B-Type Natriuretic Peptide Testing and the Accuracy of Heart Failure Diagnosis in the Emergency Department

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Background—It is often difficult to diagnose heart failure (HF) accurately in patients presenting with dyspnea to the emergency department (ED). This study assessed whether B-type natriuretic peptide (BNP) testing in these patients improved the accuracy of HF diagnosis.

Methods and Results—Patients presenting to the Alfred and the Northern Hospital EDs with a chief complaint of dyspnea were enrolled prospectively from August 2005 to April 2007. Patients were randomly allocated to have BNP levels tested or not. The diagnostic gold standard for HF was determined by 1 cardiologist and 1 emergency or respiratory physician who, blinded to the BNP result, independently reviewed all available information. The ED diagnosis of HF in the non-BNP group showed a sensitivity, specificity, and accuracy of 65%, 92%, and 81%, respectively. The BNP group had a similar sensitivity, specificity, and accuracy of 66%, 90%, and 78%, respectively, for the diagnosis of HF in the ED. There was no significant difference between the BNP and non-BNP groups in any of the measures of diagnostic accuracy for HF.

Conclusion—In the clinical setting of EDs, availability of BNP levels did not significantly improve the accuracy of a diagnosis of HF.

Clinical Trial Registration—clinicaltrials.gov. Identifier: NCT00163709.

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Key Words: heart failure ■ BNP ■ natriuretic peptides ■ dyspnea ■ emergency ■ diagnosis

The incidence of heart failure (HF) is reaching epidemic proportions in the Western world.1 With an aging population and greater survival from disease processes leading to HF, the burden of this disease on the healthcare system will only increase in the future.2

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Most patients with acute HF syndromes present to hospital through the emergency department (ED).3 Their most common presenting complaint is dyspnea.4 However, the differential diagnosis of dyspnea is myriad and includes pulmonary diseases, which often coexist in patients with HF.5 Studies examining the accuracy of ED diagnosis of HF using traditional means such as history, examination, ECG, and chest x-ray have found varying levels of accuracy resulting in misdiagnosis, delays to treatment, and increased morbidity and mortality.6–9

B-type natriuretic peptide (BNP) is a cardiac neurohormone primarily secreted from cardiac ventricles.10 BNP levels increase in patients with HF.11–13 Since the development of rapid bedside investigations to test BNP levels, BNP has been studied widely as a potential tool to enhance the accuracy of HF diagnosis.14–16 These studies show that BNP levels are significantly higher in patients with dyspnea because of HF than from another cause.17–19 Consequently, several of these studies have extrapolated through statistical analysis that, theoretically, adding a BNP test to other clinical measures could improve the accuracy of HF diagnosis.17–20 However, as yet no study has assessed the effect of real-time BNP measurement on the accuracy of HF diagnosis in the ED in a randomized clinical trial.

The European Society of Cardiology guidelines for heart failure recommends the use of the BNP test to rule out HF.21

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Drs Lokuge and Lam contributed equally to this work.

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and the American College of Cardiology suggests the use of the BNP test in the urgent care setting where the diagnosis of HF is uncertain. Recently, BNP testing for HF diagnosis in the emergency setting received government funding in Australia. Most available literature suggests a cutoff point of 100 pg/mL for the BNP test. Therefore, at a value ≤100 pg/mL HF is unlikely. Mueller et al showed that in Switzerland, patients who had BNP testing in the ED had earlier initiation of appropriate treatment, decreased hospital and intensive care unit admission rates, earlier discharge, and decreased cost of treatment. In contrast, the randomized controlled trial BNP in Shortness of Breath (SOB) study conducted in Australia by Schneider et al showed that BNP testing in dyspneic patients presenting to the ED did not improve hospital admission rates, length of hospital stay, or management in the ED.

This study analyzes data from the BNP in SOB multicenter study. With several studies demonstrating a theoretical improvement to the accuracy of HF diagnosis in the ED with BNP testing, we hypothesized that real-time BNP testing in the ED would improve the accuracy of the clinical diagnosis of HF.

Methods

Study Setting
A prospective, randomized, controlled, single-blind study “The BNP in SOB Study” conducted in the EDs of the Alfred Hospital (tertiary referral center, 45 000 patient attendances per year) and the Northern Hospital (metropolitan hospital, 70 000 patient attendances per year) Victoria, Australia, was undertaken between August 2005 and April 2007. Data from this study were retrospectively reviewed for this article.

Study Design and Consent
Eligible patients were enrolled in the study by the ED staff at presentation. They were randomized to either the BNP group (BNP levels were tested) or the non-BNP group (BNP levels not tested—control group) before consent. Randomization was by random numbers (from computer-generated random number tables) concealed in an envelope. The randomization was stratified by site. A trained research assistant gained from the patient or their next-of-kin within 24 hours of admission.

Entry criteria included an Australian Triage Scale of 1 to 3 (illness acuity requiring assessment by a doctor immediately to within 30 minutes of arrival) in patients with a primary presenting complaint of dyspnea. Exclusion criteria were ≤40 years of age, a traumatic cause of dyspnea, cardiogenic shock, a serum creatinine ≥250 μmol/L, and patients who were transferred to another hospital within 24 hours of presentation.

All patients underwent routine clinical examination by a doctor (ED registrar or consultant, or ED resident supervised by a registrar or consultant) and routine investigations, including blood tests, chest x-ray, and ECG. When possible, a transthoracic echo (TTE) and a pulmonary function test were performed within 30 days of presentation.

Doctors and nurses involved in patient care in the ED were given 4 education sessions during the study period by emergency doctors involved in the study. These education sessions familiarized staff with BNP, its role in the diagnosis of HF, and the current literature in the field. Furthermore, each treating doctor of an enrolled patient received a written guideline on the treatment of acute HF and chronic obstructive pulmonary disease and the BNP nomogram (developed by McCullogh et al) with an explanation on how to use it. Doctors were educated that dyspneic patients with a BNP value <100 pg/mL were unlikely to have HF as the primary diagnosis and that dyspneic patients with a BNP value >500 pg/mL were likely to have HF as the primary diagnosis.

Probability of HF
The treating emergency doctor for each patient was asked to assign a probability of HF as the cause of dyspnea after an initial assessment of the patient and preliminary investigations but without the BNP test. The probabilities were divided into 5 categories: 0%, 1% to 25%, 26% to 50%, 51% to 75%, and 76% to 100%.

Disposition Diagnosis
The disposition diagnosis (the diagnosis at the time of discharge from the ED; after all investigations, including the BNP test, and treatment in the ED) was recorded for the BNP and non-BNP groups. Where the patient was admitted, the disposition diagnosis was that recorded by the admitting unit registrar or resident derived from the emergency doctor’s diagnosis. Where the patient was discharged from the ED, the disposition diagnosis was the emergency doctor’s final diagnosis.

Baseline demographics, clinical information from the current and relevant previous presentations, and follow-up investigations (TTE and pulmonary function test) were gathered by trained research assistants.

BNP Testing
All patients had a 10-mL sample of blood collected in an EDTA tube on presentation to the ED. Only patients who were randomized to the BNP group had a BNP level tested and the result available on the computer. The BNP level was measured in plasma using the Abbott AxSYM MEIA Automated immunoassay (Abbott, Abbott Park, Ill). The measurable range of the BNP assay is 15 to 4000 pg/mL with an on-board 1 in 5 dilution to take the upper limit to 20 000 pg/mL. The BNP levels were available to medical staff within 1 hour of collection. This test is calibrated against the Triage B-type natriuretic peptide test (Biosite Inc, San Diego, Calif). It performs well in the clinical setting with an area under the curve (AUC) comparable to published data.

Reviewer Adjudicated Diagnosis (Final Diagnosis)
The final diagnosis of HF was made by 1 emergency physician and 1 cardiologist who independently reviewed all available information, including case notes, blood tests, ECG and chest x-ray reports, response to treatment, TTE, and pulmonary function test results. The reviewing physician was blinded to the BNP result. The reviewers received a definition of HF based on the European Society of Cardiology Working Group on HF diagnostic criteria and an algorithm for the diagnosis of HF. Patients were classified into 3 categories for the main cause of dyspnea: (1) HF in isolation; (2) HF in conjunction with another diagnosis; and (3) no HF. For this analysis, patients in categories 1 and 2 were grouped together so that the 2 categories for the final diagnosis were HF and no HF. Where the 2 reviewers agreed, the diagnosis was taken as the final diagnosis for the patient. Where they disagreed, a third physician (cardiology, respiratory or emergency) reviewed all available data (blinded to the BNP test) and made a diagnosis, which was then used as the final diagnosis.

Data and Statistical Analysis
Statistical analyses were performed using Stata version 9.0 (Stata Corp, College Station, Tex). A P value ≤0.05 was considered statistically significant. Baseline characteristics are reported in counts and proportions or mean±SD as appropriate. Univariate comparisons were made with χ² test, 2-sample t test, or the Wilcoxon 2-sample test as appropriate.

The disposition diagnosis and final diagnosis were divided into 2 groups: HF or no HF. Statistics were computed from 2×2 tables and reported as accuracy (true-positive and true-negative cases as a proportion of the total), sensitivity, and specificity.

Receiver-operating characteristic (ROC) curve analysis was performed for BNP levels, and the emergency doctors’ assessment of
the probability of HF with the final diagnosis as the reference standard. These ROC curves were compared using the AUC. An ROC curve was generated through logistic regression using the BNP group doctors’ assessment of the probability of HF and the BNP values as predictors of a final diagnosis of HF. This combined ROC curve was compared with the ROC curves of the probability of HF and BNP values to determine whether the BNP test would significantly improve the diagnostic quality of the doctor’s assessment of the probability of HF.

Agreement between the 2 reviewers for the final diagnosis was quantified using Cohen’s κ statistic.

Ethics
Ethics approval for this study was granted by the Alfred Ethics Committee, the Northern Hospital Ethics Committee, and the Monash University Standing Committee on Ethics in Research Involving Humans. The investigation conforms to the principles outlined in the Declaration of Helsinki.

Results

Study Cohort and Baseline Characteristics
Seven hundred ninety-nine patients were recruited. One hundred eighty-seven patients were excluded because of refusal of consent (n=135), exclusion criteria (n=20), refusal to be consented within 24 hours (n=19), or incomplete sample collection (n=13). Of the final cohort of 612 patients, 306 patients were randomized to have the BNP test (BNP group) and 306 patients not to have BNP test (non-BNP group).

Table 1. Patient Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>BNP Group (n=306)</th>
<th>Non-BNP Group (n=306)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>74±11</td>
<td>73±11</td>
</tr>
<tr>
<td>Range</td>
<td>42 to 98</td>
<td>49 to 98</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>166 (54)</td>
<td>162 (53)</td>
</tr>
<tr>
<td>Female</td>
<td>140 (46)</td>
<td>144 (47)</td>
</tr>
<tr>
<td>History, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD/asthma</td>
<td>202 (66)</td>
<td>186 (61)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>170 (56)</td>
<td>138 (45)</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>129 (42)</td>
<td>124 (41)</td>
</tr>
<tr>
<td>Disease</td>
<td>123 (40)</td>
<td>97 (32)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>93 (30)</td>
<td>79 (26)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>61 (20)</td>
<td>60 (20)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>32 (10)</td>
<td>37 (12)</td>
</tr>
<tr>
<td>Symptoms, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>153 (50)</td>
<td>152 (50)</td>
</tr>
<tr>
<td>Sputum</td>
<td>79 (26)</td>
<td>81 (26)</td>
</tr>
<tr>
<td>Orthopnea</td>
<td>76 (25)</td>
<td>48 (16)</td>
</tr>
<tr>
<td>Swelling of ankles</td>
<td>41 (13)</td>
<td>54 (18)</td>
</tr>
<tr>
<td>Fever</td>
<td>36 (12)</td>
<td>44 (14)</td>
</tr>
<tr>
<td>Signs, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crackles</td>
<td>168 (55)</td>
<td>173 (57)</td>
</tr>
<tr>
<td>Wheeze</td>
<td>84 (27)</td>
<td>86 (28)</td>
</tr>
<tr>
<td>Raised JVP</td>
<td>81 (28)</td>
<td>88 (30)</td>
</tr>
<tr>
<td>Displaced apex beat</td>
<td>54 (19)</td>
<td>39 (13)</td>
</tr>
<tr>
<td>Third heart sound</td>
<td>5 (2)</td>
<td>11 (4)</td>
</tr>
<tr>
<td>Vital signs, mean ±SD (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>143±30 (70 to 260)</td>
<td>141±28 (70 to 240)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>73±18 (30 to 155)</td>
<td>73±18 (23 to 140)</td>
</tr>
<tr>
<td>Heart rate, bpm</td>
<td>95±24 (46 to 178)</td>
<td>97±23 (50 to 175)</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>25±6 (6 to 46)</td>
<td>25±8 (12 to 62)</td>
</tr>
<tr>
<td>Investigations, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest x-ray</td>
<td>283 (92)</td>
<td>282 (92)</td>
</tr>
<tr>
<td>Electrocardiogram</td>
<td>236 (77)</td>
<td>236 (77)</td>
</tr>
<tr>
<td>Final diagnosis of HF, n (%)</td>
<td>148 (48)</td>
<td>126 (41)</td>
</tr>
<tr>
<td>No. admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admitted, n (%)</td>
<td>262 (86)</td>
<td>265 (87)</td>
</tr>
</tbody>
</table>

In the BNP group, the accuracy of the disposition diagnosis against the final diagnosis of the subgroup of patients with a BNP value <100 pg/mL (n=89) shows that a majority (n=75, 84%) received an accurate disposition diagnosis of no HF. In the subgroup with a BNP value >500 pg/mL (n=127), 74 patients had an accurate disposition diagnosis of HF and 18 had an accurate disposition diagnosis of no HF. However, 31 patients (24%) were underdiagnosed as having no HF, and only 4 patients were overdiagnosed as having HF.

Effect of the BNP Test on the Accuracy of the Disposition Diagnosis
In the BNP group, the accuracy of the disposition diagnosis of HF was 78%, with a sensitivity of 66% (95% CI, 57 to 73) and a specificity of 90% (95% CI, 84 to 94). In the non-BNP group, the accuracy of the disposition diagnosis of HF was 81%, with a sensitivity of 65% (95% CI, 56 to 73) and a specificity of 92% (95% CI, 87 to 96) (Figure 1).
The accuracy of the disposition diagnosis in patients given an intermediate probability of HF (26% to 75%) by the emergency doctor (n=131) was similar in the BNP and non-BNP groups. In the BNP group (n=69), the disposition diagnosis had an accuracy, sensitivity, and specificity of 64%, 66%, and 58%, respectively, and in the non-BNP group, (n=62), the disposition diagnosis had an accuracy, sensitivity, and specificity of 65%, 67%, and 58%, respectively.

**Accuracy of the BNP Test**

At a cutoff of 101 pg/mL, the accuracy, sensitivity, and specificity of the BNP test was 71%, 92%, and 51%, respectively. The optimum cutoff point for the BNP test in our study, derived from the ROC curve of the BNP test against the final diagnosis of HF was 265 pg/mL: accuracy, 82%; sensitivity, 83%; and specificity, 81%.

The overall diagnostic accuracy of the BNP test in the 2 groups with a BNP value <100 pg/mL (HF unlikely) and >500 pg/mL (HF likely) was 84%. These 2 groups combined encompassed 71% of the study cohort.

**Reference Range of the BNP Test and the BNP Levels of Our Participants**

In our study, the range of BNP values was 4 to 10,565 pg/mL. The cohort with a final diagnosis of HF (n=148) had a median BNP value of 830 pg/mL (interquartile range, 391 to 1425 pg/mL). Ninety-two percent (n=136) of these patients had a BNP value >100 pg/mL. Patients with a final diagnosis of HF and a BNP value <100 pg/mL (n=12) had a mean age of 66 years (range, 55 to 80 years) with an even distribution of gender. Half the patients had a history of ischemic heart disease and hypertension and more than half had a history of HF. TTE was available in 8 patients and of these 7 patients had a normal ejection fraction; however, interestingly, half of these patients (n=4) had evidence of diastolic dysfunction on TTE.

The cohort of patients with a final diagnosis of no HF (n=158) had a median BNP value of 99 pg/mL (interquartile range, 46 to 180 pg/mL). Only 49% (n=77) of these patients had a BNP value <100 pg/mL.

**The Probability of HF**

A probability of HF was recorded by the emergency doctor after initial assessment but before the BNP result for 593 patients. The ROC curves of the probability of HF for the whole group had an AUC of 0.86 (95% CI, 0.83 to 0.89). The BNP values ROC curve had an AUC of 0.87 (95% CI, 0.83 to 0.91). There was no significant difference between the BNP group probability of HF ROC curve AUC (0.88; 95% CI, 0.84 to 0.92) and the AUC of the BNP values (P=0.73).

The ROC curves of the BNP values and the BNP group probability of HF were combined statistically and had an AUC of 0.93 (95% CI, 0.90 to 0.96) significantly better than the AUCs of the BNP values or the BNP group probability of HF ROC curves individually, P<0.001 (Figure 2).
diagnosis in the clinical setting within 2 busy Australian EDs. Although our study found that BNP values were significantly higher in patients with a final diagnosis of HF and that the BNP test had a high level of accuracy for the diagnosis of HF, in the real-life setting, adding the BNP test to clinical judgment did not significantly add to the accuracy of the disposition diagnosis of HF.

Consistent with other studies, we found that patients with a final diagnosis of HF had significantly higher BNP levels than those of patients with a final diagnosis of no HF. However, the median BNP value of our patients with a final diagnosis of HF and patients with a final diagnosis of no HF was higher than that previously reported at 830 and 99 pg/mL, respectively. Furthermore, we found that in our study population, the recommended cutoff point of 100 pg/mL had a much lower specificity than that reported in other studies. We found similar accuracy, sensitivity, and specificity levels to those reported by Maisel et al at the optimum cutoff point of 265 pg/mL. This reflects the findings by Emdin et al that BNP cutoff concentrations are significantly dependent on the study population and the type of BNP assay used.

There are 3 main characteristics of our study population that may have led to higher BNP levels: (1) although BNP levels have been shown to be higher in patients with myocardial ischemia, we did not exclude these patients from the study population because acute HF may often coexist with myocardial ischemia in patients presenting to the ED; (2) our cohort of patients had a significant level of comorbidity and were generally older and more acutely unwell than the patients investigated in other studies. It is well known that BNP levels increase with age; (3) in the group with a final diagnosis of no HF, patients who had a history of HF were not separated out. Patients with a history of HF have been shown to have higher baseline BNP levels. However, this is a confounder that is frequently encountered in the real-life setting. This variability in BNP concentrations between different patient populations may be detrimental to the usefulness of the test in aiding diagnosis in the clinical setting.

Similar to the studies by McCullough et al and Green et al. in theory, when the BNP test is statistically combined with the emergency doctors’ assessment of the probability of HF, the accuracy of the doctors’ assessment improves significantly. In our study, if the emergency doctor had adhered strictly to the diagnostic recommendations and diagnosed all patients with a BNP value <100 pg/mL as no HF and >500 pg/mL as having HF, the disposition diagnosis accuracy would not have improved greatly (84%) and approximately 30% of patients would not have been classified. However, in the subgroup with a BNP value >500 pg/mL, more patients with HF would have been identified.

In the real-life clinical setting, this randomized controlled study found that there was no significant difference in accuracy, sensitivity, or specificity of the disposition diagnosis with or without the BNP test. This is consistent with the primary results of the BNP in SOB study, which showed that BNP testing did not alter hospital admission rates, length of stay, or 30-day mortality.

The study cohort of patients was drawn from EDs staffed by senior doctors experienced in emergency medicine with a high level of supervision of junior doctors. Consistent with this, the assessment of the probability of HF by the emergency doctor and the disposition diagnosis had a higher accuracy than described by McCullough et al. Furthermore, BNP levels may be elevated in several conditions such as a history of HF, chronic renal failure, myocardial ischemia, pulmonary embolus, and rapid atrial fibrillation. Some of these conditions may coexist with HF in a patient presenting with dyspnea to the ED.

The main strength of this study is that the effect of the BNP test on the accuracy of the diagnosis of HF was assessed in the clinical setting in real time through a randomized controlled trial. In this way, it was possible to elucidate whether the BNP test improves the accuracy of HF diagnosis in the ED. Furthermore, this study was able to define an optimum cutoff point for the BNP test in the diagnosis of HF in an Australian population of patients presenting to a tertiary referral and a metropolitan hospital.

One of the limitations of our study is that there were more patients in the BNP group with a history of hypertension and HF and a symptom of orthopnea. However, adjusting for these patients did not alter the results of the study. Another limitation is that there is no definitive test or robust clinical definition of HF: it is a syndrome characterized by a constellation of symptoms and signs. However, we counteracted this by providing each reviewer with a standardized definition and an algorithm for the diagnosis of acute HF. Reviewers were blinded to the BNP result. There was a high level of agreement between reviewers.

BNP levels would have been influenced by acute myocardial ischemia and a history of HF. These have been excluded in some studies. Because these problems are encountered in the real-life setting, we did not attempt to control for these confounders. Similarly, we did not use age-adjusted partition values given that the BNP nomogram by McCullough et al does not stratify the BNP values by age.

Conclusions

This study showed that BNP levels were significantly higher in patients with HF and that the BNP test had a high level of accuracy in the diagnosis of HF. However, in the
clinical setting, BNP testing did not add to the accuracy of the disposition diagnosis of HF in patients presenting with dyspnea to the ED.

In the future, the development of more specific BNP nomograms adjusted to variables affecting BNP values, such as age, gender, ethnicity, and a history of HF, may make the BNP test more useful in HF diagnosis in the ED.

Sources of Funding

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Disclosures

None.

References


CLINICAL PERSPECTIVE

This study is a retrospective analysis of data from the randomized controlled multicenter trial: the B-Type Natriuretic Peptide in Shortness of Breath study conducted in 2 major Australian emergency departments (ED). We assessed whether testing B-type natriuretic peptide (BNP) levels in the ED in real time would improve the accuracy of heart failure (HF) diagnosis in patients presenting to the ED with dyspnea. The diagnosis of HF is based on the dyspneic patient having a set of clinical characteristics on history, examination, and further investigation. It is often difficult to make an accurate diagnosis of HF in the ED. This potentially leads to delayed treatment and poor outcomes for the patient. Since the development of rapid reliable tests for BNP, it has been widely studied as a potential tool to aid in the diagnosis of acute HF in the ED. Several studies have shown that BNP levels are higher in patients with acute HF. Furthermore, studies have extrapolated a theoretical benefit of adding the BNP test to clinical judgment to improve the accuracy of HF diagnosis. Our study is the first to assess the effect of BNP testing on the accuracy of HF diagnosis in real time in the clinical setting. We found that testing BNP levels in the ED did not improve the accuracy, sensitivity, and specificity of HF diagnosis.
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