CLINICAL PERFORMANCE OF TOSOH AIA-PACK TROPONIN I IN A MULTICENTER TRIAL

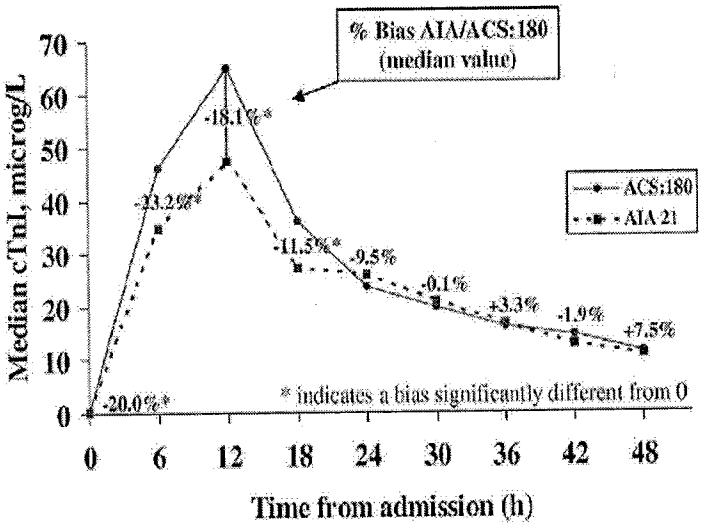
Topic: Cardiac Markers

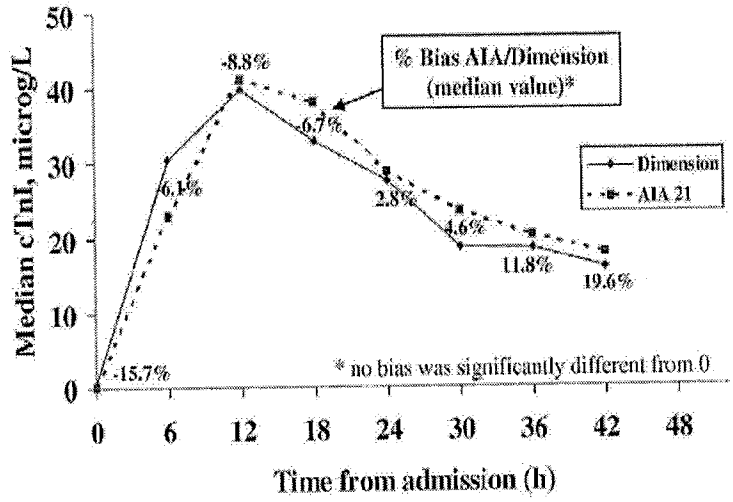
F. Pagani[1], G. Micca[2], F. Stefini[1], F. Manoni[3], L. Romano[4], S. Zofra[4], A. Iervasi[5], M. Caputo[6], R. Dorizzi[6], G. Zucchelli[5], M. Panteghini[1];
[1]Azienda Ospedaliera 'Spedali Civili', Brescia, ITALY, [2]Ospedale Civile, Alba CN, ITALY, [3]Ospedale Civile, Chioggia VE, ITALY, [4]Ospedale 'Vincenzo Monaldi', Napoli, ITALY, [5]Istituto di Fisiologia Clinica CNR, Pisa, ITALY, [6]Ospedale Civile 'Borgo Trento', Verona, ITALY.

Presentation Number: B-18

Keyword: Troponin I, Myocardial infarction, Diagnosis, Laboratory

A study, performed at 6 centers, was carried out to evaluate the clinical performance of the new generation AIA-PACK cardiac troponin I (cTnI) assay (Tosoh Bioscience) as determined on the AIA 21 immunoassay system. The protocol consisted of three sections: 1. Definition of the upper reference limit (URL), 2. Definition of the cut-off value for detecting myocardial necrosis, 3. Evaluation of AIA cTnI release kinetics after myocardial infarction (MI). To establish reference values, serum samples from 192 apparently healthy blood donors (age >40 years, 57% males) were obtained. 78% of cTnI values were ≤0.02 µg/L, i.e. the detection limit of the assay, whereas 43 subjects showed a measurable cTnI concentration. The URL, corresponding to the 99th percentile of the cTnI value distribution, was 0.051 µg/L. Since a total CV ≤10% at the MI decision limit is recommended, we calculated the cTnI concentration corresponding to this analytical imprecision by interpolating the imprecision profile obtained from data produced during the analytical evaluation of the assay (period January to May 2002). The 10% CV corresponded to a cTnI concentration of 0.19 µg/L, i.e. 3.7 x URL. This value was recommended as a defacto cut-off for detection of myocardial necrosis. Two centers studied the cTnI release kinetics after MI. 67 patients (MI onset <6 h) were enrolled. Serial serum samples were obtained every 6 h throughout the first 48 h after hospital admission. On each sample, cTnI was measured using AIA and the routinely used cTnI assay for comparison (Bayer ACS:180 at center BS and Dade Dimension at center VR). The figure displays the results showing a significant bias in the first 18 h after admission between AIA and ACS but not between AIA and Dimension. Reactivities of different assays to various cTnI forms present in the blood could explain these discrepancies.


% Bias AIA/ACS:180
(median value)
ACS:180
AIA 21
-18.1%*
-23.2%*
-11.5%*
-9.5%
-0.1%
+3.3%
-1.9%
+7.5%
-20.0%*
* indicates a bias significantly different from 0
Median cTnI, microg/L
Time from admission (h)


% Bias AIA/Dimension
(median value)*
Dimension
AIA 21
-8.8%
-6.7%
-6.1%
-2.8%
-4.6%
-11.8%
-19.6%
-15.7%
* no bias was significantly different from 0
Median cTnI, microg/L
Time from admission (h)