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

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

Topic(s): Acute Coronary Syndromes: Biomarkers

Citation:

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Background: Lately, the novel high-sensitivity cardiac troponin I (hs-cTnl) Access assay was developed. Its clinical performance in patients presenting with chest pain to the emergency department (ED) is unknown.

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

Methods: In a prospective international multicentre study 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-cTnl (Architect, secondary analysis) measurements in addition to the clinically used (hs)-cTn. Hs-cTnl-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-cTnl-Access versus the two established hs-cTn assays (hs-cTnT-Elecsys, hs-cTnl-Architect). Secondary objectives included the derivation and internal validation of an hs-cTnl-Access specific 0/1h-algorithm.

Results: AMI was the adjudicated final diagnosis in 243/1579 (15.4%) patients. The AUC at presentation for hs-cTnl-Access was 0.95 (95%CI, 0.94-0.96), significantly higher as hs-cTnl-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-cTnl-Access 0/1h-algorithm (derivation cohort n=686) to the internal 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 of 100% after 30-days and 98.4% after two years of follow up. Findings were confirmed in the secondary analyses using the adjudication including serial measurements of hs-cTnl (Architect).

Conclusions: Diagnostic accuracy of the novel hs-cTnl-Access assay is excellent and at least 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 about 75% of patients within 1-hour after presentation to the ED. Survival of patients ruled-out by the 0/1h-algorithm was very high.
Abstract: A novel high-sensitivity cardiac troponin I (hs-cTnI) assay for early diagnosis of acute myocardial infarction

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**Diagram:**

- **Suspected NSTEMI**
  - **Rule-Out**
    - @0h <4ng/L* OR @0h <5ng/L AND |Delta 1h| <4ng/L
    - n=409 (60%)
    - NPV: 99.8% (98.6-100)
    - Sens: 98.9% (94.3-99.8)
    - NSTEMI: 0.2%
  - **Observe**
    - n=179 (26%)
    - NSTEMI: 15%
  - **Rule-In**
    - @0h ≥50ng/L OR |Delta 1h| ≥15ng/L
    - n=92 (14%)
    - PPV: 73.9% (64.1-81.8)
    - Spec: 95.9% (94.0-97.2)
    - NSTEMI: 74%