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B-type Natriuretic Peptide (BNP) Is Useful in Detecting Asymptomatic Left Ventricular Dysfunction in Low-Income, Uninsured Patients

Aurelia Macabasco-O'Connell, PhD, ACNP,[1] Sheba Meymandi, MD,[2] and Robert Bryg, MD[2]

Abstract

Low-income, uninsured individuals with multiple cardiovascular risk factors (CRFs) are at risk of heart failure (HF). B-type natriuretic peptide (BNP) screening for asymptomatic left ventricular dysfunction (ALVD) has not been tested specifically in this group. The purposes of this study were to describe BNP levels in asymptomatic low-income, uninsured individuals with multiple CRFs and determine the correlation between BNP levels and echocardiography for identifying ALVD. Methods: This correlational study included 53 patients (age 55 $\pm$ 10 years, 83% non-White, 64% female). BNP testing and echocardiogram (ECHO) were performed. Results: Of the 30 patients (57%) diagnosed with ALVD by ECHO, 21 (40%) had diastolic and 9 (17%) systolic dysfunction. BNP levels were lower among those with normal left ventricular (LV) function (29.6 $\pm$ 24 pg/mL) than those with diastolic (80.2 $\pm$ 69 pg/mL, $p = .01$) and systolic dysfunction (337.1 $\pm$ 374 pg/mL, $p = .009$). sParticipants with BNP $\geq$50 pg/mL were 5.75 times more likely to exhibit diastolic dysfunction (odds ratio [OR] = 5.75, 95% confidence interval [CI] 1.29–25.51; $p < .01$) and those with BNP $\geq$100 pg/mL were 7.80 times more likely to have systolic dysfunction (OR = 7.8, 95% *CI* 1.60–37.14; $p < .005$) than those with lower levels. With BNP cut point of 50 pg/mL, area under the curve (AUC) was 0.82 (95% CI 0.63–1.00) with sensitivity of 88% and specificity of 67%. Conclusion: BNP is a low-cost method to detect ALVD in high-risk, uninsured, low-income individuals. Elevated BNP levels should prompt initiation of further diagnostic testing and early treatment.

Keywords

asymptomatic left ventricular dysfunction, Hispanics, B-type natriuretic peptide (BNP), uninsured, heart failure

Heart failure (HF) is a progressive and lethal disease affecting almost 5 million persons in the United States, with associated health care costs approaching US$25.8 billion annually (Rosamond et al., 2008). It is associated with significant morbidity and poor quality of life and disproportionately affects minority communities (Yancy, 2004). Minority groups have greater morbidity and mortality with HF compared to Whites (Rosamond et al., 2008; Wang, Levy, Benjamin, & Vasan, 2003). Low-income minorities, including Hispanics, often lack health insurance, have incomes below the poverty level (indigent), and are at increased risk of developing cardiovascular problems and HF (Maisel et al., 2001). Approximately one third of U.S. Hispanics are without any form of health insurance with almost 2 million uninsured Hispanics in Los Angeles (LA) county alone (Eberhardt et al., 2001). This situation has significant implications for HF management.

Although causes of health disparities are complex and not fully understood, poor self-care, variability in medical management, unmet health needs, barriers to accessing health care, and limited financial resources are all possible contributors (Becker, Beyene, Newsom, & Rodgers, 1998; Riegel, Carlson, Glaser, & Romero, 2006; Shi & Stevens, 2005). Numerous reports state that Hispanics have a higher prevalence of cardiovascular risk factors (CRFs) compared to non-Hispanic Whites, including metabolic syndrome (31.9% vs. 22%; Liao et al., 2004; National Cholesterol Education Program [NCEP], 2001), Type 2 diabetes (20.3% vs. 11.2%; Flegal et al., 1991; Haffner, Hazuda, Mitchell, Patterson, & Stern, 1991; Hamman et al., 1989), obesity (mean body mass index [BMI] 26.6 vs.

[1] University of California Los Angeles, Los Angeles, CA, USA
[2] Olive View-UCLA Medical Center, Division of Cardiology, Sylmar, CA, USA

Corresponding Author:
Aurelia Macabasco-O'Connell, University of California Los Angeles, School of Nursing, Acute Care Section, 700 Tiverton Ave., 4-242 Factor Building, Los Angeles, CA 90095, USA.
Email: aoconnel@sonnet.ucla.edu

26.3 kg/m^2; Mitchell, Stern, Haffner, Hazuda, & Patterson, 1990), lipid abnormalities (Mitchell et al., 1990), and lower levels of physical activity (Burchfiel et al., 1990). These CRFs, especially when grouped together, significantly affect the development of heart disease, including HF. Uninsured Hispanics with HF are more likely to be hospitalized (Mensah, Mokdad, Ford, Greenlund, & Croft, 2005; Minutello, Chou, Hong, & Wong, 2006) and are at greater risk for rehospitalization (Riegel et al., 2006) and for all-cause and cardiovascular mortality and morbidity compared to patients with higher socioeconomic status (SES). Low SES may be an important factor leading to adverse HF outcomes for Hispanics (Alboni et al., 2003; Ayanian, Weissman, Schneider, Ginsburg, & Zaslavsky, 2000; Blair, Lloyd-Williams, & Mair, 2002; Rathore et al., 2006; Ross, Bradley, & Busch, 2006; Shishehbor, Litaker, Pothier, & Lauer, 2006; Steptoe, Owen, Kunz-Ebrecht, & Mohamed-Ali, 2002; Struthers, Anderson, Donnan, & MacDonald, 2000; Winkleby, Jatulis, Frank, & Fortmann, 1992).

Detecting and treating the preclinical stages of HF is the best way to stem the current epidemic (Wang et al., 2003). The importance of early detection has been emphasized by the HF model proposed by the American Heart Association (AHA) and the American College of Cardiology (Ammar, Malani, Gupta, & Dobyan, 2006; Hunt, 2005). The model classifies HF into stages: Stage A—the presence of HF risk factors without cardiac structural or functional abnormality; Stage B—asymptomatic ventricular dysfunction including left ventricular hypertrophy (LVH), regional wall-motion abnormality, left ventricular (LV) enlargement, and systolic and diastolic dysfunction, all predictive of incident HF; Stage C—symptomatic HF associated with underlying structural ventricular dysfunction; and Stage D—end-stage HF.

Screening patients with multiple CRFs considered high risk of having asymptomatic left ventricular dysfunction (ALVD) may be one strategy for reducing both human and economic costs associated with HF. Moreover, to prevent the progression of HF, identifying patients during the early stages (Stages A and B) can lead to the initiation of medications such as angiotensin-converting enzyme inhibitor (ACE-I), proven to substantially reduce the progression of LV dysfunction and the risk of overt symptomatic HF (Goldberg & Jessup, 2006). The challenge, however, is that during these stages, patients are often asymptomatic, and LV dysfunction is undetectable. Furthermore, in general, low-income, uninsured patients do not seek health care until symptomatic, thus delaying evaluation and treatment of ALVD.

Screening for ALVD may provide cost savings for public institutions caring for uninsured patients through early detection and treatment. Echocardiography (ECHO), which is useful for detecting impaired LV function, is considered the cornerstone for identification of ALVD. However, it is expensive and associated with long wait times and may not be available to the uninsured with limited health care access. Heidenreich et al. (2004) found that screening with B-type natriuretic peptide (BNP), a cardiac neurohormone released in response to LV overload, followed by ECHO when necessary, was economically attractive for high-risk groups and significantly improved health outcomes. BNP is a less expensive and more easily available method of detecting ALVD than ECHO, requiring little technical skill to collect or analyze. Results can be obtained in a short period of time.

There is growing interest in early identification of ALVD, which has spurred several studies using BNP to screen for ALVD in the general population, as well as in those with diabetes and hypertension (Vasan et al., 2002; Wang et al., 2003). BNP has been shown to be elevated (>100 pg/mL) in the presence of ALVD and symptomatic HF. However, these studies were done primarily in Whites (Cowie et al., 1997; Krishnaswamy et al., 2001; Maisel et al., 2001, 2002; McDonagh, 2000; Wang et al., 2003; Wieczorek et al., 2002). The Breathing Not Properly study found BNP to be the single most accurate predictor of whether one has HF, revealing an odds ratio of 29.60 with a value of >100 pg/mL (Maisel et al., 2002). However, although BNP might be a reasonable alternative for screening for ALVD in patient populations that are mostly White, the influences of race/ethnicity, income, and multiple comorbidities on BNP levels is unknown. It is important to determine whether these results hold true in uninsured, low-income patients. Therefore, the purposes of this pilot study were to (a) describe BNP levels found in low-income, uninsured, asymptomatic patients with multiple comorbidities; and (b) determine the correlation between BNP levels and echocardiography for identifying ALVD in this cohort.

Methods

This study used a correlational design to establish the utility and feasibility of BNP testing for ALVD as compared with echocardiography in low-income, uninsured participants. Institutional Review Board approval from the University of California at Los Angeles and Olive View-UCLA Medical Center was obtained. Participants were recruited from an ambulatory care clinic at Olive View-UCLA Medical Center, a Los Angeles county facility, between April 2006 and February 2007. Eligibility criteria included age $\geq$30 years and a history of three or more CRFs (such as hypertension, diabetes, dyslipidemia, metabolic syndrome, obesity, smoking) with no prior history of HF or documented LV dysfunction. Exclusion criteria included known HF or myocardial infarction within the last year or renal dysfunction (serum creatinine $\geq$2.0 mg/dl).

Patients were invited to participate in the study through flyers and posters in the ambulatory care clinic. Informed consent was obtained from those who expressed interest in participating. Trained research assistants conducted one-on-one interviews to obtain sociodemographic information including age, gender, educational level, annual income level, and insurance status. Participants were classified as low-income if their annual income was $\leq$US$21 000 for a family of four, which is considered below poverty level (U.S. Census Bureau, 2007). Participants were classified as being uninsured if they reported having no insurance, having Medicaid, or having Outpatient Reduced-Cost Simplified Application (ORSA).

The research assistants also obtained medical and symptom histories, including current symptoms such as (a) shortness of breath (SOB) while at rest; (b) SOB while walking or going up the stairs; (c) awakening at night or inability to get to sleep because of cough or SOB; (d) frequent urination; (e) high level of fatigue; (f) leg swelling, feeling full, or bloated; and (g) palpitations or heart racing. Finally, they conducted a brief physical examination, which included height, weight, and waist circumference measurement. After the interview, ECHOs were performed by trained technicians and phlebotomies by trained research assistants. All procedures were conducted on the same day.

Echocardiography

The echocardiographic examination was performed using a Sequoia machine (Acuson, Stockton, CA) with a second harmonic and a 2.2 MHz mechanical transducer. Direct measurements obtained using the M-mode were diastolic aortic diameter (AoD) and left atrial systolic diameter (Las). Those obtained using the parasternal long axis view were LV diastolic diameter (LVDD), LV systolic diameter (LVSD), and LV posterior wall in diastole (LVPWD). Interventricular septum in diastole (IVSD) was obtained using the parasternal short axis view at the papillary muscle level as defined by the American Society of Echocardiography (ASE; Quiñones, Otto, Stoddard, Waggoner, & Zoghbi, 2002). Volume measurements calculated indirectly using the Teicholz formula were LV systolic and diastolic volumes (LVSV and LVDV, respectively), ejection fraction (EF), and ventricular fractional shortening during systole (delta D%). Other measurements calculated indirectly included relative wall thickness, LV mass indexed to the body surface area (LVM/BSA) and LVM indexed to height (LVM/height^2). Diastolic function was assessed by analyzing transmitral flow using pulsed Doppler echocardiography, evaluating the peak velocities of the E and A waves, E/A ratio, and E-wave deceleration time (EDT; Lang et al., 2005). An experienced cardiologist, who was blinded to the BNP levels, interpreted all ECHOs.

Participants were divided into three subgroups based on ECHO interpretation: normal LV function, systolic dysfunction, and diastolic dysfunction. Normal ventricular function was defined as EF >45%, normal LV end diastolic (3.5-5.7 cm) and end systolic (2.3-4.0 cm) dimension, and no major wall-motion abnormalities. Systolic dysfunction was defined as EF <45% or global hypokinesis or discrete wall-motion abnormalities and fractional shortening <27%. The degree of systolic impairment was estimated by the ECHO reader. Diastolic dysfunction was determined when the flow propagation velocity toward the apex was less than 45 cm/s.

Measurement of BNP Levels

Samples of blood for BNP measurement (5 ml) were collected into tubes containing potassium ethylenediaminetetraacetic acid (EDTA; 1 mg/ml blood) by venipuncture on the same day as the ECHO. Blood samples were processed and analyzed using the Triage BNP test (Biosite Diagnostics, San Diego, CA). The Triage BNP test is a rapid, objective test used to aid in the diagnosis and severity of HF. It uses a fluorescent immunoassay for the quantitative determination of BNP. Its portability and ease of use enables nurses and trained technicians to perform this test in a variety of settings, including the lab or the clinic setting during regular clinic visits (point-of-care). BNP values for the current study were determined using the point-of-care method with whole blood, as described by the manufacturer. The measurable range of the test is 5–5000 pg/mL. Blood samples were processed within 1 hr of sampling. A BNP level of >100 pg/mL was diagnostic for systolic dysfunction as noted by the Biosite recommendations (Biosite, Inc., 2007). Precision, analytical sensitivity, stability, and utility have been previously described (Krishnaswamy et al., 2001; Lubien et al., 2002; Wieczorek et al., 2002). The test has been shown to have high sensitivity and a specificity of ≥82% in a number of studies (Howie, Caldwell, & Dracup, 2003; Maisel, 2003).

Feasibility (Cost, Time, Acceptability)

Direct costs of ECHO and BNP testing were measured. To quantify the cost of ECHO, including both technical and professional components, data from the Los Angeles Department of Health Services facility fee structure were used (C. O'Donnell, LADHS Expenditure Manager, personal communication, June 1, 2007). The time to obtain a complete outpatient ECHO was based on the average time for a scheduled appointment. This time may vary depending on where the ECHO is ordered (i.e., outpatient clinic vs. hospital admission). The cost of a single BNP was based on the cost of testing with the Biosite BNP point-of-care test device. The time to obtain BNP results was based on the point-of-care test analysis and was averaged among the sample. Acceptability was based on the number of participants that agreed to have the BNP testing performed.

Statistical Analysis

Statistical analysis was performed using SPSS, version 11.5, and Stata, version 9. Baseline demographic and clinical variables were analyzed using descriptive statistics and χ^2 analysis. Univariate and multivariate analyses were conducted with logistic regression to evaluate the ability of BNP to predict ALVD. A stepwise approach was used including covariates such as gender, ethnicity, and BMI. Nonparametric tests were used for nonnormally distributed outcome variables. Nonparametric rank sum test (Kruskal-Wallis) was used to compare demographic and clinical characteristics in the normal and ALVD groups.

Receiver-operating characteristic (ROC) plots were conducted to identify the optimal cutoff values that exhibit a high sensitivity and a reasonable specificity (suggesting a high negative predictive value) for the diagnosis of ALVD. A value of $p < .05$ was set as the significance threshold.

Table 1. Baseline Sample Characteristics

Characteristic	All Patients (N = 53) M ± SD
Age (years)	55 ± 10
BMI (kg/m^2)	31 ± 9
Waist circumference (cm)	104 ± 20
Ejection fraction (%)	55 ± 14
	n (%)
Female gender	34 (64%)
Annual income < US$21 000[a]	46 (90%)
Hispanic	27 (53%)
White	9 (18%)
African American	4 (8%)
Asian	4 (8%)
Other	2 (4%)
Uninsured	51 (98%)
Ethnicity[a]	
Hispanic	34 (64%)
White	9 (17%)
African American	4 (8%)
Asian	4 (8%)
Other	2 (4%)
Cardiac risk factors	
Hypertension	39 (74%)
Diabetes	27 (51%)
Smoker	20 (38%)
Dyslipidemia	12 (23%)
Obesity	48 (91%)
Metabolic syndrome	25 (47%)
Use of medications	
ACE-I	28 (53%)
β-blocker	23 (43%)
Diabetes medications	22 (42%)
Statins	27 (51%)

NOTE: ACE-I = angiotensin-converting enzyme inhibitor; BMI= body mass index.
[a] One participant did not report income.

Results

Of the 101 patients screened for the study, 5 refused to be interviewed and 43 were ineligible because they lacked multiple cardiac risk factors for HF, admitted to having symptoms, or had a previous history of HF. All remaining eligible patients (n = 53) agreed to participate in the study. The sample consisted of mostly female, non-White patients with multiple risk factors. The overall sample was obese. Baseline sample characteristics for the sample as a whole are shown in Table 1.

ECHO results showed that over half of the participants (n = 30 [57%]) had ALVD. Furthermore, those with systolic LV dysfunction had higher BMI and waist circumference measurements as compared to those with normal LV function (See Table 2).

BNP levels ranged from <5–990 pg/mL with an overall mean BNP value of 105 ± 189 pg/mL. When comparing EF and BNP levels, a significant negative correlation was noted (Pearson's r = –.59; p = .01). Mean BNP values were lower among those with normal LV function (29.6 ± 24 pg/mL), as compared to those with diastolic dysfunction (80.2 ± 69 pg/mL, p < .01) and systolic dysfunction (337.1 ± 374 pg/mL, p < .001; Figure 1).

Based on univariate analyses, patients with BNP values ≥50 pg/mL were 5.75 times more likely to exhibit diastolic dysfunction than those with lower BNP levels (odds ratio [OR] = 5.75, 95% confidence interval [CI] 1.29–25.51; p < .01). Similarly, patients with BNP values ≥100 pg/mL were 7.80 times more likely to have systolic dysfunction than those with lower BNP levels (OR = 7.8, 95% CI 1.60–37.14; p < .005). Multivariate analyses using logistic regression were used to evaluate the association of BNP levels with ALVD. When controlling for gender, ethnicity, and BMI, higher BNP levels were associated with a fourfold increased risk of having ALVD (OR = 4.20, 95% CI 1.78–9.87; p < .001). The risk was similar for having diastolic dysfunction (OR = 4.87, 95% CI 1.61–14.74; p < .005).

ROC analysis was performed to compare sensitivity and specificity of various BNP values. A BNP of 50 pg/mL was selected as a cutoff value, showing a sensitivity of 88% and specificity of 67%, to identify patients with ALVD. The area under the curve (AUC) is 0.82 (CI 0.63–1.00; Figure 2).

The cost for screening with BNP was US$30 per test device per person, as defined by Biosite 2008 prices. The cost for an ECHO, including both technical and professional fees, was approximately US$1,000 per person. Time to results per person for BNP averaged 10 min versus 3–6 months for ECHO. All participants agreed to have BNP tested, denoting a 100% acceptability rate.

Discussion

The results of this study showed that higher BNP levels were strongly associated with severity of ALVD as determined by ECHO. BNP testing using a cutoff point of 50 pg/ml reliably identified patients with ALVD, putting them in stage B HF, providing a sensitivity of 88% and specificity of 67%. In comparison to the current findings, the landmark study Breathing Not Properly used the cutoff point of 50 pg/ml, which is higher than the upper limit of normal (20 pg/ml) for healthy participants and showed a sensitivity of 97% and specificity of 62% (Maisel et al., 2002). In that study, the optimal cutoff point was found to be 100 pg/ml, with a sensitivity of 90% and a specificity of 76%. The performance of BNP for detecting ALVD has been evaluated in several other community-based studies using various cut points (Cowie et al., 1997; McDonagh, 2000; Wang et al., 2003). Sensitivities for ALVD ranged from 26% to 92% with specificities ranging from 34% to 89%. Estimates for AUC ranged from 0.56 to 0.88 (Wang et al., 2003).

The current study is one of the first to focus on mostly Hispanic, low-income, uninsured patients in evaluating the use of BNP in screening for ALVD in a high-risk group. Results revealed the high incidence of ALVD (57%) in this group of asymptomatic patients considered "high risk" for developing

Table 2. Sample Characteristics Based on Level of Left Ventricular (LV) Dysfunction

	Normal Group, $n = 23$ (43%)	Diastolic Dysfunction, $n = 21$ (40%)	Systolic Dysfunction, $n = 9$ (17%)
Characteristic	M ± SD	M ± SD	M ± SD
Age (years)	52 ± 10	58 ± 8	54 ± 13
BMI* (kg/m^2)	31 ± 11	30 ± 7	32 ± 12
Waist circumference* [a] (cm)	103 ± 22	103 ± 15	105 ± 27
Ejection fraction (%)	62 ± 4	58 ± 8	29 ± 10
	n (%)	*n* (%)	*n* (%)
Gender			
Female* [b]	17 (50%)	12 (35%)	5 (15%)
Male	6 (32%)	9 (47%)	4 (21%)
Ethnicity** [a]			
Hispanic	16 (47%)	13 (38%)	5 (15%)
White	3 (33%)	4 (44%)	2 (22%)
African American	1 (25%)	3 (75%)	0
Asian	2 (50%)	1 (25%)	1 (25%)
Other	1 (4%)	0	1 (11%)
Cardiac risk factors			
Hypertension	16 (41%)	16 (41%)	7 (18%)
Diabetes	15 (56%)	11 (41%)	1 (4%)
Smoker	7 (35%)	9 (45%)	4 (20%)
Dyslipidemia	6 (50%)	5 (42%)	1 (1%)
Obesity	22 (46%)	17 (35%)	9 (19%)
Metabolic syndrome	12 (48%)	11 (44%)	2 (17%)
Use of medications			
ACE-I	9 (32%)	13 (46%)	6 (21%)
β-blocker	6 (26%)	10 (44%)	7 (30%)
Diabetes medications	12 (55%)	9 (42%)	1 (5%)
Statins	12 (44%)	11 (41%)	4 (15%)

NOTE: Differences between the normal group versus systolic dysfunction group. ACE-I = angiotensin-converting enzyme inhibitor; BMI = body mass index.
[a] Kruskal-Wallis.
[b] χ^2.
* $p < .05$.
** $p < .01$.

HF due to the presence of multiple CRFs. These data suggest that this population would benefit most from early detection and risk stratification using BNP.

Although this study had a small sample size, it was conducted at a major county hospital that serves largely minority, uninsured patients that are mostly Hispanic. Thus, we believe this sample is fairly representative of this population. Screening for ALVD in high-risk, uninsured minorities may be one strategy for risk stratifying those requiring further evaluation for HF. Such screening could result in earlier aggressive treatment of risk factors and ALVD, particularly in the absence of comprehensive or limited ECHO.

Furthermore, persons with Stage B HF are generally asymptomatic and do not undergo clinical evaluation unless they have some type of cardiac event or are hospitalized for symptoms (Ammar et al., 2006). Previous research shows that early screening and detection is of great importance for those with ALVD, who have a nearly fivefold higher risk than those with normal LV function of developing symptomatic HF and higher mortality (Ammar et al., 2006). Moreover, the median survival free of HF is about 10 years in those with mild ALVD, suggesting there is a window of opportunity during which individuals can be identified and treated (Wang et al., 2003).

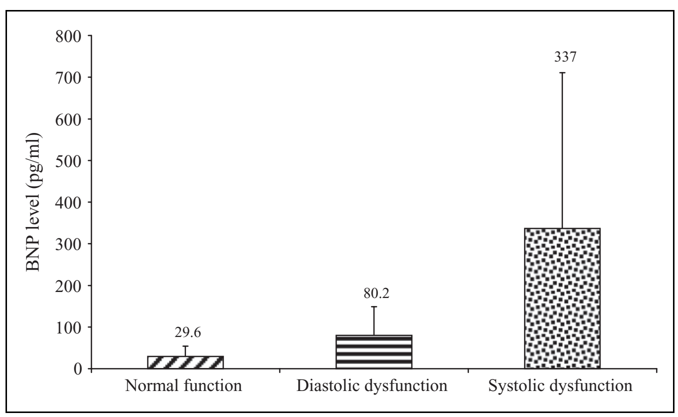

Figure 1. Mean B-type natriuretic peptide (BNP) levels for each level of left ventricular (LV) function. Bars indicate ±SD. Those patients diagnosed with systolic dysfunction had significantly higher BNP levels than those with diastolic dysfunction ($p < .01$) and normal function ($p < .001$).

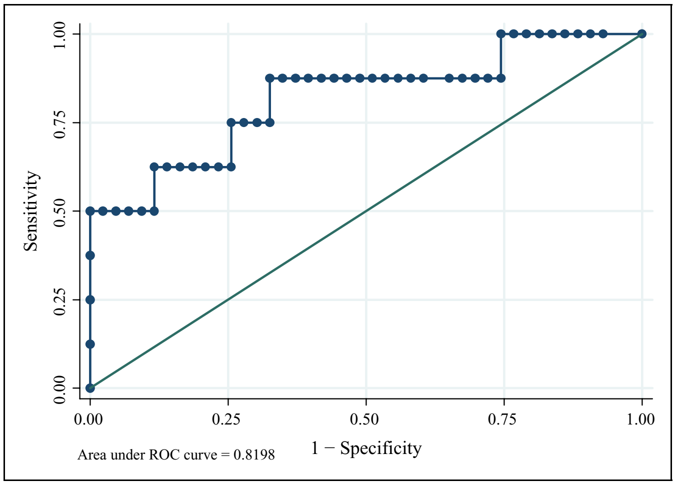

Figure 2. Receiver-operating characteristic (ROC) analysis of BNP predicting asymptomatic left ventricular dysfunction. The cutoff point of BNP >50 pg/ml was associated with 88% sensitivity and 67% specificity. Area under the curve (AUC) = 0.82.

Results of the current study show that BNP has acceptable correlations with echocardiography for detecting ALVD and is a feasible method for screening high-risk, uninsured patient populations. Patients accepted having blood draws for the BNP testing and were interested in receiving the results immediately as opposed to waiting months to have the ECHO done.

Because this was a descriptive, observational study using a convenience sample, there are several limitations. First, this is a small sample gathered from one site. Second, a large number of participants in this sample were obese ($\geq$30 kg/m^2). BNP levels may be influenced by obesity, with lower values in obese versus nonobese patients. In a substudy of patients with HF in the Breathing Not Properly study, there was a marked inverse correlation found with BNP levels and BMI in those who were obese (BMI $\geq$40; Daniels et al., 2006). Hence, BMI must be taken into account in the interpretation of BNP values due to the decreased sensitivity associated with increasing BMI for identifying those with ALVD. Thus, using a lower cut point in screening for ALVD in obese patients may yield a higher diagnostic threshold (Krauser et al., 2005).

The use of BNP measurement can dramatically lower costs for screening and early detection of ALVD, with the potential to decrease overall costs involved in HF. Although echocardiography remains the gold standard in detecting structural abnormalities in the heart and assessing LV function, it may be impractical for use in screening (Krauser et al., 2005). Access to echocardiography may be limited for those without insurance, and the procedure is associated with waiting periods of almost 6 months for nonemergent appointments. Testing BNP levels followed by echocardiography in cases where levels are elevated has been shown to be a cost-effective screening strategy (Heidenreich et al., 2004). This strategy may be used to decompress the county hospitals that have echocardiography services and reserve the ECHOs for those with true indications. More importantly, the early detection of ALVD allows for early intervention with medications such as ACE-I and β-blockers (BBl), which are proven to improve survival and increase well-being in those with LV dysfunction (The SOLVD investigators, 1992). Thus, use of screening with BNP may yield significant clinical benefit and ultimately decrease health care costs due to HF.

Declaration of Conflicting Interests

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