Evaluation of a new ultra-sensitivity troponin I assay in patients with suspected MI

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Objective
Troponin is the gold-standard for diagnostic evaluation of patients with suspected myocardial infarction (MI). We aimed to evaluate the diagnostic and prognostic performance of a new ultra-sensitivity troponin I (us-TnI) assay in patients with suspected MI.

Methods
Patients with suspected MI were included and MI diagnosis was adjudicated by two physicians based on troponin T. Us-TnI measurements were performed directly on admission and after one hour. One-year rates of mortality and incident MI were assessed. For diagnostic evaluation the negative and positive predictive value (NPV/PPV) using admission us-TnI concentrations and 0/1h delta were calculated. For rule-out an NPV >99.5% (100% for single-admission-value) and for rule-in a PPV >80% was targeted. Internal derivation/validation was used.

Results
In the derivation dataset 155/767 patients were diagnosed with having non-ST-elevation MI (NSTEMI) (Table 1). For rule-out of NSTEMI an us-TnI <1ng/L directly on admission resulted in an NPV of 100.0% (CI 98.2-100.0) (Figure 1). Using serial sampling an admission us-TnI <2ng/L and a 0/1h delta <1ng/L resulted in an NPV of 99.7% (CI 98.4-100.0) and ruled-out NSTEMI in 46.8% of all patients. The respective one-year rate of death or MI was 0.6%. For rule-in of NSTEMI an us-TnI ≥25ng/L on admission or a 0/1h delta ≥6ng/L resulted in a PPV of 81.3% (CI 73.7-87.5) and ruled-in NSTEMI in 18.5% of all patients. The one-year event rate was 12.7%. Results were similar in 767 patients from the validation cohort.

Conclusions
Application of an us-TnI assay allows the accurate triage of a large proportion of patients with suspected MI using a 0/1h algorithm.


Table 1: Baseline characteristics for the derivation and validation datasets