The Medcaptain: A Point-of-Care Device for Major Cardiac Biomarker Determination

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Objectives:

Concerns exist regarding the accuracy of point-of-care (POC) tests in emergency department (ED) settings compared to laboratory testing. This study aims to validate the Medcaptain Troponin I (hs-TnI), Heart Fatty Acid Binding Protein (HFABP), Suppression of Tumorigenicity 2 (ST2), and N-terminal Prohormone of Brain Natriuretic Peptide (NT-proBNP) assays, and to compare these results with routine laboratory methods.

Figure 1: MedCaptain device (Analis)

Methods:

We evaluated a new chemiluminescent immunoassay analyzer, the Medcaptain (Analis), for quantifying HFABP, hs-TnI, ST2, and NT-proBNP in human whole blood/serum/plasma. An analytical evaluation at three concentration levels was conducted to validate intra- and inter-assay variation, trueness, and measurement uncertainty. A comparison was performed using 23 residual samples for hs-TnI and NT-proBNP. The laboratory methods for NT-proBNP and hs-TnI were microparticle chemiluminescence immunoassays (CMIA) on the Alinity i analyzer. Passing-Bablok regression and Bland-Altman tests were used for comparisons (Medcalc), and analytical validation was performed with Enoval (Arlenda).

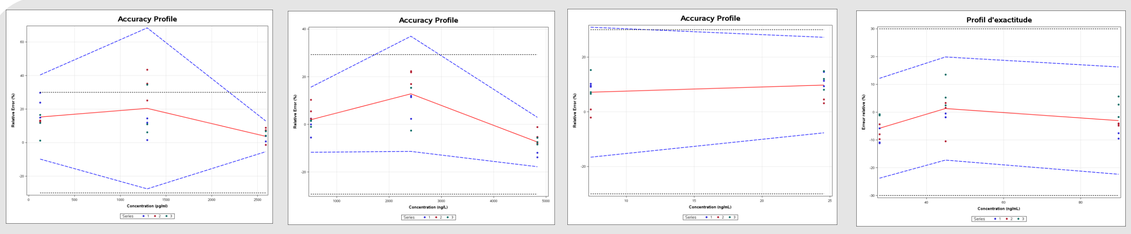

Figure 2: Comparison between routine lab method and POC method-Bland-Altman plot

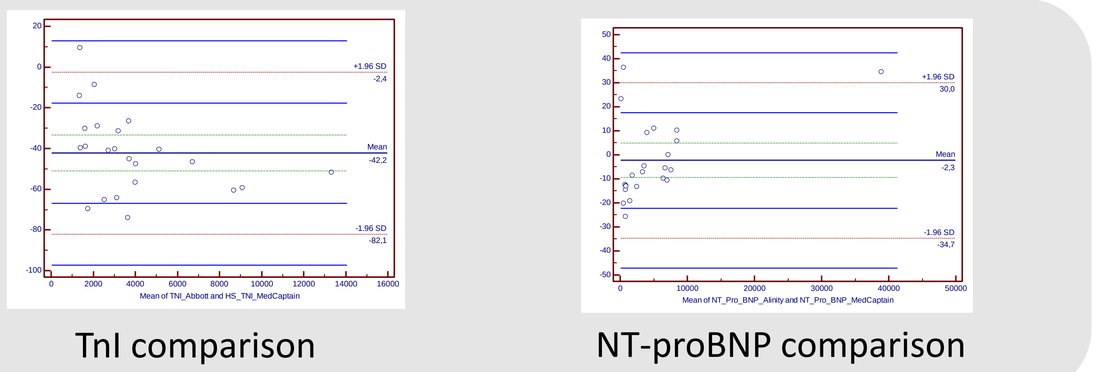

Figure 3: Comparison between routine lab method and POC method-Bland-Altman plot

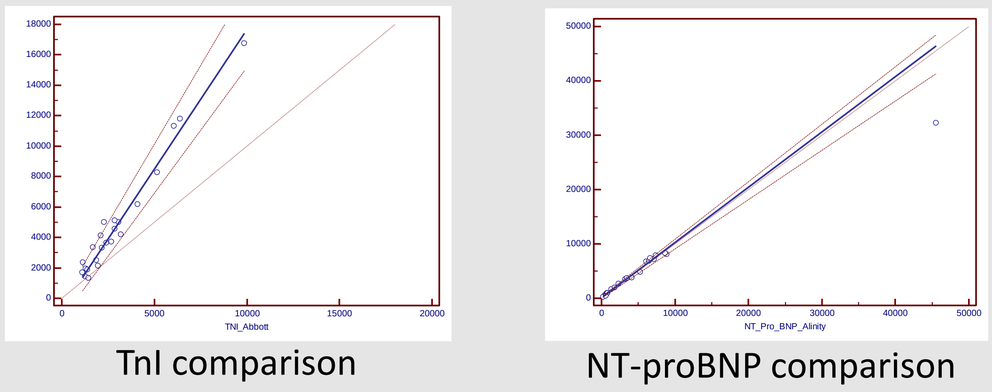

Figure 4: Comparison between routine lab method and POC method Passing-Bablok

Results :

On the Medcaptain device, the maximum intra- and inter-assay CVs were 7% and 8.7% for hs-TnI, 11% and 15.74% for NT-proBNP, 5.5% and 6.7% for ST2, and 3.2% and 6.4% for HFABP (Table 1). The maximum relative bias was 12.8%, 20.4%, 5.8%, and 9.8%, and the maximum relative expanded uncertainty was 18.9%, 34.8%, 14.7%, and 14.3% for hs-TnI, NT-proBNP, ST2, and HFABP, respectively (Figure 2). The regression equation for NT-proBNP was: NT-proBNP Medcaptain = 104.02 + 1.01NT-proBNP Alinity (95% CI intercept: 50.27-280.90; 95% CI slope: 0.90-1.06). A small systematic difference of 2.3% on average was observed between the two methods. For hs-TnI, the regression equation was: hs-TnI Medcaptain = -685.257123 + 1.833114 hs-TnI Alinity (95% CI intercept: -1363.78-215.96; 95% CI slope: 1.66-2.07). A proportional difference of 42.2% was found between the two methods, likely due to different antibodies used in the kits (Figure 3 and 4).

Concentration level (ng/L)	Mean introduced concentration (ng/L)	Repeatability (RSD%) [1]	Intermediate precision (RSD%) [1]
1.0	502.8	3.403	4.632
2.0	2416	6.963	8.693
3.0	4832	3.333	3.895

hsTnI

Concentration level (pg/ml)	Mean introduced concentration (pg/ml)	Repeatability (RSD%) [1]	Intermediate precision (RSD%) [1]
1.0	123.8	6.280	8.527
2.0	1294	11.00	15.74
3.0	2589	3.625	3.711

NT-proBNP

Concentration level (ng/mL)	Mean introduced concentration (ng/mL)	Repeatability (RSD%) [1]	Intermediate precision (RSD%) [1]
1.0	7.370	3.248	6.355
2.0	24.55	2.785	4.921

HFABP

Concentration level (ng/mL)	Mean introduced concentration (ng/mL)	Repeatability (RSD%) [1]	Intermediate precision (RSD%) [1]
1.0	27.80	2.359	4.801
2.0	44.90	5.489	6.747
3.0	89.80	2.680	5.254

ST2

Table 1:Intra-and inter-assay CVs

Conclusions:

POC testing using the Medcaptain device is accurate and correlates well with laboratory testing methods. However, troponin results exhibit significant variation due to a lack of standardization. Importantly, the diagnostic outcome remains consistent. This device can assist emergency physicians in quickly identifying cardiac injury with confidence in the accuracy of the results.