

Comparison between the Analytical Performance of Fully Automated Systems for Plasma cTnI Measurement

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Background

Cardiac Troponin I (cTnI) represents the reference method for assessment of myocardial damage. cTnI assay is routinely used for rule in/out, risk stratification and follow-up of patients with acute coronary artery syndrome.

Objective

To evaluate analytical and clinical performance of an advanced immunoassay for cTnI (ADV TnI) carried out on AxSYM (Abbott Diagnostic Division) and compared these characteristics to those of the previous version of the assay (OLD TnI) and to cTnI on ACCESS 2 Immunoassay System (Beckman Coulter, Inc).

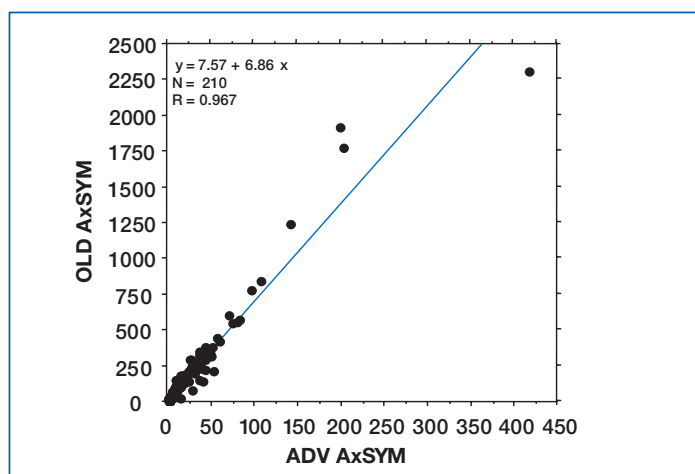
Analyzed samples. 214 sequential blood samples were collected in polypropylene tubes with lithium heparin from 131 patients with Acute Myocardial Infarction (AMI) or after surgery for other cardiac pathologies and from 66

normal subjects. Samples were rapidly centrifugated and immediately analyzed with AxSYM system. An aliquot from each samples has been frozen at -20°C for the analysis on ACCESS. The analysis was carried out within one month.

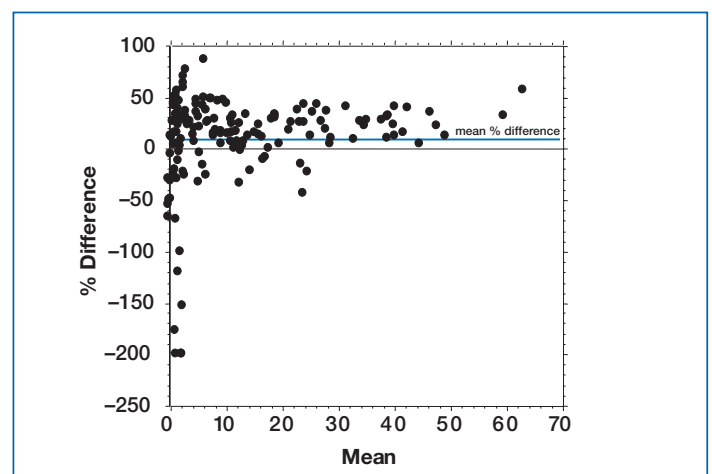
	n	M/F	Mean age (years \pm SD)
AMI patients	24	18/6	63.3 \pm 11.1
Non-AMI patients	107	74/33	65.2 \pm 11.0
Normal subjects	66	32/34	48.1 \pm 17.6

Evaluation of analytical performance. Imprecision of ADV AxSYM method according to NCCLS protocol.

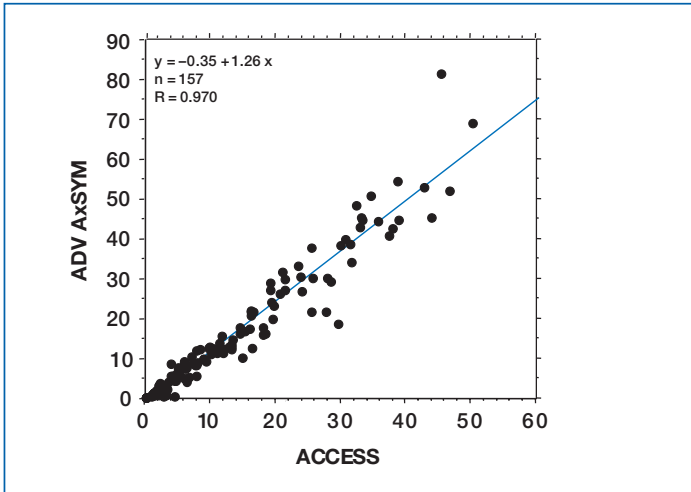
Method	LOW	MEDIUM	HIGH
OLD TnI (CV%)	9.9	6.5	8.6
OLD TnI (ng/mL)	1.9	38.1	168.4
ADV TnI (CV%)	11.2	8.3	10.1
ADV TnI (ng/mL)	0.4	7.3	22.5



Linear regression between the TnI values measured by OLD and ADV AxSYM. As expected, the OLD method overestimated the cTnI measurement about seven times the ADV method.

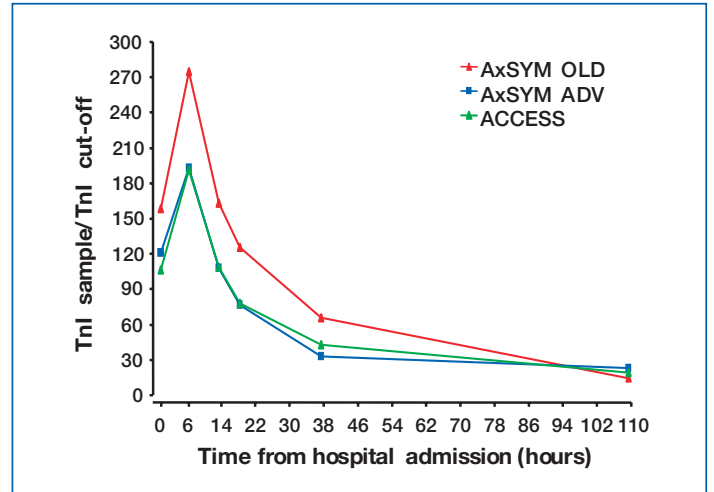


Bland-Altman plot. A slight, but significant, difference was found between the values found by the two methods (ADV vs ACCESS) (mean % difference = 2.63 ng/mL; $p < 0.0001$).



Linear regression found between the TnI values measured by ACCESS and ADV AxSYM.

Detection limits of the ADV and OLD methods were tested by repeatedly measures ($n = 20$) of the calibrators (TnI = 0 ng/mL). A mean value of 0.014 ng/mL was found for ADV, while the OLD AxSYM showed a value of 0.313 ng/mL. The TnI concentration measured in 66 normal subjects was always ≤ 0.01 ng/mL.



Typical time-course of TnI values measured by AxSYM OLD, AxSYM ADV and ACCESS in a patient with AMI. Similar trends were usually observed with all 3 methods in all 24 time-courses of AMI patients.

Conclusion

The advanced method carried out on AxSYM system shows a significantly improved analytical performance compared to the previous one. However, a significant bias always exists between advanced AxSYM and ACCESS method.