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Research Paper

Rationale and design of the CT-STEMI study (Cardiac Computed Tomography for comprehensive risk stratification of arrhythmic, atherothrombotic and heart failure events following reperfused ST-segment Elevation Myocardial Infarction)

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ABSTRACT

Background: ST-segment elevation myocardial infarction (STEMI) remains a major cause of morbidity and mortality, with survivors facing high risk of heart failure, recurrent ischemia, and arrhythmias. Risk stratification traditionally relies on echocardiography, while cardiac magnetic resonance (CMR) is the most effective tool for predicting adverse outcomes. However, its routine use is limited by accessibility, cost, and logistical constraints. Recently, cardiac computed tomography (CCT) has evolved from an angiographic tool to a comprehensive imaging modality capable of assessing wall motion abnormalities and myocadial tissue characteristics.

Objectives: The CT-STEMI study aims to (1) evaluate the diagnostic accuracy of CCT for myocardial morphofunctional assessment and tissue characterization compared to CMR, (2) determine the prognostic value of CCT-derived features for adverse outcomes, and (3) assess the role of CCT in quantifying atherosclerotic burden in STEMI patients.

Methods: CT-STEMI (NCT06020209) is a prospective, multicenter observational study enrolling STEMI patients treated with primary PCI within 24 h of symptom onset. Each patient undergoes comprehensive CCT (pre-contrast imaging, full R–R interval angiography, and late iodine enhancement) and CMR within 10 days of the acute event, with imaging sequence randomized. Patients will be followed longitudinally for heart failure, arrhythmic events, and recurrent ischemic complications.

Summary: This study aims to validate CCT as a cost-effective, comprehensive imaging modality for post-STEMI risk stratification, with the added benefit of coronary artery evaluation. If successful, CCT could serve as an efficient, one-stop diagnostic tool, enhancing patient outcomes while optimizing healthcare resources.

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Abbreviations

ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BNP	B-type natriuretic peptide
CCT	Cardiac computed tomography
CMR	Cardiac magnetic resonance
CK	Creatine kinase
CRP	C-reactive protein
ECG	Electrocardiogram
ECV	Extracellular volume
EF	Ejection fraction
eGFR	Estimated glomerular filtration rate
HF	Heart failure
ICD	Implantable cardioverter-defibrillator
IMH	Intramyocardial hemorrhage
IS	Infarct size
LGE	Late gadolinium enhancement
LIE	Late iodine enhancement
LV	Left ventricle
LVEDV	Left ventricular end-diastolic volume
LVEF	Left ventricular ejection fraction
LVESV	Left ventricular end-systolic volume
MVO	Microvascular obstruction
PCI	Percutaneous coronary intervention
RV	Right ventricle
RVEDV	Right ventricular end-diastolic volume
RVEF	Right ventricular ejection fraction
RVESV	Right ventricular end-systolic volume
STEMI	ST-segment elevation myocardial infarction
T2w-STIR	T2-weighted short-tau inversion recovery

1. Introduction

ST-segment elevation myocardial infarction (STEMI) remains a leading cause of mortality. Within the first year, STEMI survivors face a substantial risk of adverse cardiovascular events, including heart failure (HF) in up to 25 % of cases, recurrent ischemic events in 18.3 %, and life-threatening arrhythmias (LTA) up to 1.5 %.[1] Effective risk stratification is essential to tailor treatment strategies and optimize patient outcomes. However, current tools for predicting post-STEMI adverse events are limited either by reduced predictive accuracy or limited accessibility.

Cardiac imaging plays a central role in post-STEM risk assessment, with echocardiography serving as the standard modality. Current guidelines recommend routine echocardiography after primary percutaneous coronary intervention (PCI) to assess left ventricular (LV) function, right ventricular (RV) function, and valvular abnormalities while excluding early post-infarction mechanical complications and LV thrombus formation.[2] However, its predictive value for subsequent LV remodeling remains less well established.

Cardiac magnetic resonance imaging (CMR) has emerged as the most powerful tool for predicting adverse LV remodeling following STEMI.[3–6] Infarct size (IS), microvascular obstruction (MVO), and intramyocardial hemorrhage (IMH), all assessable by CMR, are independent predictors of outcome in STEMI patients. These parameters outperform clinical and reperfusion markers and predict long-term adverse remodeling, even among patients with initially preserved LV ejection fraction (EF).[3–6]

Despite its strong prognostic utility, routine implementation of CMR following STEMI remains challenging due to limited availability, high costs and logistical constraints, including time and staff allocation. Additionally, not all patients are eligible for CMR in the early post-infarction period. Furthermore, while CMR provides extensive myocardial tissue characterization, it does not assess the coronary anatomy, failing to offer a comprehensive risk evaluation that includes the atherothrombotic component.

As cardiac computed tomography (CCT) have expanded its applicability beyond morpho-functional assessment to include myocardial tissue characterization,[7–10] it may now serve as a comprehensive tool for post-STEMI risk assessment. The first report of late iodine enhancement (LIE) study with CCT in post-STEMI patients dates back to 2005.[9] Since then, technological advancements have significantly improved its diagnostic capabilities. A recent meta-analysis reported excellent diagnostic accuracy of LIE when compared to late gadolinium enhancement (LGE), with sensitivity and specificity reaching 0.96 and 0.95 respectively, at the patient level.[11] Furthermore, CCT has evolved from an angiographic tool to a fully integrated imaging modality capable of assessing wall motion abnormalities, identifying myocardial scars or necrosis, and quantifying myocardial extracellular volume (ECV).[12–14] Consequently, CCT presents an unprecedented opportunity for comprehensive post-STEMI risk stratification, offering widespread availability, moderate costs, logistic efficiency, and minimal radiation exposure with modern scanning protocols.

1.1. Study aims

The CT-STEMI study is designed to:

1. Evaluate the diagnostic accuracy of a comprehensive CCT protocol, including morpho-functional assessment and tissue characterization, in post-STEMI patients.
2. Determine the prognostic value of CCT-derived imaging features related to STEMI.
3. Assess the atherosclerotic burden in STEMI patients and its prognostic implications.

2. Materials and methods

2.1. Study design

The CT-STEMI study is a prospective, multicenter observational study registered on *ClinicalTrials.gov* (*NCT06020209*). Patients will be enrolled based on the following criteria:

Inclusion criteria:

- Age >18years
- Diagnosis of STEMI
- Primary PCI within 24 h of symptom onset
- Hemodynamic stability without inotropic support within four days of the index event
- Signed informed consent

Exclusion criteria:

- Chronic kidney disease with estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m^2
- History of allergic reaction to CCT or CMR contrast media
- Inability or unwillingness to undergo CCT or CMR
- Pregnancy or breastfeeding
- Severe atrial or ventricular arrhythmias
- Severe valvular stenosis or regurgitation
- Prior clinical diagnosis of congestive HF (asymptomatic LV dysfunction is allowed)

All enrolled patients will undergo:

- A comprehensive cardiology assessment, including a 12-lead electrocardiogram (ECG)
- Laboratory testing: Troponin, creatine kinase (CK), lactate dehydrogenase (LDH), B-type natriuretic peptide (BNP), C-reactive protein (CRP), urea, creatinine, bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT).
- Transthoracic Echocardiography
- CCT
- CMR

CCT or CMR will be performed between four and ten days after the acute event. The sequence of the two imaging modalities will be randomized with a maximum interval of ten days.

Patients will be followed clinically throughout the study period, with a focus on HF development, arrhythmias, and recurrent atherothrombotic events.

The study design flowchart is shown in Fig. 1.

2.2. Imaging protocols: CMR and CCT acquisition and interpretation

CMR will be performed following the Society of CMR guidelines.[15] The protocol includes cine steady-state free precession (cine-SSFP) imaging for cardiac structure and function, T2-weighted short-tau inversion recovery (T2w-STIR) for myocardial edema, early gadolinium enhancement, and LGE imaging for myocardial injury. When available, T1 mapping (including ECV), T2 mapping, and T2* mapping will be included. IS, MVO, and IMH will be assessed, along with myocardial salvage index (MSI).[3,16]

CCT will follow the Society of CCT guidelines.[17] The protocol includes a pre-contrast scan, angiographic imaging, and a LIE scan acquired 7 min after contrast administration.[13] Prospective ECG gating at 75 % of the R–R interval will be used for pre-contrast and LIE scans. Tube voltage settings will be adjusted based on patients' body mass index (BMI): 80 kVp for those with a BMI <25 kg/m^2, 100 kVp for a BMI ≥ 25 kg/m^2, and 120 kVp in case of spectral data acquisition. The angiographic phase is acquired according to the SCCT guidelines.[17] For volumetric evaluation, dose modulation technique is implemented as follows: in patients with heart rates below 60 bpm, a narrow acquisition window between 70 % and 80 % of the R–R interval is used at 100 % tube current, while the remainder of the cardiac cycle is scanned at 20 % of the tube current. For patients with heart rates of 60 bpm or higher, a wider window from 40 % to 80 % of the R–R interval is employed at 100 % tube current, with the rest of the cycle modulated accordingly.

Ventricular function will be assessed using multiphase reconstructions of the heart (20 phases, 0 %–95 % of the R–R interval). LIE imaging will be displayed along LV short-axis reconstructions (slice thickness = 8 mm; gap = 0 mm) in average mode, and the presence of scar will be defined as a localized area of increased attenuation relative to the surrounding myocardium. The presence of MVO will be defined as a dark non-enhancing area with low ECV within the ischemic scar on LIE images.[13]

IS, MVO, and ECV will be quantified, with artificial intelligence-based segmentation techniques applied for tissue characterization.[18]

Fig. 2 illustrates the CCT protocol used in the CT-STEMI study.

2.3. Clinical follow-up and endpoints definition

Follow-up visits will be conducted per standard secondary prevention protocols. Endpoints will be adjudicated by an independent committee. Events will be defined as in the most recent pertinent guidelines of the European Society of Cardiology.[2]

Co-primary endpoints will be:

- Atherothrombotic events: recurrent acute coronary syndrome, ischemic stroke, or cardiovascular death.
- HF and arrhythmic events: new-onset congestive HF, sustained ventricular arrhythmia, appropriate implantable cardioverter-defibrillator (ICD) intervention, sudden cardiac death or resuscitated cardiac arrest.

Secondary endpoints will be:

- All-cause mortality
- Cardiovascular mortality
- Myocardial infarction
- Urgent or clinically driven revascularization

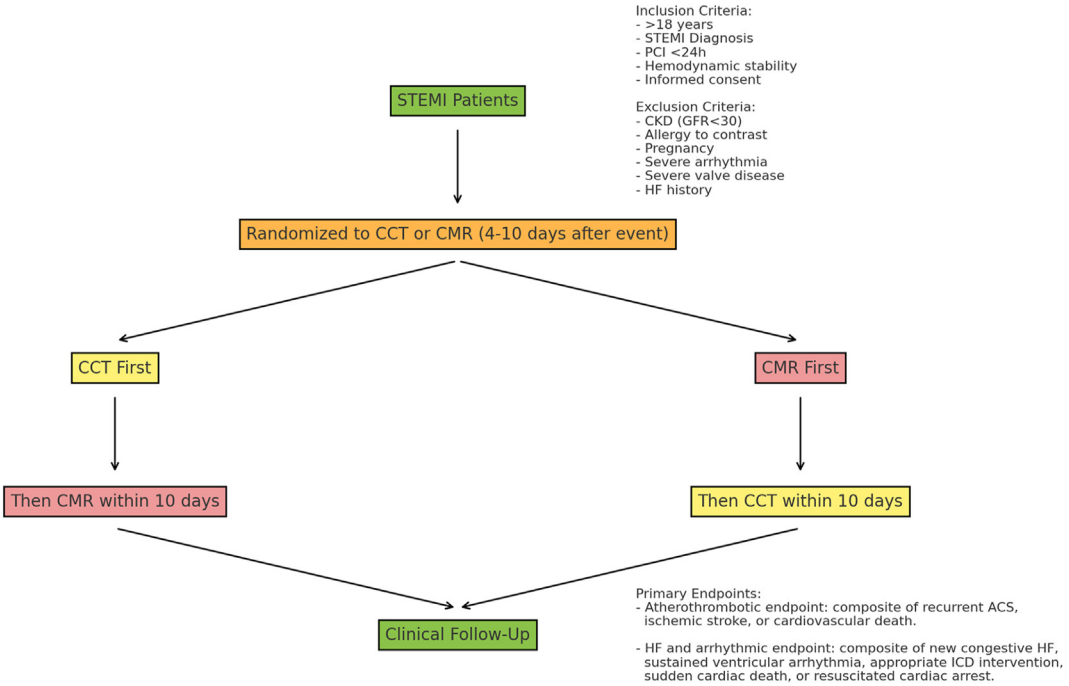

Fig. 1. CT-STEMI study design flowchart.

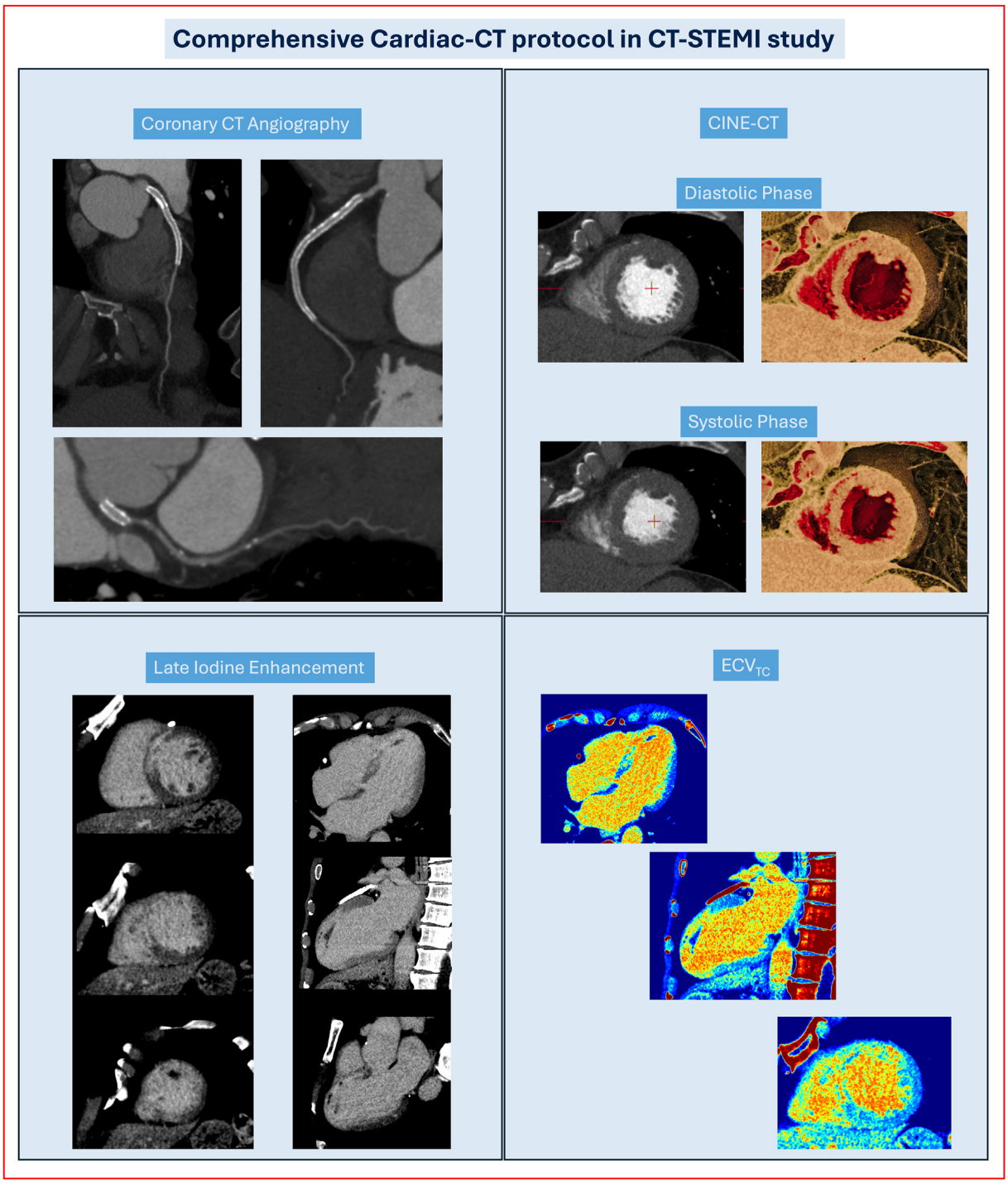

Fig. 2. CCT protocol in CT-STEMI study.

- New-onset congestive HF or HF hospitalization
- Sustained ventricular arrhythmia

2.4. Sample size

To compare the diagnostic accuracy of a comprehensive CCT protocol with that of CMR, the non-invasive gold standard, the CT-STEMI study anticipates that the CCT protocol will achieve a sensitivity and specificity of at least 80 % in identifying binary predictors, such as the presence of MVO, using CMR as the reference standard. The sample size calculation was based on the estimated prevalence of MVO, which is reported as 57 % in the target population.[5]

The required sample size was determined as follows:

- 109 subjects are needed to achieve a 95 % confidence interval (CI) with a width of 0.2, assuming a sensitivity of 0.80;
- 145 subjects are needed to achieve a 95 % CI with a width of 0.2, assuming a specificity of 0.80.
- To account for the larger sample size requirement and adjust for an anticipated 25 % dropout rate, the final sample size was set at 193 patients.

To ensure statistical robustness, we rounded the total number of enrolled participants to 200.

3. Statistical analysis

Continuous variables will be assessed for normality using the Shapiro–Wilks W test. Variables following a normal distribution will be reported as mean and standard deviation, whereas non-normally distributed variables will be expressed as median (1st-3rd quartile). Categorical variables will be presented as counts and percentages. Comparisons between categorical variables will be performed using either the chi-square test or Fisher's exact test, as appropriate. For continuous variables, comparisons will be conducted using either the parametric *t*-test or the non-parametric Mann-Whitney *U* test, depending on the distribution of the data.

To assess diagnostic performance, sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy will be calculated and expressed as percentages with 95 % confidence intervals (CI), using CMR as the reference standard.

The primary parameters of interest will include:

- morpho functional parameters: Left Ventricular End-Diastolic Volume (LVEDV), Left Ventricular End-Systolic Volume (LVESV), Left Ventricular Ejection Fraction (LVEF), Right Ventricular End-Diastolic Volume (RVEDV), Right Ventricular End-Systolic Volume (RVESV), and Right Ventricular Ejection Fraction (RVEF).
- myocardial tissue characterization parameters: IS, myocardial edema, MVO, IMH and ECV.

Receiver Operating Characteristics (ROC) curve analysis will be performed to determine optimal cut-off values for continuous variables, with the Youden's index method used to identify the best threshold. Intra-observer and inter-observer variability will be assessed using intraclass correlation coefficients (ICC) and the Cronbach's alpha coefficient to ensure measurement reliability.

For the analysis of clinical outcomes, univariate and multivariate logistic regression models will be used to identify significant predictors among clinical, transthoracic echocardiography, coronary angiography, CMR, and CCT-derived parameters at predefined follow-up intervals. To this end, we will develop a multiparametric model that incorporates clinical, echocardiographic, and coronary angiographic variables to identify independent predictors of clinical outcomes. The independent predictors identified from this comprehensive model will then be used to adjust the prognostic analysis of advanced imaging data, ensuring that their incremental value is assessed in a robust and clinically meaningful context. The collected data will also be analyzed longitudinally using mixed-effects regression models, which account for the dependency of repeated observations over time. The collected data will be analyzed longitudinally using mixed-effects regression models, which account for the dependency of longitudinal data. The prognostic value of imaging parameters will be compared between CCT and CMR, with multivariate models developed separately for each imaging modality.

To evaluate time-dependent clinical outcomes, Kaplan-Meier survival curves will be generated, and the log-rank test will be used to compare survival distributions between patient subgroups. Multivariate Cox regression analysis will be performed to identify independent predictors of time-dependent outcomes.

In all statistical analyses, p-values less than 0.05 will be considered significant, and confidence intervals will be reported at a 95 % confidence level.

Finally, machine learning algorithms will be implemented to predict cardiovascular events using a classifier trained on a combination of clinical, transthoracic echocardiography, coronary angiography and radiological variables, including CCT-derived and CMR-derived metrics. A multivariate predictive model integrating atherosclerotic plaque characteristics, morpho-functional parameters, and myocardial tissue characteristics will be developed to improve risk stratification.

4. Discussion

The CT-STEMI study will be the first to evaluate the potential of a comprehensive CCT protocol as a "one-stop shop" imaging tool for risk assessment in post-STEMI patients. The study aims to establish the non-inferiority of CCT compared to CMR in myocardial tissue characterization, while simultaneously providing coronary artery evaluation, a crucial information for complete risk stratification in CAD patients.[19]

From a morpho-functional perspective, this study will assess whether a CCT protocol encompassing the entire cardiac cycle can match CMR in both the quantitative and qualitative evaluation of ventricular motion. Additionally, the protocol may facilitate the assessment of myocardial strain, a key-marker of cardiac dysfunction, comparable to CMR-based strain imaging.

Regarding tissue characterization, the primary objective is to determine whether LIE and ECV analysis can identify key predictive parameters comparable to CMR. The study will focus on evaluating IS, MVO and ECV, which are critical for post-STEMI risk stratification. A subset of imaging studied will also incorporate dual-energy CCT technology, exploring its potential to enhance tissue characterization in this patient population.

Beyond myocardial function, atherosclerotic burden and plaque composition are emerging as powerful tools for identifying high-risk patients prone to recurrent atherothrombotic events.

These imaging-based risk markers have outperformed traditional risk stratification models, which are primarily based on clinical variables and risk factors matrices. While CCT has already been used for atherosclerotic burden assessment in chronic coronary syndrome, its role in the high-risk STEMI population remains unexplored, despite the potential for even greater clinical benefit.

If the study confirms the hypotheses, CCT could revolutionize post-STEMI risk assessment, offering a cost-effective, logistically efficient, and widely available technology, for comprehensive cardiovascular evaluation. Additionally, modern CCT scanners and protocols now provide very low radiation dose exposure, making routine implementation feasible.

The potential implications extend beyond individual patient management. CCT-based risk stratification may streamline early treatment decisions, improving patient outcomes through earlier and more targeted interventions. Moreover, a more accurate and efficient imaging strategy could optimize healthcare resource allocation, reducing re-hospitalization rates, disease progression, and long-term healthcare costs.

In conclusion, the CT-STEMI study aims to redefine post-STEMI patient management by introducing a more accessible, cost-effective, and comprehensive imaging approach for risk stratification. By integrating morpho-functional assessment, myocardial tissue characterization, and coronary artery evaluation, CCT has the potential to improve long-term clinical outcomes while promoting more sustainable healthcare practices.

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Declaration of competing interest

On behalf of all authors, I declare that there are no financial, personal, or professional conflicts of interest related to this manuscript. None of the authors have received funding, consultancy fees, stock ownership, honoraria, or any other form of compensation that could influence the content of this research.

This manuscript is an original work, has not been published previously, and is not under consideration for publication elsewhere.

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