EVALUATION OF A NOVEL N-TERMINAL PRO B TYPE NATRIURETIC PEPTIDE ASSAY AS AN AID IN THE DIAGNOSIS OF ACUTE HEART FAILURE IN THE EMERGENCY DEPARTMENT

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A-021

BACKGROUND

The signs and symptoms of acute heart failure (AHF) may overlap with other conditions and lead to diagnostic difficulty in the undifferentiated patient with dyspnea. The particularly high negative predictive value (NPV) of natriuretic peptides (NPs) in excluding AHF have rendered these assays especially useful in evaluating dyspnea in acute care setting.

This study was conducted to assess the diagnostic performance of a novel N-terminal pro-B type natriuretic peptide (NT-proBNP) assay in the intended use patient population in the emergency department (ED).

METHODS

- A multicenter study was conducted in the U.S. on individuals presenting to the ED with dyspnea and a suspicion of AHF.
- Blood specimens were collected and tested using the Beckman Coulter Access NT-proBNP assay on the DxI 9000 Immunoassay Analyzer*.
- Performance included NPV and sensitivity of an age-independent cut point of <300 ng/L to exclude AHF, and the positive predictive value (PPV) of the age-dependent cut points of >450, >900, and >1800 ng/L, for the diagnosis of AHF.

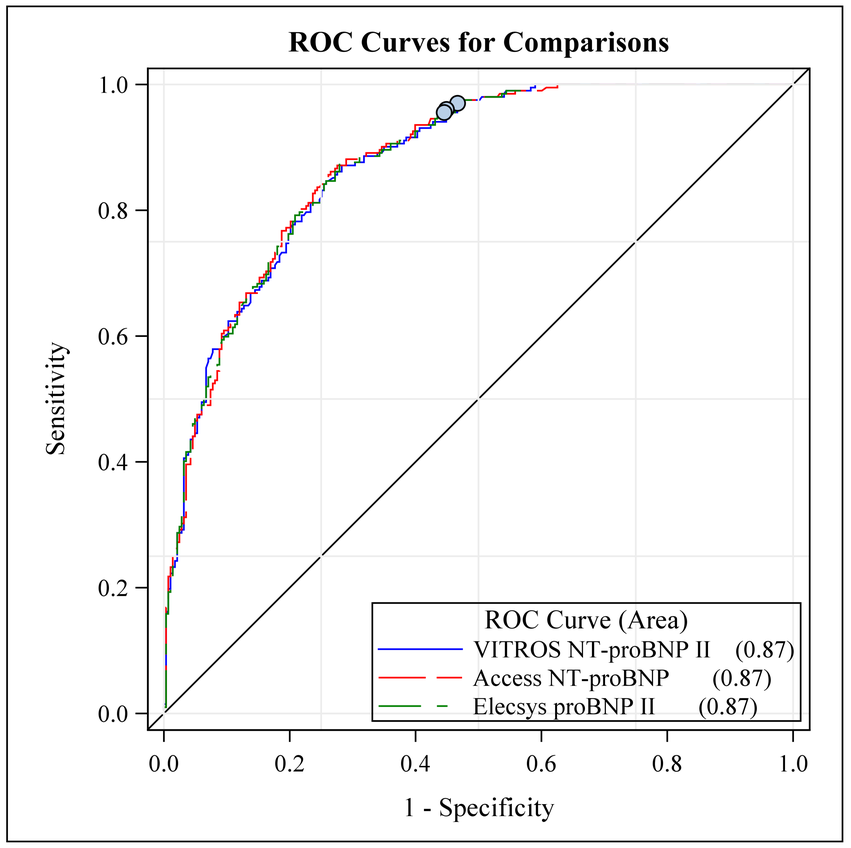
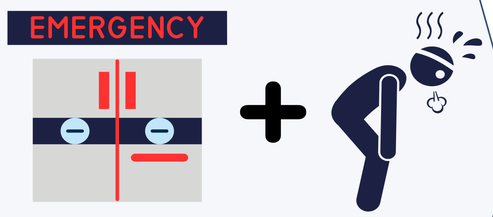


Figure 1 ROC Curve Comparison of NT-proBNP Assays for AHF Diagnosis.

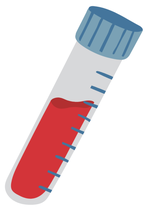
Assessing the diagnostic performance of a novel NT-proBNP assay in the undifferentiated dyspneic patient

Multi-Center Heart Failure Study



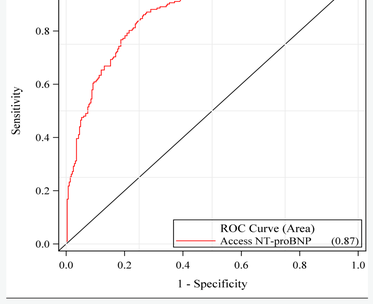
490 ED subjects enrolled with 41% adjudicated with acute heart failure.

Rule-out Cut Point Analysis



A rule-out cut point of <300 ng/L had a 96% sensitivity and NPV of 95.2%.

HF Diagnosis ROC Curve



AUC for the diagnosis of acute heart failure was 0.87.

The investigational NT-proBNP assay demonstrated high clinical performance in the diagnosis and exclusion of acute HF in the undifferentiated dyspneic patient, and performed similarly well to validated assays used in clinical practice.

Peacock, et al

RESULTS

- Of 490 enrolled patients, 41% were adjudicated with AHF with a median (Q1, Q3) age of 60 (47-76) years, and distributions of 46.1% female, 60.8% White and 38.2% Black.
- The assay had an AUROC for AHF of 0.87 (P<0.001), comparable to other commercially available NT-proBNP assays.
- The rule-out cut point of <300 ng/L had 96% sensitivity and NPV of 95%. Age-dependent cut points had sensitivity of 84%, 90%, and 87%, specificity of 81%, 70% and 61%, and PPV of 72%, 62%, and 74%, respectively.

CONCLUSION

The Access NT-proBNP assay demonstrated high clinical performance in the diagnosis and exclusion of acute HF in the undifferentiated dyspneic patient population and performed similarly well to validated assays used in current clinical practice.

Given the continued increase in importance and reach of natriuretic peptide testing, these results are useful to extend availability of this assay to a larger audience.

Table1 . Age-Dependent Diagnostic Performance

Age	N	Cut point: ng/L (pg/mL)	Sensitivity	Specificity	NPV	PPV
All Patients						
< 50 years	167	450	84%	81%	90%	72%
50-75 years	196	900	90%	70%	93%	62%
>75 years	127	1800	87%	61%	79%	74%
All Patients	490	-	87%	72%	89%	69%
Females						
< 50 years	74	450	75%	85%	90%	65%
50-75 years	89	900	84%	75%	92%	57%
>75 years	63	1800	77%	57%	67%	69%
All Females	226	-	79%	75%	87%	64%
Males						
< 50 years	93	450	88%	77%	89%	76%
50-75 years	107	900	93%	65%	93%	65%
>75 years	64	1800	97%	64%	95%	78%
All Males	264	-	93%	69%	92%	72%

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*Full name: DxI 9000 Access Immunoassay Analyzer