

<b>Project name</b>	<b>Analysis and study of risk factors for microcirculatory obstruction after PCI in patients with acute myocardial infarction</b>
<b>person in charge</b>	<b>XXX</b>
<b>administrative division</b>	<b>cardiology</b>
<b>Informed Consent</b>	<b>1.0</b>

**Informed Consent for Data Collection and Biological Specimens**

<b>Version No.</b>	
<b>Date of informed consent version</b>	<b>March 1, 2025</b>

Hello:

We invite you to participate in a study to analyze the correlation between clinical characteristics of patients with acute myocardial infarction and coronary artery no-reflow conducted by the Department of Cardiology, Xiangya Third Hospital, Central South University. This informed consent form will introduce you to the purpose of the study, the methodology, and your risks and benefits, etc. Please read it carefully and make a careful decision whether or not to participate in the study.

### **I. Background and purpose of the study**

- STUDY BACKGROUND: Despite significant advances in early diagnosis and reperfusion therapy, acute myocardial infarction (AMI) remains one of the leading causes of death and disability worldwide. Emergency percutaneous coronary intervention (PPCI) is currently the treatment of choice for AMI, but even when the vessel is opened, myocardial reperfusion failure, i.e., the no-reflow phenomenon (NR), still exists in about 60% of patients. Microvascular obstruction (MVO), on the other hand, has been shown by experimental studies to be equatable with NR. MVO can be recognized by cardiac MRI. Insulin resistance (IR) has been shown to be significantly associated with the pathogenesis, progression, and prognosis of coronary atherosclerosis, accelerating the progression of both microvascular and macrovascular disease and leading to a worse prognosis for patients. Triglyceride glucose (TyG) index, a reproducible, reliable, and validated surrogate marker of IR, has been associated with pathological processes such as atherosclerosis, arterial stiffness, and coronary artery calcification, all of which are closely related to the development of

cardiovascular disease. 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, further studies are needed to discover the potential value of TyG index and to clarify whether it can provide a basis for early identification of high-risk patients.

- Aims of the study: The aim of this study was to prospectively collect clinical data from patients with acute myocardial infarction, to understand the incidence of coronary microcirculatory obstruction after emergency PCI in our center, to analyze the risk factors of coronary microcirculatory obstruction and the relationship with triglyceride glucose index, and to provide a basis for early identification of high-risk patients.
- Entry criteria:

**Entry Criteria:**

- (1) Age  $\geq$  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  $1.73\text{ m}^2$ );
- (3) CMR The image is not clear;
- (4) People who are pregnant or planning to become pregnant;
- (5) Failed emergency PCI.

## **II. Content, methodology and process of collecting specimens and information**

Based on the literature, expert opinion and clinical experience, data collection will include baseline clinical characteristics at admission, blood laboratory indices before intervention, and emergency coronary angiography and intravascular ultrasound imaging characteristics. 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 without affecting the "door-to-door time" of emergency PCI and the emergency PCI process. We will collect baseline clinical characteristics through consultation and physical examination, including age, gender, total myocardial ischemia time, killip classification, past medical history, etc.; access the electronic medical record system of the Xiangya Third Hospital to obtain the blood laboratory indexes, including inflammation indexes, coagulation indexes, hemoglobin, NT-proBNP, and glucose, etc.; and access the SIC system of the Xiangya Third Hospital to collect the emergency coronary angiography imaging characteristics, including: coronary artery, coronary artery and coronary artery. Imaging characteristics, including: coronary flow parameters, lesion characteristics, thrombus TIMI grading, collateral microcirculation, etc.; Intravascular ultrasound imaging characterization and data collection by Volcano S5 imaging system software, including: attenuated plaque, plaque eccentricity, lipid pool-like images, plaque rupture, intra-plaque thrombus, etc. 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 3.8 and Excel software for double entry and cross-checking, which will include format consistency checking, data range checking, 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.

### **III. Risks, inconveniences**

Signing this informed consent form will not add new information collection and biospecimen collection, will not expose you to any risks beyond routine clinical practice, and the information and biospecimens are required for the routine diagnosis and treatment of your disease at no additional cost.

Your participation in this study will help your doctor to obtain more reliable research data for future understanding or scientific diagnosis of this disease or the results of this study may be useful in choosing more scientific treatments for you and patients with similar diseases in the future.

### **IV. Possible benefits**

Scientific research based on your clinical information has the potential to promote medical advances that may benefit the health of you, your loved ones, and others.

### **V. Privacy and confidentiality**

We will take the necessary technical and organizational measures to protect your privacy during the study. Your personal information will be kept confidential. When necessary, the governmental administration or the Ethics Committee will be able to access your personal information according to the regulations, and when the results of the study are published, no information about your identity will be disclosed.

### **VI. Your rights**

Your participation in the study is completely voluntary, and if you do not wish to participate, you may refuse to do so without any negative impact on your current or future medical care . Even after you have agreed to participate, you may withdraw from this study at any time and for any reason, and again, this will not affect your ability to receive your regular medical care. When you decide that you no longer want to participate in this study, you are encouraged to tell your doctor, who will be able to

provide you with advice and guidance about your health condition.

## **VII. Precautions**

In cases where the patient is unable to fully understand the study, communication with the patient's first-degree relative is needed to ensure that the first-degree relative understands the study and agrees to the patient's participation in the study. In cases where the patient is unable to make a decision, the patient's first-degree relative can make the decision jointly with the patient.

## **IX. Contact information**

If you have any questions about your rights, you may contact during business hours on national legal working days at.

Ethics Committee of Xiangya Third Hospital of Central South University

Tel: XXXXXXXX

### **Consent statement**

**VOLUNTEER DECLARATION:** I have read the above description of this study and fully understand the possible risks and benefits of participating in this study. I am volunteering to participate in this study. I will be given a signed and dated copy of this informed consent form.

I agree or refuse to have my medical records and pathology specimens utilized in research studies other than this study.

Signature of Volunteer: Date

Volunteer Contact Number: Date

**DOCTOR'S DECLARATION:** I confirm that I have explained the details of this donation matter to the volunteer and answered all the volunteer's questions about it, and that the volunteer has given his/her consent to participate out of his/her own

free will. This informed consent form is in duplicate, and the hospital and the volunteer will each keep a copy of the signed informed consent form.

Signature of physician: Date

The doctor's work phone number: