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

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

Background: The novel high-sensitivity cardiac troponin I (hs-cTnI)-Vitros assay was developed recently. Before its possible implementation into routine clinical care for triage of chest pain patients, its performance needs clinical validation.

Purpose: To clinically validate hs-cTnI-Vitros and to derive and validate an assay-specific 0/1h-algorithm following the European Society of Cardiology (ESC) recommendations.

Methods: In a prospective international multicentre study (12 centres in 5 European countries) 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-Vitros was measured at presentation and at 1h in a blinded fashion. Primary objective was direct comparison of diagnostic accuracy as quantified by the area under the receiver-operating-characteristic curve (AUC) of hs-cTnI-Vitros versus the two established hs-cTn assays (hs-cTnT-Elecsys, hs-cTnI-Architect). Secondary objectives included the derivation and validation of a hs-cTnI-Vitros specific 0/1h-algorithm.

Results: AMI was the adjudicated final diagnosis in 158/1231 (13%) patients. The AUC at presentation for hs-cTnI-Vitros was 0.95 (95% CI, 0.93–0.96), and significantly higher as hs-cTnT-Elecsys (0.94 [95% CI, 0.92–0.95; p=0.01]) and hs-cTnI-Architect (0.92 [95% CI, 0.90–0.94; p<0.001]). Applying the derived hs-cTnI-Vitros 0/1h-algorithm (derivation cohort n=519) to the validation cohort (n=520), 53% of patients were ruled-out (sensitivity 100% [95% CI, 98.6–100]), and 14% of patients were ruled-in (specificity 95.6% [95% CI, 93.4–97.2]). Patients ruled-out by the 0/1h-algorithm had a survival rate of 99.8% at 30-days and 98.7% at 2-years. Findings were confirmed in the secondary analyses using the adjudication including serial measurements of hs-cTnI (Architect).

Conclusions: The novel hs-cTnI-Vitros assay has even higher diagnostic accuracy as the current gold-standards hs-cTnT and hs-cTnI. The hs-cTnI-Vitros specific 0/1h-algorithms allows a safe rule-out and accurate rule-in of AMI in about 70% of patients within 1h after presentation to the ED.
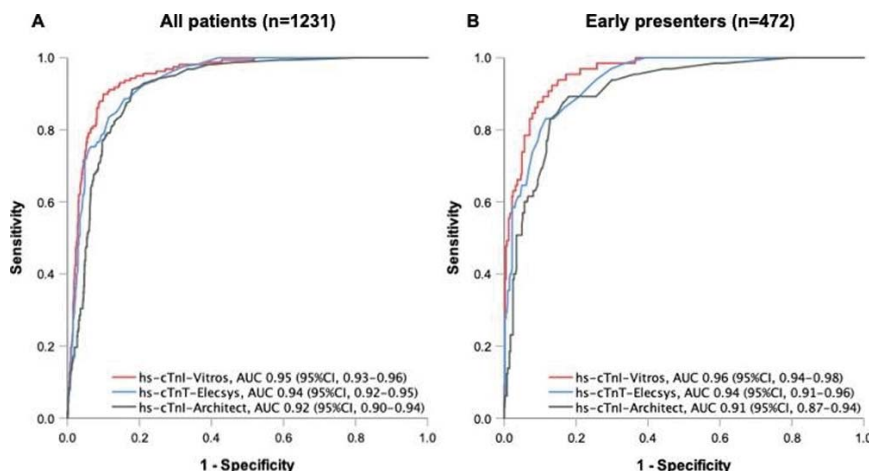
ROC Curves for the 3 hs-cTn assays at 0h