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Association of traditional Chinese medicine syndromes with blood lipid profiles and cardiovascular prognosis in post-percutaneous coronary intervention atherosclerotic cardiovascular disease patients: a prospective cohort study

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ABSTRACT

Objective Patients with atherosclerotic cardiovascular disease (ASCVD) following percutaneous coronary intervention (PCI) are classified as very-high-risk individuals in cardiovascular disease (CVD) risk stratification. The distribution pattern of traditional Chinese medicine (TCM) syndromes in this patient population, as well as its association with blood lipid profiles and clinical prognosis, remains unclear. The present prospective cohort study aims to investigate these correlations, thereby providing insights to enrich the research fields.

Methods We enrolled consecutive patients with ASCVD who underwent PCI at the Integrated Cardiology Unit of China-Japan Friendship Hospital between September 1, 2020 and December 31, 2022. Demographics and clinical characteristics, signs and symptoms defining each TCM syndrome, and fasting venous blood samples were collected at baseline and follow up or upon major adverse cardiovascular events (MACEs). We analyzed the correlation between TCM syndromes, blood lipid profiles, and MACEs, and developed a new joint prognostic model incorporating both TCM syndromes and blood lipids using logistic regression. The analyses were based on detailed baseline and one-year follow-up data.

Results A per-protocol analysis was performed on 586 patients with complete data ultimately. During the one-year follow-up, 174 patients (29.69%) experienced a MACE. We performed statistical analyses on comorbidities, medication, and biochemical indicators across groups defined by TCM syndrome differentiation. When comparing different TCM syndromes, no significant differences were found in age, body mass index (BMI), history of revascularization, comorbidities, family history of CVD, smoking or drinking, or statin intensity ($P > 0.05$). Patients with intertwined phlegm and blood stasis syndrome exhibited significantly higher levels of total cholesterol (TC, 5.27 ± 1.18 mmol/L, $P < 0.001$), triglyceride (TG, 1.96 ± 1.33 mmol/L, $P = 0.008$), low-density lipoprotein cholesterol (LDL-C, 3.35 ± 0.79 mmol/L, $P < 0.001$), and high-density lipoprotein cholesterol (HDL-C, 1.24 ± 0.81 mmol/L, $P < 0.001$) compared with those with other TCM syndromes combined. A multivariable logistic regression model was constructed to predict MACEs. The model included TCM syndrome type [with intertwined phlegm and blood stasis as a predictor, adjusted odds ratio (OR) = 1.413, 95% confidence

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interval (CI): 0.517 – 3.864, P = 0.501], age (adjusted OR = 0.97, 95% CI: 0.955 – 1.001, P = 0.057), male gender (adjusted OR = 0.698, 95% CI: 0.416 – 1.170, P = 0.173), TC (adjusted OR = 1.004, 95% CI: 0.513 – 1.965, P = 0.990), and LDL-C (adjusted OR = 5.825, 95% CI: 2.214 – 15.326, P < 0.001). This model demonstrated good discriminatory ability for MACEs in post-PCI ASCVD patients [the area under the receiver operating characteristic (ROC) curve (AUC) = 0.865, 95% CI: 0.816 – 0.914].

Conclusion The intertwined phlegm and blood stasis TCM syndrome is associated with a distinct atherogenic lipid profile characterized by elevated levels of TC and LDL-C. The prognostic model that incorporates this TCM syndrome type along with conventional lipid parameters (TC and LDL-C) shows good discriminatory ability for predicting MACEs in ASCVD patients after PCI, underscoring the potential clinical utility of integrating TCM syndrome differentiation into CVD risk assessment.

1 Introduction

Atherosclerotic cardiovascular disease (ASCVD) refers to a spectrum of cardiovascular diseases (CVD) primarily caused by atherosclerosis. Its clinical manifestations range from acute coronary syndrome, a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, and transient ischemic attack, to peripheral arterial disease—all assumed to be of atherosclerotic origin [1]. Despite advances in management, around one-fourth of all deaths in industrialized countries are attributed to ASCVD. Research has established low-density lipoprotein cholesterol (LDL-C) as its central causative agent [2]. Percutaneous coronary intervention (PCI) has become a prevalent treatment for ASCVD with moderate to severe vascular stenosis, and LDL-C lowering remaining the cornerstone of therapy [3]. However, even under standardized lipid-lowering regimens, patients undergoing PCI continue to face a high residual risk of recurrent clinical events [4], a phenomenon commonly observed in practice that may be attributed to inadequate lipid control and complex comorbidities [5]. Furthermore, ASCVD risk management is complicated by multiple factors beyond lipids, including gender, age, body mass index (BMI), inflammation, and other comorbidities [6, 7]. Given the persistent challenges in secondary prevention, researchers and clinicians have increasingly explored traditional Chinese medicine (TCM) as a complementary therapeutic approach. This interest has stimulated both basic and clinical investigations into TCM's potential role in CVD management [8]. Previous studies have supported the clinical relevance of specific TCM syndromes as important pathological indicators in the context of CVD patients and typical TCM syndrome patterns have been described in broader CVD populations [9-11], the distribution of TCM syndromes in the very-high-risk subgroup of ASCVD patients after PCI remains unclear and requires further investigation. Moreover, given the well-established prognostic role of blood lipids [7], the potential correlation between TCM syndromes and lipid profiles in ASCVD patients following PCI lacks robust clinical evidence. Therefore, we conducted an original prospective cohort study to explore the associations between TCM syndromes, lipid profiles, and clinical prognosis. Ultimately, we developed and validated a combined prognostic model incorporating TCM syndrome differentiation and key cholesterol parameters for this patient population.

2 Materials and methods

2.1 Patients and study design

This prospective cohort study was conducted in accordance with the transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) guidelines [12]. We enrolled consecutive patients with ASCVD who underwent PCI at the Integrated Cardiology Unit of China-Japan Friendship Hospital between September 1, 2020 and December 31, 2022. The studies involving human participants were reviewed and approved by the Clinical Research Ethics Committee of China-Japan Friendship Hospital (Approval No. 2020-114-K73). The studies were conducted in accordance with the Declaration of Helsinki and registered with the China Clinical Trials Registry (ChiCTR1800017891).

Diagnoses were established based on the *Nomenclature Criteria for Diagnosis of Ischemic Heart Disease* issued by the International Society and Federation of Cardiology and the World Health Organization [13], and the *Guidelines for the Diagnosis and Treatment of Stable Ischemic Heart Disease* [14]. Inclusion criteria: (i) patients were angiographically confirmed ASCVD, defined as diameter stenosis ⩾ 50% in the left main coronary artery or in any of the three major epicardial coronary arteries or their major branches; (ii) patients had successful implantation of a drug-eluting stent with achievement of complete revascularization during the procedure; (iii) patients were aged 18 – 80 years. Exclusion criteria: (i) patients were unable to provide informed consent or complete study follow-up due to mental or language barriers;

(ii) patients with comorbidities including end-stage organ failure, severe hepatic or renal dysfunction, severe hematologic or endocrine disorders, or a life expectancy of less than 12 months; (iii) patients participated in other clinical trials within the past 30 d. Removal and dropout criteria: (i) incomplete baseline or follow-up data (a loss of > 50% of key variables) that precluded meaningful analysis; (ii) participants who were lost to follow-up or voluntarily withdrew from the study. All participants provided written informed consent for study participation and the use of their data for research purposes.

2.2 Baseline data

Demographic and clinical characteristics were collected at baseline, including gender, age, height, weight, BMI, history of revascularization, and comorbidities such as hypertension, hyperlipidemia, heart failure, myocardial infarction, arrhythmia, cerebrovascular disease, chronic kidney disease, diabetes, and carotid atherosclerosis. Smoking and alcohol consumption history, family history of CVD, and use of lipid-lowering medications were also recorded.

2.3 Collection and differentiation of TCM syndromes

The diagnostic criteria for TCM syndromes were established after enrollment based on the revised *TCM Syndrome Differentiation Criteria for Coronary Heart Disease* issued by the Cardiovascular Society of the Chinese Society of Integrated Traditional Chinese and Western Medicine [15], with additional reference to the textbook *Internal Medicine of Traditional Chinese Medicine* [16]. For a TCM syndrome diagnosis, patients were required to exhibit at least one of the two cardinal symptoms—chest tightness or chest pain—along with two or more supporting symptoms corresponding to a specific TCM syndrome. All diagnoses were independently validated by at least two chief specialist physicians specializing in TCM cardiology to ensure consistency and reproducibility. The differentiation procedure was conducted and documented by two or more experts using these standardized criteria. The primary TCM syndromes identified in this cohort of post-PCI ASCVD patients were as follows: intertwined phlegm and blood stasis, phlegm-turbidity obstruction, blood stasis in heart, Qi deficiency and blood stasis, Qi stagnation and blood stasis, cold-induced blood stasis, Qi-Yin deficiency, and Yang deficiency of heart and kidney [17]. The specific signs and symptoms defining each TCM syndrome are detailed in Table 1.

2.4 Blood collection and quantification

Fasting venous blood samples were collected on the morning following admission. Follow-up samples were collected either at the 1-year visit or upon the occurrence of major adverse cardiovascular events (MACEs). All laboratory analyses were performed at China-Japan Friendship Hospital and included measurements of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglycerides (TG). Coronary angiography data and

Table 1 Signs and symptoms of corresponding TCM syndromes

TCM syndrome	Sign and symptom	Tongue	Pulse
Intertwined phlegm and blood stasis	Patients exhibit similar clinical features of phlegm-turbidity obstruction but experience more chest pain than tightness	Purplish-dark tongue or with ecchymosis	Choppy or wiry
Phlegm-turbidity obstruction	Patients tend to present with obesity or overweight, heavy limbs, excessive phlegm production, dyspnea, and pronounce chest tightness and pain; accompanying symptoms include fatigue, loose stools or constipation, copious sputum	White or slippery coating	Smooth or heavy
Blood stasis in heart	Blood stasis in heart manifests as fixed, stabbing chest pain, typically worsening at night	Purplish-dark tongue or with petechiae	Wiry
Qi deficiency and blood stasis	Qi deficiency and blood stasis is characterized by spontaneous sweating, fatigue, shortness of breath	Pale or swollen tongue with teeth marks	Weak, hesitant
Qi stagnation and blood stasis	Qi stagnation with blood stasis syndrome arises from emotional distress, often accompanied by epigastric distension and tightness relieved by belching	Purplish-dark tongue with white coating	Thready, hesitant
Cold-induced blood stasis	Cold induced blood stasis syndrome features cold limbs, pallor, spontaneous sweating, palpitations, and dyspnea, frequently triggered or worsened by cold exposure	White tongue coating	Deep, wiry or hesitant
Qi-Yin deficiency	Patients tend to present with palpitations, exertional dyspnea, fatigue	Wollen or teeth-marked tongue with scant or absent coating	Weak, slow
Yang deficiency of heart and kidney	Yang deficiency of heart and kidney features palpitations, chest pain, aversion to cold, limb edema, pallor, pale or cyanotic lips and nails	Pale or purplish tongue with white, greasy, or slippery coating	Deep or faint

other clinical information were retrieved from the hospital information system with appropriate authorization.

2.5 Endpoints and follow-up

After enrollment, patients were followed up every three months through outpatient visits or online consultations conducted by an independent physician. Follow-up time was calculated from the baseline assessment until the first occurrence of any of the following: a MACE, loss to follow-up, or the end of the study period. The primary endpoint was the occurrence of a MACE, which was a composite of all-cause death, non-fatal myocardial infarction, non-fatal stroke, any revascularization, and unplanned hospitalization due to angina or heart failure. Throughout the study, all patients received standard-of-care treatment for their comorbidities and had access to research consultation throughout the follow-up period. In accordance with the 2019 European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) Guidelines for the management of dyslipidaemias [7], individualized intensive lipid-lowering therapy was implemented and maintained. The therapy included statins (with the type and dose intensity determined clinically), fibrates, bile acid sequestrants (anion exchange resins), nicotinic acid and its derivatives, and cholesterol absorption inhibitors (ezetimibe). No pharmacological or procedural interventional measures were administered beyond standard care, and lifestyle recommendations were provided based on individual clinical conditions.

2.6 Statistical analysis

Statistical analyses were performed using SPSS 30.0, with a two-sided P value < 0.05 considered statistically significant [18]. Continuous variables are presented as mean ± standard deviation (SD) if normally distributed, or as median with interquartile range (IQR) if skewed. Categorical variables are summarized as frequencies and percentages. Group comparisons for continuous variables were conducted using the independent samples t test (for two groups) or one-way ANOVA with Tukey's post hoc test (for more than two groups) for normally distributed data; the Mann-Whitney U test (for two groups) or the Kruskal-Wallis test (for more than two groups) was used for non-normally distributed data. Comparisons of categorical variables were performed using the Chi-square test.

To identify prognostic factors, univariate analyses were conducted. Variables with P < 0.10 in univariate analysis or those of established clinical relevance were entered into a multivariable logistic regression model to adjust for potential confounding factors and to identify independent predictors of MACEs. A prognostic model for MACEs was developed using established CVD risk factors, including demographics (age and gender) and biochemical indicators of lipids. Subsequently, the potential enhancement of this model by integrating specific TCM syndromes was assessed to build a combined predictive tool. The discriminatory performance of the final prediction model was evaluated using receiver operating characteristic (ROC) curve analysis, with the area under the curve (AUC) and its 95% confidence interval (CI) reported. The AUCs of the prediction models were formally compared using DeLong's test. Based on the event rate and the number of candidate predictors, the sample size was deemed adequate for the planned logistic regression analysis [18, 19].

3 Results

3.1 Patient characteristics and clinical outcomes

Of the 669 initially enrolled participants, 83 were excluded after enrollment prior to analysis: 39 due to severe comorbidities (e.g. end-stage heart failure or malignancy) or a life expectancy of < 12 months, 1 due to concurrent participation in another clinical trial, 23 due to extensive missing baseline or follow-up data (a loss of > 50% of key variables), and 20 participants were lost to follow-up or voluntarily withdrew from the study. Therefore, a per-protocol analysis was performed on 586 patients with complete data. Of these, 80 patients presented with acute myocardial infarction and underwent emergency PCI, while the remainder underwent elective PCI. The mean age of the analyzed cohort was 62.44 years, and the mean BMI was 25.46 kg/m^2. The cohort consisted of 413 males (70.5%) and 173 females (29.5%), indicating a profile of predominantly middle-aged to elderly, overweight male patients with multiple comorbidities, which is typical for post-PCI ASCVD populations. Patients were stratified into age groups at 10-year intervals. The gender distribution differed significantly across age strata (P < 0.001), with male patients outnumbering females in all age groups above 50 years (Table 2). During the one-year follow-up, 174 patients (29.69%) experienced a MACE. The most frequent event was rehospitalization for recurrent angina (n = 149), of whom 93 subsequently underwent revascularization. Other events included cerebral stroke (n = 11), acute myocardial infarction (n = 6),

Table 2 Gender proportion of patients among different age groups

Age (year)	Total [n (%)]	Male [n (%)]	Female [n (%)]
18 – 29	0 (0.0)	0 (0.0)	0 (0.0)
30 – 39	12 (2.0)	11 (91.7)	1 (8.3)
40 – 49	62 (10.6)	52 (83.9)	10 (16.1)
50 – 59	145 (24.7)	121 (83.4)	24 (16.6)
60 – 69	202 (34.5)	136 (67.3)	66 (32.7)
70 – 80	166 (28.3)	93 (56.0)	73 (44.0)
Total	586 (100.0)	413 (70.5)	173 (29.5)
P value	< 0.001	< 0.001	< 0.001

rehospitalization for heart failure (n = 6), and the finding of new significant coronary lesions requiring revascularization upon follow-up angiography (n = 2). No deaths occurred during the study period.

3.2 Descriptions of TCM symptoms and syndrome distribution

The presence and severity of TCM symptoms and signs were meticulously assessed for each patient. These individual assessments are summarized in Table 3. By applying the diagnostic criteria outlined in Table 1 to the symptom data in Table 3, the distribution of TCM syndromes was determined. The most frequently observed TCM symptoms among the 586 patients were as follows: chest pain or chest tightness (n = 439, 74.9%), palpitations (n = 249, 42.5%), fatigue (n = 187, 31.9%), discomfort of the waist and knees (n = 134, 22.9%), dizziness or headache (n = 125, 21.3%), impatience or irritability (n = 124, 21.2%), anxiety or depression (n = 98, 16.7%), heaviness in head or drowsiness (n = 94, 16.0%), fear of cold (n = 78, 13.3%), dry mouth or throat (n = 71, 12.1%), facial or limb swelling (n = 68, 11.6%), and fear of heat (n = 67, 11.4%). The distribution of TCM syndromes among the 586 patients was uneven (P < 0.001), with intertwined phlegm and blood stasis being the most prevalent (n = 154, 26.3%), followed by cold-induced blood stasis (n = 89, 15.2%), Qi stagnation and blood stasis (n = 74, 12.6%), phlegm-turbidity obstruction (n = 71, 12.1%), Qi-Yin deficiency (n = 66, 11.3%), Qi deficiency and blood stasis (n = 53, 9.0%), Yang deficiency of heart and kidney (n = 40, 6.8%), and blood stasis in heart (n = 39, 6.7%) (Table 4).

3.3 Comparison of baseline characteristics by different TCM syndrome

Baseline characteristics stratified by different TCM syndrome type are detailed in Table 4. In summary, there were no significant differences across syndrome groups in terms of age, BMI, history of revascularization, comorbidities, family history of CVD, personal smoking or alcohol consumption history, or the use and intensity of lipid-lowering therapy (statins or ezetimibe) (P > 0.05). However, two notable exceptions were observed. First, gender distribution differed significantly among the TCM syndrome groups (P = 0.010). The intertwined phlegm and blood stasis syndrome was significantly less prevalent in males, whereas the Qi-Yin deficiency syndrome showed the opposite pattern, suggesting potential gender-specific susceptibility among post-PCI ASCVD patients. Second, the prevalence of carotid atherosclerosis varied significantly (P = 0.008), being higher in patients diagnosed with syndromes characterized by intertwined phlegm and blood stasis, namely intertwined phlegm-turbidity obstruction, and blood stasis in the heart.

3.4 Association between TCM syndromes and blood lipids profiles

The overall mean lipid levels in the cohort were as follows: TC, 4.16 ± 1.26 mmol/L; TG, 1.70 ± 1.17 mmol/L; LDL-C, 2.59 ± 0.89 mmol/L; and HDL-C, 1.08 ± 0.47 mmol/L. The mean LDL-C level exceeded the recommended LDL-C target of < 1.8 mmol/L for very-high-risk ASCVD patients, indicating overall suboptimal lipid control. A striking disparity was observed when data were stratified by TCM syndromes (Table 5). Patients diagnosed with intertwined phlegm and blood stasis syndrome exhibited significantly higher lipid levels across all parameters compared to the composite group of all other TCM syndromes: TC (5.27 ± 1.18 mmol/L, P < 0.001), TG (1.96 ± 1.33 mmol/L, P = 0.008), LDL-C (3.35 ± 0.79 mmol/L, P < 0.001), HDL-C (1.24 ± 0.81 mmol/L, P < 0.001), suggesting a strong association between this syndrome and dyslipidemia. The distribution of TCM syndromes and corresponding blood lipid profiles are presented in Table 5.

Table 3 Descriptions and statistics of the top 12 TCM symptoms

TCM symptom	Mild case [n (%)]	Moderate case [n (%)]	Severe case [n (%)]	Total case [n (%)]
Chest pain or chest distress	74 (12.6)	283 (48.3)	82 (14.0)	439 (74.9)
Palpitation	48 (8.2)	162 (27.6)	39 (6.7)	249 (42.5)
Fatigue	117 (20.0)	54 (9.2)	16 (2.7)	187 (31.9)
Discomfort of the waist and knees	96 (16.4)	34 (5.8)	4 (0.7)	134 (22.9)
Dizziness or headache	82 (14.0)	23 (3.9)	20 (3.4)	125 (21.3)
Impatience or irritability	89 (15.2)	30 (5.1)	5 (0.9)	124 (21.2)
Anxiety or depression	56 (9.6)	30 (5.1)	12 (2.0)	98 (16.7)
Heaviness in head or drowsiness	69 (11.8)	18 (3.1)	7 (1.2)	94 (16.0)
Fear of cold	53 (9.0)	19 (3.2)	6 (1.0)	78 (13.3)
Dry mouth or throat	50 (8.5)	12 (2.0)	9 (1.5)	71 (12.1)
Facial or limb swelling	45 (7.7)	20 (3.4)	3 (0.5)	68 (11.6)
Fear of heat	56 (9.6)	11 (1.9)	0 (0.0)	67 (11.4)

Table 4 Demographics and medical characteristics of different TCM syndromes

Variable	TCM syndrome 1	TCM syndrome 2	TCM syndrome 3	TCM syndrome 4	TCM syndrome 5	TCM syndrome 6	TCM syndrome 7	TCM syndrome 8	Total (n = 586)	P value[a]
Gender [male, n (%)]	90 (58.4)	48 (67.6)	30 (76.9)	41 (77.4)	57 (77.0)	68 (76.4)	52 (78.8)	27 (67.5)	413 (70.5)	**0.010**
Age (year)	62.21 ± 10.37	64.28 ± 10.37	62.79 ± 9.31	63.64 ± 11.18	63.08 ± 9.85	61.27 ± 10.69	60.06 ± 10.97	63.43 ± 10.19	62.44 ± 10.43	0.314
BMI (kg/m^2)	25.24 ± 3.45	25.38 ± 3.78	26.49 ± 4.88	24.32 ± 3.25	25.47 ± 2.78	25.15 ± 3.76	26.21 ± 3.88	26.26 ± 3.30	25.46 ± 3.62	0.135
Revascularization [n (%)]	23 (14.9)	7 (9.9)	6 (15.4)	9 (17.0)	17 (23.0)	13 (14.6)	15 (22.7)	8 (20.0)	98 (16.7)	0.410
Hypertension [n (%)]	94 (74.6)	39 (67.2)	20 (71.4)	25 (62.5)	40 (66.7)	57 (79.2)	44 (75.9)	24 (80.0)	343 (72.7)	0.436
Hyperlipidemia [n (%)]	80 (63.5)	34 (58.6)	19 (67.9)	24 (60.0)	35 (58.3)	45 (62.5)	35 (60.3)	21 (70.0)	293 (62.1)	0.954
Cerebrovascular disease [n (%)]	25 (19.8)	18 (31.0)	6 (21.4)	6 (15.0)	14 (23.3)	19 (26.4)	16 (27.6)	4 (13.3)	108 (22.9)	0.421
Heart failure [n (%)]	19 (15.1)	7 (12.1)	5 (17.9)	9 (22.5)	8 (13.3)	16 (22.2)	4 (6.9)	3 (10.0)	71 (15.0)	0.255
Arrhythmia [n (%)]	8 (6.3)	7 (12.1)	4 (14.3)	5 (12.5)	7 (11.7)	11 (15.3)	9 (15.5)	2 (6.7)	53 (11.2)	0.509
Myocardial infarction [n (%)]	32 (25.6)	14 (24.1)	8 (28.6)	10 (25.6)	20 (33.3)	23 (31.9)	24 (41.4)	8 (27.6)	139 (29.6)	0.471
Carotid atherosclerosis [n (%)]	45 (93.8)	33 (100.0)	20 (95.2)	20 (87.0)	26 (83.9)	63 (76.8)	37 (86.0)	14 (70.0)	258 (85.7)	**0.008**
Diabetes [n (%)]	52 (41.3)	21 (36.2)	14 (50.0)	16 (40.0)	26 (43.3)	36 (50.0)	22 (37.9)	11 (36.7)	198 (41.9)	0.744
Chronic kidney disease [n (%)]	7 (4.5)	5 (7.0)	2 (5.1)	5 (9.4)	6 (8.1)	6 (6.7)	2 (3.0)	2 (5.0)	35 (6.0)	0.818
Family history of cardiovascular disease [n (%)]	61 (50.4)	29 (50.9)	16 (59.3)	19 (47.5)	30 (51.7)	32 (47.1)	31 (54.4)	18 (60.0)	236 (51.5)	0.922
Smoking [n (%)]	56 (45.2)	21 (36.8)	14 (50.0)	18 (46.2)	32 (54.2)	23 (31.9)	31 (53.4)	18 (60.0)	213 (45.6)	0.069
Drinking [n (%)]	42 (34.7)	22 (39.3)	10 (37.0)	14 (37.8)	22 (37.9)	17 (25.0)	20 (34.5)	18 (60.0)	165 (36.3)	0.115
Ezetimibe [n (%)]	65 (42.2)	27 (38.0)	13 (33.3)	25 (47.2)	30 (40.5)	34 (38.2)	21 (31.8)	16 (40.0)	231 (39.4)	0.757
Statins intensity [moderate intensity, n (%)]	123 (93.9)	62 (96.9)	26 (92.9)	41 (100.0)	60 (96.8)	71 (95.9)	57 (96.6)	30 (100.0)	470 (96.1)	0.475
Total (n = 586)	154 (26.3)	71 (12.1)	39 (6.7)	53 (9.0)	74 (12.6)	89 (15.2)	66 (11.3)	40 (6.8)		**< 0.001**

[a]Demographics and medical characteristics of different TCM syndromes, with bolded values representing statistical significance ($P < 0.05$). Normally distributed data are expressed as mean ± SD, non-normally distributed data are expressed as median (IQR), count data are expressed as percentages. TCM syndrome 1, intertwined phlegm and blood stasis. TCM syndrome 2, phlegm turbidity obstruction. TCM syndrome 3, blood stasis in heart. TCM syndrome 4, Qi deficiency and blood stasis. TCM syndrome 5, Qi stagnation and blood stasis. TCM syndrome 6, cold induced blood stasis. TCM syndrome 7, Qi-Yin deficiency. TCM syndrome 8, Yang deficiency of heart and kidney.

Table 5 Blood lipids profile of different TCM syndromes

TCM syndrome	TG (mmol/L)	TC (mmol/L)	LDL-C (mmol/L)	HDL-C (mmol/L)
Intertwined phlegm and blood stasis (n = 154)	1.96 ± 1.33	5.27 ± 1.18	3.35 ± 0.79	1.24 ± 0.81
Phlegm turbidity obstruction (n = 71)	1.93 ± 1.90	4.32 ± 1.02	2.68 ± 0.75	1.08 ± 0.23
Blood stasis in heart (n = 39)	1.52 ± 0.53	3.92 ± 1.28	2.46 ± 0.98	1.01 ± 0.23
Qi deficiency and blood stasis (n = 53)	1.37 ± 0.64	3.63 ± 0.95	2.23 ± 0.69	1.01 ± 0.27
Qi stagnation and blood stasis (n = 74)	1.59 ± 0.82	3.72 ± 0.95	2.28 ± 0.75	1.02 ± 0.24
Cold induced blood stasis (n = 89)	1.55 ± 0.97	3.54 ± 1.04	2.18 ± 0.72	0.97 ± 0.21
Qi-Yin deficiency (n = 66)	1.52 ± 0.77	3.56 ± 0.89	2.16 ± 0.64	1.01 ± 0.18
Yang deficiency of heart and kidney (n = 40)	1.72 ± 1.10	3.70 ± 0.97	2.23 ± 0.66	1.05 ± 0.26
Total (n = 586)	1.70 ± 1.17	4.16 ± 1.26	2.59 ± 0.89	1.08 ± 0.47
P value	0.008	< 0.001	< 0.001	< 0.001

3.5 Development and performance of MACE prediction models

To assess the additive prognostic value of TCM syndromes beyond conventional risk factors, we developed three multivariate logistic regression models for predicting one-year MACEs. Model Ⅰ included only the TCM syndrome type (with intertwined phlegm and blood stasis as the primary indicator). Model Ⅱ incorporated the TCM syndrome indicator along with established clinical predictors: age, gender, TC, and LDL-C. Model Ⅲ included only the conventional clinical predictors (age, gender, TC, and LDL-C) for comparison. The discriminatory performance of each model is summarized in Figure 1 and Table 6. Model Ⅰ (AUC = 0.642, 95% CI: 0.593 – 0.691) demonstrated modest predictive ability. The performance improved markedly when clinical variables were added. Model Ⅱ achieved the highest AUC of 0.865 (95% CI: 0.816 – 0.914). In this full model, elevated LDL-C was the strongest independent predictor of MACEs [adjusted odds ratio (OR) = 5.825, 95% CI: 2.214 – 15.326, P < 0.001]. The adjusted odds ratios for the TCM syndrome indicator (intertwined phlegm and blood stasis), age, gender, and TC were not statistically significant (P > 0.05) (Table 6). Model Ⅲ, containing only the conventional factors, also showed high discrimination (AUC = 0.855, 95% CI: 0.805 – 0.902). Formal comparison using DeLong's test revealed no statistically significant difference in AUC between Model Ⅱ and Model Ⅲ (P > 0.05), suggesting that the inclusion of the TCM syndrome variable did not significantly improve the model's discriminatory power beyond that provided by age, gender, TC, and LDL-C.

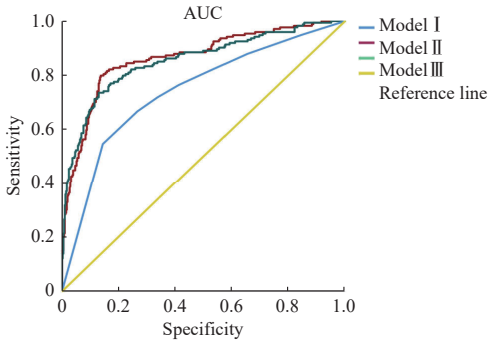

Figure 1 The AUC for the three prediction models of MACEs

Model I: includes only the TCM syndrome indicator (intertwined phlegm and blood stasis). Model II: includes the TCM syndrome indicator, age, gender, TC, and LDL-C. Model III: includes age, gender, TC, and LDL-C (without TCM syndrome). The diagonal yellow solid line represents the line of identity (AUC = 0.50), indicating no discriminative ability.

Table 6 Adjusted ORs and 95% CIs for multiple prediction models

Model	Variable	Beta	OR (95% CI)	P value
Model Ⅰ	TCM syndromes	1.863	6.441 (2.780, 14.921)	< 0.001
Model Ⅱ	TCM syndromes	0.346	1.413 (0.517, 3.864)	0.501
	TC	0.004	1.004 (0.513, 1.965)	0.990
	LDL-C	1.762	5.825 (2.214, 15.326)	< 0.001
	Age	– 0.023	0.978 (0.955, 1.001)	0.057
	Gender (male)	– 0.359	0.698 (0.416, 1.170)	0.173
Model Ⅲ	TC	0.133	1.142 (0.594, 2.198)	0.690
	LDL-C	1.791	5.993 (2.329, 15.423)	< 0.001
	Age	– 0.021	0.979 (0.957, 1.002)	0.072
	Gender (male)	– 0.421	0.657 (0.395, 1.090)	0.104

4 Discussion

4.1 Characteristics and management gaps in post-PCI ASCVD patients

This study confirms that patients with ASCVD following PCI, who are stratified as very-high risk, constitute a distinct demographic characterized by advanced age,

male predominance, and a high burden of comorbidities. Notably, our findings highlight a critical gap between clinical guidelines and real-world practice: the vast majority of these high-risk patients failed to achieve recommended lipid targets. The mean LDL-C level (2.59 mmol/L) substantially exceeded the goal of less than 1.8 mmol/L [7], underscoring a pervasive issue of suboptimal lipid management in this population [20, 21]. This gap likely stems from a combination of factors, including therapeutic inertia and suboptimal adherence to intensive lipid-lowering regimens, pointing to an urgent need for more effective, system-level strategies to bridge this divide [22, 23]. The demographic profile observed—a mean age over 60 years with a consistent male predominance across all age groups—aligns with established epidemiological data for ASCVD [24]. The sharp increase in patients meeting PCI criteria after age 50 likely reflects the cumulative progression of atherosclerosis, while the persistent gender disparity warrants further investigation into both biological and sociobehavioral determinants of cardiovascular risk [25].

4.2 Association between TCM syndromes and dyslipidemia: linking "phlegm-stasis" with elevated LDL-C

The most salient finding of this study is the strong association between the intertwined phlegm and blood stasis syndrome and a profoundly atherogenic lipid profile, characterized by significantly elevated levels of LDL-C, TC, and TG. This observation provides compelling clinical support for the classical TCM pathogenesis of "phlegm and stasis collaborating to cause vessel obstruction", suggesting that the syndrome may identify a subgroup of post-PCI patients with a particularly adverse metabolic disturbance. Importantly, the mean LDL-C level in this syndrome subgroup (3.35 mmol/L) was not only drastically higher than in other syndromes but also far exceeded the stringent contemporary goal of < 1.8 mmol/L for very-high-risk patients [7]. This highlights a critical management gap: patients exhibiting the phlegm-stasis pattern, who are theoretically at the highest risk, are in practice among the most poorly controlled. Our finding that HDL-C was also elevated in this group adds complexity, potentially indicating a dysfunctional HDL particle or a unique metabolic phenotype that warrants further investigation. While LDL-C remains the primary therapeutic target, our results suggest that TCM syndrome differentiation, particularly the identification of the phlegm-stasis pattern, could serve as a valuable clinical marker for pinpointing individuals with severe residual dyslipidemia who are likely to benefit most from intensification of lipid-lowering therapy [26, 27]. This integrative approach may help bridge the gap between guideline recommendations and real-world achievement of lipid targets.

4.3 Integrating TCM syndrome differentiation with biochemical indicators for cardiovascular risk prediction

The Framingham risk score and its derivatives are globally established tools for predicting long-term CVD risk [28]. Previous study has identified factors that provide predictive value beyond the scope of the Framingham risk score [29]. Thus, in parallel, we tried to develop novel integrated models that combine TCM syndromes differentiation with established risk factors for MACEs assessment. Previous studies have systematically examined the therapeutic benefits, potential risks, and mechanistic foundations of TCM for CVD patients [30, 31]. In TCM theory, CVD is categorized as "chest impediment" or "heart pain" based on clinical presentation, and is attributed to an imbalance between Yin and Yang. This manifests as deficiency of Qi, blood, Yin, Yang, or viscera (especially the kidney, spleen, and heart), as well as imbalance of cold and heat, ultimately generating pathological factors such as blood stasis and phlegm turbidity [32]. Epidemiological data indicate that CVD patients exhibit distinct TCM syndrome distributions, reflecting characteristic physiological and pathological patterns in this population [33]. As shown in this study, TCM syndromes correlate with blood lipid profiles, which may contribute to disease progression. Existing evidence demonstrates that biochemical indicators, clinical features, and vascular conditions serve as prognostic predictors [34, 35], while TCM syndromes similarly forecast clinical outcomes in CVD [33]. Although the inclusion of TCM syndromes did not significantly improve the performance of the predictive model, this study provides a rationale for their potential clinical utility in cardiovascular risk assessment and warrants further investigation.

4.4 Integrating TCM syndrome differentiation with dyslipidemia management: pathophysiological and clinical implications

This study advances the understanding of TCM syndromes in CVD by quantitatively linking a specific syndrome—intertwined phlegm and blood stasis—with a severe dyslipidemic phenotype characterized by markedly elevated LDL-C. This correlation provides empirical support for the centrality of "phlegm" and "stasis" in the TCM pathogenesis of atherosclerosis (vessel obstruction), suggesting these concepts may, in part, correspond to identifiable metabolic derangements. The high prevalence of phlegm-stasis syndromes in our cohort aligns with prior epidemiological reports [36, 37]. However, our data extend beyond distribution patterns by revealing a quantitative biochemical anchor for the intertwined phlegm and blood stasis syndrome. This finding challenges the notion that TCM syndromes are purely subjective patterns. Instead, it positions this syndrome as a

potential clinical indicator for a high-risk metabolic subset within the heterogeneous post-PCI population—those with significant residual lipid risk despite standard care. From a translational perspective, this association has immediate clinical relevance. Identifying patients with the intertwined phlegm and blood stasis syndrome could alert clinicians to a greater likelihood of uncontrolled atherogenic dyslipidemia, prompting more aggressive lipid-lowering therapy and closer monitoring. This represents a practical application of TCM differentiation to stratify risk and personalize management in the era of precision medicine, complementing conventional risk factors. The biological basis of this syndrome-lipid link warrants further investigation. While our study points to a clear phenotypic association, future research integrating omics technologies (e.g., metabolomics, transcriptomics) is needed to explore whether specific pathways related to lipid metabolism, inflammation, gene expression, or endothelial function underlie the phlegm-stasis syndrome [38], moving from correlation to mechanistic understanding.

4.5 Strengths and limitations

This study has several strengths. First, it is based on a prospectively enrolled, well-characterized cohort of post-PCI ASCVD patients, with a dedicated database that recorded an adequate number of clinical endpoint events for robust analysis. This design strengthens the causal inference regarding the association between TCM syndromes and outcomes. Second, we integrated TCM syndrome differentiation with conventional cardiovascular risk factors to construct a novel prognostic model. This integrative approach explores the potential of TCM patterns to provide incremental value for risk stratification beyond standard clinical variables. Third, our definition of the primary endpoint MACEs was more comprehensive than that used in many prior studies. By including ischemic and hemorrhagic strokes in addition to typical cardiac endpoints, our assessment of overall cardiovascular burden and risk is more complete. However, several limitations should be acknowledged. First, residual confounding is possible. Although all patients received guideline-directed intensive lipid-lowering therapy, we did not systematically collect detailed data on medication adherence, lifestyle factors (diet and physical activity), or a broader panel of biomarkers (e.g., apolipoproteins, inflammatory markers), which could influence both lipid profiles and clinical outcomes. Second, the generalizability of our findings is limited by the single-center design and relatively short follow-up period (one year). The patient population and clinical practices at the China-Japan Friendship Hospital may not fully represent other settings. Furthermore, the short-term follow-up precludes assessment of long-term outcomes and the potential evolution of TCM syndromes over time. Consequently, our results should be considered preliminary and hypothesis-generating. They require validation in larger, multicenter, prospective cohorts with longer follow-up. Future studies should also aim to develop more dynamic models that can account for changes in both lipid parameters and TCM syndrome patterns over the disease course.

5 Conclusion

The intertwined phlegm and blood stasis TCM syndrome is associated with a distinct atherogenic lipid profile characterized by elevated levels of TC and LDL-C. A prognostic model that incorporates this TCM syndrome type along with conventional lipid parameters (TC and LDL-C) shows good discriminatory ability for predicting MACEs in post-PCI ASCVD patients. These results underscore the potential of TCM syndrome differentiation to refine CVD risk stratification and guide personalized management in high-risk cardiovascular populations. The observed associations warrant validation in larger, multicenter cohorts.

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Ethical statement

The studies involving human participants were reviewed and approved by the Clinical Research Ethics Committee of China-Japan Friendship Hospital (Approval No. 2020-114-K73). The studies were conducted in accordance with the Declaration of Helsinki, and registered with the China Clinical Trials Registry (ChiCTR1800017891). All participants provided written informed consent to participate in this study.

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Author contributions

Huangyu Xu: conceptualization, data curation, formal analysis, investigation, methodology, and writing – original draft. Qian Li, Haozhe Xiong, Weidong Hong, and Xinyi Zhou: data curation. Xiaoyan Lu, Xiaoli Liu, and Xinrong Fan: methodology, funding acquisition, and

project administration. All authors approved the submission and take responsibility for this manuscript.

Competing interests

The authors declare no conflict of interest.

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经皮冠状动脉介入术后动脉粥样硬化性心血管疾病患者中医证候分布及其与血脂和心血管预后的相关性：一项前瞻性队列研究

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【摘要】目的 接受经皮冠状动脉介入治疗（PCI）的动脉粥样硬化性心血管疾病（ASCVD）患者被归类为心血管疾病（CVD）风险分层中的极高风险个体。该患者群体中医证候的分布模式及其与血脂谱和临床预后的关联尚不清楚，通过开展前瞻性队列研究旨在探讨这些相关性，为丰富研究领域提供见解。**方法** 纳入2020年9月1日至2022年12月31日期间在中日友好医院综合心脏病科接受PCI的ASCVD患者。在基线和随访或发生主要不良心血管事件（MACEs）时，收集人口统计数据和临床特征、体征和症状及对应中医证型，以及空腹静脉血样。我们分析了中医证型、血脂谱与MACEs之间的相关性，并使用逻辑回归开发了一个新的联合预后模型，该模型同时纳入了中医证型和血脂谱。以上分析基于详细的基线数据和一年随访数据。**结果** 对纳入的586名数据完整的患者进行了符合方案集分析。在为期一年的随访期间，174名患者（29.69%）发生了MACEs。我们对不同中医辨证分型组患者的合并症、用药情况和生化指标进行了统计分析。在比较不同中医证型分组时，未发现年龄、体重指数（BMI）、血运重建史、合并症、心血管疾病家族史、吸烟或饮酒情况或他汀类药物强度存在显著差异（$P > 0.05$）。与其他中医证型患者相比，痰瘀互结证型患者的总胆固醇（TC，5.27 ± 1.18 mmol/L，$P < 0.001$）、甘油三酯（TG，1.96 ± 1.33 mmol/L，$P = 0.008$）、低密度脂蛋白胆固醇（LDL-C，3.35 ± 0.79 mmol/L，$P < 0.001$）以及高密度脂蛋白胆固醇（HDL-C，1.24 ± 0.81 mmol/L，$P < 0.001$）水平显著升高。我们构建了一个多变量逻辑回归模型来预测主要不良心脏事件，该模型包括中医证型[痰瘀互结作为预测因子，调整后的比值比（OR）= 1.413，95%置信区间（CI）：0.517 – 3.864，$P = 0.501$]、年龄（调整后OR = 0.97，95% CI：0.955 – 1.001，$P = 0.057$）、男性（调整后OR = 0.698，95% CI：0.416 – 1.170，$P = 0.173$）、TC（调整后OR = 1.004，95% CI：0.513 – 1.965，$P = 0.990$）和LDL-C（调整后OR = 5.825，95% CI：2.214 – 15.326，$P < 0.001$）。该模型对PCI术后ASCVD患者的MACEs具有良好的判别能力[受试者工作特征（ROC）曲线下面积（AUC）= 0.865，95% CI：0.816 – 0.914]。**结论** 中医痰瘀互结证与致动脉粥样硬化脂质谱相关，其特征为TC和LDL-C水平升高。将该中医证型与常规脂质参数（TC和LDL-C）相结合的预后模型，在预测PCI术后ASCVD患者的MACEs方面具有良好的判别能力，这凸显了将中医辨证纳入心血管疾病风险评估的潜在临床价值。

【关键词】动脉粥样硬化性心血管疾病；经皮冠状动脉介入术后；中医证候；血脂；队列研究