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Distribution of traditional Chinese medicine pattern types and prognostic risk factors in patients undergoing percutaneous coronary intervention (PCI): a systematic review and meta-analysis

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A B S T R A C T

Objective To clarify the distribution of traditional Chinese medicine (TCM) pattern and its associated risk factors after percutaneous coronary intervention (PCI), and evaluate the reporting quality of existing studies to guide future research standardization.

Methods English databases including PubMed, Cochrane Library, and Web of Science, as well as Chinese databases including China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (VIP), and Wanfang Database were searched to retrieve papers about PCI. The time span for the paper retrieval was set from the foundation of the databases to October 1, 2023. Statistical analyses were performed using Stata 12 and Python (V 3.9). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement was used to assess the reporting quality of included studies.

Results Overall, 1 356 articles were selected, and 40 cross-sectional studies were included with 10 270 participants. The most common TCM patterns before, one to two weeks after, and six months to one year after PCI was Qi stagnation and blood stasis (n = 261, 36.45%), intertwined phlegm and blood stasis (n = 109, 27.18%), and Qi deficiency and blood stasis (n = 645, 37.03%), respectively. Smoking [odds ratio (OR) = 1.15, 95% confidence interval (CI) (0.83 – 1.47), I^2 = 24.7%, P = 0.257], pattern of congealing cold and Qi stagnation [OR = 4.62, 95% CI (1.37 – 7.86), I^2 = 61.6%, P = 0.074], and low-density lipoprotein (LDL) [OR = 1.38, 95% CI (0.92 – 1.85), I^2 = 12.2%, P = 0.286] were risk factors for restenosis. Hypertension [OR = 7.26, 95% CI (3.54 – 14.88), I^2 = 91.6%, P = 0.001], and overweight [i.e., body mass index (BMI) > 23] [OR = 1.20, 95% CI (1.07 – 1.35), I^2 = 85.3%, P = 0.009] were significant risk factors of concomitant anxiety.

Conclusion This systematic review and meta-analysis revealed that patients with different TCM pattern types have distinct characteristics and risk factors after PCI. More high-quality studies are warranted to provide supportive evidence for future research and clinical practice.

1 Introduction

Coronary atherosclerotic heart disease, also known as coronary heart disease (CHD), occurs when the coronary arteries become blocked or narrowed due to atherosclerosis, leading to reduced blood flow and oxygen supply to the heart muscle in patients [1, 2]. According to the China

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Cardiovascular Health and Disease Report (2021), there are 11 million individuals suffering from CHD in China at present, which not only impairs their quality of life but also imposes a significant economic burden on both their families and society [3]. Percutaneous coronary intervention (PCI) is a well-established medical procedure that can rapidly restore blood flow in ischemic myocardium by opening up blocked vessels [4]. Despite the advancements in PCI treatment, its efficacy in reducing cardiac iron load and strengthening cardiac function remain limited. A considerable number of patients still experience adverse events such as chest pain and postoperative heart palpitations, which drastically affect their quality of life, postoperative benefits, and prognosis [5].

Traditional Chinese medicine (TCM), with its unique diagnostic approach of the pattern type, offers a holistic perspective on disease management by identifying imbalances within the body's natural systems and providing individualized treatments [6-8]. In TCM philosophy, a disease consists of two aspects: "bìng" (病) means "disease entity" or "illness", and "zhèng" (证) refers to patterns of disharmony or functional disturbances within the body's functional entities, such as Qi and blood. These TCM patterns are thought to reflect intrinsic health status and the pathophysiology of patients [9]. Given the multifaceted nature of CHD and the procedural aftermath of PCI, understanding these patterns is crucial for anticipating patient recovery trajectories and optimizing postoperative care [10].

While existing studies have individually reported on these patterns and the accompanying risk factors in PCI population [3, 7], a combined and systematic synthesis of these findings is essential to inform and potentially transform clinical practices by integrating conventional and TCM approaches. Therefore, the rationale for conducting this systematic review lies in the compelling need to bridge this knowledge gap.

By aggregating and analyzing the information on TCM patterns among PCI patients, this systematic review and meta-analysis aims to systematically analyze the distribution of TCM patterns and elucidate the risk factors for PCI patients, and evaluate the reporting quality of studies pertaining to TCM pattern types to recommend areas of improvement for future research endeavors. Furthermore, by dissecting the associated risk factors linked to these TCM patterns, we wish to offer clinically valuable prognostic tools tailored to individual patient needs.

2 Data and methods

The conduction and reporting of this review were guided by the Cochrane Handbook for Systematic Reviews and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement [11]. As our study is a systematic review and meta-analysis, it does not involve any ethical issues, thus exempting it from requiring approval from an institutional review board. A comprehensive study protocol can be found on the Prospective Register of Systematic Reviews (PROSPERO) (https://www.crd.york.ac.uk/PROSPERO/) with registration number CRD42023417607.

2.1 Inclusion and exclusion criteria

Observational studies, particularly those that are cross-sectional in design, are adept at capturing the variety of TCM pattern presentations in real-world scenarios and are most reflective of the customary clinical practices within TCM. Therefore, studies were included if: (i) CHD patients who underwent PCI; (ii) TCM pattern types reported following TCM diagnostic criteria with detailed descriptions of each pattern's characteristics (TCM pattern differentiation was defined according to established diagnostic criteria within TCM, which involves a comprehensive assessment that includes patient inquiry and objective examinations such as tongue and pulse diagnostics. To ensure standardization across included studies, only those adopting recognized TCM syndrome classification systems were considered. For details, please see the Supplementary Material S1); (iii) reported data that can be used for prevalence and/or correlation calculations; (iv) prospective or retrospective observational clinical trials.

Studies were excluded if they were: (i) case reports, letters, editorials, protocols, and narrative reviews; (ii) duplicate publications; (iii) cell and animal experimental studies; (iv) research lacking detailed data; (v) clinical patients with multiple syndrome elements composing different pattern types. Besides, data solely reporting on individual pattern elements such as blood stasis, phlegm dampness, or Qi deficiency were also excluded.

2.2 Data sources and search strategy

English databases including PubMed, the Cochrane Library, and Web of Science, as well as Chinese databases including China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (VIP), and Wanfang Database were searched to retrieve papers about PCI. The time span for the paper retieval was set from the foundation of the databases to October 1, 2023. The search keywords included ("percutaneous transluminal coronary intervention" OR "PCI" OR "percutaneous coronary intervention") AND ("coronary heart disease" OR "coronary artery disease" OR "coronary disease") AND ("Chinese medicine" OR "traditional medicine"). The reference lists of the studies were manually searched to identify additional studies. Searches were also performed on the website (ClinicalTrials.gov) for studies that have been registered and are in the completed phase, but have not yet been made available for publication.

2.3 Selection criteria and data extraction

The titles and abstracts of studies identified in the databases were independently screened by two reviewers using a standardized approach. Full-text articles were obtained from all potentially eligible studies. Any disagreements regarding research qualifications were resolved through discussion or consultation with a third reviewer. Eligible studies underwent thorough screening, and a data extraction form was developed to record information such as authors, publication year, patients' gender and age, subtype of CHD (e.g., unstable angina pectoris, stable angina pectoris, acute ST-segment elevation myocardial infarction, and acute non-ST-segment elevation myocardial infarction), number of diseased vessels, TCM pattern type, comorbidities, adverse cardiovascular events, and laboratory test indicators.

To address the question of restenosis, risk factors were selected based on both their clinical relevance as informed by pre-existing literature and their frequency of reporting within identified studies. Only those factors that have been statistically analyzed concerning the occurrence of restenosis PCI were included. The selection aimed to encompass a comprehensive range of biometric indicators, clinical history elements, and TCM-specific patterns.

This information was recorded using Excel 2019. To mitigate bias and ensure a rigorous review process, any disagreements between reviewers during the data extraction were resolved through consultation with a third expert reviewer.

2.4 Data analysis

Prevalence refers to the proportion of events occurring in a population during a specific period compared to the total number of events in the study population during that same period [12, 13]. We extracted data on the number and percentage of participants with CHD after PCI from all included studies to calculate the combined prevalence of this condition. Additionally, we pooled continuous variable data such as age, blood pressure, and duration of CHD, by recombining mean and standard deviation (SD) values reported in different studies based on sample size. To evaluate risk factors, odds ratios (OR) and their corresponding 95% confidence intervals (CI) were obtained from eligible studies and summarized using Stata 12 software [14]. In stratified meta-analyses, the literature data were divided into subgroups according to the influencing factors of patients after PCI, including characteristics of influencing factors (e.g., age, gender, BMI, blood pressure, heart rhythm, and smoke); CHD classification (e.g., unstable angina, stable angina pectoris, acute ST-segment elevation coronary infarction, and acute non-ST-segment elevation coronary infarction); vascular lesion, comorbidities, TCM pattern types and laboratory test indicators (e.g., triglyceride, total cholesterol, low-density lipoprotein, blood glucose, and D-dimer) The results may be limited due to potential confounding factors not being controlled for in univariate logistic regression analysis. Therefore, multivariate logistic regression data were included for meta-analysis purposes.

According to the *Cochrane Handbook* Version 6.4 (2023) [15], heterogeneity was assessed using the Q test to estimate the SD of effect sizes. The I^2 index was utilized to determine the level of variability in effect sizes and the proportion of observed variability attributable to true heterogeneity. Heterogeneity levels were categorized as low ($I^2 < 25\%$), moderate ($25\% \leqslant I^2 < 50\%$), or high ($I^2 \geqslant 50\%$). $P < 0.05$ indicated significant heterogeneity among included studies based on performance qualification statistics. The fixed-effects model and the random-effects model were based on different assumptions [16]. Since this study will perform an explicit population-specific grouping of each subgroup. The identification of odds ratios in the present meta-analytical procedure is performed according to the fixed-effects model.

2.5 Sensitivity analysis and publication bias

To ascertain the robustness of our findings, a sensitivity analysis was conducted for the main outcomes. We employed a "leave-one-out" approach [17], individual studies were systematically removed from the meta-analysis to evaluate the impact of each study on the overall effect size. This analysis is beneficial for identifying any single study that could disproportionately influence the meta-analytic summary estimates. To assess publication bias, Egger's linear regression test was used with statistical significance set at $P < 0.05$ [18].

2.6 Criteria for risk of bias assessment

Evaluating the risk of bias within the included studies was performed using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [19, 20], which was helpful in assessing the transparency and completeness of reporting in observational studies. These items contain various sections such as title and abstract (item 1), introduction (items 2 and 3), methods (items 4 – 12), results (items 13 – 17), discussion (items 18 – 21), and additional information regarding funding sources (item 22). Specifically, we evaluated items as follows: the explanation of study design in the title or abstract (item 1); the adequacy of the description of the setting, locations, and dates of data collection (item 5); the clarity with which outcomes and exposures were defined (item 10); the validity and reliability of the TCM pattern types methods (specific to this review and extrapolated from item 12); and the extent of addressing potential sources of bias within the study (item 14).

Each study was scored against these criteria, and discrepancies in the risk of bias assessments were discussed by four members of the research team to reach a consensus. A qualitative synthesis of the risk of bias for each study was then included in the results section of the manuscript, which enhances the interpretation of the findings of this systematic review.

3 Results

3.1 Selection and characteristics of included studies

A total of 1 356 articles were initially identified for relevance, with 201 subsequently assessed for eligibility by reviewing full texts. This process resulted in the inclusion of 40 cross-sectional studies involving 10 270 participants [21-60] (Figure 1). Detailed characteristics of the studies, including geographical location, study design, and sample size were summarized in Table 1. According to our TCM clinical diagnostic criteria, enrollment of PCI participants were classified into nine different TCM pattern types. Among them, 31 studies [21-28, 30-35, 38-56, 59, 60] reported patients included Qi deficiency and blood stasis pattern; 28 studies [22-24, 26, 27, 29-35, 39-44, 58, 59] reported patients included intertwined phlegm and blood stasis pattern; 23 studies [21-26, 28-32, 35-37, 39-47, 49-51, 53, 57, 59] reported patients included Qi stagnation and blood stasis pattern; 21 studies [22, 23, 25, 26, 28-32, 34-37, 39, 41-47, 49, 51-53, 57, 58, 60] reported patients included Yang-Qi deficiency pattern; 23 studies [22, 23, 25, 26, 27-29, 31, 33, 34, 36-40, 43-47, 49-53, 55-57, 59, 60] reported patients included phlegm obstructing the heart vessels pattern; 15 studies [22-24, 29, 30, 33, 35, 38, 47, 48, 52, 54, 56, 58, 59] reported patients included Qi and Yin deficiency pattern; 12 studies [22, 26, 28, 30, 33, 36, 38, 43, 46, 47, 49, 50, 60] reported patients included cold-induced stagnation pattern; 16 studies [25, 28, 30, 30, 34, 35, 36, 39, 41, 44, 45, 49, 52, 56, 58, 61]

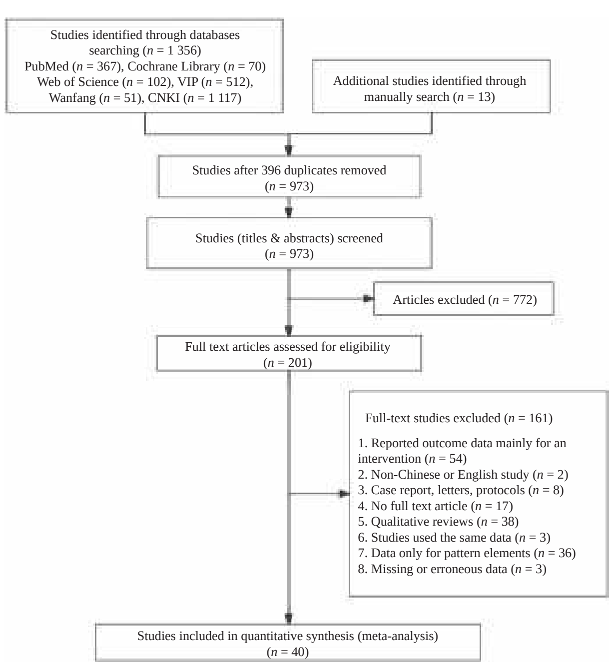

Figure 1 PRISMA flowchart for study selection

reported patients included disharmony between the heart and kidney pattern; and 14 studies [22, 25, 29, 33, 35, 36, 38, 39, 41, 43, 45, 49, 56, 60] reported patients included heart vessels stasis pattern.

3.2 Demographic characteristics and prevalence

As shown in Table 2, our analyses determined that the prevalence of TCM patterns among PCI patients presented notable gender disparity, with males representing approximately 65.83% (n = 6 761) and females 34.17% (n = 3 509) of the study population, and 9 559 sample sizes reported the average age (62.55 ± 10.91). A total of 2 367 patients reported the history of smoking and 468 patients reported alcohol drinking; 3 392 patients reported the BMI (25.22 ± 3.77); 877 patients reported systolic blood pressure (132.98 ± 21.67), diastolic blood pressure (77.50 ± 12.56) and heart rate (74.00 ± 13.89); and 1 425 patients reported the average duration of the disease was 6.61 ± 3.85 years. Among the patients enrolled in this study, patients with unstable angina pectoris (UAP) were the most common (40.4%), patients with single lesion vessel (k = 12, n = 1 267, 31.35%) at the left anterior descending branch (k = 11, n = 2 908, 39.72%) were the most commonly occurring symptom. The five most common complications in patients treated with PCI were hypertension (k = 25, n = 4 579, 35.12%), diabetes (k = 25, n = 2 790, 21.4%), hyperlipidemia (k = 21, n = 1 920, 14.73%), cerebrovascular disease (k = 12, n = 743, 5.7%), and chronic heart failure (k = 21, n = 276, 2.12%). The five most common adverse events after PCI were angina pectoris (k = 10, n = 805, 6.17%), recurrent myocardial infarction (k = 8, n = 425, 3.26%), anxiety (k = 5, n = 321, 2.46%), depression (k = 5, n = 277, 2.12%), and revascularization (k = 3, n = 73, 0.56%).

3.3 The distribution of TCM pattern types in different PCI periods

Distinct trends in the distribution of TCM patterns were observed across different PCI periods. The detailed reporting time was pre-PCI (k = 4, n = 716), three days after PCI treatment (k = 3, n = 699), one week after PCI (k = 4, n = 401), two weeks after PCI (k = 2, n = 314), three months after PCI (k = 4, n = 634), six months after PCI (k = 4, n = 1 742), and one year after PCI (k = 10, n = 3 145), respectively. As shown in Figure 2, nine TCM patterns were distinctly reported: Qi deficiency induced blood stasis pattern (n = 2 705), Qi stagnation and blood stasis pattern (n = 1 523), intertwined phlegm and blood stasis pattern (n = 950), phlegm obstructing the heart vessels pattern (n = 630), Qi and Yin deficiency pattern (n = 456), heart vessels stasis pattern (n = 441), Yang-Qi deficiency pattern (n = 355), cold induced stagnation pattern (n = 328)

Table 1 Characteristics of the studies included in the meta-analysis

First author	Year	Region (province, country)	Study design	Total sample size	TCM pattern differentiation
ZHAO YQ [21]	2023	Beijing (China)	Cross-sectional	438	①③
FAN MY [29]	2022	Sichuan (China)	Cross-sectional	184	②③④⑤⑥⑨
DENG M [24]	2022	Beijing (China)	Cross-sectional	252	①②③⑥
DUAN JQ [27]	2022	Liaoning (China)	Cross-sectional	43	②
ZHAO Y [22]	2022	Liaoning (China)	Cross-sectional	187	①②③⑥⑦⑨
YUAN HM [28]	2022	Liaoning (China)	Cross-sectional	197	③④⑤⑥⑧⑨
LIU Q [23]	2022	Nanjing (China)	Cross-sectional	210	①②③⑥⑦
LIN C [26]	2022	Anhui (China)	Cross-sectional	110	①②③
SONG JL [25]	2022	Liaoning (China)	Cross-sectional	200	①③④⑤⑥⑦⑧⑨
YUE L [33]	2021	Shandong (China)	Cross-sectional	166	①②⑤⑨
LI Y [31]	2021	Shandong (China)	Cross-sectional	130	①③④⑤⑥⑦
LI ZY [30]	2021	Guangzhou (China)	Cross-sectional	245	①②③④⑧
XIE TT [32]	2021	Jilin (China)	Cross-sectional	1 006	①②③④⑥⑦⑧
LIU GN [35]	2020	Beijing (China)	Cross-sectional	1 686	①②③④⑦⑧⑨
LUO SH [34]	2020	Yunnan (China)	Cross-sectional	1 000	①④⑤⑥⑦⑧
WEI Z [38]	2019	Guangdong (China)	Cross-sectional	90	①⑤⑨
LV Y [36]	2019	Northern Theater Command of China	Cross-sectional	82	③④⑤⑥⑧⑨
GUO B [40]	2019	Beijing (China)	Cross-sectional	121	①②③⑤⑥
CHEN H [39]	2019	Guizhou (China)	Cross-sectional	100	③④⑤⑥⑦⑧⑨
ZHANG CH [41]	2018	Beijing (China)	Cross-sectional	801	①②③④⑥⑦⑧⑨
ZHANG XJ [42]	2018	Gansu (China)	Cross-sectional	128	①②③④⑥⑦
YANG J [43]	2018	Hebei (China)	Cross-sectional	96	①②③④⑥⑨
WANG HC [46]	2017	Fujian (China)	Cross-sectional	92	①③④⑤⑥⑧
HAO XZ [47]	2017	Beijing (China)	Cross-sectional	105	①②③④⑤
FENG Y [45]	2017	Shanghai (China)	Cross-sectional	40	①③④⑤⑥⑦⑧⑨
GONG ZH [44]	2017	Guangdong (China)	Cross-sectional	556	①②③④⑤⑥⑦⑧⑨
FENG ZB [48]	2016	Shaanxi (China)	Cross-sectional	357	①②⑨
WU C [49]	2016	Beijing (China)	Cross-sectional	164	①②③④⑤⑥⑦⑧⑨
ZHANG YC [50]	2016	Yunnan (China)	Cross-sectional	207	①③⑤⑥⑦⑨
ZHOU WQ [52]	2014	Liaoning (China)	Cross-sectional	128	①②④⑤⑧
YUAN CW [51]	2014	Xinjiang (China)	Cross-sectional	375	①②③⑤⑥⑧⑨
LI XX [54]	2013	Shandong (China)	Cross-sectional	60	①
ZHU FY [61]	2013	Beijing (China)	Cross-sectional	112	①②③④⑥⑧
LI XJ [56]	2012	Shandong (China)	Cross-sectional	95	①⑤⑧⑨
ZHANG Y [55]	2012	Fujian (China)	Cross-sectional	371	①⑧
GU F [57]	2011	Beijing (China)	Cross-sectional	60	③④⑤⑥
WANG SH [58]	2008	Beijing (China)	Cross-sectional	143	①②④⑧
HE YQ [59]	2008	Beijing (China)	Cross-sectional	143	②③⑤
DU SZ [60]	2007	Fujian (China)	Cross-sectional	97	④⑤⑥⑦⑨

① Qi deficiency and blood stasis pattern; ② intertwined phlegm and blood stasis pattern; ③ Qi stagnation and blood stasis pattern; ④ Yang-Qi deficiency pattern characterized by cold intolerance; ⑤ phlegm obstructing the heart vessels pattern; ⑥ Qi and Yin deficiency pattern; ⑦ cold-induced stagnation pattern; ⑧ disharmony between the heart and kidney pattern; ⑨ heart vessels stasis pattern. For the detailed characteristics of TCM pattern differentiation, please check the Supplementary Material S1.

and disharmony between the heart and kidney pattern (n = 263). Before PCI, most patients were observed in Qi stagnation and blood stasis pattern (n = 261, 36.45%) and Qi deficiency and blood stasis pattern (n = 250, 34.92%).

Table 2 Characteristics of included patients

Variable	Category	Total study (k)	Total sample size [n (%)]	Mean ± SD
Age	/	40	10 270	62.55 ± 10.91
Gender	Male	37	6 761 (65.83%)	/
	Female	37	3 509 (34.17%)	/
BMI	Normal weight	9	96 (2.80%)	25.22 ± 3.77
	Overweight	9	3 296 (97.17%)	
Blood pressure	Systolic blood pressure	5	877 (8.50%)	132.98 ± 21.67
	Diastolic blood pressure	5	877 (8.50%)	77.50 ± 12.56
Heart rate	/	5	877 (8.50%)	74.00 ± 13.89
Duration of CHD	/	6	1 425 (13.88%)	6.61 ± 3.85
Smoke	/	20	2 367 (45.70%)	/
Alcohol drinking	/	13	468 (9.04%)	/
Classification of CHD	Unstable angina pectoris	10	1 686 (40.40%)	/
	Stable angina pectoris	6	464 (11.10%)	/
	Acute myocardial infarction	2	68 (1.60%)	/
	Acute ST-segment elevation myocardial infarction	11	868 (20.80%)	/
	Acute non-ST-segment elevation myocardial infarction	9	1 042 (24.90%)	/
	Old myocardial infarction	2	49 (1.20%)	/
Number of lesion vessel	One lesion vessel	12	1 267 (31.35%)	/
	Two lesion vessels	13	1 126 (27.86%)	/
	Three lesion vessels	12	1 104 (27.31%)	/
	Four or more lesion vessels	5	545 (13.48%)	/
Lesion vessel	Right coronary artery	12	2 170 (29.64%)	/
	Left anterior descending branch	11	2 908 (39.72%)	/
	Left circumflex branch	7	1 954 (26.69%)	/
	Left trunk	7	279 (3.81%)	/
Comorbidity	Hypertension	25	4 579 (35.12%)	/
	Diabetes	25	2 790 (21.40%)	/
	Hyperlipidemia	21	1 920 (14.73%)	/
	Cerebrovascular disease	12	743 (5.70%)	/
	Chronic heart failure	5	276 (2.12%)	/
	Arrhythmology	5	172 (1.32%)	/
	Chronic kidney disease	3	214 (1.64%)	/
	Hyperuricemia	3	128 (0.98%)	/
	Chronic obstructive pulmonary disease	1	32 (0.25%)	/
	Chronic gastritis	1	34 (0.26%)	/
	Pulmonary infection	1	32 (0.25%)	/
	Sleep disorders	1	15 (0.12%)	/
	Acute heart failure	1	11 (0.08%)	/
	Chronic hepatitis B	1	8 (0.06%)	/
	Urinary tract infections	1	5 (0.04%)	/
	Anemia	2	33 (0.25%)	/
Major adverse events	Angina pectoris	10	805 (6.17%)	/
	Recurrent myocardial infarction	8	425 (3.26%)	/
	Anxiety	5	321 (2.46%)	/
	Depression	5	277 (2.12%)	/
	Revascularization	3	73 (0.56%)	/
	Cardiogenic death	3	40 (0.31%)	/
	Stent thrombosis	2	64 (0.49%)	/
	Heart failure	2	24 (0.18%)	/
	Irregular heartbeat	2	16 (0.12%)	/

/ , not applicable.

Three days after PCI, patients were most observed in Qi stagnation and blood stasis pattern (n = 268, 38.34%). One week to two weeks after PCI were most common in the intertwined phlegm and blood stasis pattern (n = 109, 27.18% at one week; n = 78, 24.84% at two weeks). Three months after PCI, most patients were found in Qi stagnation and blood stasis pattern (n = 251, 39.59%). Patients at six months and one year after PCI were more common in Qi deficiency and blood stasis pattern (n = 645, 37.03% at six months; n = 1 379, 43.85%, at one year). The fixed effect model was used to analyze the one year after PCI of 10 studies [22, 24, 29, 32, 35, 50, 55, 57-59] with the largest sample size (Figure 3). Qi deficiency and blood stasis pattern [prevalence rate = 0.34, 95% CI (0.14 – 0.54), I^2 = 99.5%, P < 0.001] and intertwined phlegm and blood stasis pattern [prevalence rate = 0.21, 95% CI (0.11 – 0.31), I^2 = 98.9%, P < 0.001] were the two most common pattern types of one year PCI. However all the heterogeneity of different patterns was greater than 90% (I^2 = 91% – 99.5%, P < 0.001).

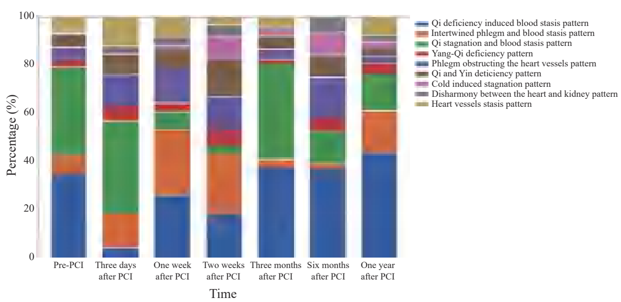

Figure 2 The distribution of nine pattern types in different PCI periods

3.4 Risk factors for restenosis of PCI

3.4.1 Correlation analysis of demographic characteristics Demographic correlation analysis was conducted on the risk factors of restenosis after PCI in five studies [22, 26, 35, 48, 59]. Figure 4 shows that age [OR = 1.00, 95% CI (0.98 – 1.03), I^2 = 12.4%, P = 0.331], BMI [OR = 1.01, 95% CI (0.96 – 1.05), I^2 = 54.4%, P = 0.139], systolic blood pressure [OR = 1.00, 95% CI (0.99 – 1.02)], diastolic blood pressure [OR = 1.01, 95% CI (0.99 – 1.02)], and heart rhythm [OR = 1.00, 95% CI (0.99 – 1.02)] were not markedly correlated. Sex [OR = 0.89, 95% CI (0.61 – 1.17), I^2 = 0%, P = 0.670] and smoke [OR = 1.15, 95% CI (0.83 – 1.47), I^2 = 24.7%, P = 0.257] were risk factors.

3.4.2 Correlation analysis of CHD classification and lesion vessels Figure 5 indicated that three studies [23, 26, 28] reported the risk factors of restenosis of lesion vessels after PCI. Compared with other types, STEMI [OR = 1.60, 95% CI (1.02 – 2.18)] and NSTEMI [OR = 1.60, 95% CI (0.82 – 1.92)] were the main types of restenosis. Left aortic injury [OR = 2.05, 95% CI (1.04 – 3.05)] and right aortic injury [OR = 1.27, 95% CI (0.83 – 1.71)] were risk factors. No significant correlation was found between PCI stent implantation time [OR = 1.08, 95% CI (1.00 – 1.15)] and SYNTAX score [OR = 1.01, 95% CI (0.98 – 1.04)].

3.4.3 Correlation analysis of comorbidities Five studies [22, 23, 26, 41, 59] were conducted to analyze the risk factors of restenosis after PCI. Figure 6 demonstrated that one study [23] reported that chronic kidney disease [OR = 2.22, 95% CI (1.13 – 3.32)] and anemia [OR = 2.24, 95% CI

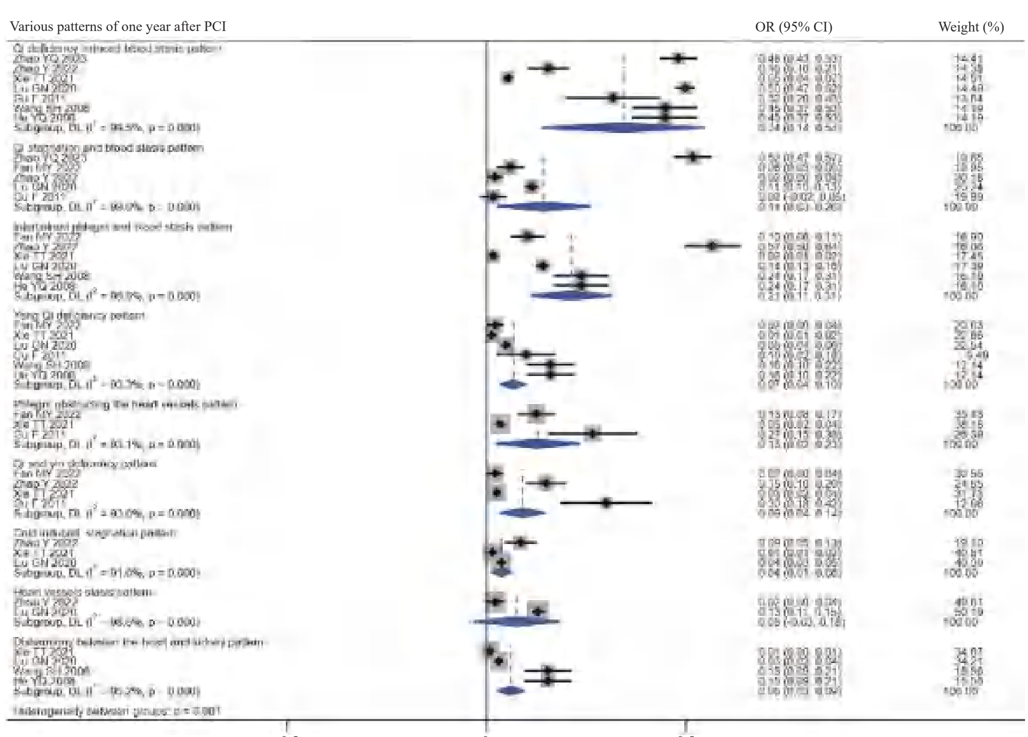

Figure 3 The prevalence of nine TCM pattern types of one year after PCI

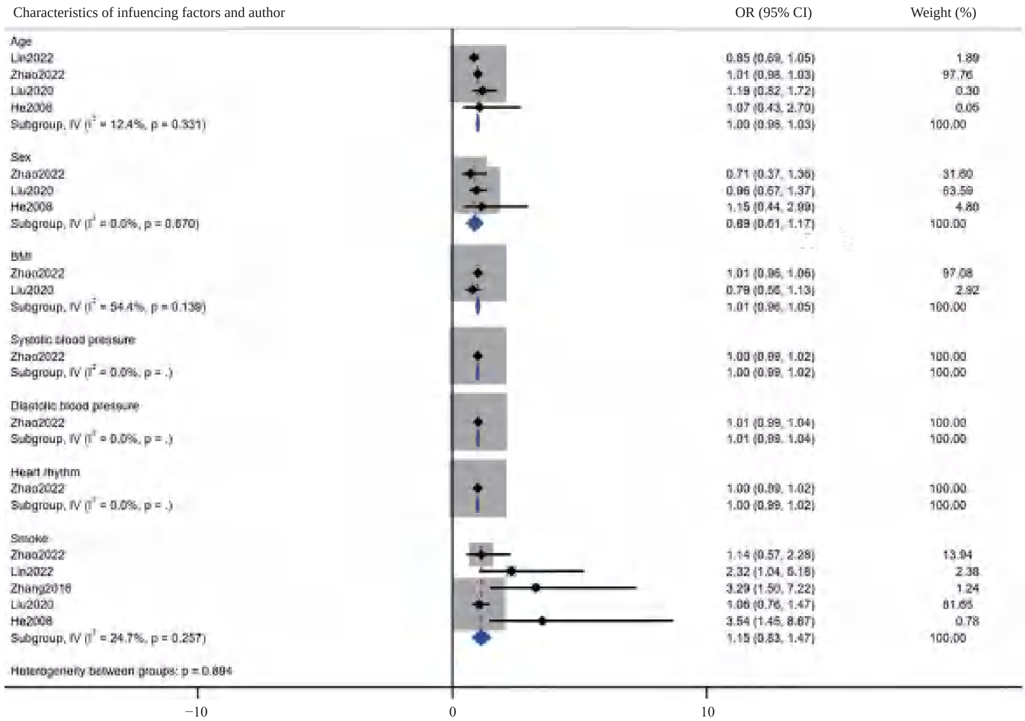

Figure 4 Stratified analysis of demographic characteristics of restenosis after PCI

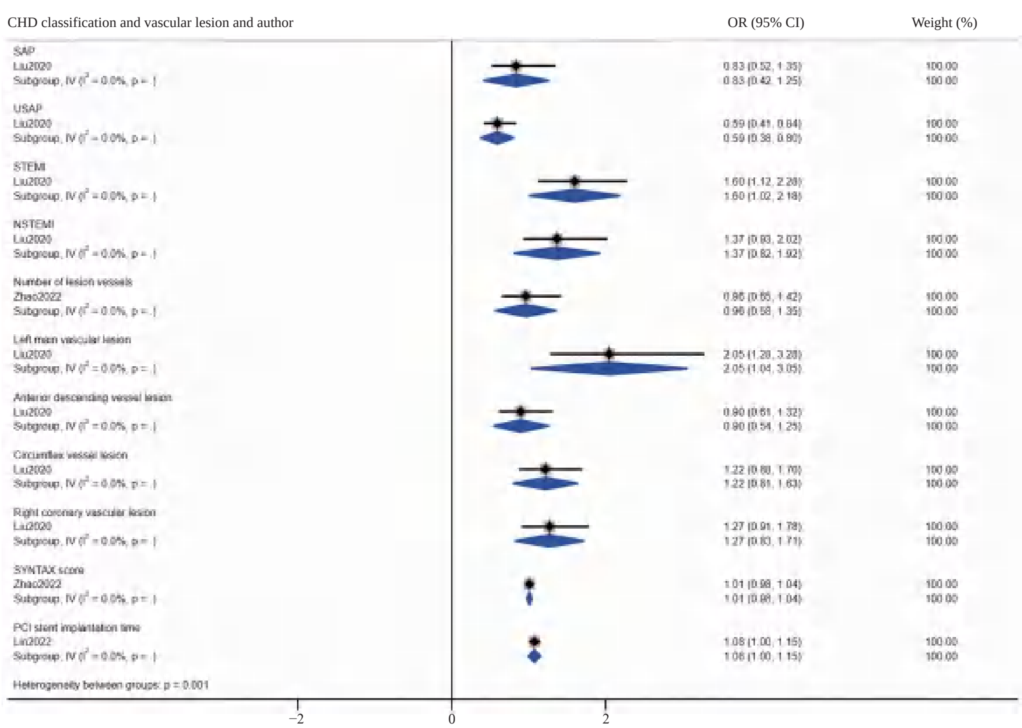

Figure 5 Stratified analysis of CHD classification and lesion vessels of restenosis after PCI

SAP, stable angina pectoris. USAP, unstable angina pectoris. STEMI, ST-segment elevation myocardial infarction. NSTEMI, non-ST-segment elevation myocardial infarction. SYNTAX, Synergy between PCI with Taxus and Cardiac Surgery.

(– 0.34 – 4.82)] were risk factors for restenosis after PCI; five studies [22, 23, 26, 41, 59] reported the correlation of hypertension in patients with CHD after PCI [OR = 1.05, 95% CI (1.00 – 1.09), I^2 = 42.2%, P = 0.140]; four studies [23, 26, 41, 59] reported the correlation of diabetes mellitus in patients with CHD after PCI [OR = 1.10, 95% CI (0.97 – 1.23), I^2 = 7.4%, P = 0.365]; two studies [23, 59] reported the correlation of hyperlipidemia in patients with CHD after PCI [OR = 1.05, 95% CI (1.00 – 1.05), I^2 = 42.2%, P = 0.140]. The correlation mentioned above was not significant.

3.4.4 Correlation analysis of different TCM patterns

Five studies [21, 23, 26, 35, 59] conducted a correlation analysis report on the risk factors of restenosis after PCI and different TCM patterns. As shown in Figure 7, the pooled analysis identified four patterns, including cold-induced stasis pattern [OR = 4.62, 95% CI (1.37 – 7.86), I^2 = 61.6%, P = 0.074], phlegm constructing the heart vessels pattern [OR = 3.56, 95% CI (0.98 – 6.14), I^2 = 0%, P = 0.383], Qi deficiency and blood stasis pattern [OR = 1.87, 95% CI (1.32 – 2.42), I^2 = 0%, P = 0.421], and disharmony between the heart and kidney pattern [OR = 1.21, 95% CI (0.32 – 2.09), I^2 = 0%, P = 0.607].

3.4.5 Related factors of laboratory indicators As shown in Figure 8, two studies [22, 26] reported the correlation analysis between restenosis after PCI and different laboratory indicators. Two studies [22, 26] reported LDL as a risk factor [OR = 1.38, 95% CI (0.92 – 1.85), I^2 = 12.2%,

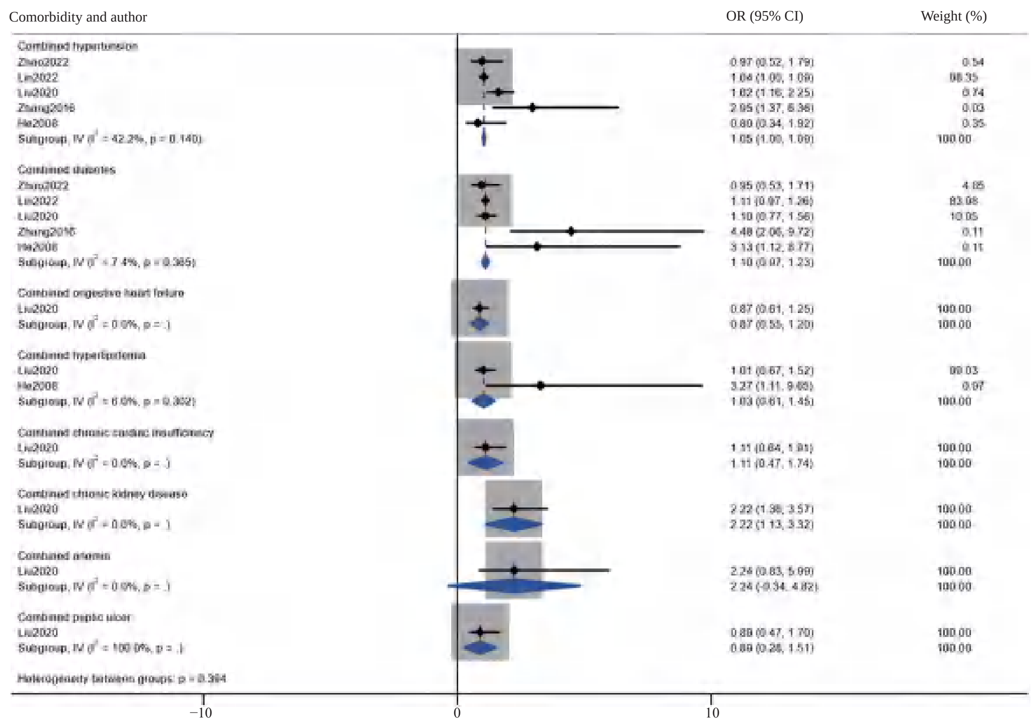

Figure 6 Stratified analysis of comorbidity of restenosis after PCI

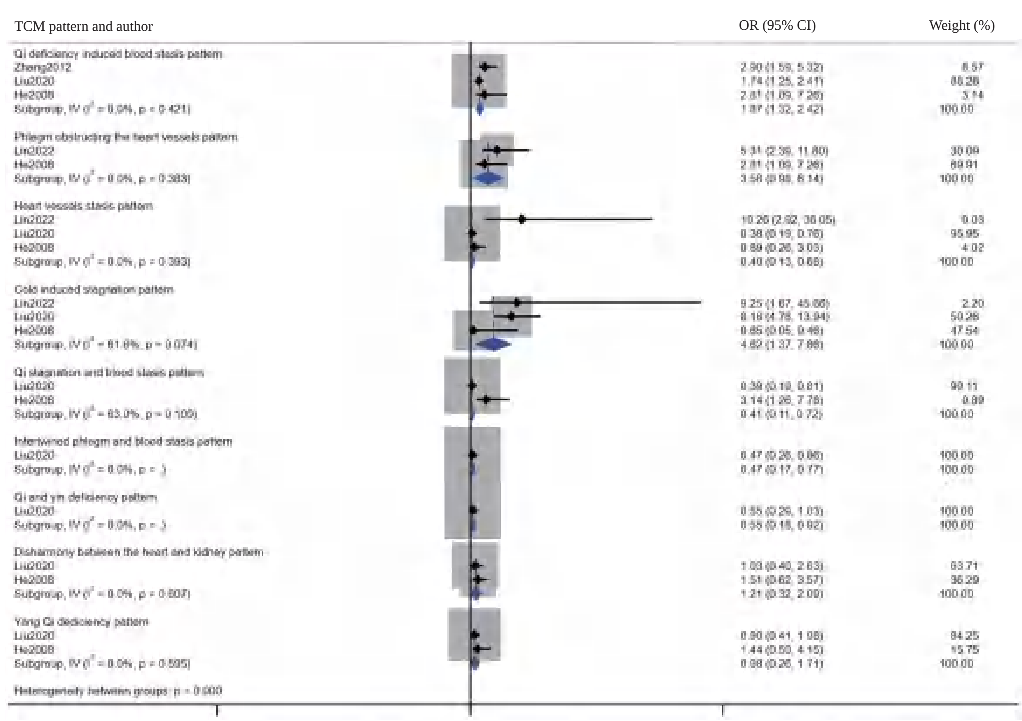

Figure 7 Stratified analysis of various TCM pattern types of restenosis after PCI

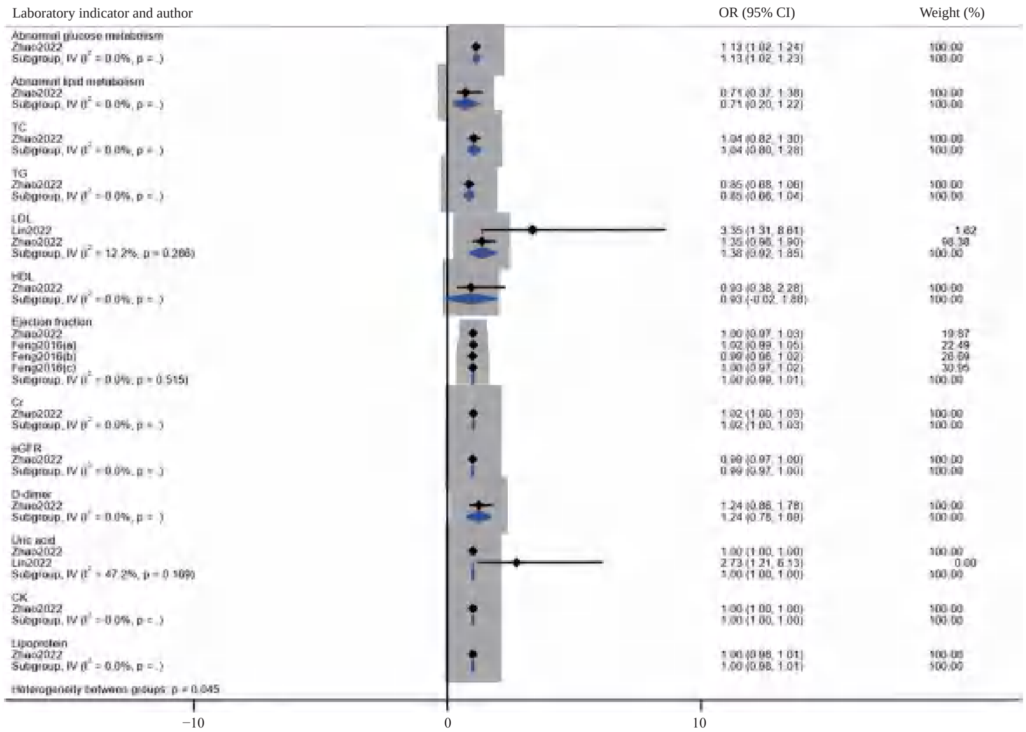

Figure 8 Stratified analysis of laboratory indicators of restenosis after PCI

TC, total cholesterol. TG, triacylglycerol. LDL, low density lipoprotein. HDL, high density lipoprotein. Cr, creatinine. CK, creatine kinase

P = 0.286]. A study [22] reported a correlation between abnormal blood glucose metabolism and restenosis after PCI [OR = 1.13, 95% CI (1.02 – 1.23)], and a correlation between D-dimer [OR = 1.24, 95% CI (0.78 – 1.69)]. Two studies [22, 48] reported no significant correlation with ejection fraction [OR = 1.00, 95% CI (0.99 – 1.01), I^2 = 0%, P = 0.515].

3.5 Risk factors for concomitant anxiety after PCI

Figure 9 demonstrated that a total of three studies [23, 42, 51] conducted statistical analysis on the related factors of concomitant anxiety after PCI. Age over 60 [OR = 0.16, 95% CI (0.01 – 3.70)], female [OR = 0.10, 95% CI (0.01 – 0.82)], hypertension [OR = 7.26, 95% CI (3.54 – 14.88),

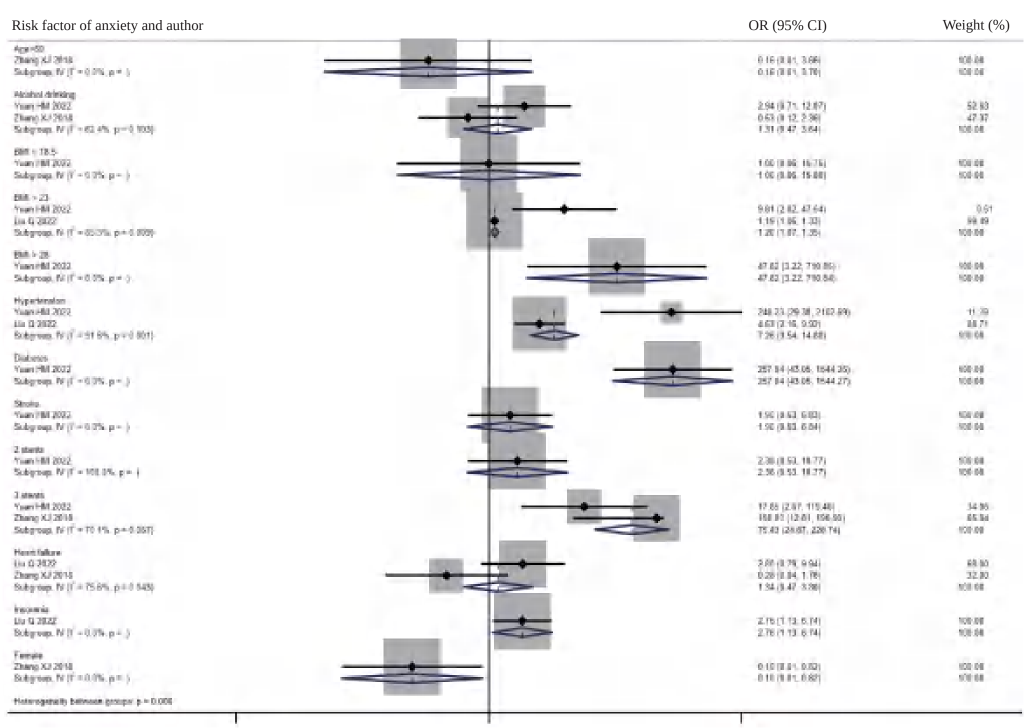

Figure 9 Stratified analysis of related factors of anxiety after PCI

I^2 = 91.6%, P = 0.001], overweight (BMI > 23) [OR = 1.20, 95% CI (1.07 – 1.35), I^2 = 85.3%, P = 0.009], stroke [OR = 1.90, 95% CI (0.53 – 6.84)], heart failure (OR = 1.34, 95% CI (0.47 – 3.80)], and alcohol drinking [OR = 1.31, 95% CI (0.47 – 3.64)] were risk factors for anxiety after PCI. It might be more significant in obese (BMI > 28) patients [OR = 47.82, 95% CI (3.22 – 710.84)]. The number of stents was also a risk factor for anxiety. This may be more significant in patients with three stents [OR = 75.43, 95% CI (24.87 – 228.74), I^2 = 70.1%, P = 0.067] rather than two stents [OR = 2.38, 95% CI (0.53 – 10.77)]. Although heterogeneity across studies was high, a robust association between lesion numbers and anxiety after PCI was still suggested.

3.6 Related factors for concomitant depression after PCI

Among all the included studies, only one study [42] mentioned the related factors of concomitant depression syndrome in patients after PCI. Female gender [OR = 0.10, 95% CI (0.01 – 0.82), P < 0.001], age over 70 [OR = 0.16, 95% CI (0.01 – 3.66), P < 0.001], and arrhythmia [OR = 0.01, 95% CI (0.00 – 0.13), P < 0.001] might be related factors. Three stents [OR = 158.8, 95% CI (12.81 – 196.9), P < 0.001] might be the risk factor.

3.7 Sensitivity analysis and publication bias

Our sensitivity analysis showed that 63 effect sizes estimated values from 2.71 to 2.73. No individual study led to significant changes in the pooled OR for the risk of restenosis, suggesting that the overall meta-analysis results are robust. In addition to sensitivity analysis, the potential for publication bias was assessed using Egger's test. The results indicated no significant publication bias, which lends further credibility to the meta-analysis findings for the risk of restenosis after PCI (P = 0.26) (Supplementary Figure S1).

3.8 Overview of study reported quality

In all of the 40 studies included, the study design was indicated with a commonly used term in the title or abstract (100%), the number of individuals in each phase of the study was reported (100%), the number of outcome events or summary measures were reported (100%), and unadjusted estimates and their precision were given (100%). Twenty eight studies (70%) have been completely provided in the abstract an informative and balanced summary of what was done and what was found. In the introduction section, a total of 32 studies stated specific objectives, including any prespecified hypotheses (80%). In the method section, only 20 studies (50%) clearly defined all outcomes, exposures, predictors, potential confounders, and effect modifiers; and provided diagnostic criteria. Fifteen studies (37.5%) reported each variable of interest, provided sources of data and details of methods of assessment, and described the comparability of assessment methods. Nine studies (22.5%) described any efforts to address potential sources of bias. Moreover, 23 studies (57.5%) described all statistical methods, including those used to control for confounding; 12 studies (30%) described any sensitivity analyses. A total of 18 studies (45%) mentioned reasons for the missing data of participants in each study phase among the whole process. Twenty studies (50%) elaborated on which confounders were adjusted for and why they were included in report category boundaries when continuous variables were categorized. Six studies (15%) considered the translation of relative risk estimates. Eighteen studies (45%) report subgroups and interactions, and sensitivity analyses. In the discussion section, 28 studies (70%) discussed the limitations of the study, taking into account sources of potential bias or imprecision. Overall, 34 studies (85.5%) discussed the generalizability (external validity) of the study results and 18 studies (45%) explained the source of funding and the role of funders for the present study (Figure 10).

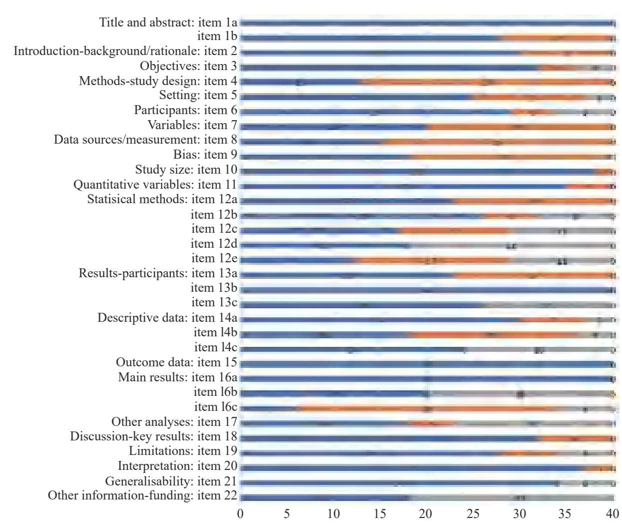

Figure 10 STROBE checklist

4 Discussion

4.1 Differentiation of TCM pattern

The findings indicated a dynamic shift in TCM pattern of PCI prevalence, reflecting the complex interplay between traditional risk factors and the unique conceptual framework of TCM. For instance, the evolution from Qi stagnation and blood stasis to Qi deficiency patterns suggested a transition from acute to chronic phases in the postoperative period [21]. This transition may have direct therapeutic implications in the management and guidance of PCI patient care within TCM practice [43].

CHD patients who underwent PCI are most commonly diagnosed with the intertwined phlegm and blood stasis pattern one to two weeks after surgery, with symptoms including chest pain, dizziness, fatigue, bitter taste, heavy stasis, yellow and greasy tongue coating, thick and greasy coating, and several smooth pulses [7]. Previous literature has also shown that after a period of recovery following PCI surgery, patients with the most common symptoms are phlegm retention and blood stasis [29]. Furthermore, phlegm retention and blood stasis can cause hypoxia in heart tissue, which can affect the normal function of the heart, causing symptoms such as chest pain and palpitations in patients, requiring additional attention [46, 47]. The results of this study indicate that patients with CHD who have undergone PCI for over six months are more likely to experience Qi deficiency and blood stasis pattern. Most patients who required PCI were middle-aged and elderly. We hypothesize that at this stage, the essence and Qi are not abundant, and the function of the organs is reduced. Additionally, postoperative ischemic reactions may cause poor blood flow, leading to a decrease in gas content in the blood, an increase in blood viscosity, obstruction of blood circulation, and insufficient Qi and blood, resulting in the symptoms of Qi deficiency and blood stasis syndrome.

According to our results, the main risk syndromes for postoperative restenosis after PCI are the cold-induced stagnation pattern and the phlegm obstructing the heart vessel pattern. In the *Synopsis of the Golden Chamber*, it was pointed out that the pathogenesis of chest pain is the "Yang micro Yin string", which means that the Yang-Qi in the upper jiao (upper heater) is not vibrating, the Yin in the lower jiao is cold inside, and the cold in the lower jiao is contrary to the heart, invading the meridians, and causing pathogenic factors to condense in the meridians, resulting in severe chest pain in patients [25, 34]. Research has shown that it is easy to alter blood flow around the stent after PCI, which can lead to vasoconstriction [22]. Consequently, the cold retention induced atrial fibrillation pattern is the most common risk type of atrial fibrillation, which can cause myocardial ischemia and myocardial necrosis.

It is worth noting that due to the limited number of included studies and the high heterogeneity of epidemiological results across various pattern types, more relevant studies are warranted in the future to obtain more reliable results.

4.2 Risk factors for adverse events after PCI

Smoking is a risk factor for cardiovascular and cerebrovascular diseases, as it not only decreases vascular HDL-cholesterol (C) concentration and increases cell viscosity but also quickens cell aggregation and loss of arterial endothelium. Additionally, smoking can cause vascular endothelial function damage, which leads to increased vascular wall fragility [61]. Additionally, smoking increases platelet aggregation, resulting in thrombosis, one of the leading causes of in-stent restenosis (ISR) [62]. Abnormal glucose metabolism can lead to thickening of the vessel walls, which narrows the vessel, which in turn leads to restenosis after PCI. Abnormal glucose metabolism can also aggravate vascular inflammation, which can cause the formation of hemangiomas, thereby increasing the risk of PCI restenosis [63]. Therefore, for PCI diabetics, care must be taken to control their glucose levels to reduce the incidence of ISR. Studies have shown a relationship between hyperlipidemia and restenosis. The main carriers of plasma cholesterol are LDL and HDL [64, 65]. The concentration of LDL-C was positively correlated with the ISR. A significant difference was observed in the incidence of postoperative restenosis between patients taking statins and those not taking statins, confirming that blood lipid levels are one of the factors affecting coronary artery stenosis [66, 67]. Body weight is another major cause of restenosis after PCI, especially for obese individuals. However, the pooled-analysis results in this study showed different conclusions. We speculate that the higher risk of postoperative stenosis in obese patients compared to normal patients is primarily due to the greater risk of severe postoperative complications in obese patients, rather than a higher risk of postoperative stenosis due to obesity [68]. This study showed that the incidence of stenosis after PCI was similar in obese patients as in normal-weight patients, suggesting that obesity might not increase the incidence of postoperative stenosis, but increase the risk of serious postoperative complications.

PCI is frequently an emergency procedure in the case of acute onset, so patients are prone to severe psychological stress in the face of sudden illness and emergency [15, 69]. Patients with residual stenosis after PCI may be more anxious about whether the residual stenosis will lead to the next acute attack, and thus are more prone to anxiety [28]. This may also explain the fact that depression and anxiety are among the most common adverse events in patients who underwent PCI.

CHD is a chronic disease; the successful implementation of PCI does not guarantee the rehabilitation of the disease. What is more important is the long-term cardiac rehabilitation after PCI [70]. Many studies have shown that TCM can improve the condition of patients with myocardial infarction, regulate blood lipid levels, lower blood pressure, reduce arrhythmia, promote recovery of myocardial contractile function, reduce the incidence of death and impaired cardiac function, and thus improve the quality of life of patients [33, 43, 71]. Therefore, it is hoped that in the future, there will be more studies exploring detailed epidemiological analysis and influencing factors of TCM pattern types to raise the quality of life of patients after PCI from different perspectives.

4.3 Reporting quality and evaluation of included studies

When presenting an observational study in a manuscript, the author needs to identify a clear presentation of the work and provide the reader with the appropriate information to enable a critical appraisal of the research. We emphasized that the STROBE statement was not developed as a tool for assessing the quality of published observational studies. However, if STROBE is adopted by authors, issues such as confounding, bias, and generalizability could become more transparent, which might help temper the over-enthusiastic reporting of new findings in the scientific community, and potentiate the methodology of long-term research. Based on the reporting quality of the 40 included cross-sectional studies, future studies need to pay more attention to reporting key elements of study design early and address potential sources of bias.

4.4 Strengths and limitations

This study conducted a systematic review and meta-analysis, which is evidenced by the highlighted link between certain TCM patterns and restenosis risk, advocating for the integration of TCM pattern recognition into PCI monitoring routines. Additionally, the quality of the available published studies has been assessed to guide the standardized reporting of future studies. However, this study still has some limitations. First, the number of studies included in this meta-analysis was limited, with some subgroup analyses combining only two or three studies, or even a single study. Therefore, more relative research is needed to clarify the conclusions. Second, there were methodological weaknesses in several included studies, such as inadequate allocation, small sample sizes, and inadequately reported statistical methods. As there is an obvious correlation between study quality and results, this problem needs to be considered seriously. Third, the sensitivity and specificity of measurements differ, and there are no utilized gold-standard TCM pattern types after PCI for CHD, which may result in highly heterogeneous results. Hence, we hope that specific guidelines can be unified in the evaluating methods in future clinical research. Last, as the studies we included required data only from cross-sectional studies on TCM pattern types, this may lead to the omission of intervention studies reporting influencing factors of recurrent adverse events after PCI. Therefore, more caution is needed in promoting the application of confounding reduction methodologies, as well as raising the reporting quality of observational studies. Future research should aim to standardize TCM pattern diagnostics and integrate them with established biomarkers of CHD to validate their prognostic utility. Prospective studies with longitudinal designs are recommended to provide more robust data on the temporal evolution of PCI TCM patterns.

5 Conclusion

Pattern differentiation of TCM is a unique diagnostic method. This systematic review and meta-analysis showed that patients with different pattern types have different characteristics and risk factors after PCI, so different treatments are needed accordingly. Besides, additional subgroup analyses and more high-quality observational studies are needed in the future that can help provide more evidence.

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Competing interests

The authors declare no conflict of interest.

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经皮冠状动脉介入治疗（PCI）患者的中医证型分布及预后危险因素：系统评价和 meta 分析

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【摘要】目的 探讨经皮冠状动脉介入治疗（PCI）中医证候分布及相关风险因素，并评估现有研究的报告质量，以期为未来的标准化研究提供指导。**方法** 分别在 PubMed、Cochrane Library 和 Web of Science 等英文数据库，以及中国知网（CNKI）、维普（VIP）和万方数据库等中文数据库中检索 PCI 相关论文。论文检索的时间跨度从数据库建立至 2023 年 10 月 1 日。使用 Stata 12 和 Python（V 3.9）进行统计分析。采用观察性研究报告规范（STROBE）声明评估纳入研究的报告质量。**结果** 共筛选出 1 356 篇文章，纳入 40 项横断面研究，涉及 10 270 名参与者。PCI 前最常见的中医证候为气滞血瘀证（n = 261，36.45%），PCI 后 1 – 2 周最常见的中医证候为痰瘀互结证（n = 109, 27.18%）, PCI 后 6 个月至 1 年最常见的中医证候为气虚血瘀证（n = 645，37.03%）。吸烟 [比值比（OR）= 1.15，95% 置信区间（CI）（0.83 – 1.47），I^2 = 24.7%，P = 0.257]、寒凝气滞证 [OR = 4.62，95% CI（1.37 – 7.86），I^2 = 61.6%，P = 0.074] 及低密度脂蛋白（LDL）升高 [OR = 1.38，95% CI（0 .92 – 1 .85），I^2 = 12.2%，P = 0.286] 是再狭窄的风险因素。高血压 [OR = 7.26, 95% CI（3.54 – 14.88），I^2 = 91.6%，P = 0.001] 和超重 [即身体质量指数（BMI）> 23] [OR = 1.20，95% CI（1.07 – 1.35），I^2 = 85.3%，P = 0.009] 是伴发焦虑的显著风险因素。**结论** 本系统评价和 meta 分析显示，不同中医证型患者 PCI 术后特点和危险因素不同，未来需要更多相对高质量的研究，以提供更多的支持性证据。

【关键词】冠心病；中医；经皮冠状动脉介入治疗；风险因素；系统评价；meta 分析