Clinical Concordance for Exclusion of Acute Heart Failure Using the RAMP and Dade Dimension RxL NT-proBNP Assays

M Offner[1], E Winckel[1], A Jung[1], T Lamy[2], G Arthur[3], ML Zucker[3]

[1]Laboratoire de Biochimie Générale et Spécialisée, Hôpital Civil, Strasbourg, France, [2]All.DIAG.SA, Strasbourg, France, [3]Response Biomedical Corporation, Burnaby, BC, Canada

Introduction

- Accurate evaluation and management of acute dyspnea remains a significant clinical challenge[1,2].
- Blood levels of NT-proBNP:
  - are indicative of the degree of heart failure (HF).
  - augment diagnosis and clinical judgment[3,4].
  - have been used for risk stratification of patients with acute coronary syndrome and congestive HF[5,6].

NT-proBNP (pg/mL) Clinical Cut-offs ([3,4])			
Age Dependent	<50	50-75	>75
Limit for Probable Acute Heart Failure	>450	>900	>1800
Age Independent Rule Out	<300		

- Compared with central lab testing, point of care testing (POC) allows rapid clinical decision making by reducing the time taken to receive test results.

Aims

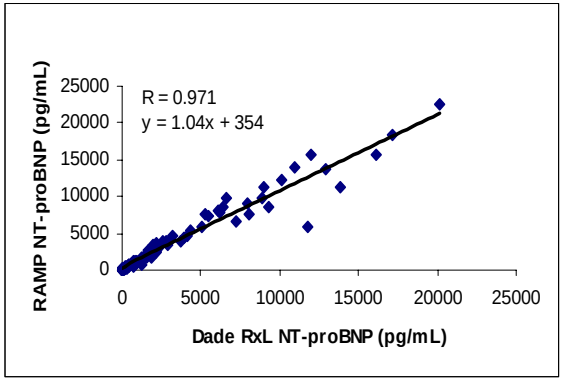
- To evaluate clinical concordance of a point of care NT-proBNP assay* (RAMP) with a laboratory assay for NT-proBNP (Dade Dimension RxL).

Methods and Procedures

- Patients (n=91) suspected of HF were enrolled (no age data available).
- EDTA and heparin anticoagulated blood samples were obtained.
- NT-proBNP determined on:
  - Dade Dimension RxL analyzer
    - Heparinized plasma in laboratory
  - RAMP Reader
    - EDTA whole blood (POC)

Results: Method Comparison

- 86 of 91 samples had NT-proBNP levels within the reportable ranges of both test systems (5 - 35,000 pg/mL).



- Linear regression analysis showed excellent correlation (R=0.971) between the two systems with a slope of 1.04.

Results: Clinical Concordance

Clinical concordance analysis of the RAMP NT-proBNP and Dade Dimension RxL results using an age independent rule out value of 300 pg/mL[3].

Table 1		Dade Dimension RxL	
		>300 pg/mL	<300 pg/mL
RAMP	>300 pg/mL	70	5
	<300 pg/mL	0	16
		Sensitivity	100.%
		Specificity	76.2%
		PPV	93.3%
		NPV	100%
		Concordance	94.5%

Clinical concordance analysis showed excellent clinical agreement between the RAMP and the Dimension.

Conclusions

- The results obtained on the RAMP POC system were comparable to those obtained on the Dade Dimension RxL laboratory analyzer.
- The RAMP NT-proBNP whole blood assay is an accurate clinical indicator that can be used to rule-out acute HF in this population.
- With results available in 15 minutes, RAMP NT-proBNP allows for rapid initiation of appropriate patient treatment.

Bibliography

1 Mueller C, Scholer A, Laule-Kilian K, et al. Use of B-Type natriuretic peptide in the evaluation and management of acute dyspnea. N Eng J Med. 2004;350:647-654.
2 Zaphirou A, Robb S, Murray T, et al. The diagnostic accuracy of plasma BNP and NTproBNP in patients referred from primary care with suspected heart failure: Results of the UK natriuretic peptide study. Eur J Heart Failure. 2005;7:537-541.
3 Januzzi JL, Camargo CA, Anwaruddin S, et al. The N-terminal Pro-BNP investigation of dyspnea in the emergency department (PRIDE) study. Am J Cardiol. 2005;95:948-954.
4 Baggish AL, Cameron R, Anwaruddin S, et al. A clinical and biochemical critical pathway for the evaluation of patients with suspected acute congestive heart failure. The proBNP investigation of dyspnea in the emergency department (PRIDE) algorithm. Crit Path Cardiol. 2004;3:171-176.
5 Jernberg T, Stridsberg M, Venge P, et al. N-terminal pro brain natriuretic peptide on admission for early risk stratification of patients with chest pain and no ST-segment elevation. J Am Coll Cardiol. 2002;40:437-45.
6 Fisher C, Berry C, Blue L, et al. N-terminal pro B type natriuretic peptide, but not the new putative cardiac hormone relaxin, predicts prognosis in patients with chronic heart failure. Heart. 2003;89:879-81.

*RAMP NT-proBNP Assay: CE self-certified. Licensed by Health Canada (country of origin approval). Test not yet cleared for sales in the US (FDA)