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Prognostic and Practical Validation of Current Definitions of Myocardial Infarction Associated With Percutaneous Coronary Intervention

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ABSTRACT

OBJECTIVES In 13,038 patients with non-ST-segment elevation acute coronary syndrome undergoing index percutaneous coronary intervention (PCI) in the EARLY ACS (Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndrome) and TRACER (Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome) trials, the relationship between PCI-related myocardial infarction (MI) and 1-year mortality was assessed.

BACKGROUND The definition of PCI-related MI is controversial. The third universal definition of PCI-related MI requires cardiac troponin >5 times the 99th percentile of the normal reference limit from a stable or falling baseline and PCI-related clinical or angiographic complications. The definition from the Society for Cardiovascular Angiography and Interventions (SCAI) requires creatine kinase–MB elevation >10 times the upper limit of normal (or 5 times if new electrocardiographic Q waves are present). Implications of these definitions on prognosis, prevalence, and implementation are not established.

METHODS In our cohort of patients undergoing PCI, PCI-related MIs were classified using the third universal type 4a MI definition and SCAI criteria. In the subgroup of patients included in the angiographic core laboratory (ACL) substudy of EARLY ACS (n = 1,401) local investigator– versus ACL-reported angiographic complications were compared.

RESULTS Altogether, 2.0% of patients met third universal definition of PCI-related MI criteria, and 1.2% met SCAI criteria. One-year mortality was 3.3% with the third universal definition (hazard ratio: 1.96; 95% confidence interval: 1.24 to 3.10) and 5.3% with SCAI criteria (hazard ratio: 2.79; 95% confidence interval: 1.69 to 4.58; $p < 0.001$). Agreement between ACL and local investigators in detecting angiographic complications during PCI was overall moderate ($\kappa = 0.53$).

CONCLUSIONS The third universal definition of MI and the SCAI definition were both associated with significant risk for mortality at 1 year. Suboptimal concordance was observed between ACL and local investigators in identifying patients with PCI complications detected on angiography. (Trial to Assess the Effects of Vorapaxar [SCH 530348; MK-5348] in Preventing Heart Attack and Stroke in Participants With Acute Coronary Syndrome [TRA·CER] [Study P04736]; NCT00527943; EARLY ACS: Early Glycoprotein IIb/IIIa Inhibition in Patients With Non-ST-Segment Elevation Acute Coronary Syndrome [Study P03684AM2]; NCT00089895) (J Am Coll Cardiol Intv 2018;11:856–64)
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Recurrent myocardial infarction (MI) is a common complication among patients with coronary heart disease, and the risk is highest following acute coronary syndromes (ACS) (1,2). Given their frequency and prognostic implications, MIs are a key efficacy endpoint in cardiovascular clinical trials and an increasingly important safety endpoint in trials assessing noncardiovascular therapies (3). MI associated with percutaneous coronary intervention (PCI) is a clinical entity whose diagnostic criteria have been subject to an ongoing controversy (4). The lack of a common pathophysiological mechanism, the relatively high incidence of elevated markers of cardiac cell necrosis during PCI, and the uncertainty over their prognostic significance have resulted in a lack of universally accepted criteria. Several diagnostic criteria and revisions have been proposed over the years, and definitions used in clinical trials have been inconsistent (5).

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The third universal definition of MI document has proposed a new definition of PCI-related MI (referred to as type 4a), which requires, in addition to increased cardiac biomarkers, the presence of clinical or electrocardiographic signs of ischemia or the documentation of procedural complications detected by coronary angiography (6). The third universal definition also raised the diagnostic cardiac troponin (cTn) threshold to >5 times the 99th percentile of a normal reference range (the upper reference limit) from a normal or decreasing pre-PCI value (6). This new definition aims to increase diagnostic specificity and prognostic relevance, while maintaining enough sensitivity in using the MI diagnosis for significant biomarker elevations in the appropriate clinical context. The definition proposed by the Society for Cardiovascular Angiography and Interventions (SCAI) relies on a >10 times increase of creatine kinase (CK)-MB (5 times in the presence of new Q waves on electrocardiography) and aims to capture "clinically relevant" MIs, without specific focus on sensitivity (7). The prognostic implications of these definitions have not been well established. Finally, as the third universal definition of PCI-related MI heavily relies on

ABBREVIATIONS AND ACRONYMS

ACL = angiographic core laboratory

ACS = acute coronary syndrome(s)

CEC = clinical event committee

CK = creatine kinase

CRF = case report form

cTn = cardiac troponin

MI = myocardial infarction

NSTE = non-ST-segment elevation

PCI = percutaneous coronary intervention

SCAI = Society for Cardiovascular Angiography and Interventions

ULN = upper limit of normal

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