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Participation Rates and Outcomes for Heart Failure Patients in Cardiac Rehabilitation

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Abstract

Purpose—Exercise training has been shown to reduce combined cardiovascular mortality and hospitalizations in patients with chronic heart failure with reduced ejection fraction (HFrEF). Whereas there is extensive data on exercise training for individuals with HFrEF in a research setting, the experience of delivering cardiac rehabilitation (CR) services in the clinical setting has not been well described. With little known regarding the number of qualifying HFrEF patients in the U.S., we describe our 18-month experience recruiting hospitalized inpatients and stable outpatients into Phase 2 CR.

Methods—Patients hospitalized with CHF were tracked for enrollment in CR. Exercise training response was described for patients identified as inpatients and for stable HFrEF outpatients referred from cardiology clinic or heart failure clinic.

Results—The cohort included 83 patients hospitalized with CHF and 36 outpatients. Only 17% (14/83) of eligible HFrEF inpatients enrolled in CR following CHF hospitalization compared to 35/36 (97%) outpatient referrals. Improvements in aerobic capacity for the total cohort were observed whether expressed as estimated METs ($n=19$, 4.6 ± 1.6 to 6.2 ± 2.4 , $p<0.0001$) or VO_{2peak} ($n=14$, 14.4 ± 3.5 to 16.4 ± 4.6 mL*kg⁻¹*min⁻¹) ($p=0.02$) for those who completed CR.

Conclusion—Significant barriers to recruiting and enrolling patients with HFrEF were observed and only 17% of inpatients attended CR. Systematic in-hospital referral with close follow-up in the outpatient setting has the potential to capture more eligible patients. The participation of referred stable outpatients with HFrEF was much higher. Regardless of referral source, HFrEF patients completing CR can expect improvements in aerobic capacity, muscle strength, and depressive symptoms.

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Introduction

Exercise training has been shown to reduce combined cardiovascular mortality and hospitalizations in patients with chronic heart failure (CHF) with reduced ejection fraction (HFrEF).^{1,2} As such, the Center for Medicare and Medicaid Services (CMS) expanded cardiac rehabilitation (CR) coverage in February 2014 to include patients with a diagnosis of stable HFrEF taking evidence-based medications. Whereas there is extensive data on the safety and efficacy of exercise training for individuals with HFrEF in a research setting,^{1,3,4} the experience of delivering CR services in the U.S. in the clinical setting has not yet been described. While patients with HFrEF benefit from exercise programs,^{2,5} they have unique and prominent comorbidity profiles compared with CR patients with coronary heart disease.⁶ Thus, CR recruitment and programmatic protocols, including exercise training and heart failure counseling, must be tailored to suit the specific needs of this population. With little known regarding the number of qualifying HFrEF patients, we sought to describe our 18-month experience with recruiting hospitalized inpatients and stable outpatients with HFrEF in Phase 2 CR. In addition we describe the trajectory of patients with HFrEF who start phase 2 CR in terms of completion rates and exercise training responses.

Methods

Subjects

The study sample included patients hospitalized with a diagnosis of heart failure with left ventricular ejection fraction (LVEF) of $\geq 35\%$. In addition, we followed similar outpatients who were directly referred from outpatient cardiology or CHF clinic to Phase 2 CR. The specific CMS description of eligibility for CR is as follows: Beneficiaries with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. Stable patients are defined as patients who have not had recent (≥ 6 weeks) or planned (≥ 6 months) major cardiovascular hospitalizations or procedures (CMS Decision Memorandum for Coverage of CR Programs for CHF, February 18, 2014). Data were prospectively collected for patients hospitalized with acute CHF from June 2014 through December 2015. Eligible participants following an acute hospitalization were identified via a weekly report generated through the electronic medical record. The report included patients with a LVEF $\geq 35\%$ measured by echocardiogram, left heart catheterization, or nuclear imaging at any point in their medical history, were hospitalized with CHF, and resided within our phase 2 CR catchment area (Chittenden Co. VT). Information obtained from the medical record included most recent LVEF measurement, HFrEF etiology (ischemic vs nonischemic), hospital discharge date, and time since original HFrEF diagnosis. Additionally, outpatients who were directly referred from a cardiology or CHF clinic to CR were tracked. For these patients, clinical data was obtained through the electronic medical record. All patients were stable as defined by the CMS decision memorandum for at least 6 weeks prior to enrolling in CR.

Attendance Rates

Participation in CR following hospitalization was defined by attendance of at least one CR session. Attendance rate at CR for hospitalized HFrEF patients was calculated by dividing the number of patients attending at least one session by the total number of eligible patients identified in hospital. Exclusion criteria included a concurrent qualifying diagnosis to CR during that hospitalization (myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, heart valve surgery) or an improved LVEF >35% on repeat echocardiogram prior to CR enrollment (Figure 1).

Clinical Demographics

During an initial visit, data was collected on age, sex, body weight, height, handgrip strength, smoking status, cardiac risk factors and co-morbidities, medication use, self-reported physical function (Medical Outcomes Study Short Form-36),⁷ and depression scores(PHQ-9).⁸

Exercise Tolerance Test

At entry and exit from the CR program, patients performed a symptom limited treadmill exercise tolerance test with expired gas analysis to determine peak aerobic capacity in mL O₂·kg⁻¹·min⁻¹ (VO_{2peak}) and/or estimated metabolic equivalents (METs). Treadmill protocols included the Bruce, modified-Balke, and modified-Naughton, depending on an initial estimation of fitness, and continued until volitional exhaustion. VO_{2peak} measurements were recorded continuously throughout the exercise tolerance test with a Medgraphics Ultima CPX (St. Paul, Minnesota). The highest average 30-second value for VO₂ was defined as VO_{2peak}. Calibration was performed before each test as described previously.⁹ Quality control is performed according to published guidelines.¹⁰ Individuals performed the same exercise testing protocol at baseline and exit from CR. Patients who performed the baseline exercise tolerance tests with their private cardiologist (n=12) did not have VO_{2peak} measured. Because expired gas analysis was not performed on all patients at baseline (39%), aerobic capacity in METs was estimated for all patients utilizing treadmill time (n=42) or average walking speed during a 6 minute walk (n=7).¹¹ Secondary outcomes analysis included 30 patients with expired gas analysis at baseline, 14 of whom repeated measures following CR.

Exercise Training Protocol

The exercise training program generally consisted of 3 sessions per week of aerobic and strength training up to a total of 36 sessions. Patients were monitored during training sessions, and exercise intensity was adjusted to maintain participant heart rate (HR) in the range of 70% to 85% of the peak HR obtained on the entry exercise tolerance test and/or a Borg scale for rating of perceived exertion between “fairly light” and “hard” (11–15 on a scale of 6–20). Typically, exercise training sessions comprised 25 minutes on the treadmill; and 8 minutes on 3 other modalities including elliptical trainers; upright and seated steppers; and cycle, arm, and rowing ergometers. Resistance training included both upper and lower extremity exercises with most patients performing 1 set of 10 repetitions with a subjective rating of “hard.” Patients were encouraged to exercise 1–2 times per week on their own to a

total of 3–5 exercise sessions per week. To reduce the risk of hospitalizations and improve clinical outcomes^{1,12,13} heart failure counseling was provided on an individual basis with topics including: symptoms, daily weights, medication adherence, sodium and fluid restrictions, aerobic and resistance exercise guidelines, food labels, and meal planning. Group CHF education sessions were also attended on a monthly basis.

Statistical Analysis

Baseline statistical analyses were performed with ANOVA and chi² tests (IBM SPSS Statistics version 22). Paired t-tests were used to compare outcomes data in patients who completed CR. Statistical significance was set at the level of $p < 0.05$. All data are reported as mean $\pm$ SD.

Results

CR Attendance Rate

The cohort included 124 patients hospitalized with a primary diagnosis of chronic heart failure with left ventricular ejection fraction $\leq 35\%$. Of these patients 34 qualified for CR for another diagnosis during hospitalization and 7 had improved ejection fractions on repeat echocardiogram before enrolling in CR and were removed from the pool. Subsequently, 83 potential CR participants were tracked for enrollment status. Prior to commencing with CR, 41 patients were deemed inappropriate for CR by clinical staff due to significant comorbidities as determined through review of the EMR or discussion with their cardiologist (hospice/palliative care ($n=27$), severe mobility disability ($n=6$), unstable CHF or other medical issues ($n=5$), dementia ($n=2$)) or no permanent address ($n=1$). An additional 8 patients declined to participate in CR and 20 did not respond to multiple follow-up calls. Ultimately 17% of patients with isolated HFrEF (14/83) enrolled in CR following an acute CHF hospitalization despite our aggressive recruiting protocol (Figure 1). Participants of CR were similar to those who did not attend in terms of LVEF, etiology of HFrEF (ischemic vs. non-ischemic), rate of new diagnosis, and time from original diagnosis (data not shown, $p=NS$). Significant differences were observed by discharge status (home, sub-acute rehab, palliative care, assisted living nursing care) with all 14 CR attendees discharged to home compared to 38 of 69 (55%) non-attendees ($p < 0.0001$). In addition to the patients identified through acute hospitalization, 36 patients with a primary diagnosis of HFrEF were referred directly from our outpatient cardiology or CHF clinic during the same period with 35/36 (97%) completing at least one session.

Clinical Demographics

Baseline demographics were obtained for the 49 HFrEF patients (19 female) who participated in phase 2 CR. No differences were noted between hospital and clinic-referred patients across all measures and thus baseline data was combined (Table 1). Twenty-seven patients completed CR, 13 discontinued for personal reasons (9 drop-out with no contact, 2 high copays, 1 transportation limitations, 1 moved out of state), 6 dropped out for medical reasons and 3 were still attending the program at the time of this analysis. Mean number of CR sessions completed for the entire sample was 26 ± 14 . No differences were observed between patients who completed or dropped out of CR across all baseline measures,

including PHQ-9, (data not shown, $p=NS$) making it unlikely that baseline measures significantly influenced program adherence.

CR Training Effects

Mean number of sessions for the 27 CR completers was 35 ± 1 with pre and post measures obtained for 19 patients (4 refused exit evaluations, 3 had exercise-limiting orthopedic issues, and 1 individual received follow-up care out of state). Significant improvements were observed in estimated METs, handgrip strength, MOS-SF-36, and PHQ-9 (Table 2). For patients who completed CR, no differences were noted in baseline measures between those who performed exit measures and those who did not (data not shown, $p=NS$). Expired gas analysis was obtained in a subgroup of 14 patients pre and post CR with an increase in VO_{2peak} from 14.4 ± 3.5 to 16.4 ± 4.6 $mL \cdot kg^{-1} \cdot min^{-1}$ ($p=0.02$) (+14%) (Figure 2). Additionally, 3 patients performed pre and post program 6 minute walk tests with an average improvement of 81.4 ± 22.3 meters ($p=0.02$) (+36%).

Discussion

Only 17% of patients following an acute CHF hospitalization attended Phase 2 CR at our institution during the first 18 months following the CMS coverage decision. Attendees of CR were more likely to be discharged to home rather than to sub-acute rehabilitative services or an assisted living nursing facility. Additionally, 36 patients were directly referred to CR from our outpatient cardiology and CHF clinics accounting for an absolute CR enrollment 2.5 times greater than from the hospital setting. Ninety-seven percent of patients specifically referred to CR by their primary cardiologist as a therapeutic intervention subsequently enrolled. For most of these patients, the cardiologist walked the patient over to the CR area and registered the patient as a part of their comprehensive care. For all patients who completed CR, improvements in aerobic capacity and muscular strength were demonstrated, consistent with previous reports.^{1,4,14}

Our analysis indicates HFrEF patients are exceptionally difficult to recruit following hospitalization using current protocols, even with an automated list of admissions data provided to the CR program. This difficulty is multifactorial. During a complex hospitalization for class IV HF symptoms, physicians may not yet consider the patient appropriate for CR and refrain from forcefully recommending participation. The strength of the physician recommendation is known to be a powerful predictor of CR participation.¹⁵ Additionally, without an automatic referral prompt or quality indicator within the discharge summary for HFrEF diagnoses, patients were not immediately identified and contacted by a liaison while hospitalized, which is another significant predictor of CR attendance.¹⁶ Further complicating recruitment is the required 6-week period to optimize CHF medications prior to CR eligibility making it difficult to schedule an early group visit at our CR program. Whereas some HFrEF patients following hospitalization display complex co-morbidity profiles, oftentimes with more severe health and physical limitations,⁶ others more rapidly return to their stable baseline and could safely commence CR without an arbitrarily imposed waiting period. For patients with coronary artery disease, delaying the start of CR results in a decreased likelihood of attendance at a rate 1% for each 1 day increment in wait time.¹⁷

Furthermore, Pack et al. showed that early appointments improved attendance to CR orientation sessions by 18% (10 days vs 35 days).¹⁸ Despite having a tracking system in place, CR staff found it challenging to determine the timeframe in which patients will be stable (6 weeks on optimal CHF medications without hospitalization), yet eligible to attend CR. Our cohort highlights this complex situation with 49% (41/83) of patient-candidates eventually determined to be inappropriate for CR. Finally, with 37% (31/83) of HFrEF patients discharged to sub-acute rehabilitative services or assisted living nursing facilities, none of whom attended CR, it may be pertinent to consider alternative cardiovascular care delivery models for those unable to complete traditional programs.¹⁹ Integrating cardiac care in skilled nursing facilities may also ease home transitions and potentially increase enrollment in CR programs.²⁰

Focusing recruitment on outpatient cardiology clinics seems to be a more promising and less time intensive approach. Tracking progress of eligible patients through outpatient clinics enables a more clear determination of patient stability and appropriateness to attend a CR program. Furthermore, referrals are obtained and endorsed directly from a physician caring for the patient, an approach known to greatly increase CR attendance.²¹ Our observations support this approach as all but one patient (medically inappropriate due to diabetic foot ulcers) of 36 attended at least one session following a clinic-based referral. Unfortunately, we are unable to determine the denominator of HFrEF patients seen in clinic and thus cannot calculate overall attendance rates from this referral source. CR programs not affiliated with outpatient cardiology or CHF clinics may be at a disadvantage in HFrEF recruitment and will need to develop innovative approaches through the offices of local cardiologists who are seeing these patients.

Our results support consistent results of multiple studies showing improvements in exercise capacity after completion of CR in patients with HFrEF.¹ Improvements were found in aerobic capacity whether calculated as estimated METs (35%, n=19) or VO_{2peak} (14%, n=14). Additionally, both objective (handgrip strength) and subjective (MOS-sf 36) measures of muscle strength and physical function improved following CR exercise. Finally, modest reductions in depressive symptoms were also noted suggesting psychosocial benefits in this population consistent with other CR participants.²²

Limitations of our study include that the analysis was observational from a single clinical center. Our findings, however, may be relevant for the methods of recruitment of HFrEF patients in other clinical CR programs. With our catchment area including a mix of urban and rural areas, our attendance rates may differ compared to other regions. Additionally, not all patients had aerobic capacity measured directly with expired gas analysis. Calculating METs based on treadmill time provides a reasonable proxy for aerobic capacity¹¹ and likely did not alter training results as confirmed by subjects with VO_{2peak} analysis.

Despite CMS approving CR for CHF in 2014, significant barriers to recruiting and enrolling patients with HFrEF remain. Striving for systematic in-hospital referrals with close follow-up in the outpatient setting has the potential to capture a large number of eligible patients without excessive time spent reviewing medical records. We would suggest that the required 6-week waiting period is a hindrance to getting these individuals in to CR as some patients

stabilize quickly and thus could be evaluated by the medical director. As more information is obtained regarding the HFrEF population eligible for CR programs, recruitment strategies must continue to evolve. Regardless of referral source, most HFrEF patients completing CR programs can expect improvements in aerobic capacity, muscle strength, depressive symptoms and clinical outcomes.

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Figure 1.

Diagram showing determination of the cohort for cardiac rehabilitation attendance and outcomes analysis. CR qualifying diagnosis included myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, heart valve surgery. Medically inappropriate conditions included hospice/palliative care, severe mobility disability, unstable CHF or other medical issues, dementia, no permanent address. CHF=Chronic Heart Failure. CR=Cardiac rehabilitation. HFrEF=Heart Failure with reduced Ejection Fraction.

Table 1Clinical Data and Demographics at Baseline for CR Participants^{a,b}

Patients (M/F)	49 (30/19)
Age, y	68 ± 10
Left ventricular ejection fraction, %	27 ± 6% (Range: 15–35%)
Origin of referral to CR, hospital/outpatient clinic	14/35
New diagnosis 4 months	20 (41%)
Time since HFrEF diagnosis, y	2.8 ± 4.1
Days to CR entry since hospital discharge ^c	76 ± 44
Ischemic cardiomyopathy	19 (39%)
Hypertension	31 (63%)
Type 2 diabetes mellitus	14 (29%)
Former smoker	28 (57%)
Beta-blocker	41 (84%)
ACE/ARB	37 (76%)
Body weight, kg	88.7 ± 24.6
Body mass index, kg/m ²	30.4 ± 7.0
METS _{peak}	4.8 ± 1.8
$\dot{V}O_{2peak}$, mL/kg/min ^d	14.6 ± 4.0
Handgrip strength, kg	30 ± 11
MOS SF-36 Physical Function score ^e	57 ± 25
PHQ-9	6 ± 6

Abbreviations: ACE, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; CR, cardiac rehabilitation; F, female; HF, heart failure; HFrEF, heart failure with reduced ejection fraction; M, male; METs, metabolic equivalent of task; MOS SF-36 Physical Function, Medical Outcomes Study Short Form Physical Function component. PHQ-9, Patient Health Questionnaire; SD, standard deviation; $\dot{V}O_{2peak}$, peak oxygen uptake.

^aData are reported as mean ± SD or number (%).

^bNo significant differences were observed between hospital and clinically referred patients (p=NS).

^cn = 14 patients entering CR following hospitalization for episode of acute HF.

^dn = 30 patients who completed a baseline cardiopulmonary exercise test.

^eMaximum possible score = 100.

Table 2Effects of Cardiac Rehabilitation Exercise Training (n = 19)^{a, b}

	Baseline	Exit	Change	P Value
Male patients, n	11	---	---	---
Age, y	67 ± 7			
METS _{peak}	4.6 ± 1.6	6.2 ± 2.4	1.6 ± 1.2	<.0001
VO _{2peak} , mL/kg/min ^c	14.4 ± 3.5	16.4 ± 4.6	2.0 ± 2.8	.02
Handgrip strength, kg	29 ± 9	31 ± 9	2 ± 2	.02
MOS SF-36 Physical Function score ^d	57 ± 18	69 ± 22	13 ± 20	.02
PHQ-9	5 ± 5	3 ± 4	-2 ± 4	.05

Abbreviations: CR, cardiac rehabilitation; METs, metabolic equivalent of task; MOS SF-36 Physical Function, Medical Outcomes Study Short Form Physical Function component; PHQ-9, Patient Health Questionnaire; SD, standard deviation; VO_{2peak}, peak oxygen uptake.

^aData are presented as mean ± SD except as otherwise noted.

^bAll patients with baseline and exit measures completed 36 cardiac rehabilitation sessions.

^cn = 14 patients who had cardiopulmonary exercise test before and after CR.

^dMaximum possible score = 100.