Diagnostic validation of a high-sensitivity troponin I assay and its use in a guideline-consistent rapid diagnostic protocol

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Funding Acknowledgement: Type of funding sources: Foundation. Main funding source(s): German Heart foundation

Background: Current ESC guidelines on management of non-ST-elevation myocardial infarction (NSTEMI) recommend rapid diagnostic protocols using validated high-sensitivity cardiac troponin (hs-cTn) assays (1). While established protocols are available for several hs-cTn assays, data on the diagnostic performance of the Siemens Atellica IM High-Sensitivity Cardiac Troponin I assay is limited.

Methods: In a cohort study including 1,800 patients presenting with suspected acute MI. Final diagnosis of MI was adjudicated by two cardiologists separately in accordance with the fourth universal definition of MI (2). We developed and validated a 0/1h diagnostic algorithm using the Siemens Atellica assay. The algorithm was established in the first 928 patients and validated in the following 872 patients.

Results: ROC analyses for the diagnosis of NSTEMI revealed high discriminatory ability of the Siemens hs-cTnI assay with an area under the curve of 0.88 (95% confidence interval (CI): 0.86–0.90) at 0h, 0.93 (CI: 0.91–0.94) after 1h and 0.95 (CI: 0.93–0.96) after 3h (Figure 1).

The derived algorithm consisted of a baseline rule-out of non-ST elevation MI using a cutoff <3 ng/L in patients with a symptom onset ≥3h or an admission troponin I <6 ng/L with a delta change from 0h to 1h <3 ng/L. For rule-in, an admission troponin I ≥120 ng/L or an increase within the first hour ≥12 ng/L was required. Application of the algorithm to the validation cohort showed a negative predictive value of 99.8% (CI 98.7%-100.0%), a sensitivity of 99.1% (CI 95.1%–100.0%) and 48.3% of patients ruled out, whereas 15.1% were ruled in with a positive predictive value of 68.0% (CI 59.1%-75.9%) and a specificity of 94.4% (92.5%–96.0%). The diagnostic performance was comparable to guideline-recommended application of an established hs-cTnI assay in a rapid 0/1h strategy (1).

Conclusion: The Siemens hs-cTnI assay is well-suited for application in rapid diagnostic stratification of patients with suspected MI and showed similar performance when compared with an established hs-cTnI assay using an algorithm recommended by recent ESC guidelines.

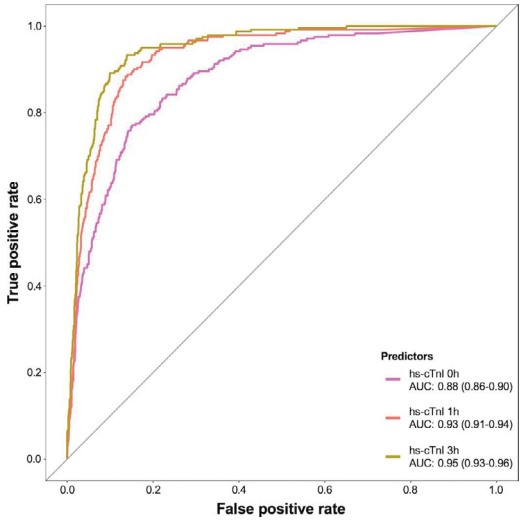

Figure 1