Clinical Trials

Randomized Clinical Trial of an Integrated Self-Care Intervention for Persons With Heart Failure and Diabetes: Quality of Life and Physical Functioning Outcomes

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ABSTRACT

Objectives: Persons with concomitant heart failure (HF) and diabetes mellitus (DM) have complicated, often competing, self-care expectations and treatment regimens that may reduce quality of life (QOL). This randomized controlled trial tested an integrated self-care intervention on outcomes of HF and DM QOL, physical function, and physical activity (PA).

Methods and Results: Participants with HF and DM (n = 134; mean age 57.4 ± 11 years, 66% men, 69% minority) were randomized to usual care (control) or intervention. The control group received standard HF and DM educational brochures with follow-up telephone contact. The intervention group received education and counseling on combined HF and DM self-care (diet, medications, self-monitoring, symptoms, and PA) with follow-up home visit and telephone counseling. Measures included questionnaires for HF- and DM-specific and overall QOL, PA frequency, and physical function (6-min walk test [6MWT]) and were obtained at baseline and 3 and 6 months. Analysis included mixed models with a priori post hoc tests. Adjusting for age, body mass index, and comorbidity, the intervention group improved in HF total ($P = .002$) and physical ($P < .001$) QOL scores at 3 months with retention of improvements at 6 months, improved in emotional QOL scores compared with control at 3 months ($P = .04$), and improved in health status ratings ($P = .04$) at 6 months compared with baseline. The intervention group improved in 6MWT distance (924 ft to 952 ft; $P = .03$) whereas the control group declined (834 ft to 775 ft; $F_{1,63} = 6.86$; $P = .01$). The intervention group increased self-reported PA between baseline and 6 months ($P = .01$).

Conclusions: An integrated HF and DM self-care intervention improved perceived HF and general QOL but not DM QOL. Improved physical functioning and self-reported PA were also observed with the integrated self-care intervention. Further study of the HF and DM integrated self-care intervention on other outcomes, such as hospitalization and cost, is warranted. (*J Cardiac Fail 2015;21:719−729*)

Key Words: Heart failure, diabetes, self-care, quality of life, intervention.

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The growing prevalence of patients with concomitant heart failure (HF) and diabetes mellitus (DM), and the complex interaction of the 2 conditions, risk factors, and treatments require additional attention to improve patient outcomes. Patients with HF and DM show specific metabolic, neurohormonal, and structural heart abnormalities that potentially contribute to worse outcomes compared with each condition individually.[1,2] Approximately 40% of patients hospitalized with HF and reduced ejection fraction have DM,[3] and recent trials have noted increased risk of mortality,[4,5] a potentially differential response to medications with greater side effects,[6] and increased rehospitalizations[7,8] compared with HF patients without DM. The prevalence of both diseases is increasing worldwide with the aging of the population: 1.5%−2% of individuals over the age of 65 years have both HF and DM, and the prevalence is expected to grow exponentially in the next decades.[9] Additionally, self-care for this comorbid group is complex and competes in recommendations for diet, medications, and symptom management.[10] Multimorbidity is associated with substantially worse health-related quality of life (QOL), especially in persons with HF and DM.[11] These adverse clinical, behavioral, and economic outcomes warrant new approaches.

Self-care of either HF or DM alone requires focused daily activities and problem solving to incorporate these behaviors into life routines. Improved knowledge and self-care in patients with either HF or DM alone has the potential to reduce rehospitalizations, reduce adverse sequelae, and improve QOL.[12] To address the complexity of comorbid HF-DM self-care, we conducted a randomized clinical trial of an integrated self-care education and counseling intervention versus a usual care control condition in persons rehospitalized or recently rehospitalized for an HF exacerbation (Quality HF-DM; ClinicalTrials.gov NCT 01606085). This study was informed by a pilot test of a portion of the intervention, in which improved HF knowledge and self-efficacy as well as improved selected self-care behaviors for both HF and DM were observed.[13] We developed a more robust clinical trial and hypothesized that an integrated HF and DM self-care intervention would demonstrate improved QOL, improved physical functioning, and reduced cost outcomes than usual care. This paper reports the QOL and physical function outcomes.

Methods

Design

A 2-group randomized design was used with data collected at baseline (entry into the study) and after 3 and 6 months. HF-DM patients were enrolled during hospitalization or within 3 months of discharge for an HF exacerbation and randomly assigned to either an integrated HF and diabetes self-care intervention group or a usual care control group. A table of random numbers was used to create group assignments that were placed in sealed envelopes until baseline data were collected. The intervention was delivered after baseline data collection and occurred in several sessions (immediately after enrollment and 48−72 hours, 7 and 14 days, and 1, 2, and 4.5 months after study entry). The INT group also received usual care from their primary and specialty care providers. Participants were enrolled from 1 of 4 large urban tertiary-care hospitals that had multidisciplinary outpatient HF clinics. The protocol and informed consent were approved by the Institutional Review Board and all participating institutions.

Participants

The inclusion criteria for this trial included current or recent hospitalization for HF within the past 3 months, ages 21−80 years, New York Heart Association (NYHA) functional class II−IV symptoms, type II DM, planned discharge to home and not to an assisted living or skilled nursing facility, English language fluency, baseline guideline-derived medical therapy unless there was documented contraindication, ambulatory and eligible for a walking physical activity (PA) program, and eligible for a low-sodium and low-carbohydrate diet. Patients with newly diagnosed or 1st HF admission were excluded, as were those with positive screenings for depressive symptoms (≥10 on Patient Health Questionnaire 9 [PHQ-9])[14] and cognitive difficulty (>11 on Blessed Cognitive Screening tool),[15] which would interfere with ability to participate in the intervention or perform adequate self-care.[16,17] Patients were excluded for any of the additional following conditions: uncorrected hearing or vision problem, undergoing cardiac transplantation or mechanical circulatory assist device implantation or evaluation at the time of enrollment, renal failure requiring renal replacement treatment, and lack of telephone access. We also excluded patients with severe chronic obstructive pulmonary disease and earlier stroke if they impeded ability to ambulate. Participants were enrolled during 2010−2013.

Overview of the Intervention

Usual Care Group (Control). Participants in the control group received routine care from their providers, and after randomization they were provided with informational brochures on "Taking Control of Your Heart Failure" (developed by the Heart Failure Society of America) and "Four Steps to Control Your Diabetes for Life" (developed by the National Diabetes Education Program). They received the standard hospital discharge patient teaching from staff in the enrolling institutions and follow-up clinic appointments including family members if present. A brief review of the HF educational materials and procedures implemented in the 4 enrolling hospitals revealed strong similarities, and none had strategies to intentionally integrate HF and DM self-care in their approach or patient education materials. Control group participants received "attention control" telephone calls on the same schedule as the intervention participants described below (at 7−10 days and 1, 2, and 4 months) with information about the trial, number of participants enrolled to date, and a reminder of their next set of study activities.

Integrated HF-DM Self-Care Group (Intervention). After baseline data collection, participants in the intervention group participated in an individualized educational and counseling session. Family members were encouraged to attend. A trained research nurse provided an overview of the content with the use of a semistructured script and coordinated set of Powerpoint illustrations viewed on a laptop computer. Corresponding written materials were developed at a 6th-grade reading level and provided in the form of an "HF-DM tool kit" to be used at home. The initial content included an overview of HF and DM