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DIETARY SODIUM ADHERENCE IS POOR IN CHRONIC HEART FAILURE PATIENTS

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Abstract

Background—We sought to determine the rates and predictors of dietary sodium restriction, while evaluating the reliability of the 24-hour urine collection as a tool to estimate dietary sodium intake in heart failure (HF) patients.

Methods and Results—We evaluated the 24-hour urinary sodium excretion of 305 outpatients with HF and reduced ejection fraction who were educated on following a <2 gm sodium diet. The mean sodium excretion using a single sample from each participant was 3.15 ± 1.58 grams, and 23% were adherent to the <2 gm recommendation. 168 participants provided two samples with urinary creatinine excretion within normative range. Averaging both resulted in a mean sodium excretion of 3.21 ± 1.20 grams and lower adherence rates to the <2-gram diet: 14% versus 23% ($p=0.019$). Multivariate logistic regression showed only male sex and higher BMI was associated

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6. Disclosures
The authors declare no conflict of interest.

with non-adherence (OR male: 2.20, 95% CI: 1.25-3.88, OR one unit BMI: 1.05, 95% CI: 1.01-1.10). Bland-Altman plots of urinary sodium and creatinine showed poor reproducibility between samples.

Conclusions—In this chronic HF population, sodium consumption probably exceeds recommended amounts, particularly in men and those with higher BMI. Urine analyses were not highly reproducible, suggesting variation in both diet and urine collection.

1. Introduction

The average daily American diet contains more than 4 grams of sodium, an amount that may lead to an exacerbation of symptoms as well as other adverse effects in adults with heart failure. [1] As a result, several major medical groups developed guidelines to limit sodium consumption. The Heart Failure Society of America (HFSA) suggests a daily consumption of 2-3 grams or less of sodium in the HF population, depending on HF severity. [2] Previously, the American Heart Association (AHA) recommended changing the guideline from less than 3 grams to an even more stringent less than 1.5 gram sodium diet for all individuals regardless of a history of cardiac disease. [3] The variability of these guidelines is, in part, due to a lack of robust data in specific populations (e.g., HF). As a result, the most recently updated ACCF/AHA Heart Failure Guidelines downgraded sodium restriction in HF from a class I to a class IIa recommendation and limited the 1.5 gram restriction to Stage A and B HF only, with Stages C and D without a clear recommendation.[4]

Although there is uncertainty as to the exact recommendation, patients with HF are instructed to limit their dietary consumption of sodium. Existing data on dietary sodium intake in patients with HF have a number of methodological limitations such as small sample sizes,[5-7] use of self-report food diaries,[5, 8, 9] and use of single urinary sodium collection to characterize intake. [6, 10, 11] In this analysis, we utilized 24-hour urinary sodium excretion as an objective measure of sodium intake in a community-based sample of an adult heart failure population. Our study purpose was to determine the rates of adherence to dietary sodium restriction, to determine the predictors of adherence, and to evaluate the reproducibility of the urine samples provided by study participants.

2. Materials & Methods

2.1 Study Population

The current study is a secondary analysis from the Heart ABC Study (Adherence, Behavior, and Cognition), an NIH-funded, ongoing longitudinal study examining the relationships among cognitive impairment and adherence to HF self-management (ClinicalTrials.gov identifier: NCT01461629). All participants provided written informed consent and the study was approved by the Human Subjects Review Board at the two participating health systems: University Hospitals Case Medical Center in Cleveland, Ohio (a quaternary-care, academic system) and Summa Health Systems in Akron, Ohio (a tertiary-care, community-based system).

Adults recruited into the parent study were ages 50-85 years, with a clinical history of HF (at least 3 months) and LV dysfunction (ejection fraction of <= 40% using standard clinical

methodology including left ventricular angiography, nuclear imaging, or echocardiography within 36 months of study enrollment). All participants were clinically stable as determined by no change in diuretic dose or regimen, no planned hospitalization, and no planned procedures. Participants were enrolled from outpatient clinic settings. Adults with conditions known to be highly associated with cognitive dysfunction were excluded. Specifically, exclusion criteria were cardiac surgery within last 3 months, history of neurological disorder or injury (e.g., Alzheimer's disease, dementia, stroke, seizures), history of moderate or severe head injury, past or current history of psychotic disorders, bipolar disorder, learning disorder, developmental disability, renal failure requiring dialysis, or untreated sleep apnea, and current substance abuse or within the past 5 years.

On enrollment, all patients received an educational handout entitled “Managing Your Heart Failure.” This handout, created by Case Western Reserve University and approved by the IRB at both sites, included recommendations for lower sodium dietary choices and recommended a less than 2 gm sodium diet. Participants were asked if they understood the less than 2 gm sodium restriction and provided additional verbal assistance, if necessary. Participants may have also received additional dietary education from physicians, nurses, or dieticians as part of their “usual” heart failure care. . Each participant had three weeks to apply these guidelines to their daily routine prior to assessment of dietary sodium consumption.

At the time of enrollment, detailed clinical and demographic data were obtained using standardized questionnaires administered to the participant and were verified by examining medical records. The Charlson Comorbidity Index was used to assess comorbid conditions. [12] Medical diagnoses were assigned points (1-4) with more severe conditions receiving higher points. A total score was calculated.

2.2 Estimating dietary sodium

In this study, 24-hour urinary sodium excretion was used to estimate adherence to guideline-based low dietary sodium recommendations for HF. Urinary sodium excretion is highly correlated with dietary intake in patients with HF, with >95% of intake being excreted in the urine in temperate climates.[13] Urinary sodium excretion may provide a more accurate assessment of sodium intake, as self-reporting food diaries often result in an under-estimation of consumption.[14] To ensure adequate urine collection, a protocol was put in place to educate and assist in the collection of specimens. The parent study consisted of four home visits. At the second home visit, participants were given a collection device, urine jug and both verbal and written instructions to collect all urine within a 24-hour window. Participants were instructed to collect a 24-hour sample ending on the morning of the third home visit. As a reminder, participants were telephoned one day prior to collection to ensure protocol fidelity. Participants were instructed to keep samples cold by storage in refrigerators and were responsible for reporting the collection start and stop times. Study personnel retrieved the urine samples during the third home visit. Additionally, to account for intra-individual variation in sodium intake, we collected two 24-hour urinary sodium measures on a majority of participants. During the third home visit, participants were given a second collection device, jug, and instructions for their second urine collection to be

picked up on the fourth home visit, approximately one month later. Participants were again reminded one day prior to the second collection day, and the process was repeated as above.

2.3 Data Analysis

Data analyses were performed using Stata 11.0. Statistics including frequencies with percentages and means with standard deviations were used to describe patient characteristics as well as urine sodium excretion and urine creatinine excretion. Adherence to sodium restriction recommendations was determined if the subject's urinary sodium excretion was under investigator-determined cut-off values based on two national society recommendations for daily sodium consumption: <2 gm/day, and <3 gm/day. Various proportions of participants who maintained sodium restrictions were tested using proportion tests. Continuous and categorical variables were summarized for different subgroups. Summary statistics were presented and group differences were determined using either t – tests or chi square statistics. A multivariate logistic regression on dietary sodium adherence was performed using the least stringent recommendation of <3gm. This value was suggested as a possible target for Class C or D HF patients according to the latest ACCF/AHA recommendations.[4] A binary logistic regression analysis on excreted sodium (<3gm vs. ≥3gm) and clinically relevant covariates were performed on this cohort. In the single predictor unadjusted logistic regression analysis, the covariates with significant association, p-value<=0.25, with the binary outcome variable were used in the multivariable logistic regression model. The multivariate logistic regression model on urinary sodium excretion was developed using these relevant covariates to determine independent predictors and to assess for possible effect modification.

For participants who provided a second urine sample, an additional descriptive analysis was performed using the second urinary sodium samples. The consistency of urine sodium excretion between the two samples was analyzed using Bland-Altman plots. The sodium values for participants was determined and analyzed in similar fashion as the initial cohort.

To assess adequacy of sample collection, 24-hour urinary creatinine excretion was measured and compared to normative ranges for 24-hour urine creatinine excretion based on age, sex, race, and weight.[15] Participants with two urine samples within the normative ranges of excreted creatinine were analyzed separately in an effort to further control for collection variation. The consistency of urine collection was analyzed using Bland-Altman plots of urinary creatinine excretion in both samples.

3. Results

A flow diagram of the number of participants in the analyses is shown in Figure 1. 309 total patients were enrolled, but 4 patients were missing height and weight information and were excluded from the analysis. The remaining 305 participants provided at least one sample for the analysis, 261 provided two samples, and 168 provided two samples in creatinine-referenced normative ranges.

Baseline characteristics for the total sample, <3gm (i.e., “sodium adherent” n=147), and ≥3gm (“sodium non-adherent” n=158) are reported in table 1. For the total sample the mean

age was 69.0 ± 9.51 years, 64% were male, 72% white. The mean 24-hour urine sodium excretion was 3.15 ± 1.58 gm. The majority of subjects were non-adherent to <3 gm restriction (158 subjects, 52%) using a single sample from all participants. Figure 2 displays the percent adherence to two dietary sodium guidelines for the three analyses. A total of 147 subjects (48%) excreted less than 3 grams, but only 71 of these subjects (23% of total cohort) excreted less than 2 grams (Figure 2, blue columns).

An unadjusted single predictor logistic regression (table 2) revealed that in comparison to participants who excreted <3gm (i.e., "sodium adherent"), participants who excreted more sodium were more likely to be younger, higher BMI, male, and currently working. Race, enrollment site, educational level, smoking status, Charlson Comorbidity Score, NYHA class, ejection fraction, beta-blocker use, and angiotensin-converting enzyme inhibitor/ angiotensin II receptor blocker use were not different in the two groups. Only male sex and higher BMI were independent predictors of greater than 3gm of sodium excretion, reflecting sodium non-adherence (OR Male 2.38 (95% CI: 1.47-3.84 and OR for each unit BMI increase 1.05 (95% CI: 1.01-1.10) (Table 3).

Two samples were provided by 261 participants. Bland-Altman plots showed significant variability in urinary excreted sodium and urinary excreted creatinine between the first and second urine collections (figures 3A and 3B). When averaging both urine samples, the mean urinary sodium excreted was 3.12 ± 1.37 grams with 133 (51%) participants excreting less than 3 grams and 54 (21%) less than 2 grams (Figure 2, red columns).

In our study, 168 participants provided two urine samples with creatinine excretion appropriate for age, sex, race, and weight-adjusted reference ranges. Despite this, Bland-Altman plots showed persistent variability in urinary excreted sodium and creatinine between the first and second collections (figures 4A and 4B). The mean sodium excretion was 3.21 ± 1.20 in this population. Adherence rates based on dietary sodium intake of less than 3 gm/day was 46% while rates for less than 2 gm/day was 14% (Figure 2, green columns). Compared to the initial analysis of 305 subjects with one sample, restricting the analysis to participants with two, creatinine-referenced urine samples (n=168) resulted in significantly lower adherence rates to the 2-gm guidelines: 14% versus 23% (p=0.019).

4. Discussion

In this well characterized cohort of participants with chronic HF and reduced ejection fraction who were provided sodium restriction instruction as part of usual, contemporary care, we found that sodium consumption exceeded the limits recommended by our research team, the prior 2005 ACCF/AHA guidelines, and the most recent 2010 Heart Failure Society of America guidelines. Despite its emphasis in clinical practice, prior reports indicate that adherence to a low sodium diet is not typical in the HF population.[9, 10] The need to improve HF patient self-management, including sodium dietary adherence has been a motivating factor for AHA's "Get with the Guidelines" initiative. Additionally, controversy remains over whether dietary sodium restriction is even beneficial, in the HF population given reports of worse outcomes and evidence of higher neurohormonal activation in stringently restricted patients.[16, 17, 18] This controversy is reflected in the variability seen in dietary

recommendations from national societies as well as a general trend in personalizing the approach to sodium consumption to individual patients. In fact, the 2011 ACCF/AHA performance measures for HF suggests "individualized low-sodium" dietary education for patients. [19]

Although our study did not have a standardized education intervention, all subjects were approached by a research nurse and educated verbally and via handouts on a <2-gm dietary sodium restriction, in addition to standard clinical practice. Despite this, 48% of patients were adherent to the least stringent, <3 gram dietary sodium recommendation. This value is slightly higher than the 34-40% adherence rate reported by others and may reflect the additional dietary education individual patients received from the research nurse and the reinforcement of this during the home nursing visits. [10,20] Additionally, we found that male sex was a significant risk factor for non-adherence, consistent with prior reports of significantly lower sodium consumption in women.[8, 10,11] Higher BMI was also an independent predictor of non-adherence and may represent worse adherence with sodium or greater total food consumption. Interestingly, we found no differences in sodium consumption based on race, enrollment site, education, employment, HF symptom severity, Charlson comorbidity score, diuretic therapy, or neurohormonal blockade therapy.

This analysis represents an investigation into the dietary sodium adherence rates of HF participants but also provides insight on the use of 24-hour urine excretion as a tool to measure adherence. Data on the adherence of HF participants with dietary sodium restrictions in the context of dietary education and heart failure clinics is scarce. The complexities in accurately assessing adherence with dietary guidelines may account for the relative lack of published reports. Our study attempted to address these complexities by obtaining two 24 hour urine collections and evaluating the adequacy of collection using urinary creatinine utilizing a broadly representative patient population from both academic and community-based health systems.

Our results indicate that a 24-hour urine test can be performed by adults in their homes and a majority of our participants provided two separate urine collections. Multiple collections enabled analysis of data reproducibility. We measured 24-hour urinary creatinine excretion referenced to previously published norms in a non-HF population. Our final step was to restrict our analysis to samples within normative ranges of 24-hour urinary creatinine, thereby reducing collection variability. Interestingly, 93 out of 261 patients who provided two urine samples failed to provide samples within normative ranges of 24-hour creatinine. This occurred despite a research assistant visiting the participant's home on the day prior to both 24-hour urine collections to inform and remind him or her. To our knowledge, the use of 24-hour urine creatinine to verify collection accuracy is not commonly seen in the HF literature. As we saw with our own data, one would expect even lower adherence rates than previously reported by only analyzing samples within normative creatinine ranges. Despite these methodological considerations, our two-sample cohort had relatively poor reproducibility of both sodium and creatinine. This implies that sodium consumption likely varies day to day as does the quality of 24-hour urine collection. A greater number of repeated samples may be necessary to improve this accuracy even further, but must be balanced with practicality and cost considerations.

Limitations to the study must be noted. Principally, the education our study participants received was not standardized, but reflected "real life" contemporary practice in a heart failure clinic setting. Although our study protocol employed educational materials and advice to adhere to a <2GM sodium restriction, the amount of face-to-face counseling our participants received by dietician, nurse, or physician may have varied. The degree of sodium restriction recommended by the provider to our study participants was not standardized and may have varied significantly. This may have been related to differences in the functional class of our patients (ie, a functional class II patient may have been advised to restrict sodium differently than a functional class III patient). However, the purpose of this analysis was not to assess the affect of an educational intervention, but rather to simply describe the sodium consumption of a "real world" chronic HF population. Using 24-hour urine sodium excretion to estimate dietary consumption has a number of potential limitations and our study participants did not provide food diaries to allow us to corroborate urine measurements with self-reported adherence data. Sodium homeostasis may be altered due to neurohormonal activation and diuretic use. Nevertheless, there is limited evidence to suggest that this alteration may stabilize in compensated HF patients on neurohormonal antagonist therapy.[7] The majority of participants in our study were on beta-blockers and angiotensin converting enzyme inhibitors and/or angiotensin II receptor blockers; all participants were either on a stable diuretic regiment or not on a diuretic at all. Furthermore, the single and multivariable analyses showed that diuretic use did not predict adherence with a 3-gram sodium diet.

Although its benefits may be debatable, sodium restriction continues to be a mainstay in the management of HF patients in the US and worldwide. Despite its prescription, the majority of even well informed, chronically followed HF patients remain non-adherent. A combination of a food diary and multiple, repeated 24-hour urine samples might be the best available way to monitor adherence. To improve adherence, however, a greater understanding of barriers to HF self-management is necessary.

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HIGHLIGHTS

- We evaluated dietary sodium restriction in chronic patients with heart failure with reduced ejection fraction
- We utilized 24-hour urinary sodium excretion to estimate sodium consumption
- Two samples and urinary creatinine were utilized to evaluate sample variability and adequacy
- Adherence to dietary sodium guidelines was poor
- Urine analytes were not highly reproducible

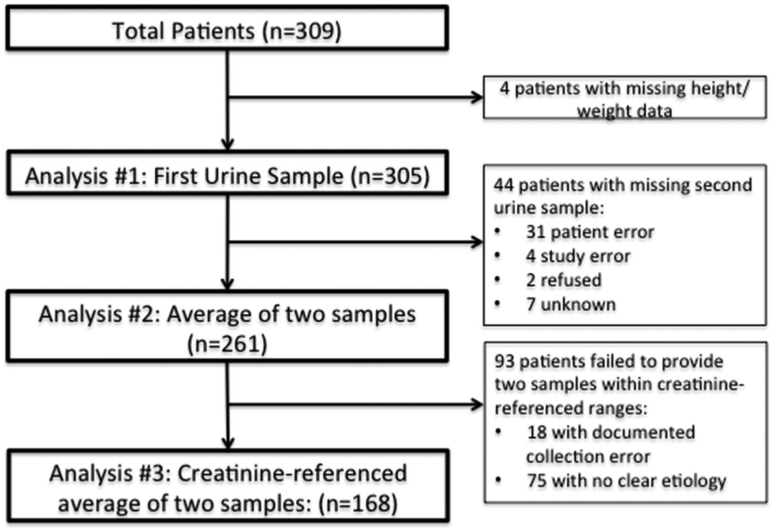


Figure 1.

Flow Diagram of Number of Participants in the Analyses.

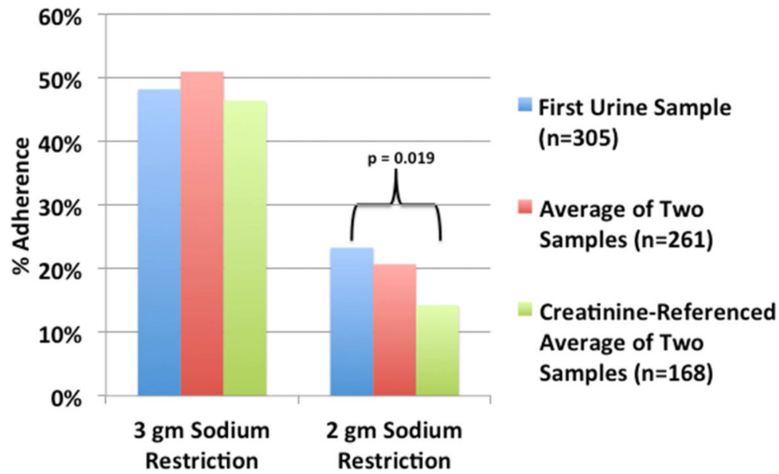
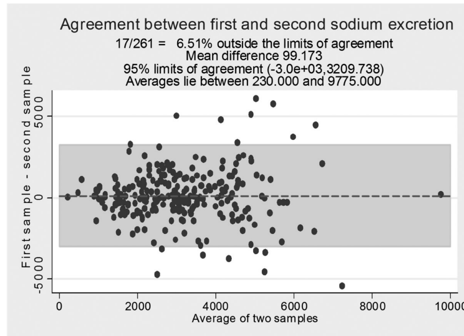


Figure 2.
Percent Adherence to Dietary Sodium Guidelines

A



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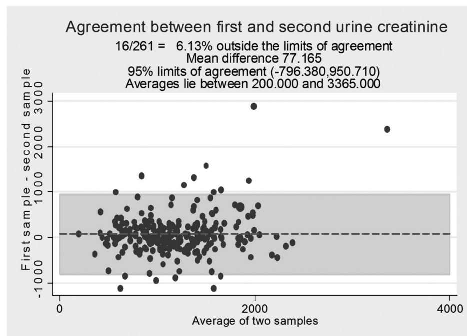
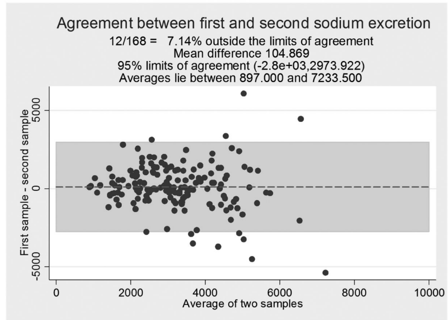


Figure 3.

Agreement between first and second urine sodium samples (n=261) (A) and first and second urine creatinine sample (B)

A



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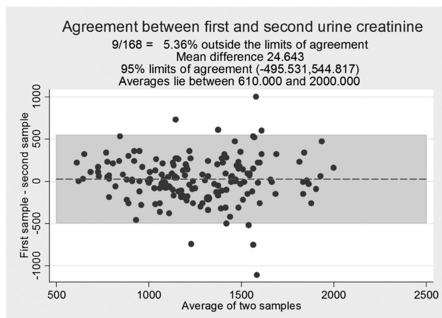

Figure 4.

Agreement between first and second samples in patients with urinary creatinine excretion in normative range (n=168) for urinary excreted sodium (A) and urine excreted creatinine (B)

Table 1

Baseline Characteristics of the study participants

Characteristic	Total N=305 N (%)	<3gm/day N=147 N (%)	≥3gm/day N=158 N (%)	p-value
Age				
50-64 years	105 (34.4)	43(41.0)	62(59.0)	0.070
65-74 years	96 (31.5)	45(46.9)	51(53.1)	
75+ years	104(34.1)	59(56.7)	45(43.3)	
Sex				
Male	195 (63.9)	79(40.5)	116(59.5)	<0.001
Female	110(36.1)	68(61.8)	42(38.2)	
Race				
White	220 (72.1)	105(46.9)	119(53.1)	0.442
Black	81 (26.6)	42(51.9)	39(48.1)	
Enrollment Location				
Cleveland	166 (54.4)	80(48.2)	86(51.8)	0.999
Akron	139 (45.6)	67(48.2)	72(51.8)	
Highest Education Level				
Less than high school	34 (11.2)	17(50.0)	17(50.0)	0.926
High school	85 (27.9)	42(49.4)	43(50.6)	
More than high school	186 (61.0)	88(47.3)	98(52.7)	
Employment Status				
Working	80(26.3)	30(37.5)	50(62.5)	0.026
Retired/unemployed	225 (73.8)	117(52.0)	108(48.0)	
Current Smoker	35 (11.5)	18(51.4)	17(48.6)	0.684
Charlson Comorbidity Score				
0-3	178 (58.4)	86(48.3)	92(52.7)	0.878
4-5	91 (29.8)	46(29.5)	45(30.2)	
6+	36 (11.8)	16(10.3)	20(13.4)	
NYHA				
1 or 2	119 (39)	56(47.1)	63(52.9)	0.750
3 or 4	189 (61)	91(48.9)	95(51.1)	
Currently on Beta-blocker	266 (87.2)	128 (48.1)	138(51.9)	0.944
Currently on ACE/ARB	234 (76.7)	110(47.0)	124(53.0)	0.451
Currently on diuretic	198 (64.9)	100(48.8)	105(51.2)	0.705

	X (SD)	X (SD)	X (SD)	p-value
Age	69.0(±9.5)	70.35 (± 9.59)	67.67 (±9.27)	0.014
BMI (kg/m2)	30.0 (±6.8)	28.67(±5.8)	31.18(±7.4)	0.003
Ejection Fraction	31.7 (±11.4)	31.7(±11.2)	31.7(±11.5)	0.970

BMI=Body Mass Index NYHA=New York Heart Association ACE-i/ARB= Angiotensin-Converting-Enzyme Inhibitor/Angiotensin Receptor Blockers. Means and standard deviations are presented for continuous variables. Sample size and percentages are presented for categorical variables. Comparison of high versus low sodium excretion performed using two-sample t-test (continuous) and chi-square tests (categorical).

Table 2

Unadjusted Single Predictor Logistic Regression Analysis Relating Demographic and Clinical Variables on Non-Adherence with 3gm Sodium Restriction

Characteristic	Odds Ratio	95% Confidence Interval	P> |z|
Age			
50-64 years	--	--	--
65-74 years	0.79	0.45-1.37	0.398
75+ years	0.53	0.31-0.92	0.023
Sex Male	2.38	1.47-3.84	<0.001
Race			
White	--	--	--
Black	0.82	0.49-1.36	0.443
Enrollment Site			
Cleveland	--	--	--
Akron	1.00	0.64-1.57	0.999
Education			
Less than High School	--	--	--
High School	1.02	0.46-2.27	0.954
More than High School	1.11	0.54-2.31	0.773
Employment			
Not Working/Retired	--	--	--
Currently Working	1.81	1.07-3.04	0.027
Active Smoker	0.86	0.43-1.74	0.684
BMI	1.05	1.01-1.10	0.004
Charlson Co-morbidity			
0-3	--	--	--
4-5	0.96	0.58-1.58	0.860
6+	1.17	0.57-2.40	0.672
NYHA			
Low (1-2)	--	--	--
High (3-4)	0.93	0.59-1.47	0.750
Ejection Fraction			
>=50%	--	--	--
35-50%	0.80	0.46-1.41	0.442
<=35%	1.16	0.50-2.67	0.727
Medications			
On Beta-Blocker	1.02	0.52-2.01	0.944
On ACE/ARB	1.23	0.72-2.09	0.451
On Diuretic	0.91	0.56-1.47	0.705

Table 3

Multivariable Logistic Regression Analysis Relating Demographic and Other Variables on Non-Adherence with 3gm Sodium Restriction

Characteristic	Odds/ratio	95% Confidence Interval	P> |z|
Age			
50-64 years	0.67	0.35-1.28	0.226
65-74 years			
75+ years	0.62	0.32-1.20	0.159
Sex			
Male	2.20	1.25-3.88	0.006
Education			
Less than High School			
High School	1.12	0.42-3.00	0.822
More than High School	1.16	0.46-2.93	0.758
Employment			
Not Working/Retired			
Currently Working	1.37	0.76-2.49	0.294
Body Mass Index	1.05	1.01-1.10	0.012
On Diuretic	1.03	0.59-1.81	0.911