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Efficacy of Chinese Medicine Formulae Combined with Western Medicine for Coronary Heart Disease: A Meta-Analysis Based on the "Qi Deficiency and Phlegm Stasis" Theory

Qiu Siwen[1,2,a], Ju Tongle[3,b], Li Jing[1,2,c,*]

[1]*The First Clinical Medical College, Shaanxi University of Chinese Medicine, Xianyang, Shaanxi, China*
[2]*Department of Traditional Chinese Medicine, Shaanxi Provincial People's Hospital, Xi'an, Shaanxi, China*
[3]*Yan'an Medical College, Yan'an University, Yan'an, Shaanxi, China*
[a]*qiusiwen0821@163.com*,[b]*2060262092@qq.com*,[c]*drlijing@126.com*
**Corresponding author*

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Abstract: The objective of the study is to systematically evaluate the efficacy of formulas based on the "Qi Deficiency and Phlegm Stasis" theory combined with Western medicine in the treatment of coronary heart disease (CHD) and their effect on atherosclerosis-related factors. The method applied in this paper is searched CNKI, Chongqing VIP Database, Wanfang Database, CBM, PubMed, Web of Science, Cochrane Library, and Embase for randomized controlled trials on the combination therapy, and the literature was included according to the inclusion criteria of this study, and the risk bias was evaluated. We use RevMan 5.4 and STATA 18.0 software to combine and analyze all the data to evaluate the clinical efficacy of the combination therapy and its impact on atherosclerosis-related indicators. As a result, a total of 32 RCTs involving 3,142 patients were included, and the meta-analysis results showed that the group receiving the qi-tonifying, blood-activating, and phlegm-resolving formula combined with Western medicine has advantages in improving clinical efficacy, angina efficacy, electrocardiogram efficacy, and traditional Chinese medicine symptom efficacy, and in reducing triglyceride (TG), total cholesterol (TC), and low-density lipoprotein cholesterol (LDL-C) levels, as well as increasing high-density lipoprotein cholesterol (HDL-C) levels. The combination therapy is better than Western medicine alone, with statistical significance. However, there was no statistically significant difference in the improvement of high-sensitivity C-reactive protein (hs-CRP). Regarding safety, 20 RCTs reported adverse events, and no significant difference was found between the two groups. The curative effect of the combination therapy is superior, but due to the quality limitations of the included studies, more rigorously designed and larger-scale RCTs are needed for further verification.

1. Introduction

Coronary heart disease is a common cardiovascular condition caused by atherosclerotic changes in the coronary arteries, leading to myocardial insufficient blood supply, hypoxia, or necrosis. This disease has been classified as one of the types with a relatively high incidence rate among cardiovascular system diseases[1]. With socioeconomic development and changes in lifestyle, the prevalence of this disease has shown a continuous upward trend in recent years[2], making it an urgent public health challenge that requires resolution. Regarding the diagnosis and treatment of coronary heart disease, although modern medicine has developed and widely applied a prevention and treatment system that includes standardized pharmacological therapy, interventional procedures, and surgical operations, numerous difficulties remain. These include common complications such as arrhythmias, heart failure, and angina pectoris, as well as phenomena like antiplatelet drug resistance and no-reflow or slow-flow phenomena after revascularization, all of which necessitate further research[3]. In the theoretical framework of traditional Chinese medicine, coronary heart disease is considered a syndrome of "deficiency in origin and excess in superficiality." Clinically, the main treatment methods often involve replenishing qi, promoting blood circulation and removing blood stasis, and eliminating phlegm and toxins[4]. To systematically evaluate the efficacy and evidence strength of the method of replenishing qi, promoting blood circulation, and removing phlegm in treating this disease, this study integrates systematic evaluation and meta-analysis methods to conduct an evidence-based medical evaluation of the therapeutic effects of relevant prescriptions. This protocol has been registered on the PROSPERO platform with the registration number CRD420251182330.

2. Materials and Methods

2.1. Literature Search

A search strategy was developed in accordance with database retrieval requirements. The Chinese search terms included coronary heart disease, ischemic heart disease, angina pectoris, chest obstruction, Qi deficiency with phlegm and blood stasis, replenishing Qi, activating blood, and resolving phlegm, and randomized controlled trials. The English search terms included Coronary Disease, ischemic heart disease, stenocardia, Chest Pain, Qi deficiency with phlegm and blood stasis, and RCT. The search covered eight Chinese and English databases, including CNKI, Wanfang, VIP, SinoMed, PubMed, Web of Science, Cochrane Library, and Embase. Randomized controlled trials (RCTs) published from the inception of each database to August 28, 2025, were retrieved to evaluate the therapeutic effects of formulas based on the "Qi deficiency with phlegm and blood stasis" theory combined with Western medicine in patients with coronary heart disease.

2.2. Inclusion Criteria

2.2.1. Study Type

Published RCTs on the treatment of coronary heart disease using formulas based on the "Qi deficiency with phlegm and blood stasis" theory in domestic and international journals. The use of blinding was not mandatory, and the language was restricted to Chinese and English.

2.2.2. Study Subjects

Patients meeting the clinical diagnostic criteria for coronary heart disease, without concurrent severe diseases such as acute myocardial infarction, heart failure, or severe liver, brain, or kidney

diseases.

2.2.3. Interventions

The control group received conventional Western medicine treatment. The replenishing Qi, activating blood, and resolving phlegm group was treated with formulas based on the "Qi deficiency with phlegm and blood stasis" theory combined with Western medicine. Inclusion criteria required that the core effects of the formula be explicitly recorded as replenishing Qi, activating blood, and resolving phlegm, or include descriptions with similar meanings. If the effects of the formula were not directly stated, they were determined by analyzing the main categories of its constituent herbs. When the herbs in the formula were primarily those that replenish Qi, activate blood, and resolve phlegm, the formula was considered to have the primary therapeutic effects of "replenishing Qi, activating blood, and resolving phlegm."

2.2.4. Outcome Measures

Clinical efficacy, angina pectoris efficacy, electrocardiogram (ECG) efficacy, and traditional Chinese medicine (TCM) symptom efficacy were assessed as primary indicators. Lipid metabolism parameters, including total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C), were analyzed to evaluate improvements in atherosclerosis-related factors, while high-sensitivity C-reactive protein (hs-CRP) was measured as an inflammatory marker. Additionally, adverse reactions were systematically recorded to assess the safety profile of the intervention.

2.3. Exclusion Criteria

Non-RCTs, reviews, and basic experimental studies; duplicate publications, studies with incomplete information or inaccessible full texts; studies with flawed designs, inconsistent interventions, or inappropriate control settings; studies that did not clearly report outcome measures; studies with a total sample size of less than 50.

2.4. Literature Screening and Data Extraction

To ensure consistency and standardization in the literature screening process, two researchers conducted a preliminary screening to fully understand the procedures for literature inclusion and key data extraction. Based on this, they independently completed the screening and data extraction of relevant studies and cross-checked the results. In case of disagreements, a third researcher was invited to participate in discussions to reach a consensus. The data extracted in this study primarily included: basic literature information, baseline characteristics of subjects, intervention details of each group, risk of bias assessment elements, and outcome measures and adverse reactions of the studies.

2.5. Literature Quality Assessment

To ensure the objectivity and accuracy of the methodological quality assessment, two researchers independently evaluated the methodological quality of the studies and cross-checked the results. In case of disagreements, a third researcher was involved in the decision-making process. Using the risk of bias assessment tool recommended by the Cochrane Collaboration, a comprehensive evaluation was conducted for each included study from six aspects: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other potential influencing factors. The risk of bias

for each study was classified as "low risk," "high risk," or "unclear."

2.6. Statistical Methods

Data analysis was performed using RevMan 5.4 and STATA 18.0 software. For categorical data, the relative risk (RR) was used as the effect measure; for continuous data, the mean difference (MD) was used as the effect measure. All results were presented with 95% confidence intervals. Heterogeneity among studies was assessed using heterogeneity tests: if $P > 0.1$ and $I^2 \leq 50\%$, a fixed-effects model was used; otherwise, a random-effects model was applied, and further sensitivity and subgroup analyses were conducted to explore the sources of heterogeneity. When the number of included studies was ≥ 10, funnel plots and Egger's test were used to evaluate potential publication bias.

3. Results

3.1. Literature Search and Screening Process

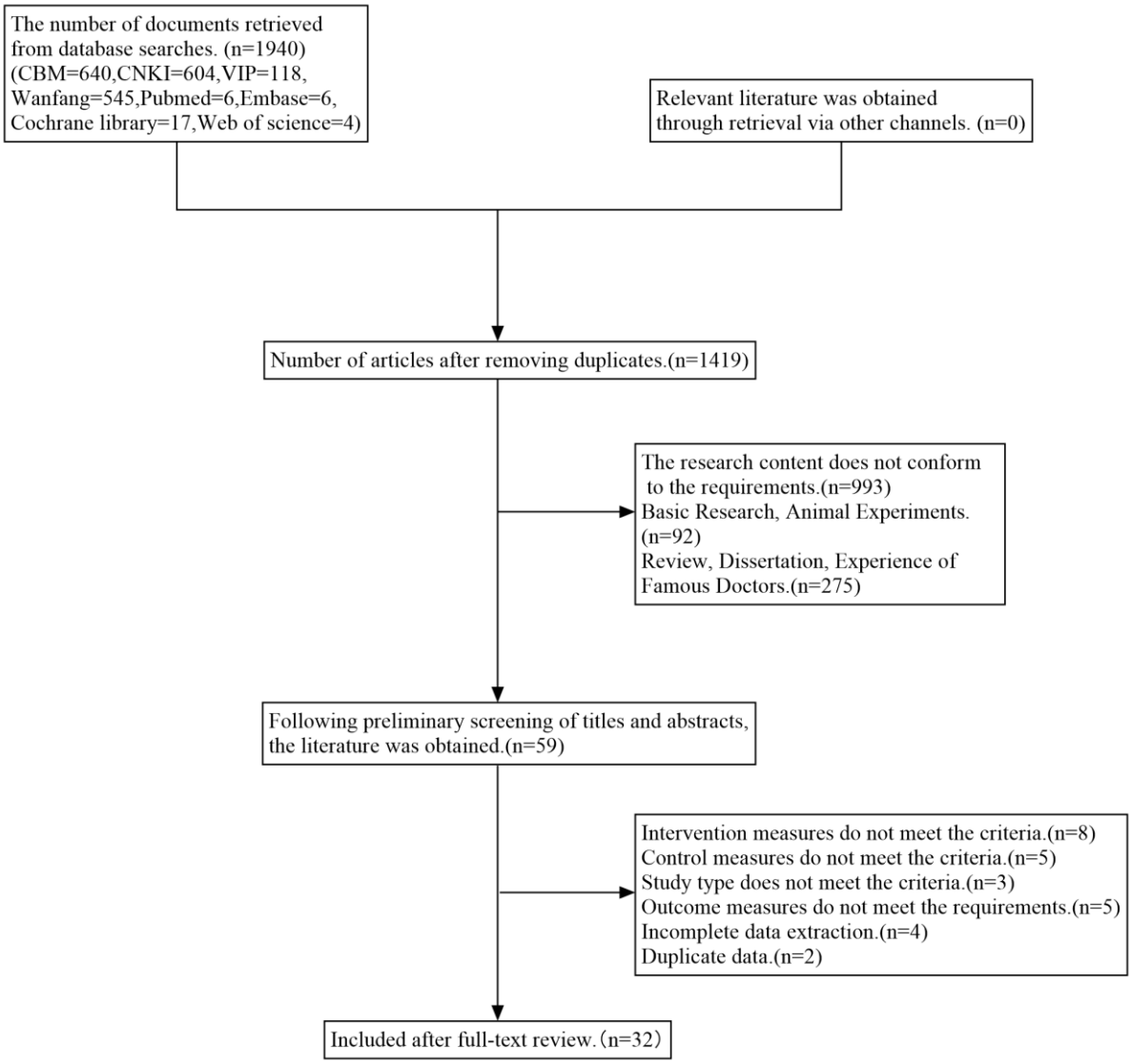

Figure 1: Literature Screening Process.

A preliminary search identified a total of 1,940 relevant articles. After duplicate checking using NoteExpress software and manual verification, 1,419 articles were retained. An initial screening based on titles and abstracts excluded 993 articles that did not match the research content, 92 animal experiments and basic studies, and 275 reviews, dissertations, and records of famous doctors' experiences. Following the initial screening, the remaining 59 articles were reviewed in full text, and 32 articles were ultimately included, among which 2 were in English, as shown in Figure 1.

3.2. Basic Characteristics of the Included Literature

A total of 32 RCTs [5-36] were included, with a total sample size of 3,142 cases, comprising 1,632 cases in the Yiqi Huoxue Huatan group and 1,510 cases in the control group. The smallest sample size was 58 cases [34], and the largest was 304 cases[31]. All included studies had clearly defined inclusion and exclusion criteria, and the baseline data among the groups were comparable. Regarding the distribution of disease types, 12 studies[7, 10, 14-18, 21, 29, 31, 32, 36]focused on stable angina pectoris, 9 studies[5, 8, 11, 13, 19, 20, 22, 26, 33]focused on unstable angina pectoris, and the remaining 11 studies [6, 9, 12, 23-25, 27, 28, 30, 34, 35] did not specify the type of angina pectoris. In terms of treatment duration, there was some variation in the intervention periods across studies, with the shortest being 2 weeks [30] and the longest being 24 weeks [14, 31, 32], as shown in Table 1.

Table 1: Information summary table.

number	Inclusion in the study	sample size (T/C)	age		Types of Angina Pectoris	course of treatment	intervention study		outcome measures
			T	C			T	C	
1	Li Gang2009	76/47	34-69	35-68	UAP	4 weeks	YQHTQY+Conventional Western Medicine	Conventional Western Medicine	②③⑤⑦⑧⑨⑩
2	Kan Shufang2008	120/80	40-82	41-80	-	4 weeks	YQHTHX+Conventional Western Medicine	Conventional Western Medicine	②③
3	Wu Huanlin2006	30/30	61.90±9.31	61.93±8.33	SAP	6 months	Deng's Coronary Heart Capsules+Conventional Western Medicine	Nifedipine Tablets	②③④⑩
4	Zhou Yuwen2009	60/58	59.5±9.0	57.0±10.6	UAP	3 months	Modified Baoshentongluo Decoction+Conventional Western Medicine	Conventional Western Medicine	③⑤⑥⑦⑧⑩
5	Li Jialong2007	64/60	61.3±4.6	62.5±5.1	-	4 weeks	Buzhong Ditan Decoction+Conventional Western Medicine	Conventional Western Medicine	②③⑩
6	Zhao Shiwei2013	30/30	62.63±8.712	63.37±8.712	SAP	4 weeks	QXCG+Conventional Western Medicine	Conventional Western Medicine	②③⑩
7	Hei Jiaming2014	39/39	50.51±2.53	52.52±2.15	UAP	4 weeks	YXHXQY+Conventional Western Medicine	Conventional Western Medicine	①③⑤⑥⑦⑧⑩
8	Cai Zhongbiao2017	41/41	55.8±9.76	56.3±10.64	-	4 weeks	shen hong hua zhuo tong luo granules+Conventional Western Medicine	Conventional Western Medicine	①
9	Jiao Shougang2005	50/42	58.6	56.7	UAP	8 weeks	SZHX+Conventional Western Medicine	Conventional Western Medicine	①③⑤⑥⑦⑩
10	Yang Hong2017	43/43	61.18±6.61	61.03±7.51	SAP	24 weeks	Coronary Blood-Flow Promoting Formula+Conventional Western Medicine	Conventional Western medicine + placebo of traditional Chinese medicine	①
11	Wu Qian2025	36/36	57.42±9.09	58.24±10.36	SAP	12 weeks	Danlou Tablets+Conventional Western Medicine	Conventional Western medicine	⑤⑦⑧⑨⑩
12	Li Shanshan2023	34/34	61.95±4.79	60.46±5.38	SAP	12 weeks	Tongbi Decoction+Conventional Western Medicine	Conventional Western medicine	①⑩
13	Wei Jiawang2014	30/30	-	-	SAP	4 weeks	Modified Wen Dan Decoction+Conventional	Conventional Western medicine	①②③⑤⑥⑦⑨

14	Zhang Chao2021	48/47	68.58±7.34	69.06±9.78	SAP	12 weeks	Western Medicine Cardiac Pain Relief Granules+Conventional Western Medicine	Conventional Western medicine	②③④⑩
15	Feng Xiaoyan2005	50/50	59.40±8.67	56.1±7.81	UAP	1 months	Cardiac Pain Relief Capsules+Conventional Western Medicine	Conventional Western medicine	②③⑩
16	Wang Qiang2007	30/30	42±7.51	41.6±6.99	UAP	4 weeks	YQHXHT+Conventional Western Medicine	Conventional Western medicine	①⑨
17	Xue Jingui2013	50/50	65.48±5.72	65.18±5.93	SAP	3 months	YQHXHT+Conventional Western Medicine	Conventional Western medicine	④⑤⑦⑧⑨
18	Cao Shoupei2009	32/30	60.18±5.63	61.21±6.39	UAP	21 Days	XBTL+Conventional Western Medicine	Conventional Western medicine	①③⑤⑥⑦
19	Huang Heyi2020	42/43	51.18±1.53	51.27±1.62	-	1 months	YQQRHT+Conventional Western Medicine	Conventional Western medicine	①
20	Chen Jie2015	40/40	57.3±5.8	57±5.7	-	1 months	YQHXTL+Conventional Western Medicine	Conventional Western medicine	①⑩
21	Wu Dong2016	35/35	60.23±2.48	61.4±2.63	-	1 months	YQHXTM+Conventional Western Medicine	Conventional Western medicine	①
22	Chen Kanggui2009	32/32	55.53±6.78	57.32±6.38	UAP	4 weeks	YQHTHX+Conventional Western Medicine	Conventional Western medicine	②③④
23	Tan Weiming2012	125/125	-	-	-	8 weeks	YQTM+Conventional Western Medicine	Conventional Western Medicine + Compound Danshen Dripping Pills	①⑩
24	Guo Jinsong2005	36/34	60.4	61.1	-	1 months	YQHXHT+Conventional Western Medicine	Conventional Western medicine	②③
25	Qu Litao2017	35/35	62.3±6.1	62.1±6.1	SAP	4 weeks	Modified Wen Dan Decoction+Conventional Western Medicine	Conventional Western medicine	①⑩
26	Sun Jiulin2005	60/40	56.4±9.28	63.5±12.41	-	2 weeks	YQXBHX+Conventional Western Medicine	Conventional Western medicine	①③⑤⑥⑦⑩
27	Zang Zhijuan2009	60/58	59.5±9.0	57±10.6	UAP	3 months	Baoxin Tongluo Decoction+Conventional Western Medicine	Conventional Western medicine	③⑩
28	Li Cunhou2014	30/28	58.4±6.7	57.2±6.9	-	60 Days	BQHX+Conventional Western Medicine	Conventional Western medicine	①⑩
29	Lu Jiang2006	45/34	65.7	61.2	-	1 months	YQHX+Conventional Western Medicine	Conventional Western medicine	①③
30	Liu Xingkui2012	40/40	-	-	SAP	4 weeks	ZYTM+Conventional Western Medicine	Conventional Western medicine	②③
31	Zeng Li2024	152/152	62.12	60.17	SAP	24 weeks	Danlou tablets+Conventional Western Medicine	Conventional Western medicine	②③④⑤⑦⑧⑩
32	WU Huanlin2005	31/31	62.13±9.24	62.06±8.23	SAP	24 weeks	CHDC+Conventional Western Medicine	Conventional Western medicine	②③④⑩

Note: T: intervention group C: control group SAP: stable angina cordis UAP: unstable angina pectoris -: not clear outcome measures: ①clinical efficacy ②efficacy of Angina Pectoris ③efficacy of ECG ④efficacy of Traditional Chinese Medicine ⑤TG ⑥TC ⑦LDL-C ⑧HDL-C ⑨hs-CRP ⑩untoward effect.

3.3. Quality Assessment of Included Studies

A total of 32 published journal articles were included as the analytical subjects in this study. The Cochrane Risk of Bias assessment tool was employed to systematically evaluate the methodological quality of each study. Six studies [8, 10, 14, 23, 29, 35] used a random number table, five studies [7, 12, 15, 18, 33] used computer-generated random allocation, and one study [24] used the coin-toss method; these were assessed as having a low risk of bias. Two studies [11, 36] used random allocation based on the order of consultation, and one study [9] used allocation based on odd/even dates of consultation; these were assessed as having a high risk of bias. The remaining 17 studies [5, 6, 13, 16, 17, 19-22, 25-28, 30-32, 34] did not specifically describe the randomization method and were assessed as having an unclear risk of bias. Regarding allocation concealment, two studies [7, 15] used sealed envelopes, and one study [33] used central randomization; these were assessed as having a low risk of bias. The

remaining 29 studies [5, 6, 8-14, 16-32, 34-36] did not mention whether allocation concealment was used and were assessed as having an unclear risk of bias. Concerning blinding, except for one study [15] which blinded the researchers, and one study [33] which blinded the outcome assessors, the remaining 30 studies [5-14, 16-32, 34-36] did not mention specific blinding methods. Regarding other bias domains, except for four studies [12, 23, 25, 27] where reporting bias could not be ascertained and were assessed as having an unclear risk of bias, all other included studies were assessed as having a low risk of bias in terms of completeness of outcome data, reporting bias, and other potential sources of bias,as shown in Figures 2 and 3.

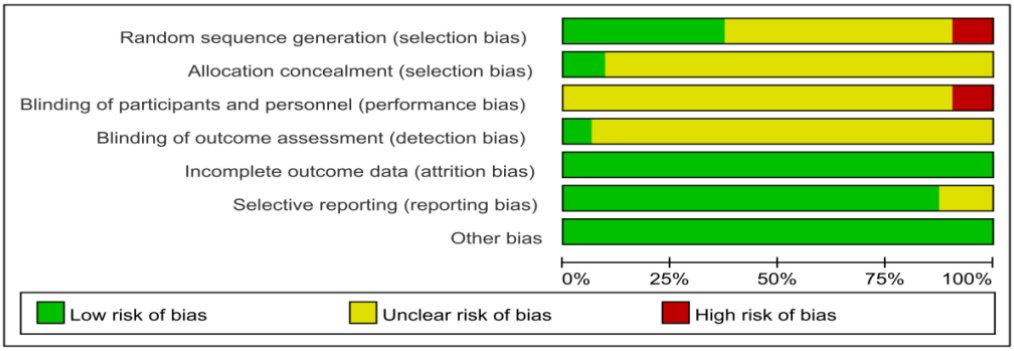

Figure 2: Overall risk bias assessment diagram included in the study.

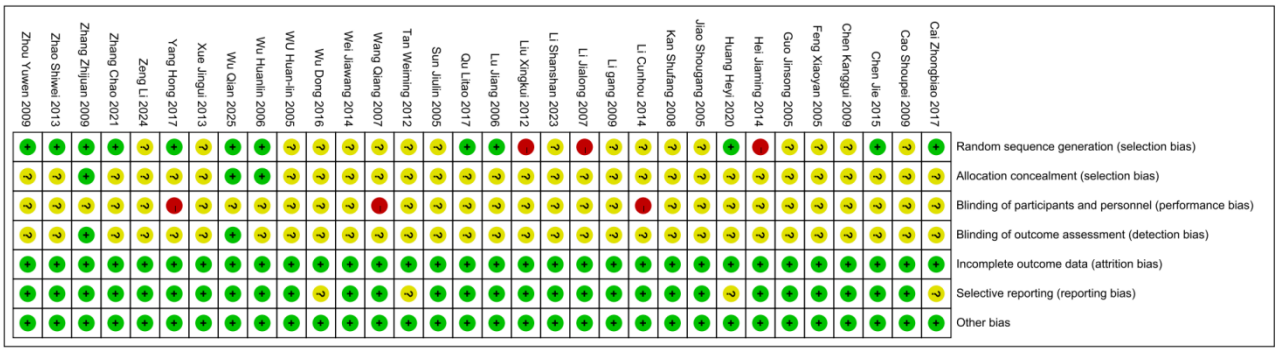

Figure 3: Specific risk bias assessment diagram included in the study.

3.4. Meta-analysis

3.4.1. Primary Outcome Measures

3.4.1.1. Clinical Efficacy

Table 2: Subgroup Analysis of Clinical Efficacy.

Groups	Subgroup	sample size（T/C）	heterogeneity test		Meta analyse		
			I^2（%）	P	RR	95%CI	P
type	SAP	142/142	0%	0.7	1.28	[1.15,1.44]	<0.0001
	UAP	151/141	0%	0.96	1.26	[1.10,1.44]	0.001
	-	424/392	9%	0.36	1.3	[1.22,1.39]	<0.00001
Course of treatment	≤ 1months	435/403	0%	0.98	1.24	[1.16,1.33]	<0.00001
	> 1months	282/272	0%	0.56	1.36	[1.25,1.48]	<0.00001

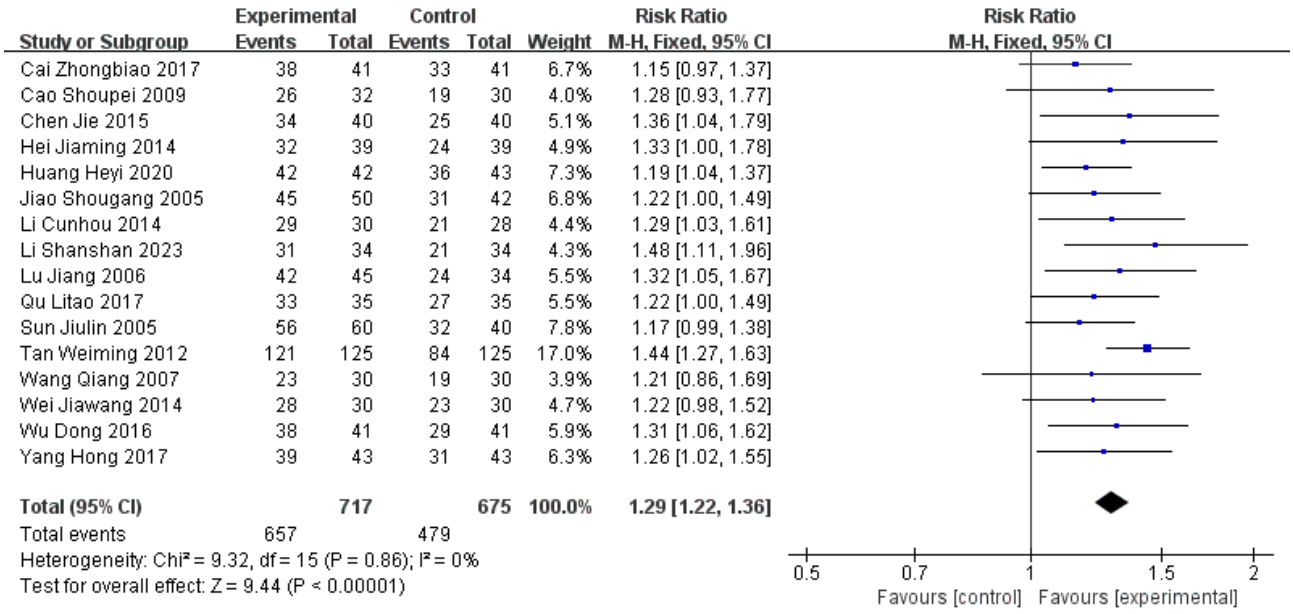

Figure 4: Meta-analysis of clinical efficacy.

Sixteen studies[11-14, 16, 17, 20, 22-25, 27, 29, 30, 34, 35]evaluated clinical efficacy, encompassing a total of 1392 patients. The heterogeneity test revealed no significant heterogeneity (I^2=0%, P=0.86), so a fixed-effects model was used for pooling. The pooled results indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of clinical efficacy, with a statistically significant difference (RR=1.29, 95%CI [1.22, 1.36], P<0.00001), as shown in Figure 4. Subgroup analysis by disease type showed that the Yiqi Huoxue Huatan group was superior to the control group in stable angina (RR=1.28, 95%CI [1.15, 1.44], P<0.0001), unstable angina (RR=1.26, 95%CI [1.10, 1.44], P=0.001), and unclassified angina (RR=1.3, 95%CI [1.22, 1.39], P<0.00001), with statistically significant differences. Subgroup analysis by treatment duration indicated that the Yiqi Huoxue Huatan group was superior to the control group in both the≤1 month duration (RR=1.24, 95%CI [1.16, 1.33], P<0.00001) and the >1 month duration (RR=1.36, 95%CI [1.25, 1.48], P<0.00001), with statistically significant differences,as shown in Table 2.

3.4.1.2. Angina Pectoris Efficacy

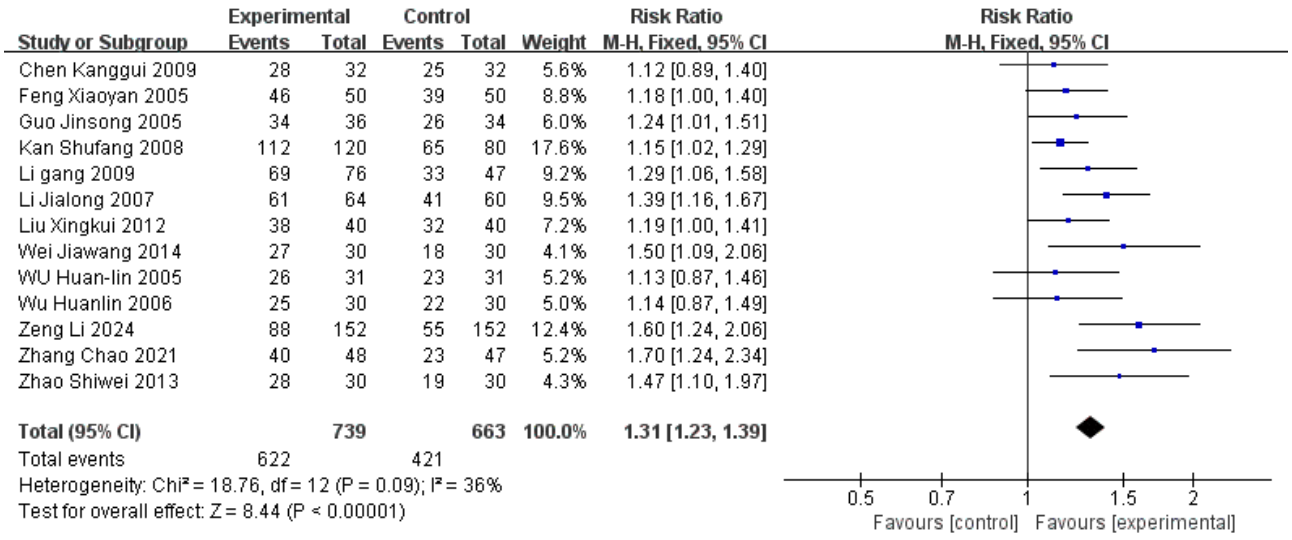

Figure 5: Meta-analysis of the efficacy of angina pectoris.

Thirteen studies[5-7, 9, 10, 17-19, 26, 28, 31, 32, 36]evaluated angina pectoris efficacy, involving a total of 1402 patients. The heterogeneity test revealed mild heterogeneity (I²=36%, P=0.09), and a fixed-effects model was used for pooling. The pooled results indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of angina pectoris efficacy, with a statistically significant difference (RR=1.31, 95%CI [1.23, 1.39], P<0.00001), as shown in Figure 5.

3.4.1.3. Electrocardiogram (ECG) Efficacy

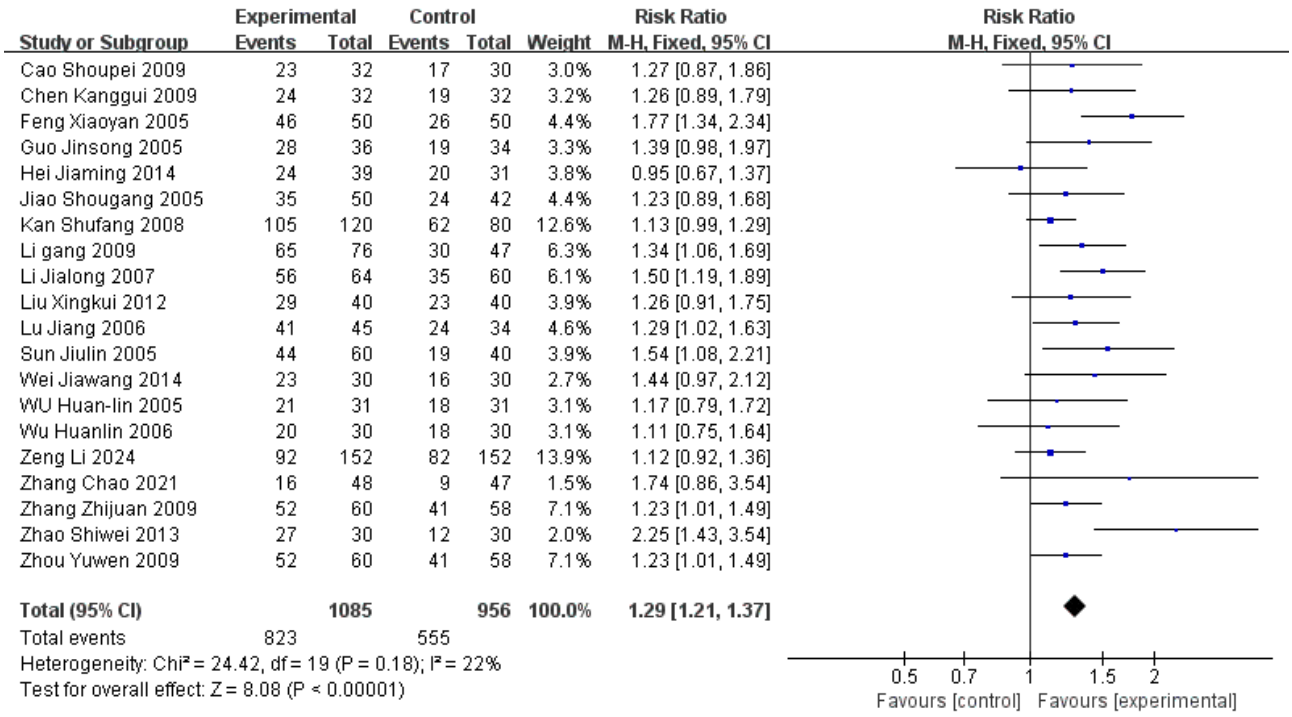

Figure 6: Meta-analysis of ECG efficacy.

Twenty studies[5-11, 13, 17-19, 22, 26, 28, 30-33, 35, 36]evaluated ECG efficacy, including a total of 2041 patients. The heterogeneity test showed mild heterogeneity (I²=22%, P=0.18), so a fixed-effects model was employed for pooling. The pooled results indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of ECG efficacy, with a statistically significant difference (RR=1.29, 95%CI [1.21, 1.37], P<0.00001), as shown in Figure 6.

3.4.1.4. Traditional Chinese Medicine (TCM) Symptom Efficacy

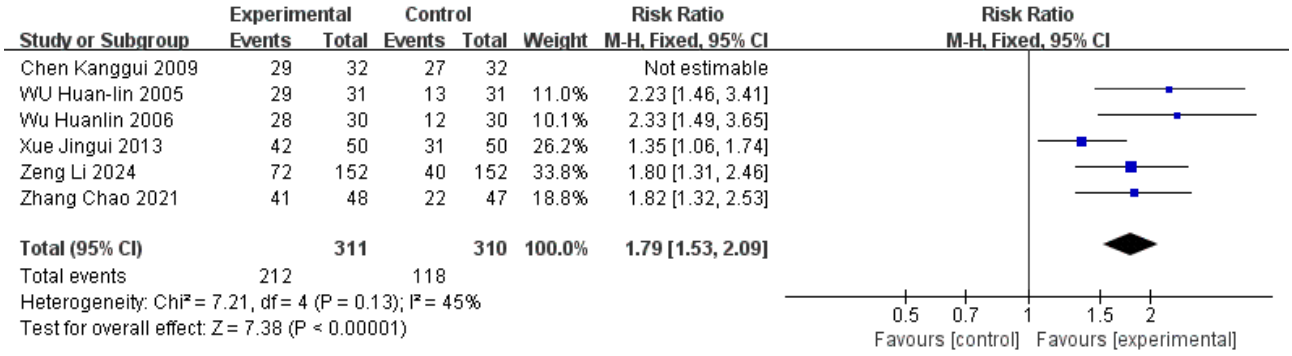

Figure 7: Meta-analysis of the efficacy of Traditional Chinese Medicine.

Six studies[7, 18, 21, 26, 31, 32]evaluated TCM symptom efficacy, comprising a total of 621 patients.

The heterogeneity test revealed high heterogeneity among the study data. Sensitivity analysis showed that after excluding the study by Chen KangGui et al[28], heterogeneity decreased significantly (I^2=45%, P=0.13). Further analysis did not identify clear clinical heterogeneity, so the possibility of statistical methodology causing the heterogeneity could not be ruled out; the study was temporarily excluded. After exclusion, a fixed-effects model was used for pooling. The final result indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of TCM symptom efficacy, with a statistically significant difference (RR=1.79, 95%CI [1.53, 2.09], P<0.00001), as shown in Figure 7.

3.4.2. Secondary Outcome Measures

3.4.2.1. Triglyceride (TG) Efficacy

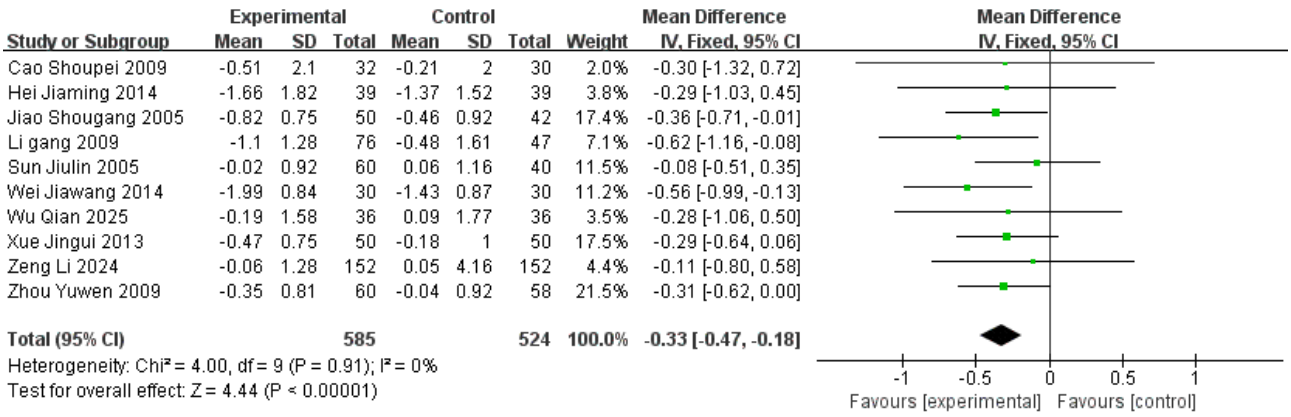

Figure 8: Meta-analysis of the efficacy of TG.

Ten studies[5, 8, 11, 13, 15, 17, 21, 22, 30, 31]evaluated TG efficacy, involving a total of 1109 patients. The heterogeneity test revealed no significant heterogeneity in the study data (I^2=0%, P=0.91), and a fixed-effects model was used for pooling. The pooled results indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of TG efficacy, with a statistically significant difference (MD=-0.33, 95%CI [-0.47, -0.18], P<0.00001), as shown in Figure 8.

3.4.2.2. Total Cholesterol (TC) Efficacy

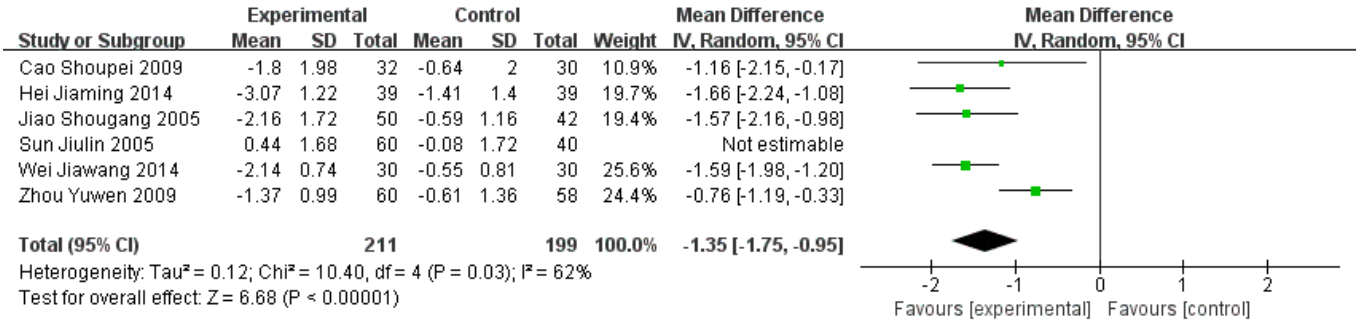

Figure 9: Meta-analysis of the efficacy of TC.

Six studies[8, 11, 13, 17, 22, 30]evaluated TC efficacy, encompassing a total of 410 patients. The heterogeneity test revealed high heterogeneity among the study data. Sensitivity analysis showed that after excluding the study by Sun JiuLin et al[30], heterogeneity decreased significantly (I^2=62%, P=0.03). Further analysis suggested that the treatment duration in this study was significantly shorter than in others, which might have caused the heterogeneity; the study was temporarily

excluded. After exclusion, a random-effects model was used for pooling. The final result indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of TC efficacy, with a statistically significant difference (MD=-1.35, 95%CI [-1.75, -0.95], P<0.00001), as shown in Figure 9.

3.4.2.3. Low-Density Lipoprotein Cholesterol (LDL-C) Efficacy

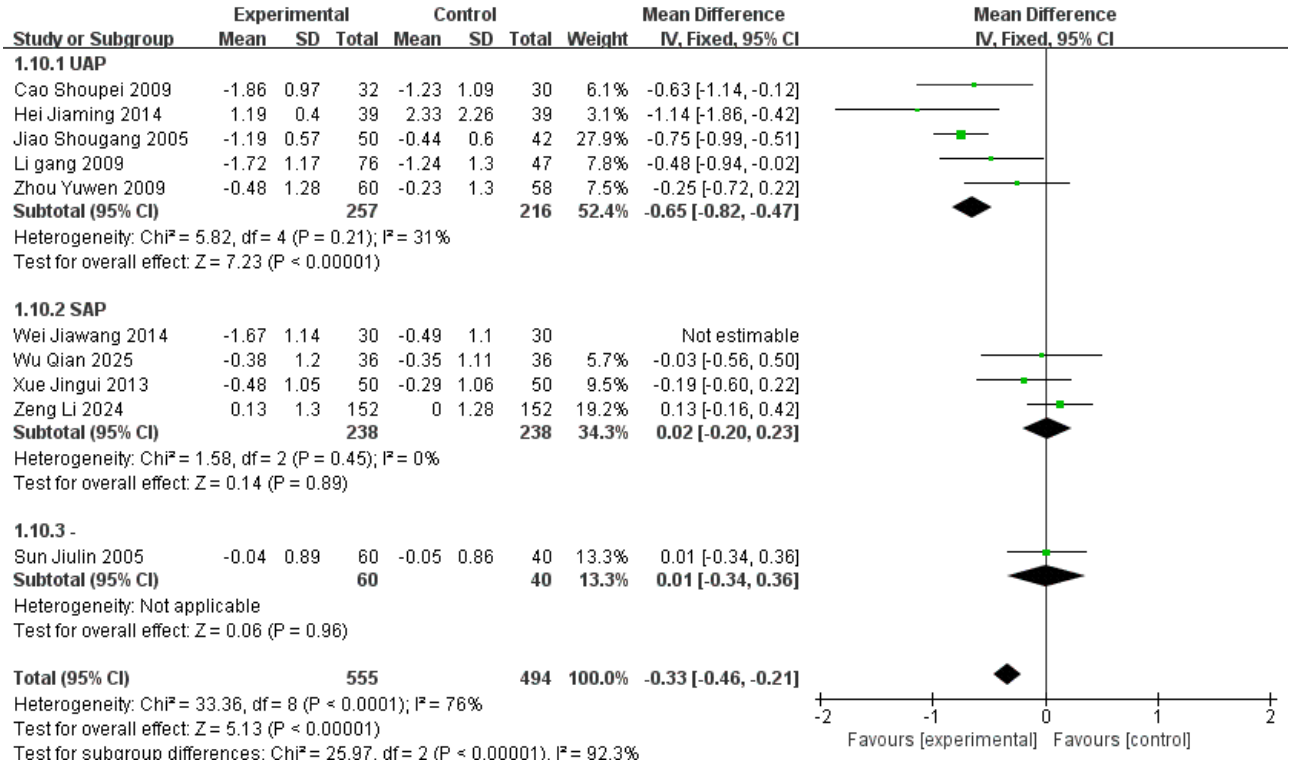

Figure 10: Meta-analysis of the efficacy of LDL-C.

Ten studies[5, 8, 11, 13, 15, 17, 21, 22, 30, 31]evaluated LDL-C efficacy, involving a total of 1109 patients. The heterogeneity test revealed high heterogeneity (I^2 = 78%, P < 0.00001), and a random-effects model was used for pooling. The pooled results indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of LDL-C efficacy, with a statistically significant difference (MD=-0.41, 95% CI [-0.70, -0.13], P=0.004). Further subgroup and sensitivity analyses were conducted. Subgroup analysis indicated that the type of angina was an important factor influencing LDL-C efficacy. In the unstable angina subgroup, heterogeneity was low (I^2=31%, P=0.21), and the Yiqi Huoxue Huatan group showed superior LDL-C efficacy (MD=-0.65, 95%CI [-0.82, -0.47], P<0.00001). In the stable angina subgroup, heterogeneity was high; after excluding the study by Wei Jia Wang et al. [17], heterogeneity decreased significantly (I^2=0, P=0.45). Further analysis suggested that baseline LDL-C levels in that study were significantly higher than in other groups, and differences in disease severity could not be ruled out as a cause of heterogeneity; the study was temporarily excluded. After exclusion, results for the stable angina subgroup showed no statistically significant difference in LDL-C efficacy (MD=0.02, 95%CI [-0.20, 0.23], P=0.89). The unclassified group contained only one study and was not statistically meaningful,as shown in Figure 10.

3.4.2.4. High-Density Lipoprotein Cholesterol (HDL-C) Efficacy

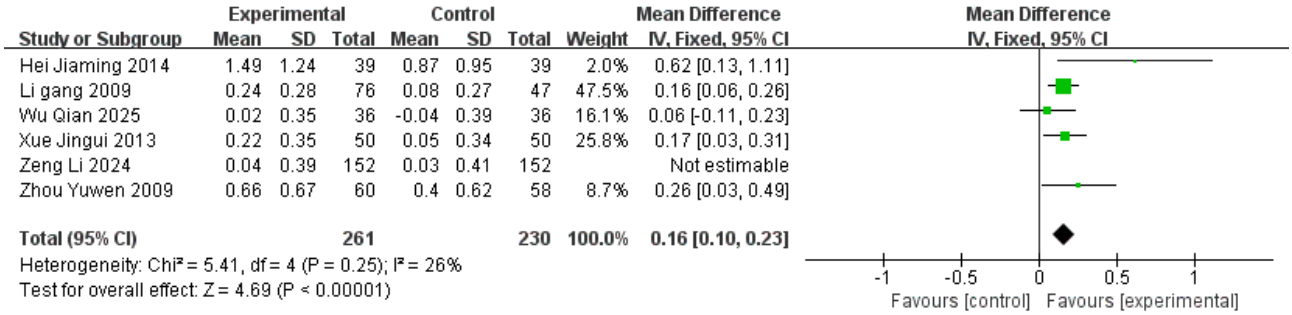

Figure 11: Meta-analysis of the efficacy of HDL-C.

Six studies[5, 8, 11, 15, 21, 31]evaluated HDL-C efficacy, involving a total of 795 patients. The heterogeneity test revealed moderate heterogeneity. Sensitivity analysis showed that after excluding the study by Zeng Li et al[31], heterogeneity decreased significantly (I^2=26%, P=0.25). Further analysis suggested that the sample size of this study was significantly larger than others, giving it excessive weight in the pooled analysis and thus causing substantial heterogeneity; it was temporarily excluded. After exclusion, a fixed-effects model was used for pooling. The final result indicated that the Yiqi Huoxue Huatan group was significantly superior to the control group in terms of HDL-C efficacy, with a statistically significant difference (MD=0.16, 95%CI [0.10, 0.23], P<0.00001), as shown in Figure 11.

3.4.2.5. High-Sensitivity C-Reactive Protein (hs-CRP) Efficacy

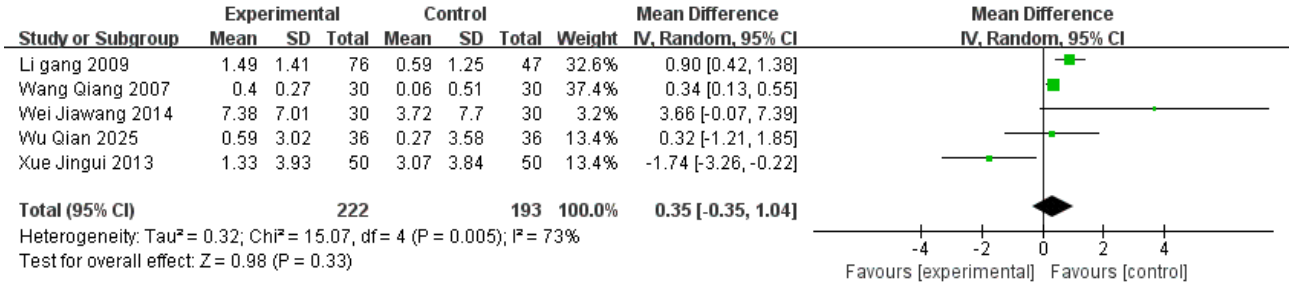

Figure 12: Meta-analysis of hs-CRP efficacy.

Five studies[5, 15, 17, 20, 21]evaluated hs-CRP efficacy, involving a total of 415 patients. The heterogeneity test revealed high heterogeneity among the study data (I^2=73%, P=0.005), and a random-effects model was used for pooling. Further sensitivity and subgroup analyses were conducted, but heterogeneity did not decrease significantly; therefore, no studies were excluded. The final results showed no statistically significant difference between the two groups in terms of hs-CRP efficacy (MD=0.35, 95% CI [-0.35, 1.04], P=0.33), as shown in Figure 12.

3.4.2.6. Adverse Reactions

Twenty studies[5, 7-11, 13-16, 18, 19, 24, 27, 29-34]reported adverse reactions. Adverse events in the Yiqi Huoxue Huatan group included emergency PCI (1 case), nausea/vomiting (5 cases), gastrointestinal discomfort (3 cases), rash (1 case), myalgia (2 cases), liver function abnormality (1 case), diarrhea (3 cases), headache/flushing/dizziness (7 cases), and unspecified adverse reaction types (21 cases). Adverse events in the control group included emergency PCI (1 case), nausea/vomiting (5 cases), gastrointestinal discomfort (4 cases), myalgia (2 cases), liver function abnormality (1 case), diarrhea (1 case), headache/flushing/dizziness (6 cases), worsened headache with nausea (1 case), and unspecified adverse reaction types (15 cases). The heterogeneity test revealed moderate

heterogeneity (I^2=50%, P=0.05), and a fixed-effects model was used for pooling. The pooled results indicated no statistically significant difference in the incidence of adverse reactions between the Yiqi Huoxue Huatan group and the control group (RR=0.84, 95%CI [0.56, 1.27], P=0.42). An analysis of potential causes of adverse reactions is as follows: Nitrates may induce headache due to their vasodilatory effects; in patients with a history of gastric ulcers, the use of non-steroidal anti-inflammatory drugs such as aspirin may exacerbate gastrointestinal mucosal irritation; statins may trigger rhabdomyolysis and myopathy, and may also cause liver function abnormalities; additionally, some patients may experience epigastric discomfort or nausea potentially related to the odor or taste of the medication,as shown in Figure 13.

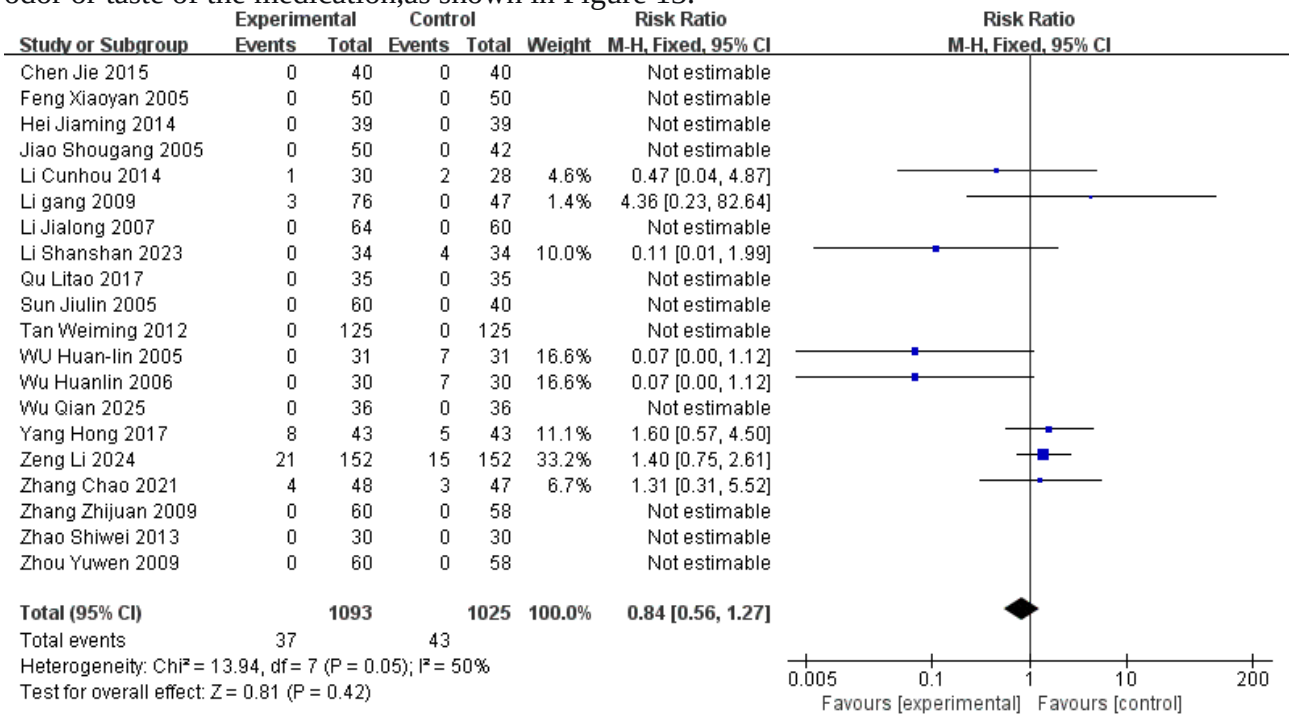

Figure 13: Meta-analysis of adverse reactions.

3.5. Publication Bias

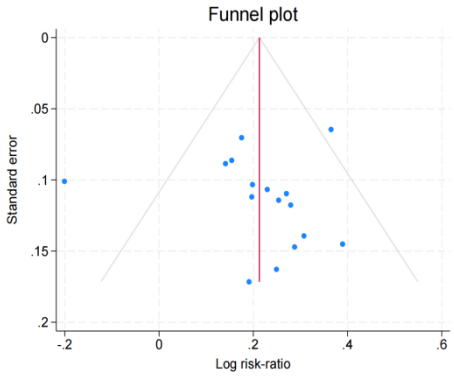

Figure 14: funnel plot of clinical efficacy.

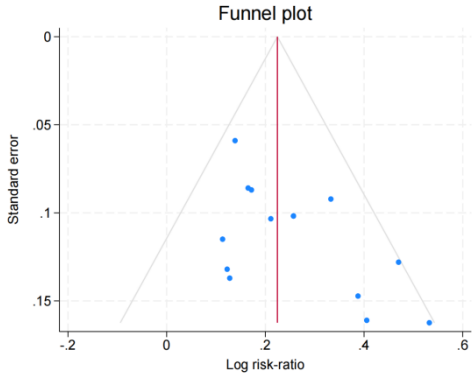

Figure 15: Funnel plot of angina efficacy.

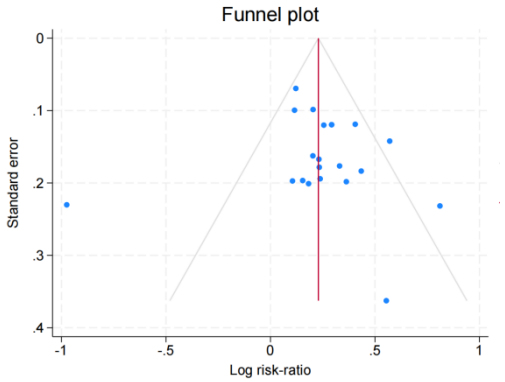

Figure 16: Funnel plot of electrocardiogram efficacy.

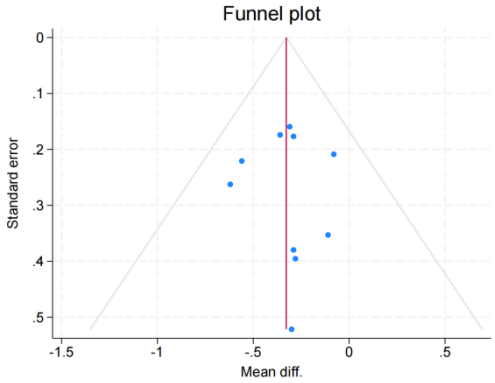

Figure 17: Funnel plot of TG efficacy.

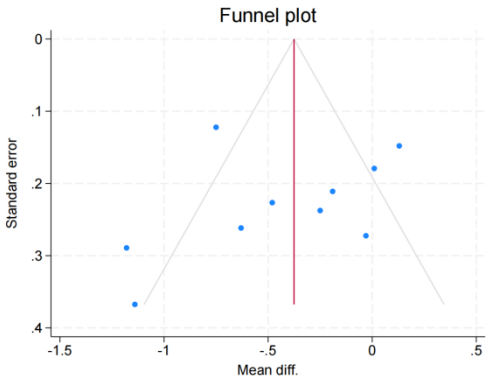

Figure 18: Funnel plot of LDL-C efficacy.

Publication bias was assessed for outcome measures that included more than 10 studies. Funnel plot analysis showed that the scatter points for clinical efficacy, ECG efficacy, TG efficacy, and LDL-C efficacy were generally symmetrically distributed along the vertical line, and Egger's test yielded P-values greater than 0.05, suggesting a low possibility of publication bias. Regarding angina pectoris efficacy, the distribution of points in the funnel plot showed poor symmetry, indicating that this result might be subject to some degree of publication bias. This phenomenon could potentially be attributed to the limited methodological quality of some included studies or the non-publication of some negative results, as illustrated in Figures 14 to 18.

4. Discussion

Coronary heart disease (CHD) is a common and frequently occurring disease that poses a serious threat to human health. Modern research has shown that atherosclerosis (AS) is one of the primary causes of CHD; therefore, reducing the incidence of AS is crucial for the prevention of CHD. Current Western medical treatments primarily focus on lipid-lowering, antiplatelet therapy, vasodilation, and anticoagulation[37]. Although modern medicine has achieved remarkable progress in the prevention and treatment of CHD, numerous clinical challenges remain.

In traditional Chinese medicine (TCM) theory, CHD falls under the categories of "chest bi" (chest obstruction) and "heart pain." Its pathogenesis can be summarized as "yang deficiency and yin excess, with root deficiency and branch excess." Qi deficiency, as the core pathological basis, is a key intrinsic factor in the development of this disease. Deficiency of heart qi leads to weakened heart yang, resulting in insufficient propulsion of qi and blood, which in turn causes blood stasis. Simultaneously, qi deficiency affects the distribution of body fluids, leading to the accumulation of dampness and the formation of turbid phlegm. The combination of phlegm turbidity and blood stasis obstructs the heart vessels and impairs heart yang. Based on this pathogenesis, treatment should focus on supplementing qi and reinforcing deficiency, supplemented by promoting blood circulation, resolving blood stasis, and eliminating phlegm and turbidity [38].

In recent years, accumulating clinical evidence has demonstrated the efficacy of Chinese herbal medicines with actions of supplementing qi, activating blood circulation, and resolving phlegm in treating CHD[39]. This study shows that combining conventional Western medical treatment with Chinese herbal medicines based on the principles of supplementing qi, activating blood circulation, resolving blood stasis, and eliminating phlegm further improves the clinical efficacy, angina relief, electrocardiogram (ECG) outcomes, and TCM symptom scores in CHD patients. Regarding lipid metabolism, this combination therapy effectively reduces total cholesterol (TC), triglycerides (TG), and low-density lipoprotein cholesterol (LDL-C) levels while increasing high-density lipoprotein cholesterol (HDL-C) levels.

Safety assessments indicate that the reported adverse reactions are mostly associated with Western medical treatments or drug intolerance due to patients' underlying conditions. No severe adverse events have been reported in the available literature, suggesting that this therapeutic approach has a favorable safety profile. To explore the prescription characteristics of this treatment principle, this study systematically analyzed medication data from 32 included studies. A total of 76 Chinese herbal medicines were identified, with a cumulative usage frequency of 327 times. Among them, Astragalus membranaceus (Huangqi), Salvia miltiorrhiza (Danshen), Ligusticum chuanxiong (Chuanxiong), Allium macrostemon (Xiebai), Paeonia lactiflora (Chishao), and Poria cocos (Fuling) exhibited relatively high usage frequencies.

Modern pharmacological research suggests that these qi-supplementing, blood-activating, and phlegm-resolving Chinese herbal medicines exert multiple effects, including inhibiting inflammatory responses, improving lipid metabolism disorders, and promoting the repair of

damaged vascular endothelium[39].

5. Conclusions

However, certain heterogeneity exists in the clinical trial designs of the included studies, and some lack rigorous randomization, blinding, and allocation concealment. Additionally, most studies are limited by small sample sizes and are primarily based on single-center data, which may introduce publication bias and restrict the generalizability of the findings. Future research should prioritize large-scale, multicenter studies that adhere to standardized diagnostic criteria and emphasize objective outcome assessments to provide higher-level evidence-based medical support.

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