Clinical Research Program

Analysis of risk factors for microcirculatory obstruction after PCI in patients with acute cardiac myocardial infarction

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CONTENTS

Summary of the research program

Study Title: Analysis of Risk Factors for Microcirculatory Obstruction after PCI in Patients with Acute Myocardial Infarction

STUDY OBJECTIVE: To analyze the risk factors for coronary microcirculatory obstruction in patients with acute myocardial infarction after emergency PCI and the relationship between triglyceride glucose index and coronary microcirculatory obstruction.

STUDY DESIGN: This study is a single-center prospective observational cohort study to include 200 patients with AMI who attended the Third Xiangya Hospital of Central South University from June 2024 to August 2025 for emergency PCI. We will collect patients' baseline clinical characteristics, preoperative blood laboratory indices, and intraoperative coronary angiography imaging characteristics. The primary outcome event will be MVO diagnosed by CMR after postoperative coronary emergency PCI.MVO is defined as the inability to reperfuse the coronary microcirculation in a previously ischemic area despite epicardial vessel opening. On late contrast-enhanced imaging (LGE) scans of CMR, bright spots in the region of infarcted myocardium and dark areas within the bright spots are defined as MVO.We proposed to analyze the baseline characteristics and postoperative outcomes of the patients using descriptive statistics. Logistic regression and Lasso regression analyses were used to screen independent risk factors from potential predictors, and then multifactorial logistic regression was used to further analyze the effects of independent predictors on coronary microcirculatory obstruction and to calculate the associated statistical efficacy.

The research process:

This study consists of four stages: data collection, data preprocessing, correlation analysis, and interpretation.

(1) Data collection:

Baseline clinical characteristics, preoperatively available biochemical markers, coronary angiographic imaging characteristics, and intravascular ultrasound imaging characteristics were collected from patients. All data were collected uniformly by trained investigators.

(2) Data preprocessing:

This includes data cleaning, data coding, data normalization, data dimensionality reduction, and variable screening.

(3) correlation analysis

We propose to use logistic regression and Lasso regression to identify i.e. analyze risk factors associated with coronary microcirculatory obstruction.

(4) account for

Explain the independent correlation between risk factors and coronary microcirculatory obstruction.

Entry Criteria:

(1) Age ≥ 18 years;

(2) STEMI symptom onset <12 hours;

(3) STEMI symptom onset time of 12-48 hours in the presence of persistent ischemic symptoms, hemodynamic instability, or life-threatening ventricular arrhythmias;

(4) Very high risk group NSTEMI;

(5) treated with emergency PCI;

Voluntary signed informed consent.

Exclusion Criteria:

(1) Nonobstructive acute myocardial infarction;

(2) Severe chronic kidney disease (defined as estimated glomerular filtration rate <20 mL/min per 1.73 m^2);

(3) CMR The image is not clear;

(4) People who are pregnant or planning to become pregnant;

(5) Failed emergency PCI.

Statistical methods:

Analyses were performed using SPSS software 26.0 and R software. Continuous variables are expressed as SD ± mean or median (interquartile range). Categorical variables were expressed as percentages. To compare continuous variables between two groups, two-sample t-test was used and Wilcoxon rank sum test was used if the data did not conform to normal distribution. To compare the categorical variables of the two groups, the chi-square test was used. Univariate and multivariate logistic regression analyses were used to determine risk factors associated with MVO. Area under the curve (ROC), sensitivity, specificity, Jordon's index, and 95% confidence intervals (CIs) were calculated for subjects' work characteristics to assess the predictive value of the associated risk factors for MVO. All tests were two-tailed and statistical significance was defined as a P-value <0.05.

Body of the study

1. Background of the study

Despite significant advances in early diagnosis and reperfusion therapy, acute myocardial infarction (AMI) remains one of the leading causes of death and disability worldwide, with high mortality rates [1-3]. Primary Percutaneous Coronary Intervention (PPCI) is currently the treatment of choice for AMI, but myocardial reperfusion is not guaranteed even after successful revascularization of the offender, and according to previous studies, up to approximately 60% of AMI patients have myocardial reperfusion failure after PPCI ([4-3]). According to previous studies, up to about 60% of AMI patients have myocardial reperfusion failure after PPCI [4-5], which is characterized by failure to restore microcirculatory perfusion to the previously ischemic infarcted area, and is traditionally defined as no-reflow (NR) [6-7]. Microvascular obstruction (MVO) is a condition in which blood flow to the myocardial microcirculation is restricted despite the opening of epicardial vessels, resulting in inadequate myocardial perfusion [8]. Experimental studies have shown that NR manifests as a failure of microvascular perfusion, which is consistent with the features of MVO [9]. In addition, the equivalence of MVO and NR is further supported by the close correlation between perfusion defects (i.e., MVO) observed in imaging studies by cardiac magnetic resonance imaging (CMR) with gadolinium contrast agent and nonfluorescent regions (NR) observed using the dye thapsigargin S[10]. Thus, MVO can be used to refer to NR, indicating the extent of myocardial microcirculatory compromise.MVO can be recognized by specific signal changes in CMR scans, which are specified by the appearance of bright spots in areas of infarcted myocardium on Late Gadolinium Enhancement (LGE) scans, and the dark areas within the bright spots are referred to as MVO. The pathophysiological mechanisms of MVO are complex and often involve a variety of factors such as microvascular spasm, endothelial cell injury or dysfunction, thrombosis and inflammatory response, and reperfusion injury [5,11], and the exact mechanism remains controversial [12].MVO is significantly associated with poor prognosis in cardiovascular disease.Suzanne et al. demonstrated that, compared with traditional prognostic markers, MVO was the strongest predictor of the occurrence of death, nonfatal myocardial reinfarction, and congestive heart failure after ST-

segment elevation myocardial infarction (STEMI) as well as CMR provided important information in assessing the long-term prognosis of patients with STEMI[12]. A study by Pei-Kun Hu and Fang-Fang Wang et al. also showed that MVO was an independent predictor of deterioration in left ventricular function and poor prognosis [17-18], and Durante et al. showed that MVO was highly significant in predicting the incidence of major adverse cardiovascular events and that the CMR provided a better prognostic stratification of patients [19]. Therefore, early identification and prevention of MVO is particularly important [20].

The detection rate of MVO varies widely, largely depending on the diagnostic method used, with different diagnostic methods and evaluation times resulting in reported rates of MVO ranging from 5% to 70% [13].Diagnostic methods for MVO include both invasive and noninvasive techniques. Invasive methods are mainly coronary angiography, which identifies microvascular obstruction by direct observation of blood flow. Noninvasive methods, on the other hand, include CMR, echocardiography, single photon emission computed tomography (SPECT), and positron emission tomography (PETCT), which indirectly diagnose MVO by evaluating myocardial blood flow (MBF) and function.Among them, CMR provides comprehensive information about cardiac structure, function, perfusion, and myocardial tissue characteristics, which helps to accurately diagnose MVO. Among them, CMR provides comprehensive information about cardiac structure, function, perfusion, and myocardial tissue properties, which helps to accurately assess the presence and extent of MVO and quantify myocardial fibrosis, and is considered to be the gold standard for identifying MVO [14-16].

Insulin resistance (IR), an impairment of insulin in stimulating glucose uptake, has been shown to be significantly associated with the pathogenesis, progression, and prognosis of coronary atherosclerosis [21-22], accelerating the development of both microvascular and macrovascular disease and leading to a poorer prognosis for patients with pre-existing cardiovascular disease [23-24]. High insulin-normal glucose (HIEG) clamp is the gold standard technique for the assessment of IR [25-26], but its widespread use is limited by the fact that it is time-consuming and complex, and is not suitable for large-scale studies.The homeostasis model assessment of IR (HOMA-IR) can be used

in large-scale or epidemiological studies [27], but its use is limited by the fact that it relies on the measurement of plasma insulin and is expensive. Triglyceride glucose index (TyG), which combines triglyceride (TG) and fasting glucose (FPG) levels, is a reproducible, reliable, and validated surrogate marker of IR [28-30].The TyG index has been associated with pathological processes such as atherosclerosis, arterial stiffness, and coronary calcification, which are all closely related to the development of cardiovascular disease. Ma J et al. demonstrated that elevated levels of TyG index were a strong independent predictor of freedom from recurrent flow in patients with T2DM combined with AMI, that the incidence of freedom from recurrent flow increased progressively with increasing tertile intervals of the TyG index, and that the addition of the TyG index to a baseline risk prediction model had incremental effect [33-34].Qu Z et al. also showed that the TyG index was a strong predictor of no-reflow phenomenon in patients with metabolic syndrome combined with STEMI undergoing PCI [35]. Previous studies have shown that increased IR is independently associated with offender vascular plaque vulnerability in patients with ACS, particularly speckled calcification [36-37].Zhao X et al. demonstrated that the TyG index, in combination with offender vascular plaque characteristics, can be used in clinical practice to support the risk stratification of patients with STEMI and to predict a poorer prognosis [38].Yin D et al. demonstrated that higher TyG index levels were associated with a better prognosis [in]patients with ACS [39]. TyG index levels were significantly associated with the prevalence of coronary artery speckle calcification, Minimum lumen area (MLA) ≤ 4.0 mm^2, and Plaque burden (PB) > 70% in patients with ACS, which can be used as a clinical predictor of invasive potential for calcification patterns and plaque characteristics that may represent unstable plaques ([39]). biomarkers [39].

Studies have shown that insulin resistance leads to an increased inflammatory response, which in turn affects vascular endothelial function and normal microvascular function [40].IVUS recognizes plaques in coronary arteries, especially unstable plaques, which are more prone to hemodynamic changes and microvascular dysfunction [41]. Insulin resistance may exacerbate this process by mechanisms such as inflammatory response, abnormal lipid metabolism, and vascular endothelial dysfunction [40-43], but the exact mechanisms need to be further investigated and validated. However, there is

a lack of research on the relationship between TyG index and MVO. Based on the above background and the fact that TyG index can more comprehensively reflect insulin resistance and disorders of glucose and lipid metabolism, which are key factors leading to endothelial dysfunction and microcirculation injury, the scientific hypothesis of this study is that elevated TyG index is an independent risk factor for MVO in AMI patients after PPCI, and its predictive ability is better than that of traditional research. and its predictive power is superior to that of traditional single lipid or glucose indices.

2. research purpose

The aim of this study was to prospectively collect clinical data from patients with acute myocardial infarction, to understand the incidence of coronary, after emergency PCI in our center, to analyze the risk factors of coronary nil flow, and to pave the way for the development of a prediction model for coronary nil flow and further exploration of the pathogenesis of coronary nil flow.

3. Research design

3.1 Sample size calculation

3.1.1 Sample size calculation according to overall outcome proportions:To ensure an accurate estimate of the overall outcome proportions at the 95% confidence level, we used the following formula to calculate the sample size[] (44) [] :

$$n = (1.96/\delta)^2 * \Phi(1-\Phi)$$

The parameters were set as follows: critical value of 95% confidence interval (constant) = 1.96, target error $\delta = 0.06$, and expected proportion of results $\Phi = 0.5$. Bringing the parameters into the above equation gives the minimum required sample size of 170.

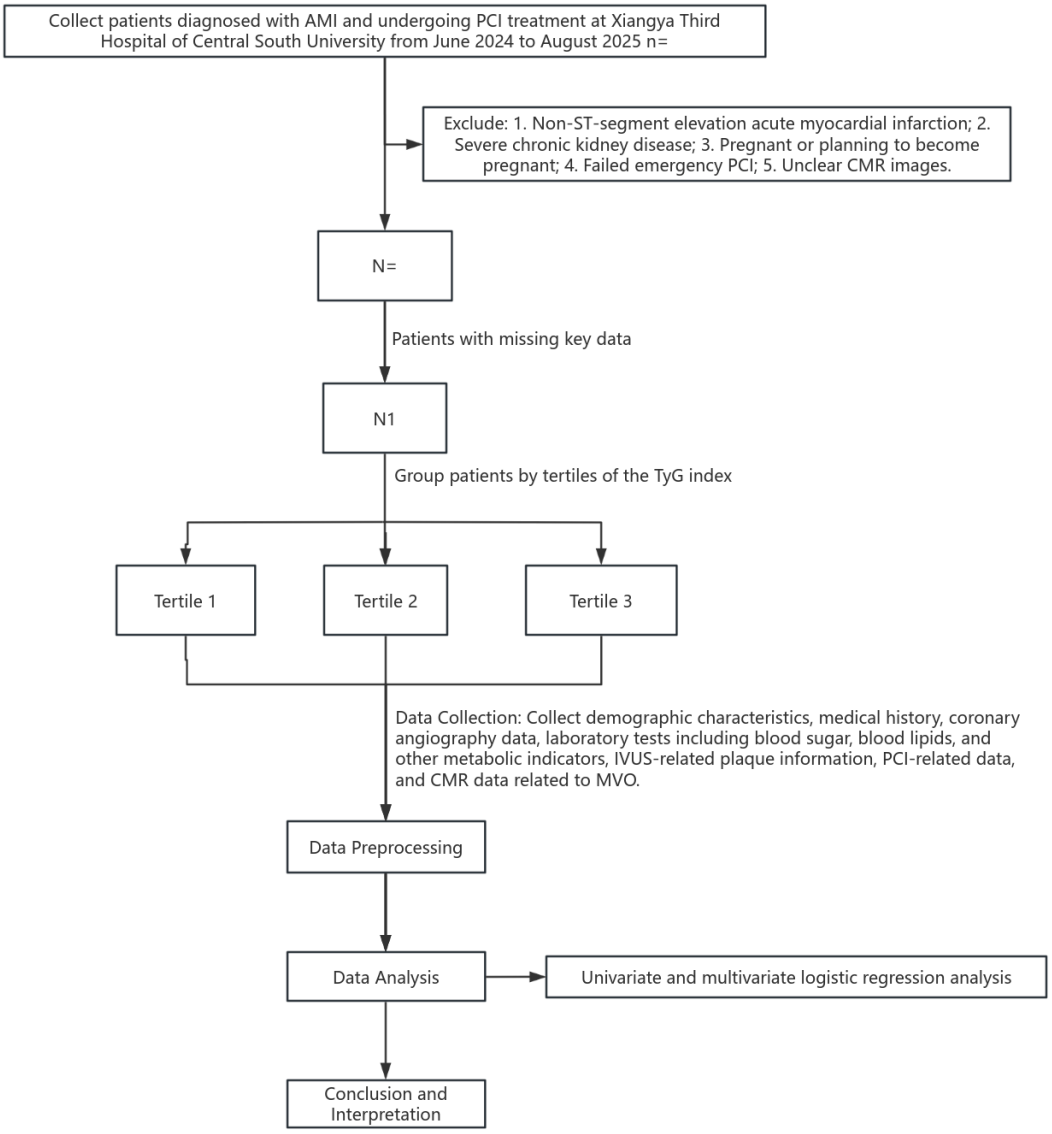
3.1.1 Sample size calculation according to prediction model accuracy:In order to ensure that the prediction model has a high prediction accuracy, we use the following formula to calculate the sample size[39] :

$$n = \exp[(-0.508 + 0.259\ln(\Phi) + 0.504\ln(P) - \ln(MAPE))/0.544]$$

The parameters were set as follows: expected outcome proportion $\Phi = 0.5$, number of predictor variable parameters P = 12, and target mean absolute prediction error MAPE = 0.1. The parameters were brought into the above equation to obtain the minimum required sample size of 191.

In summary, taking into account missing data and increasing the sample size by 10-20%, this study proposes to prospectively collect data from approximately 300 patients with acute myocardial infarction.

3.2 flow chart



4. Research

4.1 Entry criteria:

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4.1.2 Exclusion Criteria:

(1) Nonobstructive acute myocardial infarction;

(2) Severe chronic kidney disease (defined as estimated glomerular filtration rate <20 mL/min per 1.73 m^2);

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(4) People who are pregnant or planning to become pregnant;

(5) Failed emergency PCI.

4.2 Concluding events

4.1.3 Main ending events

MVO diagnosed by CMR after emergency PCI.

4.1.4 Secondary ending events

(1) MACE events during hospitalization (cardiac death, nonfatal reinfarction, nonfatal stroke, acute heart failure);

(2) Cardiac death during hospitalization;

(3) Nonfatal reinfarction during hospitalization;

(4) Acute heart failure during hospitalization;

(5) Cardiogenic shock during hospitalization;

(6) All-cause mortality during hospitalization.

4.3 research process

The study was a prospective observational clinical study that did not involve clinical interventions, and all patients received the usual clinical regimen without supra-guidelines or drug instructions for medication.

4.3.1 Patient Screening

This study intends to screen patients with acute myocardial infarction attending the Third Xiangya Hospital of Central South University from June 2024 to August 2025. It is expected to enroll a total of 300 patients who have been screened and qualified by the enrollment criteria and have signed the informed consent.

4.3.2 Data collection

Based on the literature, expert opinion, and clinical experience, data were collected on baseline clinical characteristics at admission, pre-interventional blood laboratory markers, and emergency coronary angiography and intravascular ultrasound imaging characteristics, as shown in the table below.

	Collection point in time	**Collection of content**
Baseline clinical features	Immediately after admission to the hospital, collection was performed by the researchers	· (a person's) age · distinguishing between the sexes · Killip classification · Total ischemic time · diabetes · high blood pressure · History of prior cardiovascular disease (including stroke, coronary heart disease, peripheral arterial disease) · Systolic blood pressure <100mmHg · angina pectoris without pre-infarction
Blood Laboratory Indicators	Blood specimens were collected and sent for testing immediately after admission to the hospital	· Inflammatory markers: high sensitivity C-reactive protein (hs-CRP), systemic immuno-inflammatory index (neutrophil count x platelet count/lymphocyte count), platelet count, white blood cell count, interleukin-6 (IL-6) and interleukin-8 (IL-8). · Coagulation indices: D-dimer, Fibrinogen · hemoglobin · NT-proBNP · hypoglycemia
Emergency coronary angiography imaging features	Collection by trained researchers after emergency	· Coronary flow parameters:: TIMI flow classification (to observe primary outcome), myocardial perfusion classification

	PCI	• Lesion characteristics: lesion length, lesion diameter, truncated occlusion • Thrombus TIMI classification • lesion location • collateral circulation
Intravascular ultrasonographic features	Collection by trained researchers after emergency PCI	• Attenuation patches (maximum attenuation angle >180 degrees, attenuation length >5 mm) • plaque eccentricity • Lipid pool-like images • plaque rupture • Intraplaque thrombosis

The data collection in this study will strictly follow the principles of representativeness, accuracy, completeness and safety to ensure that the constructed prediction model has good reliability and generalizability. The data collection process will be completed under the premise of not affecting the "door-to-door time" of emergency PCI and the emergency PCI process. We will collect baseline clinical data through consultation and physical examination; access to the electronic medical record system of Xiangya Third Hospital to obtain blood laboratory indexes; access to the SiChuang system of Xiangya Third Hospital to collect emergency coronary angiography imaging characteristics; and analyze intravascular ultrasound imaging characteristics and collect data through the Volcano S5 imaging system software. All participants underwent written notification of the study and their signed informed consent was obtained. We will strictly implement data quality control measures by using Epidata 3.1 and Excel software for double entry and cross-checking, which includes format consistency check, data range check, and logical validation of the data. We will perform missing value processing and outlier analysis to ensure the accuracy and completeness of the data. All data will be stored and managed safely in accordance with relevant laws and regulations, and the principle of patient privacy protection will be strictly observed.

4.3.3 statistical analysis

Analyses were performed using SPSS software 26.0 and R software. Continuous variables are expressed as SD ± mean or median (interquartile range). Categorical variables were expressed as percentages. To compare continuous variables between two

groups, two-sample t-test was used and Wilcoxon rank sum test was used if the data did not conform to normal distribution. To compare the categorical variables of the two groups, the chi-square test was used. Univariate and multivariate logistic regression analyses were used to determine risk factors associated with MVO. Area under the curve (ROC), sensitivity, specificity, Jordon's index, and 95% confidence intervals (CIs) were calculated for subjects' work characteristics to assess the predictive value of the associated risk factors for MVO. All tests were two-tailed and statistical significance was defined as a P-value <0.05.

5. Key evaluation indicators

(1) Dominance Ratio (OR): OR is the ratio of the probability of a disease occurring in a population exposed to a risk factor to the probability of a disease occurring in a non-exposed population. an OR>1 indicates that the risk factor increases the risk of a disease occurring, and an OR<1 indicates that the risk factor decreases the risk of a disease occurring. a larger OR value indicates a stronger correlation between the risk factor and the disease.

(2) Adjusted Dominance Ratio (aOR): aOR is an OR calculated after controlling for the effects of confounders. aOR can more accurately reflect the true association between risk factors and disease.

(3) Regression coefficient (β): the regression coefficient indicates the average extent to which a unit change in the independent variable affects the dependent variable.

6. Security Considerations

This was an observational clinical study, and all patients enrolled in the study received conventional clinical treatment without clinical intervention.

The researcher has pre-studied the Declaration of Helsinki, Measures for Ethical Review of Biomedical Research Involving Human Beings, Measures for Ethical Review of Life Science and Medical Research Involving Human Beings , Data Security Law of the People's Republic of China , and other relevant laws and regulations, and has passed the examination of the Good Practice for Quality Management of Clinical Trials of Drugs (GCP). The safety considerations and countermeasures mainly involve the following points:

(1) Risks to privacy and confidentiality: When collecting sensitive personal information, it is proposed that measures be taken to anonymize the data to ensure its security and confidentiality.

(2) Data quality risk: Data loss, incorrect recording, incomplete data, etc. may occur during data collection, which may affect the accuracy of the study results. Strict data collection and quality control processes should be established, and data should be verified and validated on a regular basis.

(3) Risk of analytical bias: During data analysis, researchers may unconsciously introduce analytical bias that affects the objectivity of the findings. A rigorous data analysis plan should be developed, appropriate statistical methods should be used, and sensitivity analyses should be conducted to mitigate the effects of analytic bias.

(4) Risk of misinterpretation of findings: Findings may be misunderstood or over-interpreted. The limitations of the findings and the scope of application of the findings should be clearly stated in the study report.

7. statistical analysis

7.1 Statistical methods:

Analyses were performed using SPSS software 26.0 and R software. Continuous variables are expressed as SD ± mean or median (interquartile range). Categorical variables were expressed as percentages. To compare continuous variables between two groups, two-sample t-test was used and Wilcoxon rank sum test was used if the data did not conform to normal distribution. To compare the categorical variables of the two groups, the chi-square test was used. Univariate and multivariate logistic regression analyses were used to determine risk factors associated with MVO. Area under the curve (ROC), sensitivity, specificity, Jordon's index, and 95% confidence intervals (CIs) were calculated for subjects' work characteristics to assess the predictive value of the associated risk factors for MVO. All tests were two-tailed and statistical significance was defined as a P-value <0.05.

7.2 Missing value handling:

Missing values were filled in, using plurality for categorical variables and median for continuous variables.

7.3 Sensitivity analysis:

Sensitivity analyses were performed for multiple missing value filling methods, including plurality filling and 5-fold multiple filling. Age, sex, and acute infarction type subgroups were analyzed.

7.4 Statistical software:

Data for this study will be collected and entered by Excel (Microsoft Office home and student 2019) and Epidata 3.8 and analyzed by IBM SPSS Statistics version 26.

8. quality management

The investigator should ensure that the data are true, accurate, complete and traceable, and should ensure the integrity of the basic clinical research documents during their retention to avoid intentional or unintentional alteration or loss.

9. Description of the form of publication of research results

Proposed academic paper.

10. Ethics Statement

Clinical research will be conducted in accordance with the Declaration of Helsinki of the World Medical Assembly, the Measures for Ethical Review of Biomedical Research Involving Human Beings, the Measures for Ethical Review of Life Science and Medical Research Involving Human Beings, and the Measures for the Administration of Healthcare Institutions Carrying Out Researcher-Initiated Clinical Research, and other relevant regulations. The clinical research will be implemented only after the Ethics Committee approves the study protocol before the study begins. The privacy and data confidentiality of the subjects will be protected during the study. I promise to comply with the regulations related to research norms and integrity.

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