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Title

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Permalink

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Journal

Journal of cardiac failure, 11(5)

ISSN

1071-9164

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Publication Date

2005-06-01

DOI

10.1016/j.cardfail.2004.10.005

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Validity of Pedometers for Measuring Exercise Adherence in Heart Failure Patients

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ABSTRACT

Background: Measuring adherence to exercise is important to clinicians and researchers because inadequate adherence can adversely affect the effectiveness of an exercise program and cloud the relationship between exercise and clinical outcomes. Hence, assessment strategies for adherence to exercise, as with assessment strategies for other outcomes, must have demonstrated validity if they are to be employed with confidence. We conducted this study to determine the validity of pedometers as a measure of exercise adherence to a home-based walking program in heart failure patients.

Methods and Results: Exercise adherence was measured using pedometers in 38 patients (74% men) age 54.1 ± 11.7 years who participated in a 12-month home-based walking program. A comparison of functional status as measured by the 6-minute walk distance and peak oxygen uptake (VO_2 max) at 6 months into the exercise training program was made between 2 groups of participants who were thought to represent adherers and nonadherers: participants who demonstrated $\geq 10\%$ change in pedometer scores ($n = 20$) and those who showed no change in pedometer scores ($n = 18$) from baseline to 6 months. Patients who showed improvements in their pedometer scores over 6 months had better functional status at 6 months (6-minute walk distance 1718 ± 46 versus 1012 ± 25 meters, $F = 5.699$, $P = .022$; VO_2 max 17 ± 0.7 versus 10 ± 0.5 units, $F = 7.162$, $P = .011$) when compared with patients whose pedometers reflected minimal change in distance walked (ie, $\leq 10\%$).

Conclusion: Pedometers are inexpensive and readily available to both clinicians and researchers. The results of this study suggest that they may be a valid indicator of exercise adherence in heart failure patients who participate in a home-based walking program.

Key Words: Pedometer, Adherence, Functional status, Six-minute walk test, Peak oxygen uptake.

The American College of Cardiology and American Heart Association Guidelines for Management of Chronic Heart Failure in the Adult emphasized the need to incorporate a regular exercise regimen into the heart failure (HF) regimen.¹ Preliminary research demonstrates the beneficial effects of exercise on functional capacity and quality of life,²⁻⁵ but results are dependent on patient adherence to the recom-

mended exercise regimen.⁵ The assessment of that adherence is often problematic because most patients with HF exercise at home and not in the carefully supervised setting of an exercise facility or research laboratory.

Exercise adherence refers to the level of participation achieved after agreeing to participate in an exercise program.⁶ Measuring adherence to exercise is important to both clinicians and researchers because inadequate adherence can have an adverse impact on the effectiveness of exercise as an intervention and confound the interpretation of exercise study results. Nonadherence increases physician and patient frustration and leads to incorrect diagnoses and unnecessary treatment.⁷ Conversely, patient adherence with planned interventions are generally linked to more positive outcomes.⁸ Therefore, adherence is a valuable goal of lifestyle interventions. The magnitude of the relationship between adherence and treatment outcomes, however, is poorly understood. Particularly related to exercise, very few researchers in the HF literature have mentioned adherence with protocols during exercise trials,⁹⁻¹¹ and the relationships between exercise adherence and outcomes is oftentimes only briefly mentioned or alluded to under study implications or limitations.

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All decisions regarding this manuscript were made by a Guest Editor. Manuscript received May 18, 2004; revised manuscript received October 18, 2004; revised manuscript accepted October 18, 2004.

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Partially supported by a grant from the American Heart Association Western Division (NCR, 133-09 [K.D.]) and from the University of California School of Nursing Intramural Research Grant.

1071-9164/\$ - see front matter

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doi:10.1016/j.cardfail.2004.10.005

Several instruments have been used to measure exercise adherence, including heart rate monitors and uniaxial or triaxial accelerometers (eg, the Actigraph). Such techniques are often inappropriate outside the controlled setting of an exercise laboratory because of the expense or complexity of the instrument. Researchers and clinicians continue to seek valid and inexpensive ways to measure exercise adherence.¹² Comprehensive methods of assessing exercise adherence have not been applied systematically in many studies and measurement methods that allow for more detailed assessment of exercise adherence are not clearly described in previous research.⁸ The lack of data about adherence to exercise programs makes it difficult to interpret study results or determine which exercise interventions are most effective.

The current study was conducted to determine the validity of pedometers as a measure of exercise adherence as part of a prospective trial examining the benefits of a home-based walking program on clinical outcomes in advanced HF patients. We addressed the following questions: (1) Are pedometer scores correlated with self-reported measures of exercise adherence? and (2) Can pedometer scores predict functional outcomes? The overall goal of this study was to determine if pedometers offered a practical, cost-effective, and acceptable assessment strategy that could be used with confidence to measure exercise adherence to a home-based walking program among HF patients.

Methods

Subjects

The sample included 38 advanced HF patients participating in a 12-month supervised home-based walking program designed to measure clinical outcomes, including rehospitalization events. In the parent study, 175 patients were randomized to an experimental exercise group (n = 86) or a control group (n = 87). Inclusion criteria for the parent study and the substudy reported here were as follows: English-speaking, age between 18 and 80 years with advanced HF defined as left ventricular systolic dysfunction with a left ventricular ejection fraction $\leq 40\%$ (documented by echocardiogram or radionuclide ventriculography within the previous six months), and New York Heart Association class II-IV. Exclusion criteria for participation in the study included myocardial infarction or recurrent angina within the previous 3 months, orthopedic impediments to exercise, severe obstructive pulmonary disease with a forced expiratory volume in 1 second < 1 L as measured by spirometry, stenotic valvular disease as measured by echocardiogram, history of uncontrolled ventricular tachyarrhythmias (documented by electrophysiology study or 24-hour Holter monitor) or history of sudden cardiac death, without implantable cardioverter-defibrillator, or cognitive impairment.

Procedures

Institutional Review Board approval for protection of human subjects was received before initiation of the study. Patients fulfilling the recruitment criteria were randomized to the exercise group or control group after collection of baseline samples and measurements. Patients assigned to the exercise group were asked to perform a graduated, low-level exercise protocol consisting of light

aerobic exercise and resistive training. Aerobic training consisted of an individually tailored walking program of 45 minutes' duration, designed to achieve 60% of maximal heart rate. After 6 weeks of optimization of the aerobic portion of the protocol, a light resistive training component was added to the exercise regimen, and the aerobic portion was maintained until the end of the 12-month program. Patients in the control group maintained their usual level of daily activities, with no additional exercise component. All patients were monitored by monthly home visits and interviewed about their level of physical activity. Pedometers were given to all patients in the experimental group, and these patients were also asked to complete daily activity diaries for the first 6 months of the trial. Only the 38 patients (44% of the exercise participants) who were assigned to the experimental group and had complete pedometer and daily exercise diary data for the 6-month follow-up were used for this analysis. Sociodemographic data (eg, age, gender, race, marital status, education, employment status) and health history were obtained from patient self-reports and medical records. In examining the baseline characteristics of participants who had complete data (44%) and participants who had missing pedometer and exercise diary data from the cohort randomized to the intervention in the larger study (56%), we found that there were no significant differences between these 2 groups of participants on sociodemographic and clinical factors.

Pedometers

Patients were instructed to put the hip-borne pedometer (Sportline Pedometer Model 330, Sportline Inc, Yonkers, New York) on each morning and reset the device to 0. Patients then wore the pedometers over the course of the entire day. Pedometers have been validated previously in patients with HF,¹³⁻¹⁵ and are designed to be worn on a belt to display an output proportional to the number of movements of a spring-loaded pendulum displaced by vertical acceleration of the hip during walking. This then produces a cumulative count proportional to the number of footsteps taken or distance traveled in miles. Patients were asked to write the total number of minutes walked and distance traveled on a log sheet before going to bed each night. Daily scores (total distance traveled in miles) were recorded and used to compute the monthly averages.

In a recent study comparing 13 models of pedometers in generally healthy adults, the pedometer model that was used in the current study was 1 of the 5 models that yielded mean values that were not significantly different from the criterion, as opposed to 5 models that underestimated steps and 3 that overestimated the steps when compared with the criterion. Based on their findings, the authors concluded that using 1 of the 5 models that did not significantly differ from the criterion for research purposes would provide both a statistical and practical tool for measuring distance traveled.¹⁶

Exercise Diaries

Participants were also asked to complete an exercise diary each week to provide a self-report assessment of exercise using a standardized form. They were asked to log the start and stop times of their walking regimens on a daily basis and submit the diaries to the research nurse during monthly visits. Data from the daily exercise diaries were used to compute the average monthly duration of exercise in hours per month. Survey-based measures have shown some reliability and validity^{17,18} and have been used in previous exercise studies to encourage self-monitoring behaviors

among participants and provide verification that exercise has been performed as recommended.

Six-Minute Walk Test

To measure functional performance, patients were asked to complete the 6-minute walk test (6 MWT) at baseline and 6 months into the home-based walking program. Although the 6 MWT gives only a rough estimate of the general functional status of the patient, it serves as a good reflection of capacity to undertake day-to-day activities. The 6 MWT is also highly stable and reproducible and is a suitable measure of outcome in patients with chronic HF.¹⁹ We used a standardized procedure for conducting the 6 MWT for the current study. Participants were instructed to walk from end to end of a hospital corridor, which was 914 meters long (approximately 3000 feet) for 6 minutes, covering as much distance as possible over the allotted time. No encouragement or coaching was offered during the test. Participants were allowed to rest whenever necessary and to stop if signs and symptoms of significant distress (dizziness, angina, severe dyspnea, and musculoskeletal pain) occurred. Distance traveled (as measured in feet) in the allotted time of 6 minutes was computed and used for the analysis.

Cardiopulmonary Exercise Test

Patients performed symptom-limited exercise testing at baseline and again after 6 months' participation in the home-based walking program. The workload started at 25 watts (W) and increased by 25 W every 5 minutes. Patients exhaled through a 1-way valve connected to a system to determine respiratory gas exchange data continuously throughout the exercise test. Patients were encouraged to exercise to exhaustion. Measures of peak oxygen uptake (VO_2 max), which correspond to the mean oxygen uptake in the last 3 minutes of exercise, were obtained and recorded.

Statistical Analysis

All statistical calculations were carried out using SPSS for Windows (version, 10.0, SPSS, Inc, Chicago, IL).²⁰ Descriptive data are expressed as mean \pm standard error of the mean (SEM). Non-parametric analytical methods were used to analyze the key variables (pedometer scores, exercise diaries, 6 MWT, and VO_2 max).

Validity refers to how well an instrument measures what it purports to measure.²¹ Two types of validity were considered for the current study: construct validity and criterion-related validity. Construct validity refers to the appropriateness of the selected instrument for assessing the underlying theoretical construct; it is judged by comparing the pattern of correlations between a chosen instrument and other variables with known relation to the construct.²¹ To test whether pedometers, which measured distance traveled, were a valid measure of exercise adherence, we compared its pattern of correlation with exercise diaries, which measured duration of exercise, using Spearman's rank correlation coefficient (rs). A *P* value of $<.05$ was regarded as statistically significant.

We also used criterion-related validity (believed to be the most crucial type of validity for health care measures)²¹ to determine how well pedometers predicted 2 measures of functional outcomes: 6 MWT and VO_2 max. To assess this type of validity, we computed the percent change in pedometer scores at baseline and 6 months for all participants. Those who demonstrated $>10\%$ change in pedometer scores ($n = 20$) were assigned to group 1, indicating adherers; those who showed no change in pedometer scores during the 2 time measurements ($n = 18$) were assigned to group

2, indicating nonadherers. The 10% cutoff was chosen based on a study comparing different models of pedometers; the authors identified 10% as the level of meaningful difference between methods.¹⁶

Paired *t*-tests were used to measure differences in 6 MWT and VO_2 max values between the 2 groups. For this analysis, significance was set at $P \leq .05$.

Results

Baseline demographic data of patients in the study are listed in Table 1. No significant differences were noted between adherers and nonadherers based on demographic or clinical parameters (Tables 2 and 3). The patients had advanced HF of at least 2.0 ± 1.2 years duration (range 1–5 years), and were predominantly New York Heart Association class II–III (86.8%). Ischemic heart disease was the cause of HF in 16 patients (42%), defined from coronary angiography or history of myocardial infarction, whereas the remaining 22 patients (58%) had nonischemic cardiomyopathy. There was no significant difference between the groups in the number of patients with a history of hypertension, diabetes, or hyperlipidemia. All patients were treated according to current guidelines, and no statistical difference in medication use was noted between groups either at study entry or over time ($P > .05$).

Table 3 illustrates average baseline and 6-month recordings of other pertinent clinical variables including ejection fraction, VO_2 max, 6 MWT, monthly distance traveled (feet) as reflected in the pedometer scores, and duration (hours) spent walking per month as reported in the exercise diaries by participants in both groups. Table 3 also shows that patients who showed improvements in their pedometer scores had better functional status after completion of the home-based walking program than their counterparts who

Table 1. Demographic Characteristics of Study Participants

Characteristic	Group 1* (n = 20)	Group 2† (n = 18)	<i>P</i> value
Age, y (mean \pm SD)	56.24 \pm 14.39	59.85 \pm 12.26	.461
Gender, n (%)			.213
Male	15 (75.0%)	14 (77.8%)	
Female	5 (25.0%)	4 (22.2%)	
Race, n (%)			.536
White	13 (65.0%)	13 (72.2%)	
Black	2 (10.0%)	2 (11.1%)	
Other	5 (25.0%)	3 (16.7%)	
Marital status, married, n (%)	11 (55.0%)	11 (61.1%)	.678
Education, n (%)			.440
\leq High school	6 (30.0%)	3 (16.7%)	
Vocational or junior college	6 (30.0%)	6 (33.3%)	
\geq College	8 (40.0%)	9 (50.0%)	
Employment status, yes, n (%)	2 (10.0%)	2 (11.1%)	.089

*Patients with $\geq 10\%$ improvement in pedometer scores.

†Patients with no improvement in pedometer scores.

Table 2. Clinical Characteristics of Study Participants at Baseline

Characteristic	Group 1* (n = 20)	Group 2† (n = 18)	P value
New York Heart Association class, n (%)			.504
II	9 (45.0%)	8 (44.5%)	
III	9 (55.0%)	8 (44.5%)	
IV	2 (10.0%)	2 (11.0%)	
Automatic implantable cardioverter defibrillator, yes, n (%)	4 (20.0%)	6 (33.3)	.401
Hypertension, yes, n (%)	7 (35.0%)	10 (55.5%)	.254
Diabetes, yes, n (%)	4 (20.0%)	6 (33.3%)	.235
Hyperlipidemia, yes, n (%)	11 (55.0%)	9 (50.0%)	.630
Angiotensin-converting enzyme inhibitor, yes, n (%)	16 (80.0%)	14 (77.7%)	.618
β-blocker, yes, n (%)	12 (60.0%)	12 (66.7%)	.531
Angiotensin receptor blocker, yes, n (%)	4 (20.0%)	4 (22.2%)	.677
Aldactone, yes, n (%)	12 (60.0%)	9 (50.0%)	.582
Antiarrhythmics, yes, n (%)	4 (20.0%)	3 (16.7%)	.618

*Patients with ≥10% improvement in pedometer scores.
 †Patients with no improvement in pedometer scores.

did not demonstrate improvements. We also found a significant correlation between adherence measures (ie, pedometer scores and exercise diaries) and measures of functional status (ie, ejection fraction, VO₂ max, and 6 MWT) (Table 4).

A comparison of average baseline, 3-month, and 6-month pedometer scores are illustrated in Fig. 1. There were no significant differences in the group means at baseline. However, adherers demonstrated higher distance walked by pedometer than nonadherers by the third month in the program (*P* < .05) and even a more significant difference (*P* < .001) by the sixth month.

Although there was a trend toward lower number of hospitalizations among adherers (mean, 0.64, range 0–5) versus nonadherers (mean 1.01, range 0–7) during the duration of the study, the differences were not statistically significant. Likewise, the number of emergency room visits for adherers and nonadherers were relatively the same (0.46 ± .90 versus 0.40 ± .80).

Discussion

Quality of adherence measurement affects the intervention-outcome relationship, underscoring the importance of ef-

fective adherence assessment.⁸ Although a great deal of progress has been made in the objective monitoring of exercise adherence using devices such as pedometers, their usefulness has not been clearly established in HF patients. Before the conduct of the current study, controversy existed about the use of sensory monitors for reporting exercise adherence in this population. Results from exercise studies in patients with HF have been inconsistent, yielding poor long-term reproducibility and low validity.¹² By contrast, our findings support the usefulness of pedometers as valid tools for measuring exercise adherence. We found that patients who reported high levels of exercise adherence were more likely to show improvements in functional outcomes by the end of 6 months. It is possible that changes in functional capacity were due to changes in clinical status of participants from baseline to 6 months. That the clinical characteristics (ie, ejection fraction, medication use, number of hospitalizations, and emergency room visits) of adherers and nonadherers in our sample did not significantly change over time, further supports that changes in functional capacity among participants in our sample were likely to be associated with their level of adherence. Furthermore, recent data from a study conducted by our group indicate that functional status was also an independent predictor of adherence to an exercise program.²²

Clearly, the level of intervention in this program was quite high for both groups. All patients were monitored by monthly home visits and interviewed about their level of physical activity. However, differences in pedometer scores became apparent between adherers and nonadherers at 3 months; and at 6 months the difference was even more pronounced. Although we believe that other physiologic factors (ie, possibly that some patients could not improve their exercise capacity) and psychologic factors (ie, level of perceived control) contributed to the differences in pedometer scores between adherers and nonadherers, the consistency of our findings strongly support our speculation that adherence played a major role in our findings.

A major drawback to testing the validity of pedometers in this study was the lack of complete data, with only 44% of patients having both pedometer and daily diary data. We recognize that this percentage is significantly lower compared with a parallel study conducted by our group in a sample of predominantly male veterans wherein 66% of the

Table 3. A Comparison of Clinical Variables at Baseline and 6 Months

	Adherers (n = 20)		Nonadherers (n = 18)	
	Baseline	6 Mo.	Baseline	6 Mo.
Ejection fraction, % (mean ± SD)	24.9 ± 7.0	25.7 ± 7.0	26.8 ± 5.2	27.2 ± 5.2
VO ₂ max, L/min (mean ± SD)	12.8 ± 3.9	16.8 ± 4.5*	12.8 ± 3.5	10.7 ± 4.4*
6-minute walk, feet (mean ± SD)	1355.4 ± 123.6	1717.8 ± 99.3†	1191.1 ± 167.3	1011.1 ± 134.2‡
Pedometer, distance in miles/mo (mean ± SD)	59.7 ± 22.5	82.7 ± 43.5‡	59.6 ± 25.4	67.2 ± 34.7‡
Exercise diary, duration in h/mo (mean ± SD)	23.9 ± 4.6	34.0 ± 8.6‡	24.4 ± 4.3	28.2 ± 7.3‡

*Significant group difference (*P* = .011).
 †Significant group difference (*P* = .022).
 ‡Significant group difference (*P* < .001).

Table 4. Correlational Matrix for the Key Variables (n = 38)

Variable	Pedometer	Diaries	Ejection Fraction	VO ₂ max	6-min walk test
1. Pedometer scores (pedometer)	1.000				
2. Exercise diaries (diaries)	.594 [†]	1.000			
3. Ejection fraction	.383*	.154	1.000		
4. VO ₂ max	.444*	.392*	.176	1.000	
5. 6-minute walk test	.457*	.431*	.115	.454*	1.000

**P* < .05.†*P* < .001.

patients complied with the study protocol.²² In retrospect, financial incentives for complete data may have improved the completion rates. Also, the pedometers had a plastic belt clip but no safety chain, and a number of patients reported losing them. A pedometer that provides downloadable data to investigators on a daily basis would undoubtedly improve pedometer use, as would a pedometer that had a safety chain in the design.

One of the major advantages of pedometers as a measure of exercise adherence is their ease of use. Patients readily understand the principle of measuring steps in tracking distance walked, making orientation to the device quite simple. Moreover, individual units are inexpensive in comparison to Actigraphs or other types of accelerometers. Finally, pedometer assessments overcome many of the theoretical objections to laboratory-based exercise tests as they measure patients' customary activity over a longer time.²³ However, we recognize that several factors related to the use of a pedometer remain unclear (ie, How is the pedometer reading affected by walking in shorter strides or more slowly, as might happen in patients whose symptoms did not improve as much or who got worse?) and suggest that this be explicated in future studies. We also recommend the use of exercise diaries or surveys as an acceptable and valid tool to quantify levels and patterns of physical activity that can be used concurrently with pedometer readings to validate adherence to a prescribed exercise regimen.

Evidence from the present study complements findings from intervention research that suggest that patient adherence is linked to more positive outcomes than is nonadherence, and thus adherence may be a valuable goal of intervention at the individual as well as the system level.⁸ Clearly, the adherence-outcome relationship can be complex. Other factors such as the efficacy of recommendations and treatments, genetic variations in response rates, and limitations in understanding of disease and exercise recommendations can also affect outcomes. Despite these limitations, the positive relationship between pedometer distances and functional outcomes suggest that pedometers are a valid measure of adherence in this sample of HF patients. However, because the level of intervention in this program was quite high for both groups, it is uncertain whether a less intense intervention would have led to a substantially lower rate of compliance with the exercise prescription. Likewise, the current study is limited by a volunteer sample, which may not be representative of all patients with HF and certainly is younger on average than most. Also, patients with diastolic dysfunction were not included, thereby limiting the generalizability of the findings. Additional studies about the validity of this technique for patients with special conditions and more advanced symptoms would also be quite interesting.

Conclusion

Our findings show that the pedometer was a valid measure of distance walked per month. We also found that those who had greater percent change in pedometer scores at baseline and 6 months had significant improvements in functional status as measured by the 6 MWT and VO₂ max. The results of this study suggest that the pedometer might be a valid indicator of exercise adherence in HF patients who participated in a home-based exercise-training program. Although we do make several observations in our study that advance this field of inquiry, additional measurement methods that allow for more detailed assessment of exercise adherence need to be developed and systematically applied to similar studies to accurately estimate the effectiveness of an intervention. Likewise, factors such as cost, time, and acceptability must be considered when choosing an instrument to measure exercise adherence.

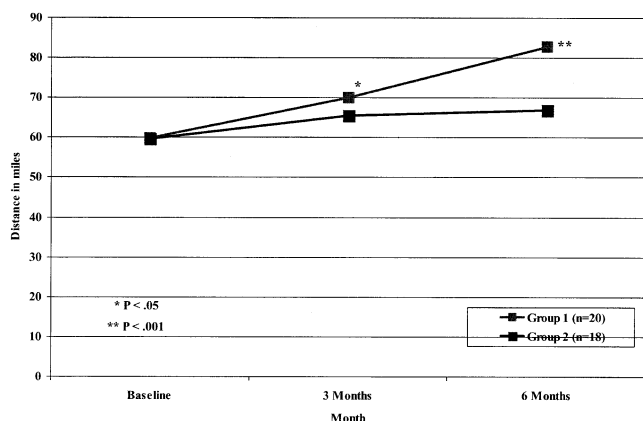


Fig. 1. Differences in average monthly pedometer scores between the two groups of patients.

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