CARDIOLOGY/ORIGINAL RESEARCH

Multicenter Evaluation of a 0-Hour/1-Hour Algorithm in the Diagnosis of Myocardial Infarction With High-Sensitivity Cardiac Troponin T

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Study objective: We aim to prospectively validate the diagnostic accuracy of the recently developed 0-h/1-h algorithm, using high-sensitivity cardiac troponin T (hs-cTnT) for the early rule-out and rule-in of acute myocardial infarction.

Methods: We enrolled patients presenting with suspected acute myocardial infarction and recent (<6 hours) onset of symptoms to the emergency department in a global multicenter diagnostic study. Hs-cTnT (Roche Diagnostics) and sensitive cardiac troponin I (Siemens Healthcare) were measured at presentation and after 1 hour, 2 hours, and 4 to 14 hours in a central laboratory. Patient triage according to the predefined hs-cTnT 0-hour/1-hour algorithm (hs-cTnT below

Importance

High-sensitivity cardiac troponin (hs-cTn) assays, which allow measurement of even low cTn concentrations with high precision, have been shown to provide high diagnostic accuracy for acute myocardial infarction already at presentation.[7-14] In parallel, several early-rule-out strategies have been developed. These include the use of very low concentrations of hs-cTn,[12,15-17] as well as the combination of cTn concentrations at 0 and 2 hours with a clinical score.[18-20] Limitations of these approaches include that they do not provide guidance for rule-in and that rule-out is possible only in 10% to 40% of patients.[12,15-20]

Accordingly, the high-sensitivity cardiac troponin T (hs-cTnT) 0-hour/1-hour algorithm has received substantial attention.[10,13] This algorithm uses hs-cTnT blood concentrations at presentation and their absolute changes within 1 hour to triage patients. It was reported to achieve a very high negative predictive value for acute myocardial infarction in the rule-out zone, to achieve a high positive predictive value in the rule-in zone, and to be very effective by

enrich the study population with the particularly challenging early presenters.[7-9] Patients with renal failure requiring long-term hemodialysis; those with trauma, cardioversion, defibrillation, or thrombolytic therapy before inclusion; individuals receiving coronary artery bypass grafting within the last month or hospitalized for acute myocardial infarction within the last 3 weeks; and pregnant and breastfeeding women were excluded. To allow the study blood draw to be performed as quickly as possible, definite interpretation of the initial ECG was not required before inclusion. Accordingly, patients with ST-segment elevation myocardial infarction (STEMI) were not excluded by the protocol. The study was carried out according to the principles of the Declaration of Helsinki and approved by the local ethics committees.

Patients underwent an initial clinical assessment that included clinical history, physical examination, 12-lead ECG, pulse oximetry, standard blood tests (including local cTn assays), and chest radiograph in accordance with local protocols. Treatment of patients was left at discretion of the attending physician. Standard data were collected on study-specific case report forms.

Editor's Capsule Summary

What is already known on this topic

Ruling out acute myocardial infarction is classically conducted with serial biomarkers during 8 to 24 hours.

What question this study addressed

Whether 2 high-sensitivity troponin (hs-cTnT) values at 0 and 1 hour can rapidly classify patients into 3 groups: no acute myocardial infarction, acute myocardial infarction, and indeterminate.

What this study adds to our knowledge

Use of hs-cTn assays at presentation and 1 hour later in a population with a 17% rate of acute myocardial infarction classified 63% of patients as having no acute myocardial infarction, with a 99.1% negative predictive value (95% confidence interval 98.2% to 99.7%); 14% as having acute myocardial infarction, with a positive predictive value of 77% (95%

triaging approximately 75% of patients presenting with suspected acute myocardial infarction to the ED to either rule-out or rule-in classifications.[10,13] Obviously, successful external validation in a global and meticulous multicenter study is mandatory before such a novel approach can be considered for widespread implementation into routine clinical practice.[21]

Goals of This Investigation

The aim of this international multicenter study, therefore, was to externally validate the diagnostic accuracy of the hs-cTnT 0-hour/1-hour algorithm for rapid rule-out and rule-in of acute myocardial infarction and thereby evaluate its suitability for routine clinical care.

MATERIALS AND METHODS

Study Design

The High Sensitivity Cardiac Troponin T Assay for Rapid Rule-out of Acute Myocardial Infarction (TRAPID-AMI) trial was a prospective international multicenter diagnostic study conducted at 12 sites on 3 continents (see