



A Novel Rehabilitation Intervention for Older Patients With Acute Decompensated Heart Failure

The REHAB-HF Pilot Study

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ABSTRACT

OBJECTIVES This study sought to assess a novel physical rehabilitation intervention in older patients hospitalized for acute decompensated heart failure (ADHF).

BACKGROUND After ADHF, older patients, who are frequently frail with multiple comorbidities, have prolonged and incomplete recovery of physical function and remain at high risk for poor outcomes.

METHODS The REHAB-HF (Rehabilitation Therapy in Older Acute Heart Failure Patients) pilot study was a 3-site, randomized, attention-controlled pilot study of a tailored, progressive, multidomain physical rehabilitation intervention beginning in the hospital and continuing for 12 weeks post-discharge in patients ≥ 60 years hospitalized with ADHF. The primary purpose was to assess the feasibility and reasonableness of the hypothesis that the novel rehabilitation intervention would improve physical function (Short Physical Performance Battery [SPPB]) over 3 months and reduce all-cause rehospitalizations over 6 months.

RESULTS The study enrolled 27 patients with ADHF (ages 60 to 98 years; 59% women; 56% African American; 41% with preserved ejection fraction [$\geq 45\%$]). At baseline, participants had marked impairments in physical function, multiple comorbidities, and frailty. Study retention (89%) and intervention adherence (93%) were excellent. At 3 months, an intervention effect size was measured for the SPPB score of $+1.1$ U (7.4 ± 0.5 U vs. 6.3 ± 0.5 U), and at 6 months an effect size was observed for an all-cause rehospitalization rate of -0.48 (1.16 ± 0.35 vs. 1.64 ± 0.39). The change in SPPB score was strongly related to all-cause rehospitalizations, explaining 91% of change.

CONCLUSIONS These findings support the feasibility and rationale for a recently launched, National Institutes of Health-funded trial to test the safety and efficacy of this novel multidomain physical rehabilitation intervention to improve physical function and reduce rehospitalizations in older, frail patients with ADHF with multiple comorbidities. (Rehabilitation and Exercise Training After Hospitalization [REHAB-HF]; [NCT01508650](#); A Trial of Rehabilitation Therapy in Older Acute Heart Failure Patients [REHAB-HF]; [NCT02196038](#)) (J Am Coll Cardiol HF 2017;5:359-66)
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ABBREVIATIONS AND ACRONYMS

GMWD = 6-min walk distance

ADHF = acute decompensated heart failure

GDS = Geriatric Depression Score

HF = heart failure

KCCQ = Kansas City Cardiomyopathy Questionnaire

MoCA = Montreal Cognitive Assessment

NIH = National Institutes of Health

SPPB = Short Physical Performance Battery

Acute decompensated heart failure (ADHF) is the leading cause of hospitalization in older adults and is associated with high rates of morbidity, mortality, and health care expenditures (1). Improving outcomes after ADHF hospitalization is a national health care priority. However, even with optimal adherence to heart failure (HF) management guidelines, outcomes after hospitalization remain poor (2,3) and >50% of patients experience readmission or death within 6 months (4).

We and others have recently shown that older patients hospitalized with ADHF are frequently frail with severe impairments in multiple domains of physical function, including strength, balance, mobility, and endurance (5-7). These impairments may help explain persistently high rehospitalization rates, the majority of which are not due to recurrent ADHF (4,8). However, current ADHF management strategies do not account for such impairments, and previous exercise training trials in HF have systematically excluded patients with current or recent ADHF (9-11). Furthermore, conventional cardiac rehabilitation programs are not designed to address the multidomain functional impairments common in older patients with ADHF, particularly balance impairments, and commencing rehabilitation without doing so can increase injuries (12). Consequently, the role of physical rehabilitation intervention in patients with ADHF and older, frail patients with HF with severe, widespread functional impairments has been identified as a critical evidence gap (11).

To begin to address this gap, we conducted a prospective, randomized, pilot study of a novel intervention designed to address the severe and widespread physical function impairments in older patients with ADHF. We hypothesize that a tailored, progressive, physical rehabilitation intervention addressing deficits in balance, mobility, strength, and endurance that begins during hospitalization and continues for 3 months after discharge will improve physical function and reduce rehospitalizations in this vulnerable population. Because there were no previous studies of such an intervention in this frail, elderly, acutely hospitalized population and considerable equipoise existed, the present pilot study was designed to determine feasibility and support the rationale and design of a future, large, definitive trial.

METHODS

STUDY DESIGN AND POPULATION. REHAB-HF (Rehabilitation and Exercise Training After

Hospitalization) (NCT01508650) was a 3-site, randomized, attention-controlled pilot study of a novel, multidomain physical rehabilitation intervention for older patients with ADHF beginning in the hospital and continuing for 12 weeks post-discharge with blinded assessment of outcome measures. As a pilot, the study was specifically not powered to definitively test the hypothesis. Rather, the study was designed to determine the feasibility of enrollment, retention, adherence, and follow-up, as well as the potential safety and potential for efficacy of the intervention, including estimate of the intervention effect size. Such data are critical to determine the reasonableness of the hypotheses and to guide the design of a larger, definitive trial.

The study was inclusive of patients with multiple comorbidities, heterogeneous functional performance, and both reduced (<45%) and preserved (\geq 45%) ejection fraction. Criteria for ADHF included acute worsening of at least 1 HF symptom (exertional dyspnea or fatigue, swelling of legs or abdomen, orthopnea, or paroxysmal nocturnal dyspnea); at least 1 sign of HF (pulmonary congestion by examination or x-ray film, elevated jugular or central venous pressure, peripheral edema, elevated B-type natriuretic peptide [>100 pg/ml] or N-terminal pro-hormone of B-type natriuretic peptide [>220 pg/ml]); and change in medical treatment consistent with HF (e.g., augmentation of diuretic agents). The diagnosis of ADHF was confirmed by a study cardiologist with expertise in HF. Additional inclusion criteria were age \geq 60 years, independence with basic activities of daily living before hospitalization, achievement of clinical stability allowing study participation, ability to ambulate at least 4 m (assistive device allowed) at the time of enrollment, and planned return to home post-discharge.

Exclusion criteria included acute coronary syndrome; severe aortic stenosis; end-stage HF requiring advanced therapies or home intravenous inotropic therapy; functional status limited by condition other than HF at the time of enrollment; advanced chronic kidney disease defined as estimated glomerular filtration rate \leq 20 ml/min/1.73 m²; terminal illness other than HF; active participation in supervised exercise training before hospitalization; or inability or unwillingness to adhere with the study protocol. All participants provided informed consent. The study was approved by the institutional review board at each center.

Before hospital discharge and after medical stabilization and acquisition of baseline measurements, participants were randomly assigned in 1:1 fashion to a novel, progressive, multidomain, 12-week physical

function intervention or attention control. Participants were randomized using a computer-generated list SAS software, version 9.0 (SAS Institute, Cary, North Carolina) and stratified by enrolling site and HF category (ejection fraction <45% or ≥45%).

STUDY INTERVENTION. The multidomain rehabilitation intervention for this study was a novel application of established rehabilitation therapies selected and integrated specifically for older patients hospitalized for ADHF. The goal of the intervention program was to improve performance in 4 domains: balance, strength, mobility, and endurance. Exercise prescription was adapted to individual functional deficits in each domain on the basis of standardized protocols and administered by trained interventionists using specific milestones for progression.

The majority of the intervention consisted of 60-min sessions 3 times per week for 12 weeks in the outpatient setting beginning immediately after discharge. When feasible, daily 30-min sessions during the hospitalization were also conducted. During the first 2 to 4 weeks after hospital discharge, supervised home-based training was allowed for patients with particularly poor functional status. Target intensity was on the basis of patient-reported rate of perceived exertion (scale from 6 to 20) and was initially low (≤12), and after 2 weeks increased to 13 (“somewhat hard”; range 11 to 15) for endurance training and 15 to 16 for strength training.

To guide exercise prescription, participants in the intervention arm were stratified into 1 of 4 levels for each functional domain (balance, mobility, strength, and endurance). Exercises appropriate to the participant’s functional level in each domain were then selected from the intervention protocols. These included static and dynamic balance training (e.g., standing with narrow base of support; stand and reach); mobility training (e.g., dynamic start and stop and changing direction while walking); functional strength training focused on lower extremities (e.g., chair rise; step-ups); and endurance training (sustained walking preferred). During exercise sessions, rest breaks were allowed as needed, and close one-on-one supervision was provided by study interventionists.

As performance improved, participants were advanced through a structured, gradual progression using specific small increments in each exercise. Standardized reassessment of performance in each domain was conducted every 2 weeks to guide exercise progression.

In addition to these supervised, facility-based sessions, participants were given a brief home

exercise prescription to be performed on non-program days. This included low-intensity walking at usual pace for up to 30 min and simple functional strengthening exercises, such as repeated chair rise or supported calf raise. After completion of the 12-week outpatient intervention, participants transitioned to an unsupervised home-based maintenance exercise program using an individualized exercise prescription developed by the intervention team.

The standardized protocol of exercises and progressions was designed to support consistent implementation of the intervention over time, between participants, and across sites. To further support intervention fidelity, in-person training of the study interventionists, who were experienced exercise physiologists and physical therapists, was conducted. An intervention leader provided ongoing oversight of study rehabilitation sessions at each site. Biweekly intervention teleconferences among all site intervention leaders and interventionists were conducted to provide continued monitoring and guidance.

ADHERENCE AND RETENTION. During the enrollment period and before randomization, participants underwent screening for potential barriers to adherence. The demands of study participation were discussed in detail with potential participants and, whenever possible, family and/or caregivers. A standardized assessment tool was used to query personal commitment to adhering to the study requirements; degree of support from family members, caregivers, and outpatient physicians; and potential transportation barriers. Those unable or unwilling to fully commit to all aspects of study participation or who lacked support were considered high risk for non-adherence and were not randomized and were excluded from the study.

Flexible scheduling; ongoing engagement of the participant, participant’s family, and caregivers; and transportation support were provided to promote study adherence and retention. In the event of an interruption because of illness, which was anticipated in this frail, high-risk population, participants in the intervention group were allowed up to 2 additional weeks to complete 36 multidomain intervention sessions. Participants in both arms were allowed up to 2 additional weeks to complete the 3-month assessments.

ATTENTION CONTROL GROUP. Participants randomized to attention control received at least monthly contact from study personnel with scheduled phone calls (months 2, 4, 5, and 6) and follow-up assessments (months 1 and 3).

USUAL CARE. Participants in both arms could receive standard therapies, including home health and

TABLE 1 Baseline Characteristics by Randomization Arm

	Intervention (n = 15)	Attention Control (n = 12)	p Value
Age (yrs)	72.7 ± 10.8	71.8 ± 9.1	0.83
Women	53	67	0.70
Race (black)	53	58	1.00
Body mass index (kg/m ²)	30.8 ± 7.1	27.3 ± 6.0	0.19
Days hospitalized	5 (2)	6 (4)	0.49
Left ventricular ejection fraction (%)	40 ± 13	34 ± 18	0.33
Preserved ejection fraction (>45%)	42	40	1.00
Previous hospitalization within 6 months	20	42	0.40
Comorbidities			
Diabetes mellitus	60	33	0.25
Hyperlipidemia	47	50	1.00
Chronic obstructive pulmonary disease	13	33	0.36
Kidney disease (estimated GFR <60 ml/min/1.73 m ²)	67	58	0.71
Anemia (Hgb <14 g/dl men, <12 g/dl women)	60	58	1.00
No. of comorbidities	4.6 ± 1.8	5.3 ± 2.1	0.39
Heart failure therapies			
Loop diuretic agent	93	100	1.00
Beta-blocker	93	75	0.29
ACE-I or ARB	53	67	0.70
Aldosterone antagonist	27	17	0.66
Implantable cardioverter-defibrillator	14	17	1.00
Study measures			
Short Physical Performance Battery	4.7 ± 2.7	6.0 ± 3.0	0.23
6-min walk distance (m)	160 ± 85	201 ± 120	0.32
Frailty (≥3 of 5 Fried criteria)	53	58	1.00
Gait speed (m/s)	0.55 ± 0.19	0.61 ± 0.28	0.50
Kansas City Cardiomyopathy Questionnaire	43 ± 19	45 ± 17	0.79
Cognitive impairment (MoCA <26)	80	83	1.00
Depression (GDS-15 >5)	33	25	0.70

Values are mean ± SD or %. The p values were determined by Student t test or Fisher exact test.
ACE-I = angiotensin converting enzyme inhibitor; ARB = angiotensin II receptor blocker; GDS-15 = 15-Item Geriatric Depression Score; GFR = glomerular filtration rate; Hgb = hemoglobin; MoCA = Montreal Cognitive Assessment.

outpatient rehabilitation, as directed by their clinical providers. In the event of scheduling conflict, priority was given to usual care therapies. Medical therapy and HF management was at the discretion of the participant’s treating physician and was specifically not addressed by the study protocol for either study arm.

OUTCOME MEASURES. The primary outcome measure was change in the Short Physical Performance Battery (SPPB) at 3 months (13). The SPPB is composed of 3 components—standing balance, gait speed, and timed repeated chair rise—each scored on a scale from 0 to 4 and combined for a total score of 0 to 12. The secondary outcome measure was all-cause rehospitalizations through 6 months after discharge from index hospitalization. Other measures included 6-month all-cause rehospitalization days,

3-month change in 6-min walk distance (6MWD), frailty status on the basis of the Fried phenotype (14), health-related quality of life on the basis of the Kansas City Cardiomyopathy Questionnaire (KCCQ) (15), cognitive function on the basis of the Montreal Cognitive Assessment (MoCA) (16), and depression symptoms on the basis of the 15-Item Geriatric Depression Score (GDS-15) (17). All baseline measures were collected during the index hospitalization before randomization. Follow-up assessments were collected by trained, blinded assessors according to standardized protocols. Collection of clinical events was on the basis of patient and caregiver report as well as review of medical records.

STATISTICAL ANALYSIS. Comparison of change in SPPB at 3 months between the attention control and intervention arms was made by analysis of covariance, with the 3-month value as the outcome and the baseline value as the covariate. Similar analyses were done for change in SPPB components, 6MWD, frailty status, KCCQ, MoCA score, and GDS-15 score.

Rehospitalizations were tracked and analyzed for all 27 participants (intention-to-treat analysis) for the entire 6-month study period. The number of all-cause rehospitalizations per participant in each study arm was compared using analysis of covariance with HF category and baseline SPPB score as covariates. Secondary analysis of total number of all-cause rehospitalization days was also performed.

Spearman rank correlations between the effect on SPPB or 6MWD and the number of all-cause 6-month rehospitalizations were calculated. The extent of the effect of group assignment (intervention vs. attention control) on all-cause 6-month hospitalization was mediated by SPPB score and assessed. A 2-tailed p < 0.05 was considered significant.

RESULTS

Of the 65 patients who met inclusion and exclusion criteria and were offered participation, 30 consented. Three patients were excluded by adherence risk screening, as per study protocol, such that 27 were randomized (15 intervention arm, 12 attention control). Baseline characteristics were balanced between the study arms with regard to older age, sex, race, number of comorbid conditions (approximately 5), markedly impaired functional status across multiple domains of physical function, high rates of frailty (≥50%), mild cognitive impairment (≥80%) and symptoms of depression (≥25%) (Table 1). Baseline functional status was very poor, with approximately 40% of participants initially at the lowest stratification for most domains, 33% at

TABLE 2 Outcome Measures in Intervention Group Compared to Attention Control

	Intervention (n = 12)			Attention Control (n = 12)		
	Baseline	3 Months	LS	Baseline	3 Months	LS
SPPB	4.8 ± 2.8	6.9 ± 3.0	7.4 ± 0.5	6.0 ± 3.0	6.8 ± 3.3	6.3 ± 0.5
SPPB components						
Balance	2.0 ± 1.5	2.8 ± 1.1	3.1 ± 0.2	2.8 ± 1.3	2.9 ± 1.4	2.7 ± 0.2
Gait speed	2.2 ± 1.0	2.6 ± 1.0	2.6 ± 0.2	2.3 ± 1.2	2.8 ± 1.3	2.7 ± 0.2
Chair rise	0.7 ± 0.7	1.5 ± 1.4	1.6 ± 0.3	0.9 ± 0.8	1.2 ± 1.2	1.0 ± 0.3
6MWD	170 ± 83	232 ± 113	247 ± 22	201 ± 120	239 ± 129	224 ± 22
Frailty						
Fried criteria*	2.58 ± 0.90	2.00 ± 1.21	1.97 ± 0.28	2.50 ± 1.31	2.33 ± 1.44	2.37 ± 0.28
Gait speed (m/s)	0.59 ± 0.19	0.73 ± 0.28	0.75 ± 0.05	0.61 ± 0.28	0.67 ± 0.27	0.65 ± 0.05
KCCQ						
Overall	40 ± 18	65 ± 19	67 ± 4	45 ± 17	63 ± 22	61 ± 4
Physical	40 ± 27	57 ± 19	59 ± 5	48 ± 24	52 ± 21	50 ± 5
Social	43 ± 28	64 ± 25	66 ± 7	49 ± 22	64 ± 27	62 ± 7
QOL	32 ± 22	62 ± 32	65 ± 7	47 ± 28	68 ± 21	64 ± 7
Symptoms	30 ± 24	66 ± 25	66 ± 6	30 ± 18	65 ± 31	65 ± 6
MoCA	20.5 ± 5.0	22.0 ± 4.7	22.1 ± 1.1	20.8 ± 4.9	20.4 ± 6.5	20.3 ± 1.2
GDS-15	5.8 ± 4.6	4.4 ± 4.1	3.7 ± 0.8	3.9 ± 3.2	3.0 ± 3.4	3.7 ± 0.8

Values are mean ± SD except LS = mean ± SE. Analysis included all participants who completed baseline and 3-month assessments. Change between groups was determined by analysis of covariance, with the 3-month value as the outcome and the baseline value as the covariate. *Fried criteria = number of the 5 Fried criteria met.
6MWD = 6-min walk distance; KCCQ = Kansas City Cardiomyopathy Questionnaire; LS = least square; QOL = quality of life; SPPB = Short Physical Performance Battery; other abbreviations as in Table 1.

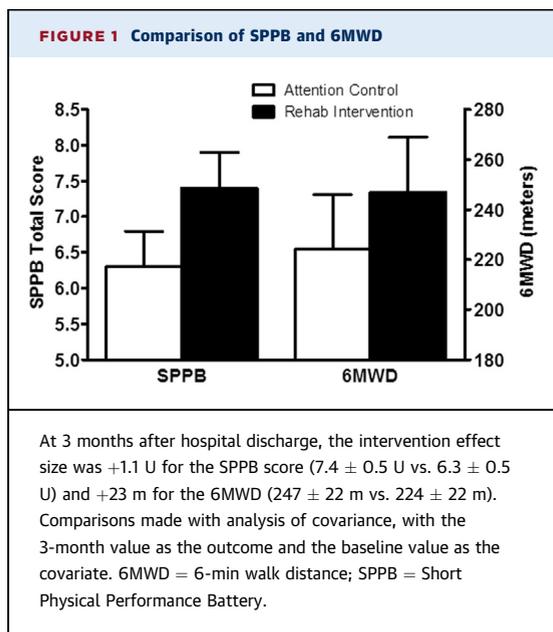
level 2, and 27% at level 3. For example, nearly one-half of the participants were unable to stand from a chair even once without the use of arms (strength level 1), stand unsupported with feet together for 10 s (balance level 1), tolerate >2 min of continuous walking (endurance level 1), and had a gait speed ≤0.4 m/s (mobility level 1).

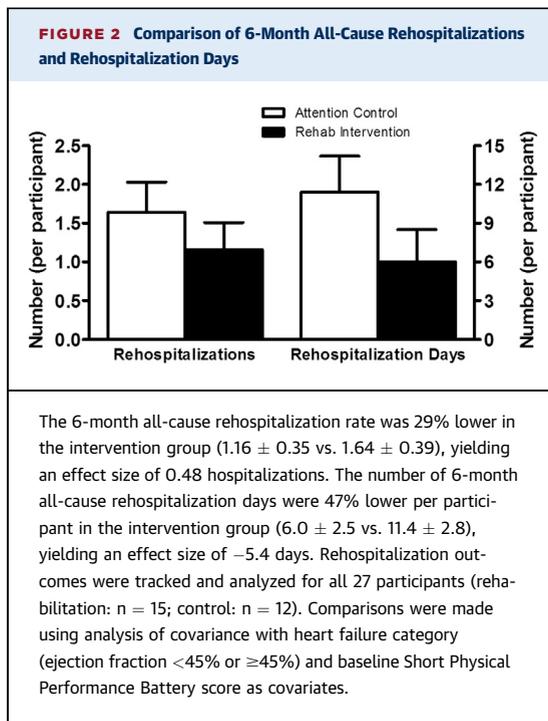
Twenty-four patients completed follow-up (3 dropouts, for 89% retention rate). Participants who completed the intervention attended 92% of scheduled sessions.

At 3 months after hospital discharge, the change in SPPB score in the intervention group (4.8 ± 2.8 U to 6.9 ± 3.0 U) compared to attention control (6.0 ± 3.0 U to 6.8 ± 3.3 U) showed an intervention effect size of +1.1 U (7.4 ± 0.5 U vs. 6.3 ± 0.5 U) (Table 2, Figure 1). For perspective on this magnitude of effect size, a clinically meaningful change in SPPB score is ≥0.6 U (18). All individual component scores of the SPPB increased, with the strongest trend seen with chair rise (lower extremity functional strength) (Table 2). At 3-month follow-up, there was an intervention effect size for 6MWD of +23 m (247 ± 22 m vs. 224 ± 22 m, intervention vs. control, respectively) (Table 2, Figure 1). A clinically meaningful change in 6MWD is ≥20 m (18).

As expected during recovery from an ADHF hospitalization, at 3-month follow-up both groups had higher KCCQ score, with an intervention effect size of +5.4 points (+5 points is considered clinically meaningful) (19). Changes at 3-month follow-up in other variables, including frailty, cognitive function, and depression, are listed in Table 2.

There were 37 all-cause rehospitalizations during the 6-month follow-up, including 22 for ADHF, with 18 of the 27 participants (67%) experiencing at





least 1 rehospitalization. The rate of 6-month all-cause rehospitalization was 29% lower in the intervention group (1.16 ± 0.35 vs. 1.64 ± 0.39), and 6-month all-cause rehospitalization days were 47% lower per participant in the intervention group (6.0 ± 2.5 vs. 11.4 ± 2.8), yielding an intervention effect size of -0.48 hospitalizations and -5.4 days, respectively (Figure 2). The change in SPPB score was inversely correlated with the change in 6-month all-cause rehospitalizations (-0.60) ($p < 0.01$). Change in 6MWD did not correlate with change in hospitalizations (-0.17) ($p = 0.42$). The change in SPPB score explained 91% of the change in all-cause rehospitalizations by mediation analysis.

One adverse event was judged to be possibly related to the study intervention. The participant had completed a study intervention session uneventfully and returned home. Several hours later, the participant had chest pain and was subsequently hospitalized with a non-ST-segment elevation myocardial infarction. No other adverse events were judged to be related to study participation, and the intervention was otherwise well tolerated without injury or falls, even among those at the lowest level of functioning. There were no deaths.

DISCUSSION

The REHAB-HF pilot study was a prospective, multi-center, pilot clinical trial evaluating a novel

rehabilitation intervention in hospitalized, older HF patients. The study successfully randomized 27 patients ≥ 60 years of age hospitalized with ADHF to either a novel multidomain physical rehabilitation intervention or attention control. In both study arms, baseline physical function impairments were severe, involving all physical function domains (balance, mobility, strength, and endurance), and frailty, severely reduced quality of life, cognitive dysfunction, and depression were common (6). The intervention, which began during the index hospitalization and continued for 12 weeks in the outpatient setting, was generally well tolerated, and retention and adherence were good. At 3-month follow-up, we observed an intervention effect size of $+1.1$ U in the SPPB score, a well-accepted, standardized measure of physical function in frail older persons that is known to be strongly correlated with important clinical outcomes, including hospitalization, disability, and death (7,13). The established threshold for clinically meaningful change in SPPB score is $+0.6$ U (18). At 6-month follow-up, we observed an intervention effect size on all-cause rehospitalizations of -0.48 and on rehospitalization days of -5.4 days. The change in SPPB score was inversely related to the change in rehospitalization rate. By mediation analysis, change in SPPB score explained 91% of the change in rehospitalization rate, supporting a potential mechanistic link between physical function and rehospitalizations in frail, older patients with ADHF.

These findings support the reasonableness of our overall study hypothesis that a novel, tailored, progressive, multidomain physical rehabilitation intervention is feasible in older patients with ADHF who have high rates of frailty and comorbidities and has the potential to improve physical function and reduce rehospitalization rates. The results of this pilot study informed the design of a subsequent multicenter clinical trial that was funded by the National Institutes of Health (NIH) and is designed to definitively test this hypothesis. The recently launched trial (NCT02196038) will enroll 360 patients, a sample size supported by the present data.

To our knowledge, this is the first randomized controlled trial of a physical rehabilitation intervention in older, hospitalized patients with ADHF. Previous trials of exercise training in HF systematically excluded such patients (10), and evidence regarding the safety and efficacy of exercise intervention within 4 to 6 weeks after an ADHF hospitalization is limited (11). Consequently, the most recent national society consensus statement recommends against enrolling recently hospitalized patients with HF in cardiac

rehabilitation (20). Such patients were excluded from the U.S. Centers for Medicare and Medicaid Services decision memo expanding coverage for cardiac rehabilitation for patients with HF (21). Addressing the critical evidence gap regarding the role of physical rehabilitation in patients recently hospitalized with ADHF has been designated as a high research priority by the NIH (11).

Our findings suggest these severe functional impairments in older patients with ADHF may be modifiable with a sustained, targeted, progressive multidomain rehabilitation intervention. The favorable trend toward reduced hospitalization observed in the intervention arm, which was almost entirely mediated by the change in physical function, provides encouraging evidence that clinical outcomes in older patients with ADHF may be improved by successfully addressing these severe functional impairments.

Although encouraging, our findings also support the need for caution and further study regarding the role and design of physical rehabilitation in older patients with ADHF. The functional impairments in older patients after an ADHF hospitalization are far more severe and widespread than those reported in patients with chronic stable HF and targeted by conventional cardiac rehabilitation (6,9). For example, the average baseline 6MWD in the present cohort (178 m) was one-half that observed in similarly aged patients in the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training) trial (~350 m) (22). Severe lower extremity weakness prevented nearly one-half of older, frail patients with ADHF from standing even once from a seated position without the use of arms (6). Importantly, older patients with ADHF also had severe deficits in balance and mobility that are not typically seen in patients with chronic stable HF and are not addressed by conventional, endurance-based cardiac rehabilitation (6,23). Initiating standard endurance exercise training in such patients without first addressing deficits in balance and mobility may limit efficacy (24) and increase the risk of injuries and falls (12). To safely address these deficits, one-on-one training is often required (25), a feature incorporated into our intervention but not typically supported under current cardiac rehabilitation reimbursement models.

The present study was intended to address a critical evidence gap regarding physical function intervention in recently hospitalized, older, frail patients with HF. In HF-ACTION, the largest trial of physical rehabilitation in HF, mean age was <60 years, and patients were mandated to have chronic stable HF and no medication changes or hospitalization within the previous 6 weeks. However, in reality, few

HF-ACTION participants had been hospitalized for HF within even 6 months of enrollment (9). Furthermore, functional impairments in older patients recovering from an ADHF hospitalization are dramatically more severe and widespread than those observed in patients with chronic stable HF (6). Recovery from this precipitous loss of function may be delayed and incomplete after hospital discharge (26). Indeed, the attention control arm of this study continued to demonstrate severe physical dysfunction even 3 months after discharge. If successful, novel physical rehabilitation interventions such as the one investigated in this study could serve as a “bridge” to more conventional cardiac rehabilitation interventions once functional impairments improve to the level for which cardiac rehabilitation has proven benefit (9,10).

STUDY LIMITATIONS. This was a pilot study and was not designed or powered to definitively assess the efficacy or safety of the physical rehabilitation intervention. The findings should be considered preliminary, and encouraging trends require confirmation in a larger, adequately powered clinical trial. There was considerable focus on retention and exercise adherence, and similar rates may not be achieved outside the clinical research setting. Because they were excluded from the study, the results may not apply to patients who were not independent before admission or who were expected to be discharged to a nursing home.

FUTURE DIRECTIONS. On the basis of these pilot data, a larger, adequately powered NIH-funded multicenter randomized clinical trial (REHAB-HF [Rehabilitation and Exercise Training After Hospitalization; NCT02196038]) was recently launched to determine whether this novel physical rehabilitation intervention will improve physical function and reduce all-cause hospitalizations in older patients with ADHF. Until results from adequately powered trials such as REHAB-HF are available, and consistent with U.S. Centers for Medicare and Medicaid Services policy (21) and the most recent society consensus statement (20), we recommend caution regarding immediate or early rehabilitation in unselected older hospitalized patients with ADHF.

CONCLUSIONS

The findings from this pilot study, although preliminary, support the feasibility and safety of a novel, tailored multidomain physical rehabilitation intervention starting in the hospital and continuing for 12 weeks immediately after discharge in older, frail patients with ADHF, who often may have severe

impairments in multiple physical domains (balance, mobility, strength, and endurance). They also support the underlying hypothesis that in older patients with ADHF, severe impairments in physical function are modifiable with a targeted intervention and that doing so may improve clinical outcomes. This pilot study informed the design of an ongoing clinical trial adequately powered to test whether this novel intervention can improve physical function and reduce all-cause rehospitalization in older patients hospitalized with ADHF.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE:

The present findings support that older patients hospitalized with ADHF have severe and widespread impairments in physical function that persist despite conventional HF treatment and contribute to adverse clinical outcomes.

TRANSLATIONAL OUTLOOK: Further study is needed to determine whether sustained and gradually progressive multidomain physical rehabilitation interventions targeting deficits in balance, mobility, strength, and endurance can improve physical function and clinical outcomes in older patients with ADHF.

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