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Feasibility of Assessing Sodium Associated Body Fluid Composition in End-Stage Renal Disease

Maya N. Clark-Cutaia, PhD, ACNP-BC, RN,

Assistant Professor, Rory Meyers College of Nursing, New York University, New York, NY

Nathaniel Reisinger, MD,

Professor, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Maria Rita Anache, BS,

Research Assistant, School of Osteopathic Medicine, Rowan University, Stratford, NJ

Kara Ramos, BSN,

Research Assistant, School of Nursing, University of Pennsylvania, Philadelphia, PA

Marilyn S. Sommers, PhD, RN, FAAN,

Professor Emerita, School of Nursing, University of Pennsylvania, Philadelphia, PA

Raymond R. Townsend, MD,

Professor, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Gary Yu, DrPH, MPH, and

Associate Research Scientist, Rory Meyers College of Nursing, New York University, New York, NY

Jamison Fargo, PhD, MS, Epi

Professor, Utah State University, Logan, UT

Abstract

Background: Cardiovascular disease accounts for more than half of all deaths in the hemodialysis (HD) population. While much of this mortality is associated with fluid overload (FO), FO is difficult to measure, and many HD patients have significant pulmonary congestion

Author Note: **Maya N. Clark-Cutaia, PhD, ACNP-BC**, Assistant Professor, New York University, Rory Meyers College of Nursing, New York, NY. Dr. Clark-Cutaia was Lecturer in the Biobehavioral Health Sciences Department, the University of Pennsylvania when the research was completed. **Nathaniel Reisinger, MD**, Nephrology Resident, Hypertension Program, and Professor of Medicine, the Hospital of the University of Pennsylvania, Philadelphia, PA. **Maria Rita Anache, BS**, Research Assistant, Rowan University, School of Osteopathic Medicine, Stratford, NJ. **Kara Ramos, BSN**, Research Assistant, University of Pennsylvania, School of Nursing, Philadelphia, PA. **Marilyn S. Sommers, PhD, RN, FAAN**, Professor Emerita, University of Pennsylvania, School of Nursing, Philadelphia, PA. Marilyn Sommers, PhD, RN, FAAN, was Professor Emerita, the University of Pennsylvania was the Lillian S. Brunner Professor of Medical-Surgical Nursing during the time that the work for this study was completed. **Raymond Townsend, MD**, Director, Hypertension Program, and Professor of Medicine, the Hospital of the University of Pennsylvania, Philadelphia, PA. **Gary Yu, DrPH, MPH**, Associate Research Scientist, New York University, Rory Meyers College of Nursing, New York, NY. **Jamison Fargo, PhD, MS-EPI**, Professor, Utah State University, Logan, UT. Corresponding author: Maya N. Clark-Cutaia, PhD, ACNP-BC, RN NYU Meyers College of Nursing, 433 First Avenue, Room 664, New York, NY 10010 (MC7009@NYU.EDU).

The authors have no conflicts of interest to report.

Ethical Conduct of Research: The study investigators are committed to advancing and safeguarding the highest academic and ethical standards by conducting ethical and responsible clinical research activities. The study was approved by the Institutional Review Board, as were written informed consent and HIPAA release forms. Data and safety monitoring was executed throughout the study.

despite the absence of clinical presentation. Cohort studies have observed that FO, as measured by bioimpedance spectroscopy (BIS), correlates with mortality. Other studies have observed that lower sodium intake is associated with less fluid-related weight gain, improved hypertension, and survival. Whether sodium intake influences FO in HD patients as measured by BIS is not known.

Objective: To determine the feasibility of assessing the impact of sodium restriction on body fluid composition as measured by BIS among patients with three levels of sodium intake; to determine if there are statistical and/or clinical differences in BIS measures across sodium intake groups.

Methods: We used a double-blinded randomized controlled trial design with three levels of sodium restriction: 2400mg per day, 1500mg per day, and unrestricted (control group) to test our aims. Forty-two HD patients from a tertiary acute care academic institution associated with three urban DaVita dialysis centers were enrolled. Participants remained in the inpatient center for five days and four nights, and were randomly assigned to sodium intake groups. Body fluid composition was measured with BIS.

Results: Recruitment, enrollment, and retention statistics supported the feasibility of the study design. Regression analyses showed that there were no statistically significant differences among sodium intake groups on any of the outcomes.

Discussion: Our data suggest the need for additional research into the effects of sodium restriction on body fluid composition.

Clinical Trial Registration:

<http://Clinicaltrials.gov> Identifier: NCT02778516. Sodium-restricted Diets and Symptoms in End Stage Renal Disease: An RCT.

Keywords

kidney failure; chronic; renal dialysis; sodium; body composition

End-stage renal disease (ESRD) affects 723,413 patients in the United States; the majority of these patients undergo renal replacement therapy via hemodialysis (HD) (United States Renal Data System [USRDS], 2016). Patients on HD have increased mortality averaging 17% per patient year; cardiovascular disease accounts for more than half of all known causes of death in this population (USRDS, 2016). Much of the mortality is associated with fluid overload (FO; Agarwal, 2010; Chazot et al., 2012; Wizemann et al., 2009; Zocalli et al. 2017), which contributes to cardiovascular morbidity and mortality via longstanding pressure and volume overload contributing to hypertension and leading to left ventricular hypertrophy (LVH) (Cader, Ibrahim, Paul, Gafor, & Mohd, 2014; Xu, et al., 2013). Yet, FO is difficult to measure and many patients have significant pulmonary congestion despite the absence of pulmonary rales or pedal edema (Torino et al., 2016; Zocalli et al., 2013).

HD patients have no residual renal function; they lack the ability to excrete sodium and water consumed throughout the day, resulting in fluid-related weight gains (Clark-Cutaia, Ren, Hoffman, Snetslaar, & Sevvick, 2013). Thus, sodium restriction has been a standard treatment recommendation for decades. Lower sodium intake is associated with less

interdialytic weight gain (IDWG), improved intradialytic blood pressure, and survival (Maduell & Navarro, 2000). Dietary restriction of sodium appears to improve blood pressure, LVH, and intradialytic hypotension (Kayikcioglu et al., 2009; Maduell & Navarro, 2000). As a result, sodium restriction is a universal recommendation for ESRD management. The National Kidney Foundation (NKF) recommendation of 2400mg per day is consensus—rather than evidence-based. The Dietary Guidelines for Americans 2010 recommend restriction of dietary sodium intake to 1,500mg per day for persons with hypertension and/or chronic kidney disease, although little empiric evidence exists to support this recommendation. Additionally, the Institute of Medicine failed to find sufficient evidence of either harm or benefit from sodium restriction at either level of restriction (Clark-Cutaia, Sommers, Anderson, & Townsend, 2016). Little is known about the appropriate degree of sodium restriction nor the clinical outcomes resulting from different levels of sodium restriction (NKF, 2015).

Bioimpedance spectroscopy (BIS)—a noninvasive instrument used to estimate body composition by applying a small alternating current at various frequencies—provides a way to accurately assess FO. Bioimpedance measures the opposition to the flow of electrical current through tissues. In the human body, only water with its dissolved electrolytes will conduct a current. Using validated estimation equations, BIS provides data on body composition including fat mass and fat free mass, extracellular water (ECF), intracellular water (ICF), and total body water (TBW) (Davenport, 2013; Davies & Davenport, 2014; Khalil, Mohktar, & Ibrahim, 2014). The goal of HD is to reduce both ECF and TBW, as well as remove excess solutes and waste.

Multiple cohort studies have demonstrated that FO as measured by BIS correlates with all-cause mortality in patients on HD (Chazot, et al., 2012; Kim, Jeon & Kim, 2015; Machek, Jirka, Moissl, Chamney, & Wabel, 2010). Zoccali and colleagues (2013) published a multicenter prospective cohort study of patients on HD who had FO measured by BIS and demonstrated it was associated with cardiovascular outcomes and mortality independent of blood pressure tertile. Additionally, patients with greater degrees of FO experienced poorer outcomes (Zocalli et al., 2017). Randomized controlled trial (RCT) data have shown that ultrafiltration prescription enhanced by BIS measurement improved LVH, blood pressure, and arterial stiffness in one study, and all-cause mortality in another. Relatively small changes in FO drove these results, and BIS was able to detect these differences (Hur et al., 2013; Onofriescu et al., 2014).

Theoretically, patients with lower dietary sodium intake would have lower ECF volume. ECF to ICF ratios have been implicated as a risk factor for cardiovascular and all-cause mortality in patients undergoing HD (Lin et al., 2003). Bioimpedance ECF and ECF% reflect hypervolemia (Arslan & Tuncalp, 2017; Kotanko, Levin, & Zhu, 2008). Arslan and Tuncalp (2017) found a reduction in sodium intake resulted in a reduction in ECF in patients that completed diet and fluid education. Whether sodium intake has an influence on FO in patients with ESRD on HD, and over what period of time, is not known. We had two study aims:

1. determine the feasibility of assessing the impact of sodium restriction on body fluid composition as measured by BIS among patients with three levels of sodium intake; and
2. determine if there are statistical and clinical differences in BIS measures across sodium intake groups.

Methods

We piloted a double-blinded RCT to assess the feasibility of our procedures and to determine the impact of dietary sodium intake restriction on HD patient outcomes. The complete study design and methods were previously described elsewhere (Clark-Cutaia, Sommers, Anderson, & Townsend, 2016).

Sample

The 42 participants were recruited from three urban DaVita dialysis centers associated with a tertiary acute care academic institution. Inclusion criteria were persons 21 years of age, who had the ability to read and write English, were undergoing maintenance HD, and had been on therapy for at least three months. Exclusion criteria were persons who intended to move out of the area or change HD centers within six months, had terminal illness or life expectancy of less than 12 months, planned to receive a living donor transplant in the study period, had cognitive impairment, were unable to provide informed consent, had New York Heart Association Class III or IV heart failure, had an internal defibrillator or pacemaker, and/or were pregnant. Because this was a pilot study, we excluded Spanish-speaking participants.

Intervention

The study was approved by the institutional review board and potential participants provided written informed consent and HIPAA release forms. Participants were randomly assigned to one of three sodium intake groups at baseline: 1,500mg of daily sodium, 2,400mg of daily sodium, or a control group with unrestricted daily sodium (these participants selected from a restaurant style menu and their sodium intake calculated based on consumption). Participants were admitted to an inpatient research unit for five days and four nights. The inpatient research unit Nutrition Core created an iso-caloric menu that varied only in sodium content to administer the randomized dietary sodium intake (mg/d). Remaining food items on each tray were collected, blended, and analyzed for remaining sodium content, which was then deducted from the dietary sodium intake total. All meals and snacks were provided by the Nutrition Core.

Measures

Demographic and health status data were obtained through self-report using a questionnaire adapted from previous studies conducted by the co-investigators. Patients were transported to and from their regularly scheduled HD sessions on admission Days 1, 3, and 5 of the 5-day study period. HD-related variables (ultrafiltration, rate, and total fluid removed) were abstracted from the postdialysis electronic medical record on dialysis days.

Body fluid composition was measured with BIS (ImpediMed® Imp_SFB7, ImpediMed Limited, Queensland, Australia). Measurements included TBW, ECF, and ICF in percentage (%). Three consecutive measurements were taken on the surface of the skin by placing electrodes on the right hand and right foot before and after dialysis. The average of these measurements was used for analysis.

Statistical Analyses

Descriptive statistics were computed for all study variables, which were then compared in terms of their distributions across sodium intake groups using chi-square (χ^2) tests for categorical and 1-way ANOVA for continuous variables. We conducted a set of three regression analyses with TBW, ICF, and ECF as outcomes with the following set of covariates: Day 1 TBW, intracellular or extracellular fluid; demographics (age, gender, race); health (tobacco use, alcohol use, perceived general health, years on hemodialysis); and sodium intake group membership (unrestricted, 1,500mg, 2,400mg). Regression models were run with and without sodium intake group membership and change in R^2 was tested with an F -test. Analyses were conducted using IBM SPSS Statistics version 23.

Results

We approached 50 potential study participants; all but one met inclusion criteria. The first 42 signed informed consent and were enrolled into the study. Two patients withdrew from the study due to illness unrelated to the study during the intervention phase, for a total sample of 40 participants. Our overall retention rate was 95%. After controlling for other variables, given a small-to-moderate effect of sodium intake group membership on our outcomes (R^2 change = .02 - .13 [Cohen's f^2 = .02 - .15]), a sample of 42 participants (14 per group), and an alpha of .05, we were able to achieve power in the 15%-69% range.

Our sample was overwhelmingly African American (85%), reported hypertension as the etiology of ESRD (45%), was balanced in terms of sex (male, 52.5%), and had a mean age of 56 years ($SD = 11.7$) (see Table 1). The majority of participants perceived their health to be at least "good" (55%). Seventy-five percent reported never using tobacco and 65% reported never consuming alcohol. For the total sample on Day 1, (1) mean dietary sodium intake was 1987.93mg Na ($SD = 1316.5$); (2) baseline (before HD on Day 1) IDWG was 2.62kg ($SD = 1.5$); (3) symptom/problem scale score was 79.63 ($SD = 12.5$); (4) ultrafiltration rate was 1.41 ($SD = 0.20$); (5) ICF was 54.89 ($SD = 10.2$); (6) ECF was 42.53 ($SD = 8.4$); and (7) TBW was 49.89 ($SD = 12.8$). On average, 2.80 liters were removed at the baseline HD session ($SD = 1.1$).

Results of regression models showed there were no statistically significant differences in TBW (Table 2), ICF (Table 3), or ECF (Table 4) among sodium intake groups. Except for etiology of HD, no predictor variables were significantly associated with any of the outcomes. Adjusting for all other predictors and regardless of sodium intake group membership, those with a diabetes etiology had significantly higher levels of ICF and ECF as compared to those with a hypertension etiology, (both $p < .02$). Hypertensive individuals had on average a 15 unit ($p = .013$) decrease in the intracellular fluid volume variance and an 11 unit ($p = .021$) decrease in the extracellular fluid volume variance compared to diabetics.

Discussion

We determined that a study of this magnitude—using these particular methods—is feasible. The PI and the research staff developed a rapport with the dialysis centers' staff and as a result, patient referral and self-referral was accomplished easily. Prior to the study, we were concerned that we would not be able to retain patients for the entire the hospital stay, or provide prepared meals that the participants would find palatable. Our recruitment, enrollment, and retention statistics allayed these concerns. We conducted a satisfaction survey in preparation for reproducing this study and found that 79% of patients would participate in a similar study in the future if contacted. Anecdotally, patients recounted the intervention phase of the study as a “vacation” or a “break” from their day-to-day lives.

We found no statistically significant differences in fluid volume body composition in our sample of HD patients regardless of group assignment. Although we did not have sufficient power to reach statistical significance, the control group had higher ECF and lower ICF volumes than the two sodium restriction groups.

In our study sample, participants who identified diabetes as the cause of their ESRD had significantly higher ICF and ECF than those with ESRD caused by hypertension. This is a potentially interesting phenomenon within this subsample of patients with respect to fluid compartments. A multicenter trial demonstrated that diabetic HD patients were had greater fluid volume between dialysis sessions than nondiabetics (Davenport, Cox, & Thuraishingham, 2008). Similarly, diabetic control or lack thereof was linked to greater fluid volume in another sample of HD patients (Ramdeen, Tzamaloukas, Malhotra, Leger, & Murata, 1998). McCafferty, Fan, and Davenport (2014) found that patients in their sample with diabetes also had higher hydration status at baseline and at follow-up. From the analyses we conducted to address our study aims, we were unable to extrapolate any conclusions other than those already posited by previous investigations into the phenomenon.

Limitations

While this preliminary work confirmed the feasibility of a RCT testing three levels of sodium intake in patients with ESRD on hemodialysis, our study was limited by a small sample size, which was not meant to provide an effect size calculation. Further, we were unable to completely control the patient's length of stay. The inpatient stay was not a five full days, as patients were admitted after and discharged before their dialysis sessions on Days 1 and 5, respectively. The mean length of stay was approximately 4.5 days and 4 nights. BIS measurements were conducted only by the study staff trained under by the primary investigator. However, environmental and participant circumstances outside of our control may have created error in the measurements. Further, strict control of dietary sodium intake required 24-hour oversight by inpatient nursing and nutrition staff, dialysis center nursing staff, and study staff. It is possible that some patients received food not on their prescribed diets by trading snacks or elements of their food tray without our knowledge.

Conclusion

Our data suggest the need for additional research into the practicality of BIS to assess the effect of sodium restriction on body fluid composition, but offer the first insight into how this effect can be assessed using BIS. Furthermore, we have developed a well-tolerated, methodologically sound investigation into body composition and sodium intake, despite the paucity of literature available in this regard. We will reproduce this study with a larger, more diverse sample in the future.

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The study was approved by the Institutional Review Board at University of Pennsylvania.

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Table 1

Baseline Categorical Descriptive Statistics

Variable	Total Sample: N (%)	CG: n (%)	1500 mg: n (%)	2400 mg: n (%)	$\chi^2(df)$	p-value
Race/Ethnicity					11.98 (8)	.035*
African American, Black, African, Afro-Caribbean: not of Hispanic origin	34 (85)	10 (66.7)	10 (90.9)	14 (100)		
Other	6 (15)	5 (33.3)	1 (9.1)	0		
Etiology					5.4 (6.0)	.494
Hypertension	18 (45)	5 (33.3)	7 (63.6)	6 (42.9)		
Diabetes	9 (22.5)	3 (20)	3 (27.3)	3 (21.4)		
Other	12 (30)	7 (46.7)	1 (9.1)	5 (35.7)		
Sex					1.07 (2.0)	.585
Female	19 (47.5)	7 (46.7)	4 (36.4)	8 (57.1)		
Male	21 (52.5)	8 (53.3)	7 (63.6)	6 (42.9)		
Tobacco Use					7.63 (2.0)	.022*
Yes	30 (75)	14 (93.3)	9 (81.8)	7 (50)		
No	10 (25)	1 (6.7)	2 (18.2)	7 (50)		
Alcohol Use					13.1 (6.0)	.041*
Never	26 (65)	13 (86.7)	8 (72.7)	5 (35.7)		
Monthly or less	9 (22.5)	1 (6.7)	2 (18.2)	6 (42.9)		
2 to 4 times a month	4 (10.0)	1 (6.7)	0	3 (21.4)		
2 to 3 times a week	0	0	0	0		
4 or more times a week	1 (2.5)	0	1 (9.1)	0		
Perceived General Health					7.14 (8)	.522
Excellent	3 (7.5)	2 (13.3)	0	1 (7.1)		
Very Good	6 (15.0)	3 (20)	1 (9.1)	2 (14.3)		
Good	13 (32.5)	3 (20)	3 (27.3)	7 (50)		
Fair	15 (37.5)	5 (33.3)	6 (54.5)	4 (28.6)		
Poor	3 (7.5)	2 (13.3)	1 (9.1)	0		

Note. CG = control group.

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$$*p < .05$$

Table 3

Intracellular Fluid Volume Variance Among Sodium Intake Groups

Predictor	Model 1					Model 2				
	β	SE	Lower Limit	Upper Limit	p-Value	β	SE	Lower Limit	Upper Limit	p-Value
	95% Confidence Interval					95% Confidence Interval				
	R^2					R^2			R^2 Change	
Intercept	53.3	24.7	2.8	103.7	.039 *	51.02	26.1	-2.5	104.5	.061
Hypertension vs. Other	1.28	5.5	9.9	12.5	.816	1.09	5.8	-10.8	10.8	.852
Hypertension vs. Diabetes	-15.03	5.2	-25.7	-4.3	.007 *	-14.78	5.6	-26.2	-3.3	.013 *
Race	-1.04	7.1	-15.5	13.4	.884	-1.13	7.8	-17.1	14.9	.886
Sex	1.39	4.6	-8.1	10.9	.767	1.92	5.0	-8.3	12.1	.704
Age	-0.09	0.33	-0.54	0.4	.680	-0.08	0.23	-0.55	0.40	.749
Tobacco Use	6.76	5.2	-3.8	17.3	.202	5.84	6.0	-6.5	18.2	.341
Alcohol Use	2.22	2.3	-2.6	7.0	.349	1.99	2.6	-3.2	7.2	.441
Perceived General Health	1.03	2.2	-3.5	5.5	.642	1.14	2.3	-3.6	5.9	.627
Day 1 Intracellular Fluid volume	0.01	0.21	-0.43	0.44	.976	-0.00	0.23	-0.47	0.46	.988
Control Group vs. 1500mg Group	--	--	--	--	--	0.86	6.96	-11.35	13.06	.887
Control Group vs. 2400 mg Group	--	--	--	--	--	1.55	6.28	-11.31	14.40	.807
1500 mg Group vs. 2400 mg Group	--	--	--	--	--	2.40	5.97	-9.82	14.62	.691

Note. CG = control group.

* $p < .05$

Table 4

Extracellular Fluid Volume Among Sodium Intake Groups

Predictor	Model 1					Model 2				
	β	SE	Lower Limit	Upper Limit	p-Value	β	SE	Lower Limit	Upper Limit	p-Value
	95% Confidence Interval					95% Confidence Interval				
	R^2					R^2			R^2 Change	
Intercept	24.38	19.3	-15.0	63.8	.216	22.91	20.41	-18.90	64.72	.271
Hypertension vs. Other	1.26	4.5	-7.9	10.5	.781	0.59	4.79	-9.22	10.40	.902
Hypertension vs. Diabetes	-10.90	4.3	-19.7	-2.1	.017*	-11.15	4.56	-20.49	-1.82	.021*
Race	0.24	5.9	-11.8	12.3	.968	1.52	6.69	-12.19	15.23	.822
Sex	-1.05	3.8	-8.8	6.7	.785	-0.86	4.08	-9.22	7.50	.835
Age	0.10	0.19	-0.29	0.49	.600	0.11	0.20	-0.30	0.51	.593
Tobacco Use	4.68	4.2	-4.0	13.3	.277	4.74	4.93	-5.35	14.83	.344
Alcohol Use	1.62	1.9	-2.3	5.6	.408	1.80	2.14	-2.59	6.18	.409
Perceived General Health	1.59	1.8	-2.0	5.2	.379	1.80	1.87	-2.03	5.63	.344
Total Body Water Day 1	0.20	0.23	-0.28	0.67	.411	0.14	0.27	-0.41	0.68	.613
Control Group vs. 1500mg Group	--	--	--	--	--	2.81	5.19	-7.81	13.44	.592
Control Group vs. 2400 mg Group	--	--	--	--	--	-0.95	5.26	-11.73	9.82	.858
1500 mg Group vs. 2400 mg Group	--	--	--	--	--	1.86	4.91	-8.20	11.92	.708

Note. CG = control group.

* $p < .05$