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PATHFAST cTnI Meets the Criteria for High-Sensitivity Troponin Assays and is Comparable to High-Sensitivity Troponin T (hs cTnT) for Detection of Myocardial Infarction

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Background

The measurement of troponin for the early diagnosis of acute myocardial infarction using point-of-care assays in patients presenting with chest pain at the emergency department is limited because commercially available point-of-care assays cannot provide the analytical imprecision and the diagnostic accuracy required by international guidelines.

Aim of the study

To evaluate the diagnostic performance of the quantitative point - of - care (POC) assay PATHFAST® cTnI (Mitsubishi, Japan) for early detection of non-ST segement myocardial infarction (NSTEMI) in patients presenting with acute chest pain at the emergency room.

Methods

193 emergency patients with chest pain admitted to an emergency room (ER) were consecutively enrolled. We analysed samples collected at admission (baseline, 0 hours), 3 and 6 hours. cTnI concentrations were determined in lithium heparin plasma aliquots which were stored at -80°C until measurement using the PATHFAST cTnI assay (99th percentile cutoff = 0.020 ng/ml). High sensitivity cTnT (Elecsys hs cTnT, Roche Diagnostics) was determined routinely in a central laboratory.

Results

The results of the troponin measurements were interpreted with respect to the final diagnoses which were independently established during the clinical course of the patients. Patients with non-ST-elevation myocardial Infarction (NSTEMI, N = 72), unstable angina pectoris (uAP, N = 80), ST-elevation myocardial infarction (STEMI, N = 7), non cardiac chest pain (NCCP) (N = 29), and others (N = 5) were included. Detection of NSTEMI was analyzed by ROC curves using the manufactorer recommended 99th percentile cutoffs. The corresponding sensitivities and specificities are displayed in Tab. 1.

Tab. 1: Sensitivity and specificity data for detection of NSTEMI from ROC analysis

	hs cTnT Cutoff ≥ 14 pg/ml		PATHFAST cTnI Cutoff ≥ 0.02 ng/ml		hs cTnT Cutoff ≥ 30 pg/ml***)**	
	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Admission	85.5	83.8	82.4	92.7	72.7	95.2
3 hours	94.3	75.5	91.9	96.3	90.5	96.9
6 hours	95.7	72.4	90.3	93.6	92.5	96.5

***)** 99th percentile cutoff of the 4th generation Elecsys TnT

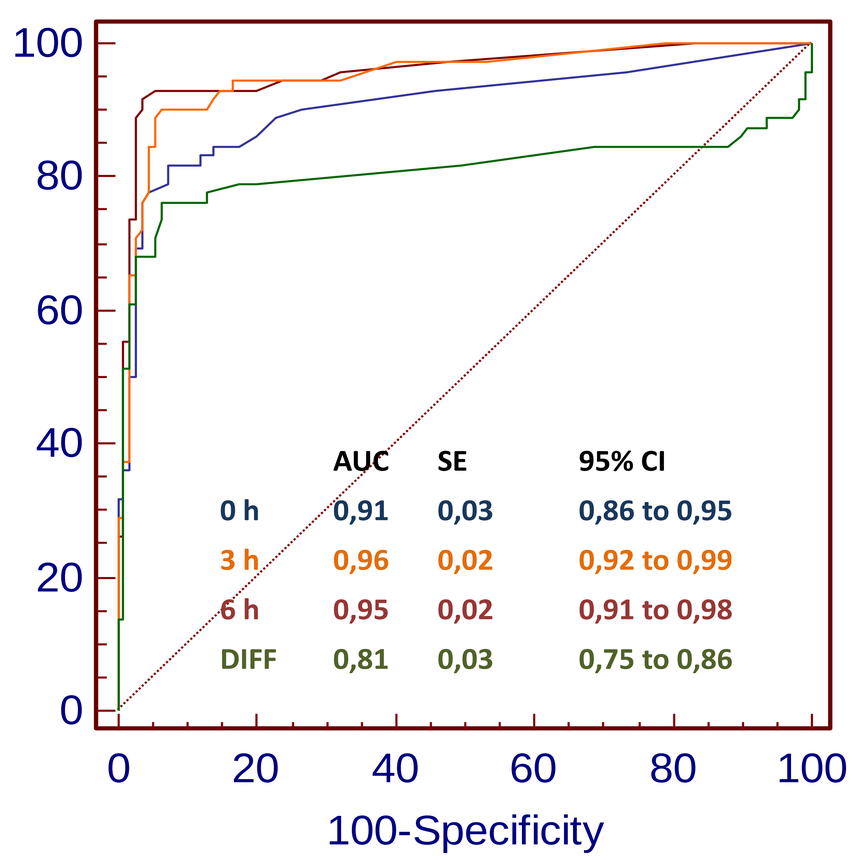
Tab. 2: Comparison of predictive values from ROC analysis

	hs cTnT Cutoff ≥ 14 pg/ml		PATHFAST cTnI Cutoff ≥ 0.02 ng/ml	
	NPV (%)	PPV (%)	NPV (%)	PPV (%)
Admission	91.6	**72.3**	86.1	**93.4**
3 hours	96.0	**73.0**	94.6	**94.4**
6 hours	97.0	**71.4**	93.6	**90.3**

PATHFAST cTnI revealed negative predictive values (NPV) for the detection of NSTEMI at different time points which were slightly but not significantly lower than the corresponding values for hs cTnT. In comparison, hsTnT revealed markedly lower positive predictive values (PPV).

Note: *predictive values are only shown for the purpose of comparing two assays. However, they should not be further interpreted because this study cohort is not necessarily a representative sample.*

Fig. 1: Comparison of ROC curves for PATHFAST cTnI (at admission (blue line), 3 hours after admission (brown line), 6 hours after admission (orange line), difference between troponin I concentration at admission and 3 hours after admission (green line))



Tab. 3: Comparison of AUC values from ROC analysis for PATHFAST cTnI, hs cTnT and TnI Ultra

	PATHFAST cTnI	**Hs cTnT**	TnI Ultra***)**
Admision	**0.91**	**0.92**	0.96
3 hours	**0.97**	**0.96**	0.96
6 hours	**0.96**	**0.97**	0.99
Difference 0 – 3 hours	**0.82**	**0.83**	0.85

***)** adapted from Keller et al. Sensitive troponin I assay in early diagnosis of acute myocardial infarction. N Engl J Med 2009;361:868-77

The ROC anaylsis revealed comparable AUC values 3 hours and 6 hours after admission and for the difference (rise or fall) between admission and 3 hours (Fig. 1 and Tab. 3) suggesting that the dianostic accuracy of the examined cTn assays allows the **diagnosis of NSTEMI already at 3 hours with similar reliability as after 6 hours**.

The size of the rise or fall in cTn concentration between admission and 3 hours was specified by ROC analysis with comparable results for PATHFAST cTnI, hs cTnT and TnI Ultra (Tab. 3) .

Conclusion

The findings suggested that the POC assay PATHFAST cTnI which can provide the test results within 17 min from whole blood samples in the ER may be able to improve the early diagnosis of acute myocardial infarction and save precious time until a definite diagnosis is established in emergency patients with acute chest pain.