Clinical Trials

A Randomized Controlled Pilot Study of Outcomes of Strict Allowance of Fluid Therapy in Hyponatremic Heart Failure (SALT-HF)

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ABSTRACT

Background: Currently, fluid restriction recommendations in heart failure (HF) are based on expert opinion. After implementing a 1,000-mL/d fluid restriction for 60 days after discharge, outcomes were examined.
Methods and Results: In a randomized controlled design, hyponatremic patients (serum sodium ≤137 mg/dL) received usual care (UC; n = 26) or 1,000 mL/d fluid restriction (n = 20) at discharge. Quality of life (QoL), thirst, difficulty following fluid recommendations, adherence to fluid restriction, HF emergency care, HF rehospitalization, and all-cause death were examined. Mean age was 62.8 ± 12.8 years; 46% were white. There were no differences by group in baseline demographics, comorbidities, and QoL, except that more UC patients had New York Heart Association (NYHA) functional class III/IV status ($P = .019$). Median [interquartile range] QoL scores were better in the 1,000 mL/d group for symptom burden (83.3 [68.8−91.7] vs 50 [29.2−79.2]; $P = .018$), total symptoms (77.1 [58.1−91.7] vs 54.2 [30.2−73.9]; $P = .022$), overall QoL summary (72.6 [52.2−86.3] vs 51.0 [37.7−68.5]; $P = .038$), and clinical QoL summary (75.5 [57.8−92.9] vs 59.1 [35.7−77.3]; $P = .039$). There were no group differences in thirst, difficulty adhering to fluid recommendations, adherence to fluid restriction, or health care consumption.
Conclusions: The 1,000 mL/d fluid restriction led to improved QoL at 60 days after discharge. Future research in a larger more heterogeneous sample is needed. (*J Cardiac Fail 2013;19:1−9*)
Key Words: Fluid restriction, quality of life, thirst, fluid adherence.

Nonpharmacologic treatment in patients with chronic heart failure (HF) and hypervolemia, especially in the setting of hypervolemic or euvolemic hyponatremia, includes restricting daily fluid intake. Although specific recommendations for fluid restriction in the treatment of hyponatremia vary in the literature, it is cited as the cornerstone of therapy.[1] In asymptomatic hyponatremic[1] and elderly hypervolemic hyponatremic[2] patients, 800 mL/d or less was recommended to achieve a negative water balance; however, these fluid recommendations were not specific to patients with HF. In a pilot randomized controlled study of sodium and fluid restriction in patients with HF and normal serum sodium levels, intervention patients (n = 17) received 1,500 mL/d fluid restriction and 2−3 g/d sodium-restricted diet for 12 weeks. Intervention patients reduced fluid intake to a mean (SD) of 1,200 (500) mL/d that was significantly better than control subjects[3]; however, no clinical outcomes were measured. When fluid intake was assessed in 63 patients with chronic stable HF, mean intake was 20 mL kg^{-1} d^{-1} or ∼1,740 mL/d.[7] After categorizing patients based on median fluid intake per day, those with fluid intake above the median value had a decreased sense of thirst, but there were no differences in quality of life (QoL), symptoms, body weight, physical capacity, or diuretic use compared with those who restricted fluid intake to a greater degree.[4]

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The American College of Cardiology and American Heart Association[5] and Heart Failure Society of America[6] chronic HF guidelines recommend a 2,000 mL/d fluid restriction to control fluid retention in patients with stage D HF with persistent and recurrent hypervolemia despite sodium restriction and high-dose diuretics[5] and in patients with severe hyponatremia (serum sodium <130 mEq/L).[6] Further, a 2,000 mL/d fluid restriction should be considered in patients with fluid retention that is not controlled with diuretic therapy and a sodium-restricted diet.[6] Despite current HF guideline recommendations, many health care providers order fluid restriction as one of many self-care management strategies in patients with intermittent or persistent New York Heart Association functional class (NYHA-FC) III/IV symptoms, regardless of the current HF stage.[7] Without randomized controlled studies, expert opinion and limited evidence prevail when considering fluid restriction recommendations.

Methods

Setting and Patients

The Strict Allowance of Fluid Therapy in Hyponatremic Heart Failure (SALT-HF) study design was a single-center, parallel-group, single-blind, randomized controlled pilot trial that investigated the effects of 1,000 mL/d fluid intake restriction. The main campus of the Cleveland Clinic, a $>1,200$ bed quaternary-care referral and transplant medical center in northeastern Ohio, was the recruitment site. In 2010, patients hospitalized for acute decompensation of chronic HF were recruited if they had hypervolemic or euvolemic hyponatremia, defined as a serum sodium ≤ 137 mg/dL any time during the hospitalization episode, regardless of HF dysfunction from reduced or preserved ejection fraction. In research studies of routine laboratory results during hospitalization with acute decompensated HF, trends in 1-year mortality, as a function of serum sodium levels, increased when serum sodium levels were <137.6 mg/dL[8] and <138 mg/dL.[9] Additionally, in a study of elderly community subjects, even mild hyponatremia, defined as a serum sodium of 135−137 mg/dL, led to adverse outcomes over time.[10] Inclusion criteria were history of chronic HF, defined as having been diagnosed for ≥ 3 months or, if unable to determine length of time with HF, had ≥ 1 HF-related medical care office visit before hospitalization for HF; age ≥ 18 years; ability to read and write; discharged home or to an assisted living apartment dwelling; control of purchasing food, making food selections at meals and controlling fluid intake; routine use of Cleveland Clinic system hospitals or health care providers for HF care and willingness to participate. Patients were excluded if they had a history of HF after cardiac transplantation, restrictive HF etiology, or congenital heart disease; had chart-documented psychiatric or cognitive conditions that limited understanding or adherence to dietary and fluid intake restriction recommendations (Alzheimer condition, dementia, schizophrenia, other neurologic history that impairs memory); lived in a nursing home or received hospice care; were enrolled in another experimental HF research study; or had chronic renal failure, defined as receiving chronic hemodialysis therapy for an estimated glomerular filtration rate of <30 mL min^{-1} 1.73 m^{-2}.

Randomization and Treatment Allocation

The Cleveland Clinic Institutional Review Board approved the study protocol, and each patient provided written informed consent. After completing baseline data, participants were randomly allocated to usual care or strict fluid restriction of 1,000 mL/d. Randomization envelopes were created in blocks of 10. Group allocation was blinded to hospital health care providers (physicians and nurses) to prevent communication of encouragement or disregard of fluid restriction early after enrollment.

Fluid Restriction Intervention

Patients received usual care (UC) discharge instructions and education as ordered by their health care providers (UC group) or a daily fluid allowance of 1,000 mL/d fluid allowance for 60 days plus the UC discharge instructions and education (intervention group). A 1,000 mL/d limitation was based on the following rationale. Registry patients who were hospitalized for acute HF decompensation due to medication and dietary nonadherence presented with greater signs of congestion and had more frequent previous HF hospitalizations.[11] Trends in HF hospitalization rates are significant and have not changed over time,[12] regardless of a 2,000 mL/d fluid restriction as part of the treatment plan. Furthermore, when 1,000 mL/d fluid restriction was applied after hospital discharge as part of a combination intervention that also included randomization to a diet with moderate or strict sodium restriction and a loop diuretic agent with aggressive or nonaggressive daily dosing, patients receiving 1,000 mL/d fluid restriction, regardless of the assigned diet and diuretic dose, had improved outcomes at 180 days.[13] The 1,000 mL/d fluid allowance included liquid drinks and foods with a high concentration of natural liquids, such as watermelon. Patients assigned to the 1,000 mL/d group received a 1-page single-sided handout with information on quenching thirst without increasing fluid intake, measuring fluid intake, and determining fluid sources.

Outcomes and Measures

The primary outcome was 60-day postdischarge HF-related QoL. Secondary outcomes were 60-day postdischarge HF-related emergency department (ED) services, HF-related rehospitalization, sense of thirst, level of difficulty adhering to fluid intake recommendations, and adherence to fluid restriction behaviors. HF-related QoL was measured with the use of the Kansas City Cardiomyopathy Questionnaire (KCCQ), a 23-item tool that quantifies physical function, symptoms, self-efficacy, social function (limitations), and QoL.[14,15] The KCCQ clinical and overall QoL summary scores were the primary outcomes. Of QoL domains, the clinical QoL summary score includes physical function, symptoms, social function, and QoL. The overall QoL summary score includes all domains.[14] KCCQ is a valid, reliable, and responsive health measure.[15] When 2 generic QoL tools were compared with KCCQ at baseline and 6 weeks for clinical changes, the KCCQ outperformed the 2 generic tools (EQ-5D and Rand-12).[16] The KCCQ clinical summary score was significantly associated with NYHA-FC and changes in NYHA-FC over time.[14,16] A mean change in score by 4.5−5 points (higher or lower) reflected a 1-level change in NYHA-FC (higher or lower).[16]

Sixty-day HF ED and rehospitalization events were measured by medical record chart review and patient contact at 30 and 60 days after discharge. Sense of thirst was measured using a 100-mm numeric rating scale with line markings at every 10 points and anchors that were labeled ‘‘no thirst’’ on the left (0 points) and ‘‘constant thirst’’ on the right (100 points). This scale was previously used to measure thirst in patients with chronic HF, cancer, and renal failure.[4] Difficulty adhering to fluid intake