Abstract: P175

A novel high-sensitivity cardiac troponin i assay for early diagnosis of acute myocardial infarction

Authors:
J Boedinghaus¹, T Nestelberger¹, R Twenerbold¹, M Rubini Gimenez¹, L Koechlin¹, V Troester¹, D Wussler¹, P Badertscher¹, K Wildi¹, J Du Fay De Lavallaz¹, JE Walter¹, C Puelacher¹, T Reichlin¹, C Mueller¹, ¹University Hospital Basel, Cardiovascular Research Institute Basel (CRIB) - Basel - Switzerland,

On behalf: Advantageous Predictors of Acute Coronary Syndrome Evaluation (APACE) Investigators

Topic(s):
Acute Coronary Syndromes: Biomarkers

Citation:

Funding Acknowledgements:
Swiss National Science Foundation, the Swiss Heart Foundation, the KTI, the European Union, the Stiftung für kardiovaskuläre Forschung Basel

Background: The clinical performance of the novel high-sensitivity cardiac troponin I (hs-cTnI) Access assay is unknown.

Purpose: To clinically validate the novel hs-cTnI-Access assay and to derive and validate an assay specific 0/1h-algorithm accordingly to the current European Society of Cardiology (ESC) recommendations for early triage of chest pain patients.

Methods: We enrolled patients presenting to the emergency department with symptoms suggestive of acute myocardial infarction (AMI). Final diagnoses were centrally adjudicated by two independent cardiologists including all clinical information including cardiac imaging twice: first, using serial hs-cTnT (Elecsys, primary analysis) and second, using hs-cTnI (Architect, secondary analysis) measurements in addition to the clinically used (hs)-cTn. Hs-cTnI-Access was measured at presentation and at 1h. Primary objective was a direct comparison of diagnostic accuracy as quantified by the area under the receiver-operating-characteristic curve (AUC) of hs-cTnI-Access versus the two established hs-cTn assays (hs-cTnT-Elecsys, hs-cTnI-Architect). Secondary objectives included the derivation and validation of an hs-cTnI-Access specific 0/1h-algorithm.

Results: AMI was the adjudicated final diagnosis in 243/1579 (15.4%) patients. The AUC at presentation for hs-cTnI-Access was 0.95 (95%CI, 0.94-0.96), significantly higher as hs-cTnI-Architect (0.92 [95%CI, 0.91-0.94; p<0.001]), and comparable to hs-cTnT-Elecsys (0.94 [95%CI, 0.93-0.95; p=0.12]) Applying the derived hs-cTnI-Access 0/1h-algorithm (derivation cohort n=686) to the validation cohort (n=680), 60% of patients were ruled-out (sensitivity 98.9% [95%CI, 94.3-99.8]), and 15% of patients were ruled-in (specificity 95.9% [95%CI, 94.0-97.2]). Patients ruled-out by the 0/1h-algorithm had a survival rate of 98.4% after two years of follow up. Findings were confirmed in the secondary analyses using the adjudication including serial measurements of hs-cTnI (Architect).

Conclusions: Diagnostic accuracy of the novel hs-cTnI-Access assay is excellent and comparable to the two established hs-cTn assays. The assay-specific 0/1h-algorithm allows a safe rule-out and accurate rule-in of MI in most patients within 1-hour after presentation to the ED. Long-term survival of patients ruled-out by the 0/1h-algorithm is very high.
Abstract: A novel high-sensitivity cardiac troponin I assay for early diagnosis of acute myocardial infarction

Authors: J Boeddinghaus, T Nestelberger, R Twerenbold, M Rubini Gimenez, L Koechlin, V Troester, D Wussler, P Badertscher, K Wildi, J Du Fay De Lavallaz, JE Walter, C Puelacher, T Reichlin, C Mueller

University Hospital Basel, Cardiovascular Research Institute Basel (CRIB) - Basel - Switzerland,

On behalf: Advantageous Predictors of Acute Coronary Syndrome Evaluation (APACE) Investigators

Topic(s): Acute Coronary Syndromes: Biomarkers

Citation:

Background: The clinical performance of the novel high-sensitivity cardiac troponin I (hs-cTnI) Access assay is unknown.

Purpose: To clinically validate the novel hs-cTnI-Access assay and to derive and validate an assay specific 0/1h-algorithm accordingly to the current European Society of Cardiology (ESC) recommendations for early triage of chest pain patients.

Methods: We enrolled patients presenting to the emergency department with symptoms suggestive of acute myocardial infarction (AMI). Final diagnoses were centrally adjudicated by two independent cardiologists including all clinical information including cardiac imaging twice: first, using serial hs-cTnT (Elecsys, primary analysis) and second, using hs-cTnI (Architect, secondary analysis) measurements in addition to the clinically used (hs)-cTn. Hs-cTnI-Access was measured at presentation and at 1h. Primary objective was a direct comparison of diagnostic accuracy as quantified by the area under the receiver-operating-characteristic curve (AUC) of hs-cTnI-Access versus the two established hs-cTn assays (hs-cTnT-Elecsys, hs-cTnI-Architect).

Secondary objectives included the derivation and validation of an hs-cTnI-Access specific 0/1h-algorithm.

Results: AMI was the adjudicated final diagnosis in 243/1579 (15.4%) patients. The AUC at presentation for hs-cTnI-Access was 0.95 (95%CI, 0.94-0.96), significantly higher as hs-cTnI-Architect (0.92 [95%CI, 0.91-0.94]; p<0.001), and comparable to hs-cTnT-Elecsys (0.94 [95%CI, 0.93-0.95]; p=0.12) Applying the derived hs-cTnI-Access 0/1h-algorithm (derivation cohort n=686) to the validation cohort (n=680), 60% of patients were ruled-out (sensitivity 98.9% [95%CI, 94.3-99.8]), and 15% of patients were ruled-in (specificity 95.9% [95%CI, 94.0-97.2]). Patients ruled-out by the 0/1h-algorithm had a survival rate of 98.4% after two years of follow up. Findings were confirmed in the secondary analyses using the adjudication including serial measurements of hs-cTnI (Architect).

Conclusions: Diagnostic accuracy of the novel hs-cTnI-Access assay is excellent and comparable to the two established hs-cTn assays. The assay-specific 0/1h-algorithm allows a safe rule-out and accurate rule-in of MI in most patients within 1-hour after presentation to the ED. Long-term survival of patients ruled-out by the 0/1h-algorithm is very high.

A

All patients (n=1579)

B

Early presenters (n=580)