Published in final edited form as:

J Cardiovasc Nurs. 2009 ; 24(4): 299–307. doi:10.1097/JCN.0b013e3181a6a1e5.

Adherence to the low sodium diet plays a role in the interaction between depressive symptoms and prognosis in patients with heart failure

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INTRODUCTION

Due to advances in medical therapy, the prevalence and mortality rate related to coronary artery disease, including myocardial infarction and angina pectoris, have stabilized over the last 10 years. This, along with the aging of the population, has contributed to an increase in the incidence and prevalence of heart failure (HF), and to increases in the HF hospitalization and mortality rates in South Korea.¹ The 1-year mortality rate following a diagnosis of HF is about 20% in Korea similar to that seen in the United States,² and estimates of rehospitalization rates due to worsening HF within 6-month after discharge are as high as 50%.^{3, 4}

Prior investigators have demonstrated that fluid overload secondary to excessive dietary sodium intake is the most common reason for rehospitalization related to acute decompensated HF.^{5–8} The current guideline from the Heart Failure Society of America (HFSA) recommends that patients follow a low sodium diet containing less than 3g of sodium per day for patients with mild HF and less than 2g for patients with moderate to severe HF.⁹ Patients with HF have considerable difficulty initiating and maintaining a low sodium diet.¹⁰ In one study, only about 40% of the patients had a daily sodium intake that was less than 3g.¹¹ Most patients indicate that they do not know how to follow a low sodium diet.^{10, 12}

Depression is 4 to 5 times as common in patients with HF as in the general population.¹³ Depression predicts worse prognosis including recurrent rehospitalizations and increased mortality.^{14, 15} The prevalence of depression in patients with HF ranges from 11% to 58% and the presence of depressive symptoms varies between 51% and 69%.^{14–16} According to recent meta-analyses,^{14, 15} HF patients with depressive symptoms are twice as likely to experience rehospitalization or death when compared to those without depressive symptoms.

Depressive symptoms have been linked to non-adherence, and subsequently confer a higher risk for worse prognosis in patients with HF.^{13, 16} Investigators have focused on the link between depressive symptoms and medication adherence or adherence to exercise.^{17–20} Given the importance of the low sodium diet to the management of patients with HF, it is important to investigate whether adherence to the low sodium diet plays a role in the

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interaction between depressive symptoms and worse prognosis. Therefore, the purpose of this study was to determine whether adherence to a low sodium diet (defined as sodium intake less than 3g)⁹ altered the link between depressive symptoms and event-free survival among patients with HF after controlling for other risk factors.

METHODS

Design, Participants, and Setting

This was a prospective study of patients with HF recruited from outpatient HF clinics between September 1, 2005 and December 31, 2006. Patients with HF were referred to this study from several outpatient HF clinics at two tertiary medical centers located in Seoul, South Korea. At each clinic, patients were asked to follow a low sodium diet by their clinicians. Eligibility criteria for participation in this study included the following: (1) confirmed diagnosis of chronic HF with either impaired left ventricular systolic function (left ventricular ejection fraction [LVEF] $\leq 40\%$) or preserved systolic function (LVEF $> 40\%$); (2) no acute myocardial infarction within the previous 6 months; (3) taking stable doses of HF medications for at least 3 months; (4) no cognitive impairment; (5) no history of cancer, severe thyroid disease, liver or renal failure as defined as serum creatinine level higher than 2.0 mg/dL.

A total of 295 patients were eligible for this study. Thirteen patients refused to participate in this study and 5 patients withdrew from this study. Fifteen patients didn't complete the 24-hour urine collection and 8 patients were lost to follow-up. Thus, data from 254 patients were included in this study.

Measurements of variables

Adherence to the low sodium diet—Adherence to the low sodium diet was defined as intake less than 3g of sodium per day. Level of adherence to 3g sodium intake was determined by measurement of 24-hour urinary sodium excretion.²¹ 24-hour urinary sodium excretion accounts for approximately 95% to 98% of dietary sodium intake,²² and 24-hour urinary sodium excretion is correlated with dietary sodium intake measured by food diaries.²³ The measurement of 24-hour urinary sodium excretion is considered to be the most objective and accurate indicator of dietary sodium intake.

After patients received detailed written and verbal instructions about the procedures for urine collection, they collected all of their urine for a specified 24 hour period. To insure an accurate and complete 24-hour urine collection, a trained research assistant called patients to review the procedure for 24-hour urine collection and remind them of the beginning and ending times of urine collection, and requested that patients record urine volume with each urination. If patients forgot to save urine or collected urine for more than 24 hours, those cases were considered incomplete and were not included in data analysis. To define the level of adherence to 3g sodium intake recommended by the HFSA,⁹ urine sodium excretion in mmol was converted to mg ($\text{mg} = \text{mmol} \times 22.99$).

Depressive symptoms—Depressive symptoms were assessed by using the Korean version of the Beck Depression Inventory (K-BDI).²⁴ The K-BDI is a self-report instrument consisting of 21 items rated on a 0 (not at all) to 3 (very much so) scale. One of four ratings describing how they felt over the past 2 weeks is chosen by the patient. A total score was obtained by adding the rating of the 21 items; higher scores indicate higher levels of depressive symptoms. The total score can range from 0 to 63.

The K-BDI was validated in a clinical sample of about 4,000 Korean participants and has acceptable reliability with a coefficient α of 0.86.²⁴ The K-BDI was correlated positively with the Geriatric Depression Scale (GDS) and the Center for Epidemiologic Studies Depression Scale (CES-D) both widely used for measuring depressive symptoms among Korean patients with HF ($r = 0.63$ to 0.83).²⁵

Patients were divided into 2 groups based on their total score on the K-BDI: those with depressive symptoms (total K-BDI score ≥ 16) and those without depressive symptoms (total K-BDI score < 16). Sixteen is the published cut-point for the K-BDI.²⁵ This cut-point has a sensitivity of 68% and a specificity of 66% for diagnosing major depressive disorder.²⁵ In this study, the coefficient α of the K-BDI was 0.91.

Other clinical variables—Age, gender, etiology of HF, New York Heart Association (NYHA) functional class, LVEF, and total comorbidity reflected by the Charlson comorbidity index were collected through patient interview and review of medical records. Height and weight were measured by a trained research assistant using calibrated scales in the outpatient HF clinics, and body mass index (BMI) was calculated. All patients still took their medication and then had fasting blood drawn to measure the level of N-terminal pro B type natriuretic peptide (NT-pro BNP). The electrochemiluminescence immunoassay (Roche Diagnostics)²⁶ was used for analysis of NT-pro BNP level.

Event-free survival—The primary outcome of this study was the composite end-point of time to first event of cardiac hospitalization or cardiac death during the 12-month follow-up period. Patients were asked about all hospitalizations during monthly telephone follow-up interviews and their responses were confirmed by review of hospital records. Data about death were collected from interviews with family members and physicians, and were confirmed by review of medical records and death certificates.

Procedure

This study was approved by the Institutional Review Board at each hospital. Eligible patients were referred from cardiologists to this study. After the primary investigator explained the purposes and procedures for this study, written informed consent was obtained from patients. Patients were given the urine container with the 24-hour urine collection and a sheet to record volume and time of urination. After patients completed the 24-hour urine collection, they brought their urine container to the outpatient HF clinic. At the outpatient HF clinics, patients had venous blood drawn, and then completed a series of questionnaires. A trained research assistant reviewed the questionnaires and the 24-hour urine collection sheet to ensure completeness. Each encounter lasted about 30 minutes. After baseline assessment, patients were followed up by telephone interview every month for 12 months.

Statistical Analysis

Statistical analyses were conducted using SPSS for Windows 15.0. Frequencies with percents were calculated for categorical variables, and means with standard deviations were calculated for continuous variables. The serum level of NT-pro BNP was log transformed for use in analyses because it is markedly skewed. Hierarchical Cox proportional hazards regression were used to determine whether non-adherence to the low sodium diet predicted event-free survival in patients with HF after controlling for age, gender, etiology of HF, BMI, NYHA functional class, LVEF, NT-pro BNP and total comorbidity scores. Hierarchical Cox proportional hazards regression with standard survival curves was used to determine whether non-adherence to the low sodium diet played a role in the interaction between depressive symptoms and event-free survival after controlling for the same risk

factors. A hazard ratio (HR) for rehospitalization and death was obtained for all independent variables along with 95% confidence intervals (CIs).

RESULTS

Sample characteristics

Sample characteristics are shown in Table 1. The majority of patients were over 65 years old with an age range of 34 to 92 years. According to the cut-off points for obesity suggested by the World Health Organization for Asian people,²⁷ 18% of patients were obese and 7.5% were underweight. As a group, patients were primarily in NYHA functional class II/III. Nearly half of the patients had ischemic heart disease as the underlying etiology of HF. Almost one third of the patients had preserved systolic function with LVEF > 45%. The common comorbidities were hypertension and diabetes mellitus. The mean value of NT-pro BNP was 1,049 pg/ml while the median value was 815 pg/ml with a range from 107 to 4,099 pg/ml. Forty one percent of patients had a 24-hour urinary sodium excretion of 3g or less. Approximately 45% of patients had 24-hour urinary sodium excretion that indicated a daily sodium intake of more than 4,000 mg. Forty eight percent of patients had depressive symptoms as indicated by a K-BDI score greater than or equal to 16. Less than 15 % of patients were prescribed antidepressant agents.

Non-adherence to the low sodium diet and depressive symptoms as independent predictors of event-free survival

In hierarchical Cox regression, non-adherence to the low sodium diet and the presence of depressive symptoms independently predicted event-free survival after controlling for other risk factors (Table 2). Patients who had a 24-hour urinary sodium excretion greater than 3,000 mg had shorter event-free survival than patients with a 24-hour urinary sodium excretion less than 3,000 mg ($p = .028$) (Figure 1). Patients with depressive symptoms had shorter event-free survival than those without depressive symptoms ($p < .001$) (Figure 2).

The relationship of non-adherence to the low sodium diet, depressive symptoms, and event-free survival

After controlling for the same risk factors, patients with a 24-hour urinary sodium excretion greater than 3g who also had depressive symptoms demonstrated a 3.7 times higher risk for cardiac events than patients with a 24-hour urinary sodium excretion below 3g per day who were without depressive symptoms (Figure 3). In patients without depressive symptoms, there was a significant difference in adjusted event-free survival between patients above and below the cutpoint of 3g for 24-hour urinary sodium excretion (hazard ratio [HR] = 2.18, 95% confidence interval [CI] = 1.16 – 4.08). In patients with a 24-hour urinary sodium excretion less than 3g, patients with depressive symptoms had a 2.9 times higher risk for cardiac events, compared to those without depressive symptoms.

DISCUSSION

The most significant finding of this study was the association of the interaction between adherence to the low sodium diet and depressive symptoms to event-free survival in patients with HF. Moser and colleagues,²⁸ who examined the mediator effect of non-adherence to the low sodium diet, showed that non-adherence to the low sodium diet didn't mediate the link of depressive symptoms to cardiac event-free survival in patients with HF although medication adherence did. However, our study showed that non-adherence to 3g sodium intake had more powerful prognostic value in the context of concurrent depressive symptoms. Our findings suggest a tentative behavioral mechanism through which depressive

symptoms confer worse prognosis in patients with HF. That is, patients with depressive symptoms are more likely to be non-adherent to the low sodium diet.

To date, few have investigated behavioral mechanisms (i.e., non-adherence) for the link between depressive symptoms and morbidity and mortality in patients with HF. However, the negative association between depressive symptoms and adherence to self-management has been supported by several investigators.^{17–20} Dunbar and colleagues²⁹ controlled for the possible effects of depressive symptoms on self-management in their study to test the effects of a family education and support intervention on improving adherence to the low sodium diet among patients with HF. A putative behavioral pathway was supported by our findings that non-adherence to the low sodium diet had an additive effect on the link of depressive symptoms to worse prognosis in patients with HF.

Since depressive symptoms had a significant prognostic value in patients with HF in consistent with prior studies,^{14, 15} a strategy of increased awareness and monitoring for depressive symptoms should be emphasized to clinicians. Screenings for depressive symptoms in patients with HF need to be included in routine care. Effective interventions for depressive symptoms including cognitive behavioral therapies and exercise programs are practical and easily used in clinical settings.³⁰ Also, adherence to treatment should be more carefully monitored in patients with HF who have depressive symptoms.

In this study, evidence for the significant impact of adherence to the low sodium diet on clinical outcomes was provided. This finding demonstrated that non-adherence to 3g sodium intake independently predicted worse event-free survival in patients with HF after controlling for other traditional risk factors. One previous study³¹ demonstrated a similar finding about the impact of 3g sodium intake on event-free survival in patients with HF. Lennie and colleagues³¹ reported that patients whose sodium intake was less than 3g per day had better event-free survival without adjustments for other risk factors. Our study extended this finding to demonstrate that adherence to 3g sodium intake was an independent predictor for event-free survival after controlling for other risk factors which have been found to predict worse prognosis in HF. This finding is important because it helps clinicians target education to a specific guideline for low sodium diet which leads to better health outcomes. Therefore, it seems important to emphasize that patients have a sodium intake lower than 3g per day.

The findings of this study have particular relevance to Korean patients with HF, because Koreans tend to have higher dietary sodium intake compared to Western countries.³² The Korean Health and Nutrition Survey³³ estimated that the daily dietary sodium intake of Korean was 4.5 to 5.3 gram, whereas American's daily sodium intake was 2.9 to 4.1 gram.³⁴ The average 24-hour urinary sodium excretion was 4,082 ($\pm$ 1,840) mg in this study, whereas the mean value of 24-hour urinary sodium excretion ranged from 2,932 mg to 3,723 mg among HF patients from America.^{11, 12, 29} Forty-five percent of patients in this study had a daily intake of more than 4,000 mg, whereas prior investigators in America have demonstrated that 35% of patients consumed greater than 4,000 mg of dietary sodium per day.¹² One explanation for the higher sodium intake of Koreans can be found in examining the favorite dishes of Koreans, which include Kimchi, soybean paste soup, fish, shellfish, and Ramyeon, all of which contain high amounts of salt.³⁵ Additionally, Koreans' food-preparation habits and dietary behavior could contribute to high sodium consumption in Korean. Some of these habits include 'eating soybean paste soup more than once a day', 'preferring Kimchi to fresh vegetables', 'adding more soy sauce to foods at the table', 'making Kimchi with vegetables dipped in salted water', and 'eating stir and fried rice frequently with sliced vegetables preserved in soy sauce'.³⁶ Therefore, Korean patients with HF may be ideal candidates for life style modification programs, especially for diet modification. In the

cultural context of Korea, it is difficult for individuals to accurately measure the level of dietary sodium that is included in home-made salty condiments or ingredients (i. e., soy sauce, or bean paste). Accordingly, a convenient tool for measuring dietary sodium level at home would be useful to monitor and improve adherence to the low sodium diet.

There are potential limitations to be noted in this study. Although 24-hour urinary sodium excretion has been shown to be a good measure of sodium intake, urinary sodium excretion represents sodium intake in stable patients who are presumed to have a normal fluid and sodium balance. Diuretics and angiotensin-converting enzyme (ACE) inhibitors reverse sodium retention, and may affect the balance between sodium intake and urinary sodium excretion. This study recruited patients who were stable on all medications for 3 months before enrollment. Another limitation is that 24-hour urine was measured one time only in this study. Any conclusions drawn from this single 24-hour urinary sodium excretion may not reflect adherence to the low sodium diet for long term periods. Future researchers should consider repeated measurements of 24-hour urinary sodium excretion and depressive symptoms to further clarify their respective roles in outcomes.

CONCLUSIONS

Patients who followed a low sodium diet had better event-free survival when compared to those who didn't follow a low sodium diet. Further, non-adherence to a low sodium diet had stronger prognostic value when coupled with depressive symptoms in Korean patients with HF. A diet modification program for the low sodium diet should be targeted on Korean patients with HF, primarily those who have depressive symptoms. Prognosis could be improved in Korean patients with HF through improvement of adherence to the low sodium diet and treatment for depressive symptoms.

Acknowledgments

The author would like to acknowledge Dr. Terry A. Lennie and Dr. Debra K. Moser at the University of Kentucky for their mentorship. The project described was partially supported by a Center grant, 1P20NR010679 from NIH, National Institute of Nursing Research. The content is solely the responsibility of the author and does not necessarily represent the official views of the National Institute of Nursing Research or the National Institutes of Health.

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Figure 1.
Difference in time to first event of hospitalization or death split by adherence to the low sodium diet (N=254)

Figure 2.
Difference in time to first event of hospitalization or death divided by presence of depressive symptoms (N=254)

Figure 3.
Adjusted event-free survival among groups stratified by adherence to the low sodium diet and depressive symptoms (N=254)

Table 1

Patient characteristics N = 254

Characteristics		N (%)	Mean ($\pm$ SD)
Age (years)			62 ($\pm$ 14)
Gender	Male	145 (57.1)	
	Female	109 (42.9)	
Body mass index (kg/m ²)			23.9 ($\pm$ 4.1)
	Underweight (<18.5)	19 (7.5)	
	Normal weight (18.5 ~ 22.99)	105 (41.3)	
	Overweight (23.0 ~ 27.59)	84 (33.1)	
	Obesity ($\geq$ 27.60)	46 (18.1)	
NYHA functional class	I	35 (13.8)	
	II	86 (33.9)	
	III	98 (38.6)	
	IV	35 (13.8)	
Underlying etiology of heart failure	Non-ischemic heart disease	123 (48.4)	
	Ischemic heart disease	131 (51.6)	
Left ventricular ejection fraction (%)			35.8 ($\pm$ 14.0)
Total comorbidity score			3.2 ($\pm$ 1.8)
N-terminal pro B type natriuretic peptide (pg/ml)			1,049 ($\pm$ 1,066)
Medication	ACE inhibitors	172 (67.7)	
	Angiotension II receptor blocker	39 (15.4)	
	Digoxin	79 (31.1)	
	β blocker	213 (83.9)	
	Diuretics	187 (73.6)	
	Aldosterone antagonist	62 (24.4)	
	Antidepressants	36 (14.2)	
24-hour urinary sodium excretion (mg/day)			4,082 ($\pm$ 1,840)
	< 3,000	104 (40.9)	
	$\geq$ 3,000	150 (59.1)	
The Korean version for the Beck Depression Inventory score			17.9 ($\pm$ 9.6)
	No depressive symptoms	131 (51.6)	
	Depressive symptoms	123 (48.4)	

ACE; angiotensin-converting enzyme, NYHA; New York Heart Association

Table 2

Independent predictors of event-free survival in patients with heart failure N = 254

Characteristics		Adjusted Hazard Ratio	95% CI	<i>p</i>
Age (year)		0.99	0.98 – 1.01	.201
Female gender		1.18	0.80 – 1.76	.408
Body mass index (kg/m ²)		0.90	0.85 – 0.95	<.001
NYHA functional class	II	1.04	0.53 – 2.04	.908
	III	1.57	0.53 – 2.18	.853
	IV	0.82	0.35 – 1.91	.648
Underlying etiology of heart failure	IHD	1.31	0.87 – 1.97	.191
Left ventricular ejection fraction (%)		1.00	0.98 – 1.01	.759
Total comorbidity		1.08	0.89 – 1.32	.444
Log NT-pro BNP		1.20	1.03 – 1.40	.022
Non-adherence to the low sodium diet		1.56	1.05 – 2.32	.028
The presence of depressive symptoms		2.21	1.47 – 3.33	<.001

NYHA; New York Heart Association, IHD; ischemic heart disease, NT-pro BNP; N-terminal pro B type natriuretic peptide