# Establishment of Disease and Symptom Characteristics and Traditional Chinese Medicine Prognostic Risk Model After Coronary Revascularization Based on a Large-Sample Database

**Study Type:** Prospective Cohort Study

**Study Centers:** The Third Affiliated Hospital of Zhejiang Chinese Medical University (Lead Site)

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**Responsible Department at This Site:** Department of Cardiovascular Medicine

**Signature of Local Principal Investigator:**

Date: April 2026

This study will be conducted in accordance with this clinical study protocol and GCP.

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# Study Protocol

## 1. Study Background

### 1. Poor clinical prognosis in patients after coronary revascularization

Coronary artery disease (CAD) is a leading non-communicable cause of death and disability worldwide[1]. Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) are the core revascularization techniques for improving the prognosis of patients with severe CAD. In China, PCI has developed rapidly. In 2018, the total number of PCI procedures in mainland China exceeded 919,000, and this number continues to rise[2].

However, revascularization does not fully resolve the long-term prognosis of CAD, which is a chronic disease. Approximately 20%–30% of patients still experience recurrent angina after successful revascularization[3]. In-stent restenosis occurring 3–6 months after PCI is an important mechanical cause[4]. In addition, non-mechanical factors – such as incomplete revascularization (e.g., due to diffuse coronary disease), peri-procedural myocardial injury or microembolization, coronary microvascular dysfunction (incidence 30%–60%), coronary spasm, and psycho-cardiac factors – collectively contribute to myocardial ischemia and functional decline[5][6][7][8]. As a result, about 10%–15% of patients experience major adverse cardiovascular events (MACE) within one year after surgery[9]. These events severely affect the quality of life and long-term survival of patients after revascularization, posing a major challenge to postoperative management.

### 2. Lack of multidimensional, comprehensive identification and prediction methods after coronary revascularization

Confronted with these multifactorial, highly heterogeneous clinical problems, existing single-domain assessment tools show clear limitations. Traditional scoring systems such as GRACE and SYNTAX-II, along with laboratory and imaging examinations, can effectively evaluate anatomical and some physiological risks, but they fail to capture the systemic, functional, and psychological factors that lead to poor prognosis. They also overlook the physiological-psychological-social dynamic interactions emphasized by the

holistic view of Traditional Chinese Medicine (TCM), and cannot reflect the individual's dynamic overall state. The holistic view and syndrome differentiation system of TCM provide a complementary theoretical framework. According to TCM, the pathogenesis after PCI is mostly "root deficiency and branch excess, intermingled deficiency and excess," with qi deficiency, blood stasis, and phlegm turbidity persisting throughout. This is intrinsically related to the microcirculatory disorders, inflammatory state, and decreased cardiac function recognized by modern medicine. However, TCM syndrome differentiation still lacks unified and objective standards, limiting its value in large-scale clinical research and application.

The integration of artificial intelligence (AI) and multi-omics technologies makes it possible to construct a multi-dimensional identification and prediction system that integrates "macro-symptoms and micro-indicators". This system aims to: first, use machine learning algorithms to integratively analyze patients' structured electronic medical records, continuous physiological signals, imaging features, and TCM four-examination information to achieve objective and quantitative identification of TCM syndromes; second, introduce cutting-edge technologies such as metabolomics, proteomics, and tongue-coating microbiomics[10] to explore the molecular basis of different TCM syndromes from a systems biology perspective, thereby promoting precision-oriented syndrome differentiation; third, construct a comprehensive prognostic prediction model that integrates modern medical indicators and TCM syndrome information. Such a model will not only enable more accurate individual risk stratification but also provide a modern tool for the TCM principle of "preventing disease progression and recurrence after recovery," guiding early, targeted interventions in line with the strategic direction of "Healthy China".

Based on this, our team, relying on abundant clinical resources and preliminary data analyses, has already built a preliminary model framework. The present study is proposed to systematically complete the construction and validation of this integrated system, with the ultimate goal of substantially

improving risk management after revascularization.

## 2. Main Research Content, Objectives, Plan, Progress and Key Problems to be Solved

### 1. Research Content

#### 1.1 Development of the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”

First, to address the lack of unified standards for TCM assessment, this study will systematically review relevant TCM classics, TCM-Western medicine clinical studies, diagnostic and treatment experiences of renowned senior TCM experts, guidelines and consensus documents. Key information including TCM syndrome characteristics, imaging and laboratory results will be extracted. On this basis, data mining and natural language processing techniques will be used to develop a standardized “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”, establishing a unified data collection tool for subsequent research.

#### 1.2 Construction of a prospective longitudinal cohort and a multi-source clinical research database

This study will enroll 600 patients after coronary revascularization and conduct a prospective longitudinal study. At enrollment, demographic data, medical history, the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”, laboratory tests, imaging indicators, and biospecimens (tongue coating, blood) will be comprehensively collected. These will be analyzed using proteomics, metabolomics, and microbiomics technologies. Subsequently, patients will be followed up at 3, 6, 9, and 12 months after surgery to record MACE and dynamic changes in TCM-Western medicine clinical information. This will result in a multi-source, longitudinal clinical research database integrating macroscopic clinical indicators and micro-omics data.

### 1.3Establishment, validation and optimization of a TCM prognostic risk model after coronary revascularization

Based on the above database, after standardized data cleaning, LASSO regression and other feature selection methods will be used to select predictive variables. Model construction will proceed in three progressive steps: First, baseline clinical data, laboratory indicators, and imaging indicators will be used to construct a baseline prediction model (Model_Base) using a Cox proportional hazards model. Second, on the basis of Model_Base, multidimensional quantitative TCM syndrome characteristics (e.g., symptom scores, pattern element scores) will be introduced to construct a TCM-integrated model (Model_TCM) using machine learning algorithms (random forest, support vector machine). Third, on the basis of Model_TCM, micro-omics biomarkers including tongue-coating microbiota, proteomics, and metabolomics will be further integrated to construct a full-dimension fusion model (Model_Full) using deep learning algorithms (convolutional neural network, transformer). Finally, the model performance will be evaluated by external validation in at least three medical institutions, achieving a predictive accuracy of >85% to confirm the model’s stability, discriminative ability, and clinical applicability.

## 2. Study Objectives

(1) Based on literature research, develop the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”.

(2) Conduct a longitudinal study after coronary revascularization, construct a multi-source clinical research database integrating macro- and micro-indicators, screen out at least three sensitive and specific biomarkers for typical TCM patterns, and clarify their molecular biological characteristics.

(3) Based on the multi-source clinical research database and using AI, construct one prognostic risk model for post-revascularization outcomes, and conduct clinical validation in at least three medical institutions, achieving a predictive accuracy above 85%.

## 3.Study Plan

### 3.1 Literature research on post-coronary revascularization

Systematically review TCM classics, TCM-Western medicine clinical studies, diagnostic and treatment experiences of renowned senior TCM experts, guidelines and expert consensus related to post-coronary revascularization, as well as information on TCM syndrome characteristics, imaging and laboratory results. Using data mining and natural language processing techniques, develop the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”.

#### 3.1.1 Literature sources

(1) TCM literature: TCM clinical studies on post-coronary revascularization (2017-2025) indexed in major domestic and international databases; records related to post-coronary revascularization in TCM classics on chest stuffiness and pain (胸痹, 心痛), and diagnostic and treatment experiences of renowned senior TCM experts.

(2) Western medicine literature: Western clinical studies on post-coronary revascularization (2017-2025) indexed in major domestic and international databases.

#### 3.1.2 nclusion and exclusion criteria for clinical research literature

(1)Inclusion criteria

① Clear Western medicine diagnosis of post-coronary revascularization according to the *2025 Guidelines for Percutaneous Coronary Intervention*;

② For TCM clinical research literature, clear TCM pattern differentiation and case numbers (referencing the *Guideline for Integrative Medicine Diagnosis and Treatment of Acute Myocardial Infarction*).。

(2) Exclusion criteria

① For duplicate literature from the same source, retain the one with more complete information and exclude the others;

② Case reports, experience summaries, and literature reviews;

③ Incomplete or erroneous information.

### 3.1.3 Data cleaning and extraction

Information on disease diagnosis and TCM syndromes in the TCM-Western medicine literature will be standardized according to the *2025 Guidelines for Percutaneous Coronary Intervention* and the *2021 Integrative Medicine Diagnosis and Treatment Guideline for Angina Pectoris (After Coronary Revascularization)*. Content not mentioned will be retained as originally reported. Classification of pattern elements will refer to the *Diagnostic Criteria for Pattern Elements of Coronary Heart Disease Angina*. Extraction will be performed using named entity recognition (NER) technology, rule engines, and deep learning models.

### 3.1.4 Data statistical analysis

Descriptive statistical analysis will be performed using SPSS 26.0. Data mining and natural language processing techniques will be used to develop the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”.

## 3.2 Longitudinal study after coronary revascularization and construction of multi-source database

Conduct a longitudinal study after coronary revascularization, collecting TCM-Western medicine clinical indicators and biospecimens. Apply proteomics, metabolomics, and microbiomics technologies to analyze biospecimens, and construct a multi-source clinical research database integrating macro- and micro-indicators.

### 3.2.1 Diagnostic criteria

(1) Western medicine diagnostic criteria: refer to the *2025 Guidelines for Percutaneous Coronary Intervention*.

(2) TCM syndrome differentiation criteria: refer to the *2021 Integrative Medicine Diagnosis and Treatment Guideline for Angina Pectoris (After Coronary Revascularization)* for TCM syndrome diagnosis.

### 3.2.2 Inclusion and exclusion criteria

(1) Inclusion criteria: ① Meet the diagnostic criteria for post-coronary revascularization; ② Age ≥18 years; ③ Sign informed consent.

(2) Exclusion criteria: ① Patients with malignant arrhythmias, severe heart failure, myocardial diseases, structural heart disease or other severe cardiovascular diseases; ② Severe pulmonary insufficiency, severe liver or kidney dysfunction, severe electrolyte disturbances; ③ Pregnant or breastfeeding women; ④ Patients with severe psychiatric disorders, tumor-related blood diseases, rheumatic immune diseases or severe infections; ⑤ Other reasons leading to poor cooperation or compliance.

### 3.2.3 Clinical information collection

(1) Information collection on the day of enrollment includes:

① Demographics, medical history, medication use, etc.;

② The “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”;

③ Procedural characteristics: access route (radial/brachial/femoral artery), target vessel information (number, location), stent data (number, length, diameter);

④ Routine blood tests, blood lipids (total cholesterol, LDL, triglycerides, HDL), blood glucose (fasting glucose, HbA1c), cardiac enzymes (CK-MB), liver and kidney function, etc.;

⑤ Echocardiography;

⑥ Ambulatory ECG;

⑦ Collection of biospecimens (tongue coating, blood) for multi-omics (proteomics, metabolomics, microbiomics) analysis.

(2) At 12, 24, 36, and 48 weeks after enrollment, follow up for cardiovascular adverse events and repeat the “Information Collection Form for Traditional Chinese and Western Medicine After Coronary Revascularization”.

### 3.2.4 Sample size calculation

Based on preliminary literature research, this study plans to include approximately 60 TCM-Western medicine clinical indicators. According to Freeman’s rule of thumb (sample size ~10 times the number of parameters), approximately 600 patients after coronary revascularization will be enrolled.

### 3.2.5 Data quality control, extraction and cleaning

All researchers will receive uniform training by the research team to standardize data collection. After data extraction, mean imputation, K-nearest neighbors (KNN) imputation, Z-score normalization, one-hot encoding, principal component analysis (PCA), and LASSO regression will be applied. Finally, the collected macro- and micro-indicator information will be integrated and written into the database.

### 3.2.6 Statistical analysis

SPSS 26.0 will be used. Continuous variables will be analyzed by t-test or ANOVA; categorical variables by chi-square test; correlations by multiple logistic regression and Spearman correlation. Models will be built using traditional machine learning, deep learning, and large-model techniques. Cluster analyses will use hierarchical clustering, PCA + clustering, and K-means clustering. Sensitivity analysis will use Kappa coefficients and ROC curves. Multiple cross-validation will be used to reduce overfitting risk.

### 3.2.7 Data analysis requirements

Perform cross-dimensional and cross-modal analysis of multi-source data from patients after coronary revascularization to clarify the disease and symptom characteristics, biomarkers, TCM syndrome distribution, pattern element combination rules, and diagnostic indicators. Reveal their molecular biological characteristics and construct the multi-source clinical research database integrating macro- and micro-indicators.

### 3.2.8 Removal and dropout criteria

(1) Removal criteria (for enrolled patients who meet any of the following, they should be removed):

① During the study, it is found that they do not meet inclusion/exclusion criteria;

② Occurrence of serious complications or diseases unrelated to the study requiring withdrawal;

③ Failure to complete baseline assessments and biospecimen collection after enrollment.

④ Research fraud or major errors.

*Note: The reason for removal should be documented; original records should be retained for reference; data from removed patients will not be included in the final model construction, but baseline safety/tolerability data already collected may be used for relevant analyses.*

(2) Dropout criteria (enrolled patients who do not complete all required follow-up visits will be considered dropouts in the following situations):

① Patient voluntarily withdraws (revokes informed consent) or is lost to follow-up (cannot be contacted after repeated attempts);

② Missing rate ≥50% (i.e., missing 2 or more) of key follow-up time points (3, 6, 9, 12 months post-surgery);

③ Occurrence of a serious adverse event during the study that, in the investigator's judgment, makes continued participation inappropriate.

④ Investigator's decision to withdraw.

*Note: Dropouts should be documented with reasons. If baseline data are available and at least one follow-up assessment has been completed, the last available follow-up primary outcome data (e.g., MACE status, TCM syndrome score) may be carried forward and included in the prognostic model performance analysis; the study record should be retained for reference. All data collected before dropout will be retained and used in analyses.

### 3.3 Establishment of a TCM prognostic risk model after coronary revascularization

Perform standardized cleaning of information from the multi-source clinical research database. Select the most predictive feature set and build a TCM prognostic risk model for patients after coronary revascularization. Use external validation to assess model calibration and net benefit by decision curve analysis, thereby confirming model stability and clinical applicability.

(1) Feature processing: Standardized cleaning of information from the multi-source clinical research database after coronary revascularization. Use LASSO regression and other feature selection methods to select the most predictive feature set.

(2) Model construction:

① Model_Base (baseline model): incorporating routine laboratory indicators (complete blood count, blood glucose, blood lipids, markers of myocardial injury, inflammatory markers, etc.), imaging indicators (degree of coronary stenosis, echocardiography, ambulatory ECG, etc.) and basic clinical data, using a Cox proportional hazards model.

② Model_TCM (syndrome model): on the basis of Model_Base, introduce multidimensional quantitative TCM syndrome characteristics (including TCM symptom scores and pattern element scores) and use machine learning algorithms (random forest, support vector machine) to build a TCM syndrome model.

③ Model_Full (fusion model): on the basis of Model_TCM, further integrate micro-omics biomarkers (tongue-coating microbiota, proteomics, metabolomics) and use deep learning algorithms (convolutional neural network, transformer) to build a fusion model.

(3) **Model validation:** Use external validation in at least three medical institutions, assess model calibration and net benefit by decision curve analysis, achieve predictive accuracy >85%, and confirm model stability and clinical applicability.

4. Study Progress

(1) January 2026 – June 2026: Finalize study protocol and related inclusion/exclusion criteria, develop clinical information collection form, build clinical information management cloud platform, complete standardized training of researchers, perform ethics review and clinical study registration.

(2) July 2026 – December 2026: Enroll 50% of the target sample size for the longitudinal study, collect clinical data and biospecimens (tongue coating, blood).

(3) January 2027 – June 2027: Complete enrollment of all subjects for the longitudinal study, perform follow-ups, collect clinical data and biospecimens (tongue coating, blood). Publish 2 papers.

(4) July 2027 – December 2027: Complete multi-omics analysis of biospecimens, screen at least three sensitive and specific biomarkers for

typical TCM patterns, clarify molecular biological characteristics. Construct one prognostic risk assessment model. Publish 2 papers.

(5) January 2028 – June 2028: Complete longitudinal study follow-up. Perform clinical validation of the prognostic risk assessment model after revascularization in at least three medical institutions, achieve predictive accuracy >85%. Publish 2 papers.

### 5. Key Problems to be Solved

(1) Clarify the intrinsic associations and biological basis between macroscopic clinical indicators, micro-omics biomarkers, and typical TCM patterns after coronary revascularization.

(2) Construct and validate a prognostic risk prediction model integrating multidimensional TCM-Western medicine information after coronary revascularization, achieving progressive construction and performance evaluation from “basic clinical model” to “TCM-integrated model” to “full-dimension fusion model”.

(3) Elucidate the incremental value and advantages of the TCM-syndrome-informed prognostic model compared with traditional Western-medicine-only models in terms of risk stratification accuracy and clinical applicability.

## 3. Adverse Events

This study is a prospective longitudinal study with no additional interventions. The scale assessments involved pose no risk. Echocardiography, ECG, and chest X-ray are non-invasive procedures and generally without risk. Transthoracic echocardiography may cause chest pressure due to transducer pressure. Chest X-ray involves minimal radiation within a safe range; possible adverse effects include fatigue and decreased white blood cell count. Peripheral venous blood collection uses disposable needles and aseptic technique; possible complications include needle phobia or blood phobia, subcutaneous bleeding or local hematoma, local skin allergic reaction, or blood collection failure. Investigators will explain the potential adverse events to subjects. Any adverse events occurring during the study will be recorded in the CRF (onset time,

symptoms, severity, duration, management measures, outcome), signed and dated. Serious adverse events will be reported to the relevant authorities and ethics committee within the required time frame, in accordance with regulations.

## 4. Ethics and Quality

Before the start of this study, the study protocol, informed consent form, and related materials will be submitted for review and approval by the ethics committees of the lead site and all participating centers.

Before enrollment, written informed consent must be obtained from each subject, authorizing the use of their personal health data and biospecimens for this study. To protect subject privacy, a unique study ID will be used to identify and record all data. All personally identifiable information will be de-identified.

This is a multi-center study. CRF data collected from each center will be centrally managed and checked for consistency. Any identified inconsistencies or questionable data will be addressed via a data query form, which will be sent to the investigator at the original center for verification and clarification.

## 5. Data Management

### 1. Completion and Transfer of Case Report Form (CRF)

Completed CRFs will be reviewed by clinical investigators and monitors, then sent to the statistical unit for data entry and management. All processes will be documented according to the protocol.

### 2. Data Entry and Modification

Data entry and management will be performed by data administrators from the statistical unit. Two data administrators will independently perform double data entry and cross-check.

For queries arising from the CRF, the data administrator will complete a data query form (DRO) and, through the clinical monitor, ask the investigator for clarification. The investigator will respond as soon as possible. Based on the investigator’s response, the data administrator will modify, confirm, and enter the data, and may issue another DRO if necessary.

### 3. Database Lock

After blind review and confirmation that the built database is correct, the database will be locked by the principal investigator and statisticians. If problems are discovered after database lock, they may be corrected during statistical analysis after confirmation, with appropriate documentation.

## 6. Statistical Analysis

### 1. Statistical Software

Statistical analysis will be performed by an independent third-party statistician not involved in the earlier study phases, using SPSS 26.0, Python, and R language.

### 2. Data Description

(1) Continuous variables:

① Central tendency and dispersion: described as mean ± SD or median (IQR), depending on normality.

② Data standardization: Z-score normalization before modeling to eliminate scaling effects.

(2) Categorical variables:

① Frequency and proportion: described as n (percentage).

② Encoding: One-hot encoding will be used to convert multi-category variables into binary dummy variables.

### 3. Data Statistics

#### 3.1 Data Preprocessing

(1) Missing value handling: For continuous variables with few missing values, mean imputation will be used; for missingness with complex patterns, K-nearest neighbors (KNN) imputation will be used based on sample similarity to maximize information retention.

(2) Data standardization: To eliminate the influence of different scales and value ranges, all continuous variables will be Z-score standardized to a distribution with mean 0 and standard deviation 1.

(3) Categorical variable encoding: For unordered multi-category variables (e.g., TCM pattern types, diseased vessels), one-hot encoding will be used to

convert them into a set of binary dummy variables.

(4) Dimensionality reduction and feature selection:

① To reduce redundancy in high-dimensional data and reveal underlying structure, principal component analysis (PCA) will be used to extract principal components explaining most of the variance.

② To further select variables most relevant to the prognostic endpoint and prevent overfitting, LASSO regression (L1 regularization) will be used for automated variable selection.

### 3.2 Statistical Analysis

SPSS 26.0 will be used. Continuous variables will be analyzed by t-test or ANOVA; categorical variables by chi-square test; correlations by multiple logistic regression and Spearman correlation. Models will be built using traditional machine learning, deep learning, and large-model techniques. Cluster analyses: hierarchical clustering, PCA + clustering, K-means clustering. Sensitivity analysis: Kappa coefficient, ROC curve. Multiple cross-validation will be used to reduce overfitting risk.

### 4. Statistical Analysis Plan

A professional statistician will complete the statistical analysis plan. After all data have been entered and verified, the statistician will complete the statistical analysis in a timely manner and produce a written statistical analysis report.

## 8. Final Report and Publication

After the study is completed, the study report will include a description of the study objectives, methods used, results, and conclusions.

## 9. Quality Control

This study will establish and implement a systematic quality control system to ensure procedural rigor and scientific reliability of the data.

(1) Standard Operating Procedures (SOPs) and training: The research team will develop and unify the “Clinical Study Operations Manual”, the “Standards for TCM-Western Medicine Clinical Information Collection”, and various SOPs

(e.g., for biospecimen collection, processing, and storage). Before the formal start of the trial, centralized training will be provided to all participating researchers, focusing on the study protocol and SOPs to ensure that every researcher is familiar with the procedures and details.

(2) Source data verification and process monitoring: All observed results in the clinical study will be verified and repeatedly confirmed to ensure data reliability and originality. Clinical study quality checks will be performed monthly.

(3) Data management and statistical control: Dedicated personnel will be responsible for collecting trial data. A professional data management company will be commissioned for clinical data management to control trial bias and ensure that study conclusions are based on traceable original data.

## 10. References

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