Exercise Rehabilitation Improves Functional Outcomes and Peripheral Circulation in Patients with Intermittent Claudication: A Randomized Controlled Trial

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OBJECTIVE: To determine the effects of a 6-month exercise program on ambulatory function, free-living daily physical activity, peripheral circulation, and health-related quality of life (QOL) in disabled older patients with intermittent claudication.

DESIGN: Prospective, randomized controlled trial.

SETTING: University Medical Center and Veterans Affairs Medical Center, Baltimore, Maryland.

PARTICIPANTS: Thirty-one of 61 patients with Fontaine stage II peripheral arterial occlusive disease (PAOD) were randomized to exercise rehabilitation and 30 to usual-care control. Three patients from the exercise group and six patients from the control group dropped out, leaving 28 and 24 patients, respectively, completing the study in each group.

INTERVENTION: Six months of exercise rehabilitation.

MEASUREMENTS: Treadmill distance walked to onset of claudication and to maximal claudication, ambulatory function, peripheral circulation, perceived QOL, and daily physical activity.

RESULTS: Compliance with the exercise program was 73% of the possible sessions. Exercise rehabilitation increased treadmill distance walked to onset of claudication by 134% ($P < .001$) and to maximal claudication by 77% ($P < .001$), walking economy by 12% ($P = .003$), 6-minute walk distance by 12% ($P < .001$), and maximal calf blood flow by 30% ($P < .001$). Changes in distance walked to maximal pain correlated with changes in walking economy ($r = -.50$, $P = .013$) and changes in maximal calf blood flow ($r = .38$, $P = .047$). Exercise rehabilitation increased accelerometer-derived daily physical activity by 38% ($P < .001$); this change correlated with the change in distance walked to maximal pain ($r = .45$, $P = .020$). These improvements were significantly better than the changes in the control group ($P < .05$).

CONCLUSION: Improvements in claudication following exercise rehabilitation in older PAOD patients are dependent on improvements in peripheral circulation and walking economy. Improvement in treadmill claudication distances in these patients translated into increased accelerometer-derived physical activity in the community, which enabled the patients to become more functionally independent. **J Am Geriatr Soc 49:755–762, 2001.**

Key words: ambulation; circulation; exercise rehabilitation; intermittent claudication; peripheral arterial occlusive disease

Symptomatic peripheral arterial occlusive disease (PAOD) afflicts 6% of the U.S. population age 55 and older.[1] PAOD patients frequently experience intermittent claudication during ambulation because peripheral circulation is inadequate to meet the energy needs of the active leg musculature. Ambulatory dysfunction in patients with intermittent claudication[2–5] results in a sedentary lifestyle,[6] self-perceived ambulatory dysfunction,[7] and lower health-related quality of life (QOL).[8] Surgical therapy (e.g., percutaneous transluminal angioplasty or peripheral arterial bypass) is usually indicated only for patients who have ischemic pain at rest or limb-threatening ischemia. Because the majority of PAOD patients are not at risk for immediate tissue loss, the primary therapeutic goal is to improve ambulatory function through exercise rehabilitation.[9]

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Exercise rehabilitation for the treatment of intermittent claudication has been studied extensively over the past 35 years.[10] Although nearly 40 studies have reported changes in claudication distances following exercise rehabilitation, few used a randomized controlled design[11–16] or examined other clinically important functional outcome measures such as physical activity levels, perceived QOL, or ambulatory function.[12,16–18] Furthermore, most studies were limited by their small sample sizes and did not assess mechanisms for improved claudication distances, such as increased peripheral blood flow. The purpose of this prospective, randomized controlled trial was to determine whether a 6-month progressive treadmill exercise rehabilitation program was more effective than nonexercise usual care in improving ambulatory function, free-living daily physical activity, health-related QOL, and peripheral circulation in older PAOD patients functionally limited by intermittent claudication.

METHODS

Patients

Recruitment

The institutional review board at the University of Maryland, Baltimore (UMB), approved all procedures. Written informed consent was obtained from each patient before investigation. Nonsmoking patients with Fontaine stage II PAOD[19] (i.e., intermittent claudication upon ambulation) were recruited to participate in this study at the Claude D. Pepper Older Americans Independence Center at UMB. Six hundred and forty-one patients were recruited from vascular clinics at the Baltimore location of the Maryland Veterans Affairs Health Care System and the University of Maryland Medical System and via newspaper and radio advertisements. During a telephone screening, the Rose questionnaire for intermittent claudication was administered[20] and a brief medical history was taken. The interviewed patients were age 68 ± 11 (mean ± standard deviation), ranging between age 60 and 93. The self-reported gender and racial breakdown was 410 (64%) men and 231 (36%) women and 449 (70%) Caucasians, 179 (28%) African Americans, and 13 (2%) Hispanics. The smoking prevalence of these patients consisted of 205 (32%) who had never smoked and 436 (68%) who were former smokers who had stopped smoking at least 1 year before. Of the 641 patients, 199 (31%) satisfied the Rose criteria for intermittent claudication and 442 (69%) were excluded because they either did not meet the Rose criteria for intermittent claudication (n = 377), had other significant medical conditions (n = 44), or were not interested in participating (n = 21). The 199 patients who reported intermittent claudication underwent further screening tests at our laboratory to determine the extent of PAOD by measuring the ankle brachial index (ABI). One hundred twenty-five patients who had an ABI value <0.97[21] and were willing to participate in the study underwent further medical evaluation.

Medical Evaluation

A comprehensive medical evaluation was given that included a physical examination; medical history; complete blood count; fasting plasma glucose and lipid concentrations; glycosylated hemoglobin, liver, and renal function; and a screening maximal effort treadmill test.[3] All tests were performed with patients on their usual medications. As previously described,[17] patients were included in the study if they had a positive Rose questionnaire for intermittent claudication,[20] age ≥ 60, an ABI <0.97 at rest,[21] and evidence of functional limitation due to intermittent claudication during the screening treadmill test. Based on the guidelines of the American College of Sports Medicine[22] and Regensteiner et al.,[16] patients with any of the following criteria were excluded from the study: Fontaine stage I PAOD (ambulation not limited by claudication); Fontaine stage III PAOD (pain at rest); exercise tolerance limited by factors other than claudication (e.g., severe coronary artery disease (CAD), poorly controlled hypertension, pulmonary disease, hemiparetic gait, severe arthritis, or orthopedic conditions); poorly controlled diabetes mellitus; or other active major medical problems including cancer, renal or liver disease, anemia, substance abuse, or dementia

Fifty-three of the 125 eligible patients were excluded: 17 because of severe CAD, six with stage I PAOD, four with poorly controlled diabetes mellitus, four with poorly controlled hypertension, two with stage III PAOD, two with active cancer, and 18 for various other active medical problems. Of the 72 eligible patients, 11 dropped out of the study during baseline testing before randomization and the remaining 61 were enrolled in this study.

Randomization and Baseline Characteristics

Thirty-one of the 61 PAOD patients enrolled in the study were randomized to an exercise rehabilitation group and 30 to a usual-care, nonexercise control group. Three patients from the exercise group and six patients from the control group withdrew from the study soon after randomization. Therefore, 28 and 24 patients completed posttreatment measures. The clinical characteristics obtained at baseline were statistically similar between the two groups (Table 1).

Exercise Rehabilitation

The exercise rehabilitation program consisted of 6 months of supervised, intermittent treadmill walking to near maximal claudication pain 3 days per week as previously described.[17] There were no complications during the exercise training sessions. The control group did not receive any recommendations regarding exercise and both groups received usual medical care from their healthcare providers. Both groups were assessed on the following measurements before and after the 6-month study.

Ambulatory Measurements

Maximal Treadmill Test. Patients performed a progressive, graded treadmill protocol (2 mph, 0% grade with 2% increase every 2 minutes) until maximal claudication pain. The distance walked to onset of claudication pain, distance walked to maximal claudication pain, time to relief of claudication pain after the test, and peak oxygen uptake were measured.[23]

Submaximal Treadmill Test. This test measures the economy of walking at a constant, submaximal work rate.[23]

Table 1. Baseline Clinical Characteristics of Patients with Peripheral Artearial Occlusive Disease and Intermittent Claudication Who Completed the Study

Variable	Exercise Group (n = 28)	Control Group (n = 24)
Age (years)	71 ± 1	70 ± 1
Duration of intermittent claudication (years)	3.7 ± 1.0	3.7 ± 0.6
Walking distance to intermittent claudication (blocks)	2.8 ± 0.6	2.4 ± 0.5
Gender (% male)	89%	92%
Race (% Caucasian)	46%	67%
Coronary artery disease	50%	46%
Hypertension	82%	79%
Diabetes mellitus	46%	38%
Hyperlipidemia	64%	88%
Obesity	50%	42%
Cancer	18%	29%
Stroke	21%	8%
Chronic obstructive pulmonary disease	18%	4%

Note: Values are means ± standard deviation for the 3 variables and the remaining variables are percentage of patients in each category.

Patients walked at a treadmill speed of 2 mph and a grade of 0% until maximal claudication pain, or for a maximum of 20 minutes. Because the duration of submaximal exercise affects oxygen uptake, we compared the oxygen uptake of each patient at the same time point before and after the study.[23] Consequently, walking economy was measured as oxygen uptake during the final minute of walking at baseline and at the same time point during the posttest.

6-Minute Walk Test. Patients performed an overground, 6-minute walk test supervised by trained exercise technicians as previously described.[24] The distance to onset of claudication and total distance walked during the test were measured.

Walking Impairment Questionnaire (WIQ). Self-reported ambulatory ability was assessed using a questionnaire validated for PAOD patients in which the patients evaluated their walking ability at various speeds and distances and their ability to climb stairs.[25]

Physical Activity Measurements

Doubly Labeled Water. Energy expenditure of physical activity was determined over a 10-day period using doubly labeled water (DLW) and resting metabolic rate techniques as previously described.[26,27]

Accelerometer Monitoring. Free-living daily physical activity was monitored over 2 consecutive weekdays by a Caltrac accelerometer (Muscle Dynamics, Torrance, CA) as previously described.[26] The accelerometer assessed daily physical movements by converting vertical accelerations of the body into caloric expenditure during the 48-hour monitoring period.[28,29]

Physical Activity Questionnaires. Self-reported physical activity habits were assessed with two validated questionnaires. The Peripheral Arterial Disease Physical Activity Recall (PAD-PAR) was administered to assess the amount of physical activities (metabolic equivalents [MET] - hours/day) performed under work, leisure, and household settings.[16] Additionally, the Minnesota Leisure Time Physical Activity Questionnaire determined the self-reported daily energy expenditure of physical activity (kcal/day).[30]

Quality of Life

Health-related QOL was assessed with the Medical Outcomes Study Short-Form 36 (MOS SF-36) General Health Survey.[31] The MOS SF-36 is a reliable and valid generic instrument that includes multi-item scales that assess two components of health. The physical health component is a weighted composite score of the following four subscales: physical function, role limitations due to physical problems, general health, and bodily pain. The mental health component is a composite of the following four subscales: social function, role limitations due to emotional problems, mental health, and vitality.

Peripheral Circulation

Calf blood flow was obtained under resting, reactive hyperemic, and maximal hyperemic conditions in the more severely diseased leg using venous occlusion mercury strain-gauge plethysmography.[32] Patients rested supine for 10 minutes, after which five measures were taken and averaged. Reactive hyperemia was then performed by inflating a thigh blood pressure cuff to at least 200 mmHg to induce arterial occlusion for 3 minutes. Measurement of post-occlusive reactive hyperemia calf blood flow was obtained within the first minute following the 3-minute occlusion. The maximal hyperemic test was then performed by inflating the thigh cuff to 300 mmHg while the patients stood and performed heel raises for as long as they could tolerate. Maximal hyperemic calf blood flow was obtained within the first minute following the combined arterial occlusion and ischemic exercise.

Body Composition

Body mass index was calculated as weight in kilograms divided by height in meters^2 (kg/m^2). Percentage of body fat was determined after a 12-hour overnight fast by a total

body scan with dual-energy x-ray absorptiometry (model DPX-L, LUNAR Radiation, Madison, WI) in the supine position. All scans were analyzed using the LUNAR Version 1.3 DPX-L extended analysis program for body composition.

Statistical Analyses

A series of one-factor (group, exercise vs control) analyses of covariance (ANCOVA) were used to compare the changes in the functional, QOL, and physiological variables between the exercise and control groups using an intention-to-treat approach in patients having both pretest and posttest data points. The dependent variable in each of the ANCOVAs was the within-person difference (posttest minus baseline) in the variable being analyzed. The initial value of the dependent variable was included as an independent covariate to adjust the difference for its initial value. Pearson product-moment correlation coefficients (r) were calculated to determine the bivariate relationships between the changes in the functional and physiological measurements following exercise rehabilitation. Statistical significance was set at $P = .05$. Measurements are presented as means ± standard errors.

RESULTS

The randomization resulted in study groups of patients with comparable clinical characteristics (Table 1). The baseline measures of ambulatory function (Table 2), peripheral hemodynamics (Table 3), physical activity (Table 4), and health-related QOL and self-reported ambulatory function (Table 5) were comparable in both groups. The baseline characteristics of the three exercisers and four controls who withdrew after randomization were similar to the patients who completed the study. Baseline body mass index (29.8 ± 0.8 vs 30.1 ± 0.9 kg/m^2), body weight (88.9 ± 2.4 kg vs 89.7 ± 2.9 kg), and percentage body fat (30.6 ± 1.4 vs 31.5 ± 1.5 %) did not differ significantly between the exercise and control groups and did not change with the intervention.

The mean compliance in the 28 exercisers was 73% ± 28% (SD), with 19 patients attending at least 70% of the sessions. The skewed nature of data toward higher compliance did not permit calculation of the dose-response effect of exercise. Nevertheless, the intention-to-treat analyses included the patients who were less compliant with the exercise program. There were no complications during the exercise sessions or in the control patients that could be attributed to participation in the study.

The exercise rehabilitation program increased the treadmill distances walked to onset and to maximal claudication pain by an average of 134% and 77% ($P < .001$), respectively; these improvements were significantly better than those observed in the controls (Table 2). Despite the greater distances walked by the exercisers, there was no change in the time to relief of claudication pain. Peak oxygen uptake increased by 7% in the exercise group and decreased by 3% in the controls, but the change between the groups did not reach statistical significance ($P = .058$). Walking economy improved by an average of 12% following rehabilitation ($P = .003$); this was significantly different than the change in the controls ($P = .041$). In the exercise group, the change in walking economy correlated with the change in distance walked to onset of claudication pain ($r = -.48$, $P = .016$) and with the change in distance walked to maximal pain ($r = -.50$, $P = .013$). Exercise rehabilitation increased the distance walked to onset of pain during the 6-minute walk by 44% ($P < .001$) and the total 6-minute distance walked by 12% ($P < .001$); these changes were significantly better than in the controls ($P = .040$ and $P < .001$, respectively). In the exercise group, the change in the 6-minute distance walked to onset of pain correlated with the change in the treadmill distance walked to maximal claudication pain ($r = .53$, $P = .005$) and the change in walking economy ($r = -.45$, $P = .020$).

There was no change in the resting calf blood flow or ABI in either group (Table 3). In contrast, exercise rehabilitation increased calf blood flow measured during reactive hyperemia and maximal hyperemia by an average of 27% ($P < .001$) and 30% ($P < .001$), respectively; these changes

Table 2. Ambulatory Function in Patients with Peripheral Arterial Occlusive Disease and Intermittent Claudication Before and After Randomization into 6 Months of Exercise Rehabilitation (n = 28) or Usual Care Control (n = 24)

	Exercise Group		Control Group		
Variable	Pretest	Posttest	Pretest	Posttest	*P*-Value*
Treadmill distance to onset of claudication pain (meters)	172 ± 26	402 ± 56‡	163 ± 23	203 ± 43	.012
Treadmill distance to maximal claudication pain (meters)	396 ± 43	702 ± 57‡	379 ± 48	425 ± 56	<.001
Time to relief of claudication pain (min:sec)	6:29 ± 0:50	6:50 ± 58	8:42 ± 0:48	7:56 ± 0:52	.560
Peak oxygen uptake (ml/kg/min)	15.2 ± 0.7	16.2 ± 0.8	14.9 ± 0.8	14.4 ± 0.8	.058
Walking economy (ml/kg/min)	12.7 ± 0.5	11.2 ± 0.4†	11.8 ± 0.5	11.7 ± 0.4	.041
6-minute walk distance to onset of claudication pain (meters)	175 ± 15	252 ± 22‡	140 ± 17	165 ± 26	.040
6-minute walk distance (meters)	388 ± 16	433 ± 16‡	406 ± 18	388 ± 23	<.001

Note: Values are means ± standard errors.
*Significance of the group by test interaction term.
Significantly different from the pretest value †$P < .01$, ‡$P < .001$.

Table 3. Peripheral Hemodynamics in Patients with Peripheral Arterial Occlusive Disease and Intermittent Claudication Before and After Randomization into 6 Months of Exercise Rehabilitation (n = 28) or Usual Care Control (n = 24)

Variable	Exercise Group		Control Group		*P*-Value*
	Pretest	Posttest	Pretest	Posttest	
Calf blood flow: rest (ml/100 ml/min)	3.54 ± 0.19	3.75 ± 0.23	3.56 ± 0.22	3.52 ± 0.25	.400
Calf blood flow: reactive hyperemia (ml/100 ml/min)	9.84 ± 0.68	12.50 ± 0.85†	11.00 ± 0.79	9.76 ± 0.81	.004
Calf blood flow: maximal hyperemia (ml/100 ml/min)	13.50 ± 0.69	17.60 ± 1.24†	15.90 ± 0.94	14.50 ± 1.33	.002
Ankle brachial index: rest	0.68 ± 0.04	0.67 ± 0.04	0.69 ± 0.04	0.72 ± 0.05	.027

Note: Values are means ± standard errors.
*Significance of the group by test interaction term.
†Significantly different from the pretest value $P < .001$.

were significantly greater than the small changes in the controls ($P = .004$ and $P = .002$, respectively). The change in calf blood flow during maximal hyperemia correlated directly with the change in the treadmill distance walked to onset of claudication pain ($r = .38$, $P = .047$) and the change in the treadmill distance walked to maximal pain ($r = .38$, $P = .048$).

The accelerometer-derived measure of free-living daily physical activity increased by an average of 38% following exercise ($P < .001$) and decreased by 34% in the controls ($P < .001$, Table 4). This between-group difference of 299 kcal/day was significant ($P < .001$). The increase in free-living daily physical activity correlated directly with the change in the treadmill distance walked to onset of claudication pain ($r = .46$, $P = .019$), and the change in treadmill distance walked to maximal pain ($r = .45$, $P = .020$), but not with the changes in 6-minute distances walked or calf blood flow. There was a 31% increase in DLW-derived energy expenditure of physical activity in the exercise group, which neither reached statistical significance ($P = .100$) nor differed significantly from the 4% decrease in the controls ($P = .880$). The self-reported measures of physical activity did not change within each group and were not different between groups.

The physical and mental health composite scores of the MOS SF-36 were similar between the two groups and did not change during the study (Table 5). Consequently, no analyses were performed on the individual subscales. The baseline scores on the three WIQ subscales ranged between 32% and 52%. Although the exercise group increased by 22% and 34% on the distance and speed subscales, respectively, these changes were not significant and did not differ from the changes in the controls.

DISCUSSION

The primary findings of this prospective, randomized controlled trial were that 6 months of exercise rehabilitation significantly improves ambulatory function and peripheral circulation in older PAOD patients with intermittent claudication. These gains in physical performance translated into an increase in accelerometer-derived daily physical activity in the community. The level of compliance and the lack of exercise-related complications indicate that an exercise rehabilitation program should be considered as part of standard medical care for older patients whose physical function is limited by intermittent claudication.

The increase in treadmill claudication distances following exercise rehabilitation in this trial was similar in magnitude to that reported in our meta-analysis summarizing the results of exercise studies in PAOD patients.[10] Consequently, our results confirm the efficacy of exercise rehabilitation in PAOD patients with intermittent claudication. It is noteworthy that the time to relief of claudica-

Table 4. Physical Activity in Patients with Peripheral Arterial Occlusive Disease and Intermittent Claudication Before and After Randomization into 6 Months of Exercise Rehabilitation (n = 28) or Usual Care Control (n = 24)

Variable	Exercise Group		Control Group		*P*-Value*
	Pretest	Posttest	Pretest	Posttest	
Accelerometer (kcal/day)	366 ± 39	504 ± 49†	472 ± 49	311 ± 72†	<.001
Doubly labeled water (kcal/day)‡	497 ± 54	649 ± 80	525 ± 86	506 ± 72	.190
Minnesota LTPA (kcal/day)	128 ± 22	145 ± 45	136 ± 26	135 ± 33	.452
PAD-PAR (MET-hrs/day)	109 ± 7	106 ± 8	119 ± 13	106 ± 14	.668

Values are means ± standard errors.
*Significance of the group by test interaction term.
†Significantly different than the pretest value $P < .001$.
‡Exercise group (n = 17) and control group (n = 14).
LTPA = leisure time physical activity; PAD-PAR = peripheral arterial disease physical activity recall; MET = metabolic equivalents.

Table 5. Health-Related Quality of Life and Self-Perceived Ambulatory Measures in Patients with Peripheral Arterial Occlusive Disease and Intermittent Claudication Before and After Randomization into 6 Months of Exercise Rehabilitation (n = 22) or Usual Care Control (n = 18)

	Exercise Group		Control Group		
Variable	Pretest	Posttest	Pretest	Posttest	*P*-Value*
Physical composite score	41 ± 2	41 ± 2	40 ± 3	39 ± 2	.625
Mental health composite score	55 ± 3	59 ± 2	53 ± 3	53 ± 3	.431
WIQ distance (%)	41 ± 7	50 ± 7	33 ± 6	36 ± 7	.285
WIQ speed (%)	32 ± 4	43 ± 6	34 ± 4	32 ± 6	.146
WIQ stairs (%)	50 ± 6	52 ± 7	43 ± 7	41 ± 8	.514

Note: Values were obtained from the Medical Outcomes Study Short-Form 36 and the Walking Impairment Questionnaire (WIQ) and are presented as means ± standard deviation.
*Significance of the group by test interaction term.

tion pain following the treadmill test did not increase, despite an increase of more than 300 meters walked to maximal claudication pain following rehabilitation. Hence, these patients were capable of exercising for a greater percentage of time during a given exercise session following the rehabilitation program without a prolongation in their recovery from pain.

Reactive hyperemic and maximal calf blood flow increased following exercise rehabilitation, suggesting that enhanced peripheral circulation is one potential mechanism for the improvement in claudication distances. Exercise-dependent improvements in the peripheral circulation of patients with PAOD and intermittent claudication is not a consistent finding because some studies report a significant increase,[33–37] whereas others report no significant change in perfusion.[11,14,38–41] A closer examination of these studies reveals that maximal calf blood flow, measured using venous occlusion plethysmography, increased by an average of 19%, closely approximating the increase found in this randomized trial. Because many of the previous studies had small sample sizes, it is likely that inadequate statistical power partially accounts for the inconsistent findings. Collectively, these findings suggest that exercise rehabilitation can increase maximal calf perfusion by up to 30% in patients with PAOD and intermittent claudication, and that improved peripheral circulation contributes to improved ambulatory function.

Patients with claudication rarely need to walk at the intensity attained during a maximal, graded treadmill test. Thus, a submaximal treadmill test and a 6-minute walk test provide more clinically relevant information on the benefits of exercise rehabilitation in allowing these patients with PAOD to perform activities of daily living. We found that walking economy at a given submaximal work load improved by 12% following exercise rehabilitation, indicating that patients with symptomatic PAOD became more efficient in ambulating by expending less energy. The increase in walking economy suggests that exercise rehabilitation improves the biomechanical efficiency of ambulation,[42] thereby lowering the metabolic demand of walking on the active calf musculature. Consequently, patients were able to perform the submaximal walking test at only 69% of their peak oxygen uptake following exercise rehabilitation compared with 84% at baseline. The lower relative intensity of walking may have important clinical implications in performing activities of daily living in the community setting.

Claudication occurs in muscles distal to arterial lesions whenever the metabolic demand of the active musculature exceeds the capacity of the peripheral circulation to deliver oxygen. This mismatch can be ameliorated either by decreasing metabolic demand, increasing oxygen delivery, or both. Consequently, improvements in walking economy and calf perfusion are two mechanisms that act synergistically to relieve claudication by decreasing the metabolic demand of walking and increasing oxygen delivery, respectively. The better match between energy utilization and energy delivery in the active leg musculature leads to a delay in the development of claudication, manifested by increased distances walked.

This is the first study to use three separate measures—accelerometers, doubly labeled water, and questionnaires—to assess the impact of the exercise rehabilitation intervention on these patients' physical activity in the community. Accelerometer-measured free-living daily physical activity increased by 38% following rehabilitation, indicating that the patients walked and moved more throughout the course of a day. This increase in physical activity would equate to approximately 1.5 miles more of walking per day, as indicated by earlier studies.[16,17] The energy expenditure of physical activity assessed by DLW had a nonsignificant increase of 31% following the exercise rehabilitation program. The improved walking economy may in part explain why the nonsignificant increase in energy expenditure assessed by the DLW technique was slightly less than the increase in movement recorded by the accelerometer. The lack of statistical significance for the DLW measure of physical activity was also probably due to low statistical power because only 60% of the patients in the exercise and the control groups completed these studies. Despite the comparable percentage increases in free-living daily physical activity objectively measured by the accelerometer and DLW following rehabilitation in the present study, there was no change in self-reported physical activity or perceived ambulation assessed by the WIQ. It is possible that the additional physical activity may have consisted primarily of unstructured types of activity, such as walking in and around the home, which is difficult to discern using standardized physical activity questionnaires because they focus more on structured activities.

Exercise rehabilitation resulted in no change in the physical and mental health components of the MOS SF-36 survey. This finding is in contrast to the significant 38% to 67% gains in physical functioning following exercise programs found in smaller samples of claudicants.[16,18] Several factors may account for this discrepancy. Our sample was older and had a higher percentage of patients with low socioeconomic status. In our cohort of chronically ill PAOD patients, ambulatory dysfunction may be only one of many factors influencing self-perceived health-related QOL. Finally, it is also possible that the perceived improvements in QOL may lag behind the improvements in ambulatory function achieved at 6 months.

The major strength of this clinical trial is the integrated examination of the effects of exercise rehabilitation across the domains of function, exercise physiology, energy expenditure, and QOL in a well-characterized cohort of older patients with Fontaine stage II PAOD. We were able to demonstrate not only that exercise rehabilitation improved objective measures of physical performance and peripheral circulation, but also that these gains in performance translated into increased monitored physical activity. The primary limitations of this study include the select nature of the participants and the high percentage of men who were enrolled despite extensive efforts to recruit women.

In summary, the primary findings of this prospective, randomized controlled trial are that a 6-month program of exercise rehabilitation effectively improves ambulatory function by increasing peripheral circulation and walking economy in older patients with PAOD functionally limited by claudication. These functional gains translated into increased accelerometer-derived physical activity in the community, which enabled these patients to become more functionally independent. Therefore, exercise rehabilitation should be considered as part of standard medical care for older patients limited by intermittent claudication.

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