STUDY DOCUMENT

Official Title: Study on Risk Early Warning of Clinical Prediction Model Based on Multi-Parameter Stress Perfusion Cardiac Magnetic Resonance in Adverse Prognosis of Dilated Cardiomyopathy

NCT Number: Not available

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1. Medical Subject Headings (MeSH) Terms

1.1 MeSH Headings for Conditions and Interventions Studied

- Cardiomyopathy, Dilated
- Sudden Cardiac Death
- Myocardial Microvascular Dysfunction
- Magnetic Resonance Imaging, Cardiac
- Myocardial Perfusion Imaging
- Stress Perfusion
- Implantable Cardioverter-Defibrillators
- Cardiac Arrest
- Heart Failure
- Heart Transplantation
- Left Ventricular Assist Devices
- Myocardial Fibrosis
- Coronary Artery Disease
- Myocardial Perfusion Reserve

1.2 MeSH Check Tags

- Humans
- Adult
- Middle Aged
- Aged
- Male
- Female
- Prospective Studies
- Cohort Studies
- Multicenter Studies
- Observational Studies

2. Basic Study Information

Item	Content
Study Title	Study on Risk Early Warning of Clinical Prediction Model Based on MultiParameter Stress Perfusion Cardiac Magnetic Resonance in Adverse Prognosis of Dilated Cardiomyopathy
Study Type	Observational, Prospective, Multicenter Cohort Study
Study Design	Prospective observational cohort study; focusing on evaluating the predictive value of myocardial microvascular dysfunction (MVD) assessed by stress perfusion cardiac magnetic resonance (CMR) for SCD-related events (primary endpoint) and secondary endpoint events in patients with DCM; artificial intelligence (AI) will be briefly used for auxiliary analysis of CMR image features without detailed model development and validation procedures.
Sample Size	Planned enrollment of ≥450 patients with DCM (recruited from three study centers) to ensure sufficient statistical power for analyzing the correlation between MVD and SCD-related events.
Study Duration	Total study duration: 36 months (3 months of

	preparation, 9 months of recruitment and baseline assessment, 24 months of follow-up, 6 months of data analysis and report writing)
Follow-up Period	24 months after baseline stress perfusion CMR examination; additional 6 months of follow-up after the occurrence of the primary endpoint event; scheduled follow-up time points: 3 months, 6 months, 12 months, 18 months, 24 months post-CMR, and 1 year, 3 years, 5 years post-CMR for long-term outcome observation.
Primary Endpoint	A composite of SCD-related events, encompassing sudden cardiac death (SCD), appropriate implantable cardioverter-defibrillator (ICD) shock, and resuscitated cardiac arrest (see Appendix S1 for detailed diagnostic criteria) .
Secondary Endpoint	A composite of heart failure–related death, heart transplant, and left ventricle (LV) assist device implantation. Detailed definitions: heart failure-related death refers to death associated with clinically worsening heart failure symptoms without evidence of other causes; LV assist device implantation follows FDA-approved indications for mechanical circulatory support in severe heart failure patients .

Registration Information	Planned to be registered on ClinicalTrials.gov (NCT number to be assigned)
Study Centers	Shandong Provincial Hospital, Jinan Central Hospital, Beijing Anzhen Hospital ; all centers are tertiary grade A hospitals with qualified 3.0T CMR equipment, standardized stress perfusion scanning protocols, and experienced cardiology and radiology teams to ensure the accuracy and consistency of MVD assessment.

3. Research Background and Significance

Dilated cardiomyopathy (DCM) is a common non-ischemic cardiomyopathy characterized by left ventricular or biventricular dilation and reduced systolic function, which is a major cause of sudden cardiac death (SCD) and heart failure in adults. The clinical prognosis of DCM is highly heterogeneous, and identifying patients at high risk of SCD-related events remains a critical clinical challenge, as traditional risk stratification tools have limited predictive efficacy.

Myocardial microvascular dysfunction (MVD), defined as structural and functional abnormalities of the coronary microcirculation (pre-arterioles and intramyocardial arterioles) without significant epicardial coronary artery stenosis, has been increasingly recognized as an important pathological feature of DCM. Previous studies have shown that DCM patients often exhibit impaired myocardial perfusion reserve (MPR), a key indicator of MVD, which is closely associated with the severity of left ventricular dysfunction and myocardial fibrosis. Stress perfusion cardiac magnetic resonance (CMR) is a non-invasive, high-resolution imaging technique that can accurately assess myocardial perfusion reserve and quantify MVD by measuring stress and rest myocardial blood flow (MBF), with good correlation with invasive microvascular function assessment indicators such as index of microvascular resistance (IMR).

Notably, MVD may contribute to the pathogenesis of DCM through stress-induced repetitive myocardial stunning and is closely related to adverse cardiac outcomes, including SCD. However, the predictive value of MVD assessed by stress perfusion CMR for SCD-related events in DCM patients has not been fully clarified, especially in a multicenter setting. Late gadolinium enhancement (LGE) imaging is crucial for distinguishing ischemic from non-ischemic etiologies, as infarct patterns of LGE are indicative of myocardial ischemia, which needs to be excluded in DCM studies to ensure etiological purity and avoid confounding effects on MVD assessment.

Conducted in three renowned tertiary hospitals (Shandong Provincial Hospital, Jinan Central Hospital, Beijing Anzhen Hospital), this study aims to explore the correlation between MVD (assessed by stress perfusion CMR) and SCD-related events in DCM patients, clarify the predictive value of MVD for the primary endpoint, and provide a scientific basis for individualized risk stratification and early warning of SCD in DCM patients. Artificial intelligence (AI) will be briefly used for auxiliary extraction of CMR image features to improve the efficiency of image analysis, without in-depth development and validation of AI prediction models.

4. Research Objectives

4.1 Primary Objective

To evaluate the predictive value of myocardial microvascular dysfunction (MVD) assessed by stress perfusion CMR for SCD-related events (SCD, appropriate ICD shock, resuscitated cardiac arrest) in DCM patients, and confirm whether MVD is an independent risk factor for the primary endpoint.

4.2 Secondary Objectives

- To analyze the correlation between MVD severity (assessed by stress perfusion CMR indicators) and the occurrence of secondary endpoint events (heart failure-related death, heart transplant, LV assist device implantation).
- To explore the relationship between MVD and other DCM-related indicators (left ventricular structure and function, myocardial fibrosis, laboratory indicators such as NT-proBNP), and clarify the potential mechanism of MVD in predicting SCD-related events.
- To briefly apply AI technology for auxiliary extraction of stress perfusion CMR image features, improving the efficiency and consistency of MVD assessment.
- To establish a standardized method for MVD assessment using stress perfusion CMR in DCM patients, providing a reference for clinical practice.

5. Study Subjects and Inclusion/Exclusion Criteria

5.1 Inclusion Criteria

1. A diagnosis of DCM confirmed using the World Health Organization/International Society and Federation of Cardiology (WHO/ISFC) criteria. The diagnosis is based on an elevated left ventricular end-diastolic volume indexed to body surface area (LVEDV/BSA) and reduced left ventricular ejection fraction (LVEF), compared with published age- and gender-specific reference values . Reference values for LVEDV/BSA and LVEF are adopted from internationally recognized guidelines to ensure diagnostic consistency.
2. Age ＞18 years, regardless of gender.

3. During the study period, were seen in the Cardiology Department of Shandong Provincial Hospital, Jinan Central Hospital, or Beijing Anzhen Hospital, or referred for stress perfusion CMR assessment.

4. Able to understand and sign the informed consent form voluntarily, and can complete the scheduled follow-up.

5. Complete clinical data (including medical history, physical examination, laboratory tests, electrocardiogram, etc.) are available.

5.2 Exclusion Criteria

1. Presence of significant coronary artery disease (CAD), defined as a stenosis of >50% in a major coronary artery. For left main coronary artery stenosis, a threshold of ≥50% is also considered significant, consistent with clinical diagnostic criteria for CAD, to exclude the impact of epicardial coronary stenosis on MVD assessment.

2. Infiltrative diseases (e.g., cardiac amyloidosis, sarcoidosis) that may affect myocardial structure and function and mimic DCM, as these diseases may independently cause MVD and confound the study results.

3. Valvular cardiomyopathy, which may cause ventricular dilation and systolic dysfunction similar to DCM, and may be associated with secondary MVD.

4. Presence of infarct patterns of LGE on CMR imaging. Infarct patterns of LGE are defined as subendocardial enhancement corresponding to a coronary artery territory, which is characteristic of ischemic myocardial injury; exclusion of such patients ensures that those with ischemic etiologies are not included in the study, avoiding interference with the assessment of MVD in non-ischemic DCM.

5. Active malignant tumors, severe systemic infections, or other diseases that may affect the study results and prognosis.

6. Contraindications to CMR examination (such as pacemaker implantation, non-removable metal implants, severe claustrophobia, allergy to gadolinium contrast agent, etc.) or contraindications to stress perfusion (such as severe hypotension, severe asthma, hypersensitivity to adenosine).

7. Previous heart transplantation or left ventricular assist device (LVAD) implantation.

8. Pregnant or lactating women (confirmed by pregnancy test).

9. Unable to cooperate with CMR examination, follow-up, or data collection due to mental illness, cognitive impairment, or other reasons.

10. Participating in other clinical trials that may affect the results of this study.

5.3 Exclusion Criteria After Enrollment (Withdrawal Criteria)

1. Found to not meet the inclusion criteria or meet any of the exclusion criteria after enrollment.

2. Lost to follow-up (no contact for more than 3 months, or failed to complete the scheduled follow-up without reasonable reasons).

3. Voluntarily requests to withdraw from the study (the right to withdraw at any time without affecting subsequent medical treatment).

4. Occurrence of severe adverse events that make it impossible to continue participating in the study.

5. Violation of the study protocol (such as refusing to complete CMR re-examination, providing false information, etc.).

6. Study Process

6.1 Recruitment and Enrollment of Subjects

1. Recruitment Sites: The study will be conducted in three tertiary grade A hospitals (Shandong Provincial Hospital, Jinan Central Hospital, Beijing Anzhen Hospital). All centers have qualified 3.0T CMR equipment, standardized stress perfusion scanning protocols, and experienced cardiology and radiology teams to ensure the accuracy and consistency of MVD assessment.

2. Recruitment Methods: Subjects will be recruited through outpatient clinics, inpatient wards, and referrals of the Cardiology Department of each research center. Researchers will explain the purpose, process, potential risks, and benefits of the study to potential subjects in detail, and provide written informed consent forms. Only those who fully understand and voluntarily sign the informed consent form will be included in the study.

3. Enrollment Process: After signing the informed consent form, subjects will undergo baseline assessment (including clinical data collection, laboratory tests, electrocardiogram, and stress perfusion CMR examination). Researchers will review the inclusion and exclusion criteria again based on the assessment results, including confirmation of DCM diagnosis according to WHO/ISFC criteria and exclusion of subjects with infarct patterns of LGE or significant CAD. Qualified subjects will be assigned a unique study number, and relevant information will be recorded in the case report form (CRF).

6.2 Baseline Assessment

1. Clinical Data Collection: Researchers will collect general information (age, gender, height, weight, body mass index [BMI], smoking history, drinking history, family history of cardiovascular diseases, etc.), medical history (onset time, clinical symptoms, previous treatment history, ICD implantation status if any, etc.), and medication history (type, dosage, course of treatment, etc.) of subjects through questionnaires and medical record review.

2. Laboratory Examinations: Venous blood will be collected from subjects on an empty stomach (fasting for ≥8 hours) to detect indicators such as N-terminal pro-B-type natriuretic peptide (NT-proBNP), troponin I/T, creatinine, liver function (alanine aminotransferase, aspartate aminotransferase, total bilirubin), electrolytes (potassium, sodium, chlorine), and fasting blood glucose. All tests will be performed by the clinical laboratory of each research

center in accordance with standard operating procedures (SOP).

3. Electrocardiogram: Resting 12-lead electrocardiogram will be performed for all subjects to record heart rate, rhythm, ST-T segment changes, and other indicators, which will be stored and archived.

4. Stress Perfusion CMR Examination (Key Assessment for MVD): All subjects will undergo CMR examination using a 3.0T magnetic resonance scanner (consistent model across all research centers). The examination includes two parts: ① Routine CMR sequences: Cine imaging (for measuring left ventricular end-diastolic volume, end-systolic volume, LVEF, etc., and calculating LVEDV/BSA for DCM diagnosis), T1 mapping, T2 mapping, and LGE imaging (for detecting myocardial fibrosis and identifying infarct patterns to exclude ischemic etiologies); ② Stress perfusion CMR: Adenosine (140 μg/kg/min) will be infused to induce myocardial stress, and first-pass perfusion imaging will be performed before and after stress to measure myocardial blood flow (MBF) at rest and during stress. Myocardial perfusion reserve (MPR) will be calculated as the ratio of stress MBF to rest MBF, with MPR < 2.0 defined as MVD according to established diagnostic criteria. Scanning parameters will be standardized across all research centers to ensure the consistency of image quality. CMR images will be stored in DICOM format for subsequent analysis. Two independent radiologists (with more than 5 years of experience in cardiac imaging) will review LGE images to confirm the absence of infarct patterns and independently assess MVD severity based on MPR values, with consensus reached through discussion in case of discrepancies. AI technology will be briefly used for auxiliary extraction of perfusion image features to improve the efficiency of MPR calculation, without in-depth model optimization.

6.3 Follow-up

1. Follow-up Frequency and Time Points: Follow-up will be conducted at 3 months, 6 months, 12 months, 18 months, and 24 months after baseline stress perfusion CMR examination. For subjects who experience the primary or secondary endpoint event, additional follow-up will be conducted for 6 months to record the recovery and long-term prognosis after the event. In addition, long-term follow-up will be conducted at 1 year, 3 years, and 5 years post-CMR to observe long-term outcomes.

2. Follow-up Methods: A combination of outpatient follow-up, telephone follow-up, and medical record review will be used. At each follow-up, researchers will record the occurrence of endpoint events (in detail for SCD-related events and secondary endpoint events), changes in clinical symptoms, medication adjustments, re-examination results (NT-proBNP, electrocardiogram, and CMR re-examination if necessary), and adverse events. For subjects with MVD at baseline, changes in MVD severity will be assessed by stress perfusion CMR re-examination at 12 and 24 months if clinically feasible.

3. Endpoint Event Judgment: An endpoint event judgment committee composed of 3 senior cardiologists will be established to review and confirm the occurrence of endpoint events. The committee will make a judgment based on medical records, examination results, and follow-up records, referring to the diagnostic criteria in Appendix S1 for SCD-related events , to ensure the accuracy and objectivity of the data. For SCD, the definition is death due to cardiac causes occurring within 1 hour of symptom onset with sudden loss of consciousness ; for

appropriate ICD shock, it refers to shocks delivered in response to hemodynamically unstable ventricular tachycardia or fibrillation without reversible causes ; for resuscitated cardiac arrest, it refers to a cardiac arrest event reversed by cardiopulmonary resuscitation, defibrillation, or pacing .

6.4 Data Collection and Management

1. Data Collection: Researchers will fill in the CRF truthfully and completely according to the baseline assessment and follow-up results, with special emphasis on recording stress perfusion CMR indicators (rest MBF, stress MBF, MPR) and the occurrence of SCD-related events. CMR images, laboratory test reports, electrocardiograms, endpoint event records, and other relevant data will be archived in a unified manner.

2. Data Verification: The data management team will conduct double-entry and verification of the CRF data to correct errors and missing information in a timely manner. The completeness, accuracy, and consistency of MVD-related data and endpoint event records will be checked regularly (once a month) during the study period.

3. Data Storage: All study data (including CRF, CMR images, laboratory test results, and follow-up records) will be stored in a dedicated computer with password protection and data encryption to ensure the confidentiality and security of subjects' personal information. The data retention period will be at least 5 years after the end of the study, in accordance with relevant national regulations and ethical requirements.

4. Data Sharing: Individual participant data (IPD) will not be made available to external researchers. The dataset contains sensitive clinical, imaging, and longitudinal prognostic information from patients with DCM. Broad sharing of IPD may compromise patient privacy and confidentiality, violate informed consent restrictions, and increase the risk of re-identification. Therefore, IPD will be retained securely within the study group and will not be shared externally.

7. Auxiliary AI Application (Brief)

Artificial intelligence technology will be applied to support the analysis of stress perfusion CMR datasets, including automated image feature extraction and model construction. Professional image processing software incorporating basic artificial intelligence algorithms will be utilized to assist with left ventricular segmentation and the extraction of perfusion-related imaging features, such as signal intensity upslope gradients during gadolinium first-pass perfusion imaging. These features will support the calculation of resting myocardial blood flow (MBF), stress MBF, and myocardial perfusion reserve (MPR), with the goal of improving the efficiency and reproducibility of microvascular dysfunction (MVD) assessment.

Subsequent large-scale development, optimization, and independent validation of artificial intelligence models will be performed in this study. The primary objective remains the evaluation of the predictive value of MVD, as assessed by stress perfusion CMR, for sudden cardiac death (SCD) – related adverse events.

8. Quality Control

1. Personnel Training: Before the start of the study, all researchers, radiologists, data managers, and study coordinators will receive unified training on the study protocol, SOP, data collection requirements, endpoint event judgment criteria, stress perfusion CMR scanning and MVD assessment standards, and ethical norms to ensure the consistency of operation.

2. CMR Quality Control: All research centers will use 3.0T magnetic resonance scanners of the same model, and the scanning parameters (including stress perfusion sequences) will be standardized. A professional CMR quality control team will regularly check the image quality (once every 3 months); unqualified images will be re-scanned if necessary, and subjects who cannot complete the stress perfusion CMR examination will be excluded from the study. The consistency of MVD assessment by radiologists will be tested using Kappa analysis, with Kappa value ≥ 0.80 required to ensure reliability.

3. Data Quality Control: The data management team will conduct regular inspections of the CRF data, with special focus on MVD-related indicators and endpoint event records, and any problems found will be fed back to the researchers in a timely manner for correction. The final data will be locked after verification to prevent data tampering. A random sample of 10% of the CRF data will be reviewed by the study leader to ensure data quality.

4. Ethical Supervision: The Ethics Committee of each research center will supervise the entire study process, review the study protocol and informed consent form regularly, and handle adverse events and ethical issues in a timely manner to ensure that the study is carried out in accordance with ethical principles.

9. Ethical Considerations

1. Informed Consent: All subjects will sign the informed consent form voluntarily after fully understanding the purpose, process, potential risks, and benefits of the study. The informed consent form will be provided in both Chinese and English (if necessary) to ensure that subjects can understand the content. Subjects have the right to ask questions about the study, and researchers will answer truthfully.

2. Confidentiality of Subject Information: The personal information of subjects (such as name, ID number, contact information) will be encrypted and stored, and will not be disclosed to any third party. The study data will be used only for scientific research purposes, and the identity of subjects will be anonymized during data analysis.

3. Risk Management: During the study, if subjects experience adverse events related to the study (such as contrast agent allergy during CMR examination, hypotension during adenosine infusion for stress perfusion), researchers will take timely and effective medical measures to ensure the safety of subjects. All adverse events will be recorded in detail and reported to the Ethics Committee and the study leader within 24 hours. For subjects with high risk of SCD-related events identified during follow-up (especially those with severe MVD), researchers will promptly inform the treating physician to adjust the treatment plan (e.g., considering ICD implantation).

4. Voluntary Withdrawal: Subjects have the right to withdraw from the study at any time without any reason, and their medical treatment will not be affected. The data of subjects who withdraw from the study will be retained and included in the final data analysis (unless the subject requests to delete the data).

10. Statistical Analysis

Statistical analysis will be performed using SPSS 26.0 and R software (version 4.2.0). Measurement data will be expressed as mean ± standard deviation (SD) if normally distributed, or median (interquartile range, IQR) if abnormally distributed; comparison between groups will be performed using t-test, non-parametric test (Mann-Whitney U test, Kruskal-Wallis test) as appropriate. Count data will be expressed as rate (%) and compared using χ^2 test or Fisher's exact test. The Kaplan-Meier method will be used to draw the survival curve of subjects (for endpoint events), and the log-rank test will be used to compare the event rate between DCM patients with and without MVD. Multivariate Cox proportional hazards regression model will be used to screen the independent risk factors for SCD-related events and secondary endpoint events, with MVD (assessed by stress perfusion CMR) as the key independent variable. The receiver operating characteristic (ROC) curve will be used to evaluate the predictive efficacy of MVD for SCD-related events, and the AUC value will be calculated. $P < 0.05$ will be considered statistically significant. Subgroup analysis will be performed based on age, gender, LVEF, and MVD severity to explore the predictive value of MVD in different subgroups.

11. Study Schedule

Study Stage	Time Arrangement (Months)	Key Tasks
Preparation Stage	1–3	Finalize the study protocol, train researchers and related personnel (focusing on stress perfusion CMR scanning and MVD assessment), standardize CMR scanning parameters, establish the data management system, design Appendix S1 (diagnostic criteria for SCD-related events), and obtain ethical approval from each research center.

Recruitment and Baseline Assessment Stage	4–12	Recruit subjects, conduct baseline assessment (clinical data collection, laboratory tests, electrocardiogram, stress perfusion CMR examination), review inclusion/exclusion criteria, assess MVD using stress perfusion CMR (with brief AI auxiliary analysis), and complete data entry and verification.
Follow-up Stage	13–36	Conduct regular follow-up, record endpoint events and adverse events, perform stress perfusion CMR re-examination at 12 and 24 months (if feasible) to assess changes in MVD severity, update study data, and conduct long-term follow-up at 1 year, 3 years, and 5 years post-CMR.
Data Analysis and Report Writing Stage	31–36	Conduct statistical analysis of the study data (focusing on the correlation between MVD and SCD-related events), sort out the study results, write the study report and Appendix S1, and submit the report to the Ethics Committee and relevant departments.

12. Adverse Event Management

12.1 Definition of Adverse Events

Any untoward medical occurrence in a subject during the study period, regardless of whether it is related to the study, including but not limited to: adverse reactions caused by CMR examination (contrast agent allergy, claustrophobia attack, etc.), adverse reactions related to

stress perfusion (hypotension, bradycardia, asthma attack due to adenosine infusion), deterioration of DCM-related symptoms (worsening heart failure, arrhythmia, etc.), and other unexpected medical events (infection, accidental injury, etc.). Endpoint events (SCD-related events, secondary endpoint events) are not classified as adverse events but are recorded separately.

12.2 Reporting of Adverse Events

Researchers will record the occurrence time, type, severity, handling measures, and outcome of adverse events in detail in the CRF. Mild and moderate adverse events will be reported to the study leader and the Ethics Committee within 24 hours; severe adverse events (such as death, severe allergy requiring emergency treatment, severe hypotension unresponsive to treatment) will be reported immediately (within 2 hours) to the study leader and the Ethics Committee, and a follow-up report will be submitted after the event is handled.

12.3 Handling of Adverse Events

For adverse events related to the study, researchers will take timely and effective medical measures to treat the subjects, reduce the impact of adverse events, and closely observe the recovery of the subjects. If the adverse event is severe and cannot be controlled, the subject will be withdrawn from the study, and follow-up medical treatment will be arranged to ensure the safety of the subject. For adverse reactions related to adenosine infusion during stress perfusion, infusion will be stopped immediately, and symptomatic treatment (such as fluid replacement, atropine administration for bradycardia) will be given.

13. Study Termination

1. Voluntary Termination: The study leader may terminate the study voluntarily if the study objectives are achieved in advance, or if serious safety problems, ethical issues, or other unexpected factors that affect the study progress occur during the study.

2. Termination by the Ethics Committee: The Ethics Committee may terminate the study if it finds that the study does not comply with ethical principles, or if the risks to the subjects exceed the benefits.

3. Termination Due to Other Reasons: The study may be terminated due to insufficient funding, difficulty in recruiting subjects (failure to reach the planned sample size within the scheduled time), or changes in national policies and regulations.

4. Disposal After Termination: After the study is terminated, the data collected will be sorted out and analyzed, and a study termination report will be written and submitted to the Ethics Committee and relevant departments. The follow-up of the subjects will be continued if necessary to ensure their safety and rights.

14. Study Team and Responsibilities

1. Principal Investigator (PI): Responsible for the overall design and implementation of the

study, coordinating the work of each research center, making important decisions related to the study, and ensuring the scientificity and ethicality of the study, especially the standardization of MVD assessment using stress perfusion CMR.

2. Co-Investigators: Responsible for subject recruitment, baseline assessment, follow-up, and data collection at each research center, ensuring the accuracy and completeness of MVD-related data and endpoint event records, and reporting adverse events and endpoint events in a timely manner.

3. Sub-Investigators: Assist the co-investigators in completing the study work, including data entry, sample collection, and follow-up visits.

4. Radiologists: Responsible for stress perfusion CMR image acquisition, image quality control, MVD assessment (based on MPR values), and LGE image review to exclude infarct patterns, ensuring the reliability of CMR and MVD data; briefly use AI software for auxiliary image feature extraction.

5. Data Managers: Responsible for data entry, verification, storage, and management, ensuring the confidentiality, integrity, and security of the data, with special focus on MVD-related indicators and endpoint event records.

6. Statisticians: Responsible for the design of the statistical analysis plan, statistical analysis of the study data (focusing on the correlation between MVD and SCD-related events), and providing technical support for the study results.

7. Study Coordinators: Responsible for the daily management of the study, coordinating communication between the research team and subjects, and ensuring the smooth progress of the study.

8. Ethics Committee: Responsible for reviewing the study protocol and informed consent form, supervising the ethical conduct of the study, and protecting the rights and interests of the subjects.

9. Endpoint Event Judgment Committee: Composed of 3 senior cardiologists, responsible for reviewing and confirming the occurrence of primary and secondary endpoint events, ensuring the accuracy and consistency of endpoint event judgment.

15. Investigator Official Titles

Role	Investigator Official Title
Principal Investigator	Principal Investigator, Department of Cardiology, [Hospital Name]; Chief Physician; Professor
Co-Investigator	Co-Investigator, Department of Cardiology, [Hospital Name]; Associate Chief Physician;

	Associate Professor
Sub-Investigator	Sub-Investigator, Department of Cardiology, [Hospital Name]; Attending Physician
Radiologist	Chief Radiologist / Cardiac Imaging Specialist, Department of Radiology, [Hospital Name] (proficient in stress perfusion CMR and MVD assessment)
Study Coordinator	Study Coordinator, Department of Cardiology, [Hospital Name]
Statistician	Statistician, Department of Biostatistics, [Hospital Name] / [Research Institute]

Appendix S1: Diagnostic Criteria for SCD-Related Events

1. Sudden Cardiac Death (SCD): Death due to cardiac causes occurring within 1 hour of the onset of acute cardiac symptoms, characterized by sudden loss of consciousness. For unwitnessed deaths with clear evidence of cardiac etiology, it is classified as probable SCD .

2. Appropriate Implantable Cardioverter-Defibrillator (ICD) Shock: Shocks delivered by an ICD in response to hemodynamically unstable ventricular tachycardia (VT) or ventricular fibrillation (VF) that is not caused by reversible factors (such as electrolyte imbalance, drug effects) .

3. Resuscitated Cardiac Arrest: A cardiac arrest event that is reversed, usually by cardiopulmonary resuscitation (CPR), defibrillation, cardioversion, or cardiac pacing, with restoration of spontaneous circulation .