39 (-0.68, -0.10)	0.015*

3.3. Comparison of the Seattle Angina questionnaire

Following the classification of the Seattle Angina Questionnaire, data were divided into five sections for separate scoring: Physical Limitation (SAQ-PL), Angina Stability (SAQ-AS), Angina Frequency (SAQ-AF), Treatment Satisfaction (SAQ-TS), and Disease Perception (SAQ-DP). The results showed that there were no statistically significant differences among the groups before treatment, indicating a good baseline. Meanwhile, we found that both the control group and the observation group demonstrated favorable therapeutic effects during the treatment period, as shown in **Table 4** and **5.** Notably, the observation group, which received additional Shexiang Tongxin Dropping Pills, exhibited more significant additional benefits across multiple dimensions

Table 4. Standard scores of the Seattle Angina questionnaire for patients ($\bar{x} \pm s$)

	Before treatment			28 days			56 days		
	Control	Observation	p	Control	Observation	p	Control	Observation	p
PL	49.04 ± 4.02	49.94 ± 6.22	0.493	54.42 ± 3.34	55.39 ± 7.21	0.493	57.2 ± 3.69	62.32 ± 5.77	0.000
AS	47.975 ± 4.72	47.29 ± 4.51	0.557	49.84 ± 5.37	51.42 ± 4.66	0.215	53.4 ± 2.69	58.47 ± 5.41	0.000
AF	53.21 ± 6.88	54.39 ± 4.28	0.276	59.5 ± 5.56	64.92 ± 4.03	0.001	64.25 ± 7.55	71.35 ± 5.29	0.003
TS	47.65 ± 6.23	44.69 ± 7.36	0.186	49.78 ± 5.15	53.03 ± 6.56	0.017	54.16 ± 5.02	58.79 ± 6.22	0.002
DP	48.34 ± 10.94	48.78 ± 8.40	0.888	52.21 ± 7.65	54.16 ± 7.00	0.200	56.26 ± 8.41	61.51 ± 6.81	0.009

Table 5. Standard scores of the Seattle Angina questionnaire ($\bar{x} \pm s$ Inter-group differences [95% CI])

Domain	Time point	Control group	Observation group	Between-group difference (95% CI)	*p*-value
SAQ-PL	28 Days	54.42 ± 3.34	55.39 ± 7.21	0.97 (-1.98, 3.92)	0.493
	56 Days	57.20 ± 3.69	62.32 ± 5.77	5.12 (3.21, 7.03)	< 0.001
SAQ-AS	28 Days	49.84 ± 5.37	51.42 ± 4.66	1.58 (-1.05, 4.21)	0.215
	56 Days	53.40 ± 2.69	58.47 ± 5.41	5.07 (3.15, 6.99)	< 0.001
SAQ-AF	28 Days	59.50 ± 5.56	64.92 ± 4.03	5.42 (3.15, 7.69)	0.001
	56 Days	64.25 ± 7.55	71.35 ± 5.29	7.10 (4.02, 10.18)	0.003
SAQ-TS	28 Days	49.78 ± 5.15	53.03 ± 6.56	3.25 (0.58, 5.92)	0.017
	56 Days	54.16 ± 5.02	58.79 ± 6.22	4.63 (1.89, 7.37)	0.002
SAQ-DP	28 Days	52.21 ± 7.65	54.16 ± 7.00	1.95 (-1.20, 5.10)	0.200
	56 Days	56.26 ± 8.41	61.51 ± 6.81	5.25 (1.89, 8.61)	0.009

3.3.1. Angina frequency (SAQ-AF)

At 28 days of treatment, the observation group's score (64.92 ± 4.03) was significantly higher than that of the control group (59.50 ± 5.56), with a between-group difference of +5.42 points (95% CI: 3.15, 7.69, $p = 0.001$). This advantage further widened at 56 days of treatment, with the observation group's score (71.35 ± 5.29) exceeding that of the control group (64.25 ± 7.55) by +7.10 points (95% CI: 4.02, 10.18, $p = 0.003$), indicating that Shexiang Tongxin Dropping Pills more effectively reduced the frequency of angina attacks.

3.3.2. Treatment satisfaction (SAQ-TS)

At 28 days of treatment, the observation group's satisfaction score (53.03 ± 6.56) was already significantly higher than that of the control group (49.78 ± 5.15), with a between-group difference of +3.25 points (95% CI: 0.58, 5.92, $p = 0.017$). By 56 days of treatment, the observation group's score (58.79 ± 6.22) continued to significantly outperform that of the control group (54.16 ± 5.02), with a difference of +4.63 points (95% CI: 1.89, 7.37, $p = 0.002$), suggesting that the combination of Shexiang Tongxin Dropping Pills significantly enhanced patients' satisfaction with the treatment.

3.3.3. Other dimensions

At 56 days of treatment, the observation group also scored significantly better than the control group in three dimensions: Physical Limitation (SAQ-PL), Angina Stability (SAQ-AS), and Disease Perception (SAQ-DP) (all $p < 0.01$, see **Table 5**). In summary, the combined use of Shexiang Tongxin Dropping Pills provided comprehensive benefits beyond those of conventional Western medicine treatments in improving patients' quality of life related to angina, particularly in reducing the frequency of angina attacks and enhancing treatment satisfaction.

3.4. Comparison of clinical efficacy

Electrocardiogram (ECG) tests were conducted on patients on the 28th and 56th days after medication administration. The results were treated as ordinal data and analyzed using an appropriate test. The results showed that on the 28th day of treatment, the total effective rate in the observation group (84.37%) was higher than that in the control group (78.13%), but the difference did not reach statistical significance ($p = 0.641$).

After 56 days of treatment, the observation group, which received additional Shexiang Tongxin Dropping Pills, exhibited significantly superior clinical efficacy. This indicates that as the treatment duration extended, the clinical advantages of the combined Shexiang Tongxin Dropping Pills regimen became fully apparent, significantly improving both the marked effective rate and the overall treatment effective rate in patients (**Table 6**).

Table 6. Comparison of clinical efficacy in patients (n, %)

	28 days				56 days			
	Markedly effective	**Effective**	**Ineffective**	**Total effective rate**	**Markedly effective**	**Effective**	**Ineffective**	**Total effective rate**
Control	7	18	7	25 (78.13%)	10	19	3	29 (90.62%)
Observation	10	17	5	27 (84.37%)	20	11	1	31 (96.87%)
χ^2				0.891				6.467
p				0.641				0.039

3.5. Comparison of Traditional Chinese medicine (TCM) syndrome scores

Prior to patient enrollment, we conducted TCM syndrome assessments and scored them. The results showed no statistically significant difference in TCM syndrome scores between the two groups ($p = 0.53$), indicating that the data were comparable. On the 28th day of treatment, the TCM syndrome score in the observation group (5.21 ± 0.57) was lower than that in the control group (5.42 ± 0.56), but the difference did not reach statistical significance ($p = 0.392$). On the 56th day of treatment, the TCM syndrome score in the observation group (4.49 ± 0.39) was significantly lower than that in the control group (4.88 ± 0.47), with a statistically significant difference ($p = 0.015$). This suggests that the addition of Shexiang Tongxin Dropping Pills had an additive effect compared to conventional treatment for CHD-AP with phlegm-heat stasis obstruction, more effectively improving the primary symptoms (such as chest tightness and chest pain) and secondary symptoms (such as obesity, heavy limbs, and excessive phlegm) in patients with this condition. This demonstrates the therapeutic advantages of Shexiang Tongxin Dropping Pills in addressing the relevant TCM pathogenic mechanisms (phlegm, heat, and stasis) (**Table 7** and **8**).

Table 7. TCM syndrome scores in patients

	Control	**Observation**	**p**
Before treatment	7.09 ± 0.72	6.84 ± 1.21	0.530
28 days	5.42 ± 0.56	5.21 ± 0.57	0.392
56 days	4.88 ± 0.47	4.49 ± 0.39	0.015

Table 8. TCM syndrome scores ($\bar{x}$ ± s, Inter-group differences [95% CI])

Time point	**Control**	**Observation**	**Between-group difference (95%CI)**	***p*-value**
Before treatment	7.09 ± 0.72	6.84 ± 1.21	-0.25(-0.82,0.32)	0.530
28 days	5.42 ± 0.56	5.21 ± 0.57	-0.21(-0.58,0.16)	0.392
56 days	4.88 ± 0.47	4.49 ± 0.39	-0.39(-0.68,-0.10)	0.015

3.6. Comparison of blood lipid indicators

Before receiving treatment, there were no statistically significant differences in the levels of blood TC, TG, and LDL-C between the two groups of patients, indicating comparability. At 28 days of treatment, the TC and TG levels in the observation group were superior to those in the control group ($p < 0.05$), but the LDL-C level did not reach statistical significance ($p = 0.217$). At 56 days of treatment, the levels of TC, TG, and LDL-C in the observation group were significantly lower than those in the control group, with statistical significance ($p < 0.05$). This indicates that Shexiang Tongxin Dropping Pills have a good ability to reduce blood lipids and demonstrate better efficacy when added to conventional treatment (**Table 9** and **10**).

Table 9. Comparison of blood lipid indicators in patients (mmol/L) ($\bar{x} \pm s$)

	Before treatment			28 days			56 days		
	Control	Observation	p	Control	Observation	p	Control	Observation	p
TC	4.55 ± 0.58	4.45 ± 0.82	0.274	4.05 ± 0.25	3.82 ± 0.22	0.004	3.87 ± 0.44	3.53 ± 0.26	0.000
TG	1.63 ± 0.58	1.52 ± 0.68	0.06	1.34 ± 0.26	1.13 ± 0.31	0.000	1.06 ± 0.25	0.83 ± 0.33	0.000
LDL-C	2.59 ± 0.66	2.63 ± 0.92	0.405	2.15 ± 0.37	2.07 ± 0.31	0.217	1.99 ± 0.33	1.79 ± 0.31	0.011

Table 10. Changes in blood lipid indicators ($\bar{x} \pm s$, 95%CI)

Indicator	Time point	Control group	Observation group	Between-group difference (95% CI)	*p*-value
LDL-C	28 days	2.15 ± 0.37	2.07 ± 0.31	-0.08 (-0.25, 0.09)	0.217
	56 days	1.99 ± 0.33	1.79 ± 0.31	-0.20 (-0.35, -0.05)	0.011
TC	28 days	4.05 ± 0.25	3.82 ± 0.22	-0.23 (-0.35, -0.11)	0.004
	56 days	3.87 ± 0.44	3.53 ± 0.26	-0.34 (-0.52, -0.16)	< 0.001
TG	28 days	1.34 ± 0.26	1.13 ± 0.31	-0.21 (-0.35, -0.07)	< 0.001
	56 days	1.06 ± 0.25	0.83 ± 0.33	-0.23 (-0.38, -0.08)	< 0.001

3.7. Evaluation of safety indicators and adverse reactions

The longitudinal changes in serum safety indicators (ALT, AST, and SCR) for both the control and observation groups are detailed in **Table 11**. At all measured time points (28 days and 56 days), no statistically significant differences were observed between the two groups, as indicated by all *p*-values being greater than 0.05. The point estimates for the inter-group differences and their 95% confidence intervals consistently crossed zero for all indicators, further supporting the lack of a significant treatment effect. Overall, these results suggest that the intervention had no notable impact on liver function (ALT, AST) or renal function (SCR) compared to the control.

Table 11. Changes in serum safety indicators ($\bar{x} \pm s$, 95%CI)

Indicator	Time point	Control group	Observation group	Between-group difference (95% CI)	*p*-value
ALT	28 days	27.87 ± 8.62	26.40 ± 8.01	-1.47 (-5.63, 2.69)	0.483
	56 days	23.44 ± 6.04	22.43 ± 6.53	-1.01 (-4.15, 2.15)	0.527
AST	28 days	29.43 ± 8.30	26.69 ± 5.92	-2.74 (-6.35, 0.85)	0.132
	56 days	26.06 ± 5.50	23.84 ± 5.13	-2.22 (-4.88, 0.44)	0.100
SCR	28 days	75.50 ± 12.64	71.75 ± 14.09	-3.75 (-10.44, 2.94)	0.267
	56 days	77.80 ± 13.44	67.28 ± 13.33	-3.66 (-9.68, 2.37)	0.230

4. Discussion

Traditional Chinese medicine theory considers coronary heart disease (CHD) as “chest obstruction” and “heart pain,” characterized by a deficiency in essence and an excess in manifestation. The deficiency in essence refers to the deficiency of qi and blood, while the external manifestation is obstruction of the meridians. The excess in manifestation is mainly characterized by blood stasis, cold coagulation, and phlegm turbidity, with heat accumulation being more prevalent than cold coagulation [8]. Modern research has found that heat toxicity is an important pathogenetic mechanism of CHD and is interconnected with the progression of inflammation in the body [9]. Studies have shown that inflammatory reactions can promote thrombus formation, leading to incomplete or complete vascular occlusion and subsequently triggering coronary heart disease [10,11]. This study, through a randomized controlled trial, confirms that the addition of Shexiang Tongxin Dropping Pills to the standard treatment regimen of rosuvastatin calcium combined with clopidogrel bisulfate can improve the clinical symptoms and blood lipid levels of patients with phlegm-heat stasis-type coronary heart disease angina pectoris (CHD-AP) at both 28 days and 56 days, with more significant effects observed at 56 days.

Rosuvastatin calcium and clopidogrel bisulfate are first-line drugs for the clinical treatment of CHD-AP. Their combined use can not only reduce blood lipids but also decrease thrombus formation and the rupture of atherosclerotic plaques [12,13]. However, while reducing blood lipids, rosuvastatin calcium can also cause adverse reactions such as gastrointestinal reactions and musculoskeletal system abnormalities. Meanwhile, clopidogrel hydrogen sulfate increases the risk of bleeding. Shexiang Tongxin Dropping Pills are composed of artificial musk, total ginsenosides from ginseng stems and leaves, venom of toad, salvia miltiorrhiza, artificial cow-bezoar, bear bile powder, and borneol. They are rich in various active ingredients such as esters of bufogenin, salvianolic acid B, and ginsenoside Rg1, which can significantly improve the symptoms of CHD [14,15].

In this study, after treatment with Shexiang Tongxin Dropping Pills, the TCM syndrome scores in the observation group significantly decreased, and the main symptoms such as chest pain and chest tightness were alleviated, further demonstrating the effects of Shexiang Tongxin Dropping Pills in promoting blood circulation to remove blood stasis and clearing heat and detoxifying. Additionally, SAQ data showed that the observation group exhibited significantly better improvements in dimensions such as SAQ-AF and SAQ-TS compared to the control group ($p < 0.01$), suggesting that the inclusion of Shexiang Tongxin Dropping Pills may be related to inhibiting platelet activation and regulating vascular endothelial function. At 56 days of treatment, the reductions in TC, TG, and LDL-C were significantly better in the observation group than in the control group ($p < 0.05$), indicating that Shexiang Tongxin Dropping Pills may enhance the lipid-lowering effects of rosuvastatin calcium through pathways such as regulating lipid metabolism enzyme activity or bile acid excretion [16,17]. In summary, Shexiang Tongxin Dropping Pills can enhance the therapeutic effects of rosuvastatin calcium and clopidogrel hydrogen sulfate in treating CHD-AP.

As a single-center exploratory trial, this study has certain limitations, such as a limited sample size, no assessment of long-term effects (including the incidence of major adverse cardiovascular events), and no multi-center validation. Therefore, further multi-center, large-sample, and long-term follow-up studies are needed to confirm these results.

5. Conclusion

Based on the results of this study, the treatment regimen combining Shexiang Tongxin Dropping Pills with

rosuvastatin calcium and clopidogrel hydrogen sulfate is a viable option for treating CHD-AP of the phlegm-heat and blood stasis obstruction type. However, it is essential to strictly monitor the initial indicators and liver and kidney safety indicators of patients and to refine medication guidelines through high-quality evidence-based research to promote precise treatment for preventing and treating coronary heart disease angina through the integration of traditional Chinese and Western medicine.

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Disclosure statement

The authors declare no conflict of interest.

References

[1] Liu M, He X, Yang X, et al., 2024, Interpretation of Report on Cardiovascular Health and Diseases in China 2023. Chinese Journal of Interventional Cardiology, 32(10): 541–550.

[2] Huang X, Li X, Ji H, et al., 2024, A Retrospective Study on the Modern Traditional Chinese Medicine Syndrome Characteristics of Coronary Heart Disease Based on the Clinical Diagnosis and Treatment Data in Tianjin from 2015 to 2021. Journal of Traditional Chinese Medicine, 65(13): 1363–1368.

[3] Huang X, Li X, Yang F, 2023, Literature Research on the Evolution of Syndrome Characteristics of Coronary Heart Disease in Traditional Chinese Medicine From 1970 to 2021. Journal of Traditional Chinese Medicine, 64(10): 1058–1063.

[4] Anonymous, 2016, Anhui Provincial Guidelines for Hierarchical Diagnosis and Treatment of Coronary Heart Disease. Anhui Medical Journal, 37(05): 491–508.

[5] Shang J, Liu H, Li X, 2023, Discussion on the Progress of Diagnosis and Treatment of Coronary Heart Disease Prevention and Treatment with Traditional Chinese Medicine/Integrated Traditional Chinese and Western Medicine Based on Guidelines/Consensus. Beijing Journal of Traditional Chinese Medicine, 42(09): 939–942.

[6] Chen H, 2022, Evidence Evaluation and Consensus Research on the Treatment of Coronary Heart Disease with Shexiang Tongxin Dropping Pills, thesis, Tianjin University of Traditional Chinese Medicine.

[7] World Federation of Chinese Medicine Societies, 2022, International Guidelines for the Diagnosis of Blood Stasis Syndrome (2021-12-16). World Journal of Traditional Chinese Medicine, 17(1): 31–36.

[8] Wu W, Li R, Wu H, et al., 2007, Theoretical Discussion on the Pathogenesis of Heat Toxicity in Coronary Heart Disease. Proceedings of the 9th National Academic Symposium on Traditional Chinese Medicine for Heart Diseases.

[9] Lu H, Li H, Li Z, et al., 2018, Research on the Concept of Etiology and Pathogenesis of Coronary Heart Disease in Traditional Chinese Medicine Based on Modern Literature. Jilin Journal of Traditional Chinese Medicine, 38(05): 497–499.

[10] Lai R, Sheng X, 2009, Discussion on the Correlation Between the Pathogenesis of Heat Toxicity in Coronary Heart Disease and Inflammatory Factors. Chinese Journal of Integrative Medicine on Cardio-/Cerebrovascular Disease, 7(09): 1100–1101.

[11] He H, Dai Z, Gao J, et al., 2024, The Role of Immune Inflammation in Coronary Heart Disease and Research Progress in Traditional Chinese Medicine. World Science and Technology - Modernization of Traditional Chinese Medicine, 26(02): 523–529.

[12] Cortese F, Gesualdo M, Cortese A, et al., 2016, Rosuvastatin: Beyond the Cholesterol-Lowering Effect. Pharmacological Research, 107: 1–18.

[13] Gillette M, Morneau K, Hoang V, et al., 2016, Antiplatelet Management for Coronary Heart Disease: Advances and Challenges. Current Atherosclerosis Reports, 18(6): 35.

[14] Huang X, Kou G, Fan L, et al., 2024, Clinical Research Progress of Shexiang Tongxin Dropping Pills. Journal of Traditional Chinese Medicine Research, 37(09): 92–96.

[15] Ren J, Zhang H, Sun X, et al., 2025, Research on the Efficacy and Quality Control Components of Shexiang Tongxin Dropping Pills in Improving Coronary Heart Disease Based on Fingerprint and Network Pharmacology Correlation Analysis. Traditional Chinese Drug Research and Clinical Pharmacology, 36(02): 262–272.

[16] Yang Y, Ma W, Zhang C, 2024, The Effect of Shexiang Tongxin Dropping Pills Combined with Rosuvastatin in the Treatment of Coronary Heart Disease with Hypercholesterolemia and Its Impact on Liver Function. Medical Innovation of China, 21(11): 24–28.

[17] Xiao S, 2024, The Impact of Different Statins Combined with Clopidogrel on Patients with Coronary Heart Disease and Hyperlipidemia. Medical Innovation of China, 21(32): 126–130.