Long-term results of peripheral arterial disease rehabilitation

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Purpose: **Although the Peripheral Arterial Disease Rehabilitation Program (PADRx) improves walking ability and quality of life over brief periods of follow-up, the long-term durability of results has not been established. This study examined functional status, walking ability, and quality of life in patients several months after completion of a 12-week PADRx.**
Methods: **Patients who completed a PADRx were eligible for participation. A Medical Outcomes Study 36-Item Short Form (SF-36), Walking Impairment Questionnaire (WIQ), and physical activity questionnaire were administered by telephone. A progressive treadmill test was performed on-site.**
Results: **Of 63 eligible patients, 14 were lost to follow-up, 11 refused participation, and four died. Thirty-four patients had completed PADRx 20 to 80 months previously (mean, 48.2 ± 13.7 months), and completed the phone survey. Fifteen patients reported exercising a minimum of 60 min/wk for 3 months (EX group), and 19 had not exercised in the preceding 3 months (SED group). Self-reported SF-36 values were significantly different between the EX and SED groups for Physical Function (43.3 ± 8.2 vs 34.2 ± 7.8), Role–Physical Function (41.2 ± 7.7 vs 32.8 ± 9.2), and Bodily Pain (46.9 ± 8.8 vs 38.9 ± 7.1), as well as the Physical Composite (43.5 ± 6.5 vs 34.0 vs 5.8) domains of the SF-36. Similarly the WIQ demonstrated significant differences in Walking Distance (46.8 ± 36.2 vs 7.8 ± 9.4), Walking Speed (47.5 ± 32.6 vs 14.5 ± 13.9), and Stair Climbing (60.6 ± 36.6 vs 37.1 ± 27.6), favoring the EX group. Sixteen patients, equally distributed between the EX and SED groups, completed the progressive treadmill test. Both groups had experienced improvement ($P < .05$) in claudication pain time and maximal walking time after completing the 12-week supervised program. The EX group maintained increased claudication pain time of 121% and maximum walking time of 109% over baseline, whereas the SED group values had returned to baseline ($P < .05$).**
Conclusions: **Patients with claudication realize symptomatic and functional improvement with supervised exercise programs. Those who continue to exercise will potentially maintain these benefits and experience improved health-related quality of life. (J Vasc Surg 2004;39:1186-92.)**

Peripheral arterial disease (PAD) affects approximately 8 million to 12 million persons in the United States, causing significant morbidity and mortality.[1] There is considerable evidence that exercise rehabilitation can improve exercise performance and community-based functional status of patients with claudication.[2,3] Results from previous studies demonstrate that 12 weeks of supervised exercise training for patients with PAD improves peak exercise performance and decreases severity of claudication pain.[4-8]

Most studies have examined relatively short-term results of exercise therapy. We evaluated long-term effects on functional status and quality of life in patients who completed a 12-week supervised vascular exercise program.

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METHODS

Patients

Beginning in 1995, a vascular rehabilitation exercise program was established, initially hospital-based and subsequently offered in an independent practice setting. All patients who completed the vascular rehabilitation exercise program at least 12 months before this study were eligible for participation. Regardless of site, the structure of the 12-week program was consistent throughout the study period. Patients entered the program on a rolling admission policy, resulting in a variable length of follow-up in the study population.The Peripheral Arterial Disease Rehabilitation Program (PADRx) is open to all patients with PAD as documented by presence of intermittent claudication, with a resting ankle-brachial index (ABI) less than 0.9 and a decrease in ankle pressure of 15 mm Hg or more after a progressive treadmill protocol is administered. Therapy was consistent throughout the study period, and consisted of 12 weeks of formal supervised exercise training with three 1-hour exercise sessions per week of treadmill training, arm and leg ergometry, light free weight training, and flexibility exercises. In addition, patients received counseling about nutrition, exercise, risk factors for atherosclerosis, and potential complications of cardiovascular disease. Each patient performed a progressive treadmill test before entry in and after completion of the exercise program.[5]

Study design

The study was approved by the University of Rhode Island institutional review board. All eligible patients were sent a letter outlining the study and informing them that they would be contacted by telephone. Those who agreed to participate gave informed consent, and were administered a 1-hour telephone survey to update their medical history and assess quality of life, functional status, and current exercise habits. On completion of the telephone survey each patient was asked to return to the exercise program to perform a follow-up progressive treadmill test. Long-term follow-up treadmill test results were compared with baseline and immediately post-PADRx treadmill test results.

Measures

Quality-of-life questionnaire. Health-related quality of life was assessed with the Medical Outcomes Study Short-Form 36, version 2 (SF-36). The SF-36 contains 36 questions that refer to patient health over the previous 4 weeks and measures eight health domains, including physical functioning, role limitations due to physical problems, bodily pain, general health perception, vitality, social functioning, role limitations due to emotional problems, and mental health.[9]

Functional status questionnaire. The Walking Impairment Questionnaire (WIQ) is a validated questionnaire[10] designed to assess the degree of impairment experienced by patients with intermittent claudication during daily activities.[11] Regensteiner et al[10] found that the WIQ distance score is correlated ($r = 0.68$) with peak treadmill walking time. Although usually administered in a clinical setting, the WIQ has good reliability and validity with telephone administration.[12] The WIQ yields scores for walking distance, walking speed, stair-climbing ability, and pain. Outcome is expressed as a percentage of full function.

Self-reported exercise. A questionnaire was developed to evaluate exercise habits since leaving the PADRx (see Appendix). Patients reported the frequency, intensity, duration, and mode of exercise since program completion, as well as the length of time they had been involved in their routine. Using American College of Sports Medicine (ACSM) guidelines,[13] we dichotomized individuals into two groups on the basis of exercise duration of at least 60 min/wk during the last 3 months (exercise group, EX) or less than 60 min/wk for the past 3 months (sedentary group, SED). Subjective ratings of improved functional status in a community setting were evaluated.

Treadmill testing. Before the treadmill test all patients provided written informed consent. All hemodynamic measures were performed with the patient supine. ABI was obtained with a standard protocol.

Exclusion criteria for treadmill testing included resting systolic blood pressure greater than 190 mm Hg, resting diastolic blood pressure greater than 100 mm Hg, recent chest discomfort, frequent use of nitroglycerin for daily activities, obvious shortness of breath, tachycardia, previously undiagnosed irregular heart rhythm, or patient refusal.

Patients underwent the same validated graded treadmill protocol performed before participation in the supervised exercise program. In brief, the protocol begins at 1 mph and 5% grade, and speed or grade, or both, are increased every 5 minutes.[14] At the end of each stage, blood pressure, heart rate, and a five-point claudication scale are recorded. Patients continue walking until they reach maximum claudication pain or another clinical indication for stopping the test.[15]

Statistical analysis

To examine changes in maximum walking time and claudication pain time across time (pre-PADRx, completion of PADRx, follow-up) a multivariate repeated measures design (MANCOVA) was used. An alpha level of 0.05 was used for all tests of statistical significance. Data are presented as mean ± SD. Because there was a great deal of variability in the amount of time elapsed since completion of the 12-week supervised program, the number of months since program completion was included as a covariate. Pearson product moment correlations were used to determine any additional potential covariates or between-subject factors to include in the repeated measures analyses. Age and resting right and left ABI at baseline and exercise status at follow-up were correlated with maximum walking time and claudication pain time at follow-up. The dichotomous variable, exercise status, was the only significant predictor of maximum walking time ($r = 0.66$; $P < .05$) and claudication pain time ($r = 0.66$; $P < .05$). Therefore exercise status was included as a between-subjects factor in the repeated-measures MANCOVA. In the event of a significant f value, post hoc analysis with the Bonferroni correction was used to identify which time points differed.

Since exercise status was the only significant variable in the MANCOVA, independent sample t tests were used to examine differences in descriptive characteristics, WIQ scores, and health-related quality of life (SF-36) among those individuals who continued to exercise at follow-up versus those who were sedentary.

RESULTS

Demographic data. Sixty-three graduates of the vascular exercise program were eligible for the study. Of these patients, 18 could not be contacted (14 were lost to follow-up, four had died) and 11 refused participation. A series of independent-sample t tests found no significant differences ($P > .05$) at baseline for individuals who agreed to participate in the study compared with those who did not participate, with regard to age, gender, months since program completion, baseline ABI, claudication pain time, maximum walking time, smoking history, or presence of diabetes mellitus. The study population included 34 patients, 19 men and 15 women. Average age was 74.1 ± 9.1, mean baseline resting ABI was 0.53 ± 0.18, mean baseline claudication pain time was 4:49 ± 3:13 minutes, and maximum walking time was 7:30 ± 4:19 minutes. This follow-up investigation was completed 20 to 80 months (mean, 48.2 ± 13.7 months) after completion of the PADRx.

Table I. Study population demographic data

	Total population (n = 34)	*Exercise (n = 15)*	*Sedentary (n = 19)*
Average age (y)	74.1 ± 9.1	75.6 ± 9.2	73.0 ± 9.2
Male gender (%)	55.9	60	52.6
Months since program completion	48.2 ± 13.7	48.2 ± 15.6	48.2 ± 12.4
Resting ankle-brachial index*	0.53 ± 0.18	0.54 ± 0.13	0.53 ± 0.22
Claudication pain time (min)*	4.49 ± 3.13	4.56 ± 3.11	4.44 ± 3.19
Maximum walking time (min)*	7.30 ± 4.19	7.41 ± 4.31	7.21 ± 4.17

Unless otherwise specified, values represent mean ± SD.
*Before peripheral arterial disease rehabilitation.

Table II. SF-36 scores for exercise and sedentary groups

	Exercise group	*Sedentary group*
Physical functioning	43.3 ± 8.2	34.2 ± 7.8*
Role–physical	41.2 ± 7.7	32.8 ± 9.2*
Bodily pain	46.9 ± 8.8	38.9 ± 7.1*
General health	47.0 ± 9.4	41.5 ± 9.3
Vitality	52.3 ± 8.5	46.4 ± 13.4
Social functioning	49.6 ± 8.4	44.8 ± 13.6
Role–emotional	43.7 ± 13.1	37.7 ± 16.8
Mental health	50.0 ± 10.0	49.7 ± 9.0
Physical composite score	43.5 ± 6.5	34.0 ± 5.8*
Mental composite score	50.7 ± 10.3	49.3 ± 14.1

*Difference between exercise and sedentary groups, $P < .05$.

Exercise. Exercise behaviors were defined on the basis of the minimum guidelines of the ACSM[13] as 60 or more minutes of exercise per week for the preceding 3 months or less than 60 minutes per week for 3 months. These groups were clearly delineated, with the EX group exercising on average 162.3 ± 86.1 minutes per week and the SED group exercising on average 0.79 ± 2.5 minutes per week. There was no difference between the EX and SED groups in age, baseline resting ABI, claudication pain time, maximum walking time, or amount of time elapsed since completing the PADRx (Table I). The EX group seem less likely to smoke (27% vs 42%) or to have diabetes (7% vs 32%) at enrollment in the PADRx; however, these differences were not significant.

Of those patients who were no longer exercising at follow-up, 11 patients reported regular exercise habits for greater than 1 year (mean, 2.5 years), four patients reported less than 12 months of continued exercise, and four patients stopped exercising immediately after program completion. This represents a mean sedentary period from end of regular exercise to follow-up of 24 months. Reasons given for discontinuing regular exercise were lack of motivation (n = 5), orthopedic problems (n = 7), general health concerns (n = 2), and unspecified (n = 5).

Home-based versus clinic-based exercise. Functional ability and quality of life were compared in patients who continued to exercise on their own (n = 6) and those who continued to exercise in the maintenance phase of a supervised program (n = 9) either at the institution exercise clinic or at a community organized program. There were no statistical differences between theses groups in WIQ or SF-36 scores.

Interval interventions. Seven patients in the study, two in the EX group and five in the SED group, underwent vascular interventions during follow-up. Both patients in the EX group had progression of claudication symptoms to ischemic rest pain, requiring aortobifemoral bypass in one patient and extensive aortobifemoral and left femoral popliteal bypass grafting in the other patient. In the SED group five patients progressed to rest pain, one with tissue loss. Three patients were managed surgically, one with femorofemoral bypass, one with bilateral iliac and common femoral patch endarterectomy, and one with femoro–posterior tibial bypass. Two patients were managed with endovascular iliac stents. There were no amputations during follow-up in either group.

Questionnaire scores for EX and SED groups. Results from the SF-36 are presented in Table II. The EX group exhibited significantly higher Physical Function, Role–Physical Function, Bodily Pain, and Physical Composite scores, compared with the SED group ($P < .05$). No significant difference was found between the two groups in five of the eight standard subscales (General Health, Vitality, Social Function, Role–Emotional, and Mental Health) or in the Mental Composite scores.

WIQ scores are presented in Fig 1. In the EX group, distance, speed, and stair-climbing scores were significantly higher than in the SED group ($P < .05$). There was no significant difference in degree of pain between groups.

Treadmill testing. Of the 34 patients who answered the questionnaire, 17 (nine men, eight women) participated in a follow-up progressive treadmill test; however, one patient was unsuccessful in completing the treadmill test, because of arthritis. Reasons for nonparticipation in the EX group were medical (n = 5) and patient refusal (n = 2), and in the SED group were medical (n = 5), patient refusal (n = 3), and availability (n = 2). Overall, 16 patients, eight in the EX group and eight in the SED group, completed the treadmill test.

Two patients in the EX group completed the 25-minute protocol. Four patient tests were terminated because of shortness of breath or rise in systolic blood pressure to 200 mm Hg or greater, and two patient tests were

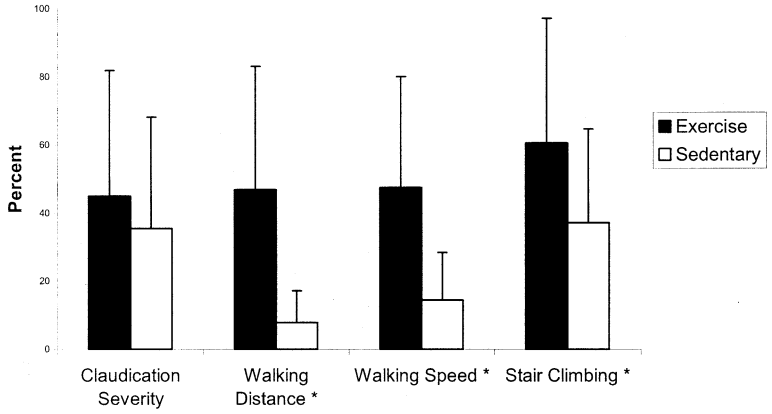

Fig 1. Values for Walking Impairment Questionnaire in exercise and sedentary groups at follow-up. Score of 100% means no claudication pain; score of 0% means patient limited by severe pain. Results represent mean ± SD. *$P < .05$, exercise vs sedentary groups.

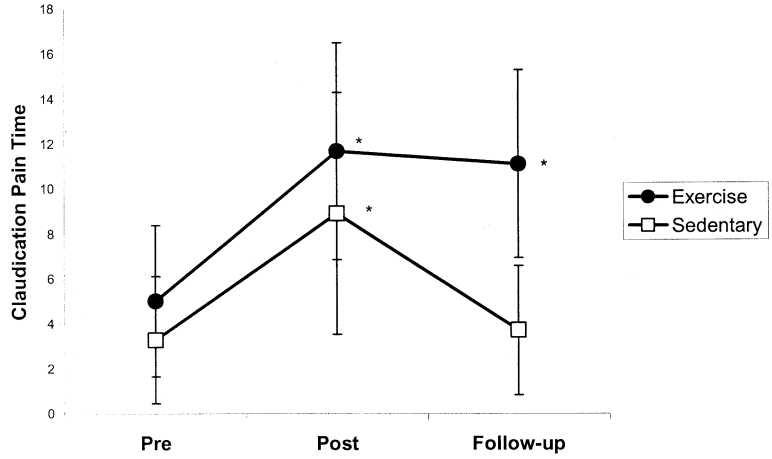

Fig 2. Values for claudication pain time in exercise and sedentary groups before and after supervised exercise program and at follow-up. Results represent mean ± SD. *$P < .05$, pre-program vs post-program and pre-program vs follow-up progressive treadmill tests.

terminated because of maximum claudication pain. In the SED group, two patient tests were terminated because of rise in systolic blood pressure to 200 mm Hg or greater, and six tests were terminated because of maximum claudication pain.

In review of treadmill testing before and after PADRx, claudication pain time and maximum walking time significantly improved in both the SED and EX groups after completion of the 12-week exercise program. At long-term follow-up, values in the SED group returned to baseline, while the EX group maintained increased claudication pain time (Fig 2) of 121% above baseline and increased maximum walking time (Fig 3) of 109% above baseline ($P < .05$).

DISCUSSION

Although studies of pharmacotherapy for claudication often have large study populations,[16-19] randomized controlled trials of supervised exercise therapy for the treatment of claudication have relatively small study populations and limited follow-up.[20] Larger studies of exercise[21] use home exercise therapy or instructions, with results inferior to those of supervised programs in short-term studies.[5,22,23] Despite numerous studies demonstrating the benefits of a supervised exercise program for treatment of claudication,[24] there is a paucity of data on the durability of results.

Our study represents follow-up of patients who had participated in a supervised exercise program over the preceding 80 months. Because of program changes due to funding and administration, regular follow-up (similar to graft surveillance) was not performed; thus our population represents patients with a variable time to completion of the program. The data show that continuation of an exercise program, either supervised or at home, is necessary for

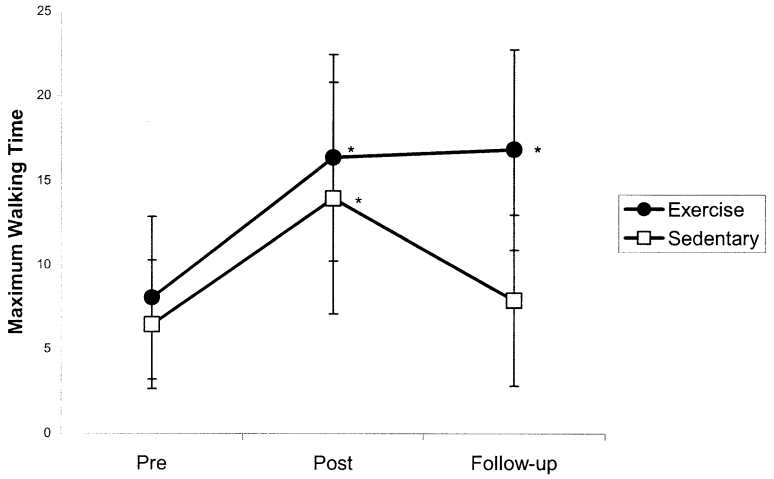

Fig 3. Values for maximum walking time in exercise and sedentary groups before and after supervised exercise program and at follow-up. Results represent mean ± SD. $*P < .05$, pre-program vs follow-up progressive treadmill tests.

maintenance of the positive effects of PADRx in the treatment of intermittent claudication. In addition, patients who continue to exercise maintain a higher health-related quality of life and greater daily functional status than do those who discontinue training.

Although not specific for patients with PAD, the SF-36 evaluates aspects of both physical and mental health–related quality of life, and has been extensively validated in patients with somatic and psychiatric conditions of varying severity.[9] Our results are consistent with those of previous studies that evaluated quality of life in patients with PAD, and found no change in the mental domain after 3 or 6 months of exercise rehabilitation,[5,7] with values close to the age-specific population norms.[9] Patients who continued to exercise had higher scores in the physical domain, findings supported by Bauman and Arthur,[25] who found a significant positive correlation between functional exercise capacity and physical domains of the SF-36.

Because only half of the patients in our study were able to perform a follow-up progressive treadmill test, we administered the WIQ to better represent functional status of the entire study population. The WIQ has been rigorously evaluated,[12] and is a satisfactory surrogate for treadmill testing. The consistency between our total population and patients completing follow-up treadmill testing further strengthens our conclusions. Results from this questionnaire show that patients who continued to exercise had significantly higher scores than sedentary patients for WIQ distance score, speed, and stair-climbing ability.

Similarly, exercise training significantly improves both claudication pain time and maximum walking time after 12 weeks of training, and individuals who continue exercise training maintain improvements 20 to 80 months (mean, ~4 years) after program completion. Two of the patients who continued to exercise completed the 25-minute treadmill protocol without limiting claudication symptoms. Their contribution actually underestimates the maximum walking time of the exercise group. Follow-up results for individuals who did not continue to exercise after completing the supervised program showed that they did not maintain improvements, and claudication pain time and maximum walking time returned to pre-PADRx levels.

Although the ACSM defines sedentary as less than 60 minutes of weekly exercise, we were somewhat surprised at the dramatic difference in self-reported exercise at follow-up, which may reflect the underlying reasons for discontinuing exercise. Ultimately it would be beneficial to identify characteristics of patients with PAD who are likely to continue an exercise program. Because of the small number of patients in this study, we were unable to define this subset. Individually, orthopedic and arthritic complaints were the primary reason patients discontinued exercise. In many patients disabling arthritis developed, and their claudication symptoms were no longer the limiting factor in walking ability. Lack of motivation was also cited by several patients as a reason for discontinuation. These patients may benefit from more frequent follow-up, and potentially from a structured maintenance program after the 12-week PADRx.

General medical concerns and comorbid disease can also limit patient functional status. In comparing the EX and SED groups for presence of diabetes mellitus and smoking history, the SED group had higher rates of diabetes and were more likely to smoke. Patients with diabetes are at significant risk for other comorbid conditions that may lead to a more physically limited lifestyle. In addition to tobacco use contributing to pulmonary, cardiac, and PAD progression, smokers are less physically active in general.[26] Identifying physical limitations, medical comorbid conditions, and smoking habits may help to predict which patients will continue an exercise program after the PADRx and to identify a patient population that will be successfully treated with conservative management. Continuing to exercise and maintaining walking distance may primarily re-

late to overall health status. However, since both the SED and EX groups demonstrated initial improvement after program completion, and there was no statistically significant difference between the groups at baseline, predictors of failure cannot be reliably determined from this study.

Few studies have compared the outcomes of exercise therapy versus surgical or endovascular intervention, because outcomes data for assessing patency of grafts, angioplasty, or stents usually rely on hemodynamic measurements.[27] With prospective randomized trials, Creasy et al[28] and Perkins et al[29] compared exercise training versus percutaneous transluminal angioplasty (PTA) for stable claudication, using ABI and treadmill testing, with claudication distance and mean walking distance as outcome measures. At 15-month follow-up there was a significantly greater improvement in the exercise training group than in those undergoing angioplasty; however, at 60-month follow-up outcomes were similar. Another prospective trial[30] randomized patients with claudication with angiographically documented lesions amenable to PTA to either medical treatment (aspirin, and instruction on smoking cessation and exercise training) or PTA. At 24-month follow-up there were no significant differences in quality-of-life measures or functional measures of ABI, patient-reported maximum walking distance, maximal treadmill walking distance, or distance to onset of claudication. Angiography at follow-up did show lesser degrees of stenosis in the PTA-treated patients; however, this did not translate into a functional advantage.

If we define long-term success of exercise programs as continued walking, good functional status in a community setting, and maintained improvement in claudication symptoms, the successful outcome rate of these study patients is 44% at a mean 48-month follow-up. If obstacles to continued exercise, such as lack of motivation, were overcome, perhaps more patients would benefit. Simply put, for the treatment of intermittent claudication the success rate of exercise therapy compares favorably with PTA and some infrainguinal bypass studies, with very low threat to limb viability and without the risk of surgical complications.

CONCLUSION

Although exercise therapy decreases atherosclerosis associated with PAD or change in hemodynamic measures, it can decrease claudication symptoms, improve functional ability, and greatly enhance quality of life in patients with intermittent claudication. This study demonstrates that patients who continue to exercise after completing a 12-week vascular exercise program not only maintain greater functional ability but also experience greater quality of life.

APPENDIX. HEALTH AND EXERCISE STATUS EVALUATION FOR PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

General Health History

1. Since completing the exercise program have you had any other health problems? If yes, describe.
2. Since completing the program have you undergone any major surgery or been hospitalized for any major illness? If yes, describe.
3. Have you undergone any additional treatment for vascular disease since completing the exercise program? If yes, describe.
4. Have you continued to exercise after participating in the vascular exercise program? If yes, are the exercises you do similar to the ones you did in the exercise program? Describe. If no, choose the reason that best describes why you have not exercised.
   a. General health concern.
   b. Orthopedic problems.
   c. Not enough time.
   d. No motivation.
   e. Other. Please explain.
5. What is your usual pace of walking?
6. How many flights of stairs do you walk up each day? (1 flight = 10 stairs)
   a. Never walk stairs.
   b. 1-5.
   c. 6-10.
   d. Greater than 10.

Exercise Habits Since Leaving Program

7. How would you rate your current exercise habits?
   a. Similar to the exercises you did during the program.
   b. Less than you did at the program.
   c. More than you did at the program.
8. What type of exercise do you do?
   a. Walk/run.
   b. Bike.
   c. Swim.
   d. Other. Please explain.
9. How long did you exercise after the program and then stopped exercising regularly?
   a. A couple of weeks.
   b. A couple of months.
   c. A couple of years.
   d. I still exercise regularly.
   e. I stopped immediately after the program ended. If you have stopped, why?
10. Over the past 7 days, how often did you take a walk outside your home or yard for any reason, eg, for fun or exercise, walk to the store, walk the dog?
    a. Never.
    b. Seldom (1-2 days).
    c. Sometimes (3-4 days).
    d. Often (5-7 days).
11. How many times a week do you engage in regular physical activity long enough to work up a sweat, get your heart thumping, or get out of breath?
12. On average, how many minutes per day do you work up a sweat, get your heart thumping, and find yourself out of breath?

13. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or push-ups?
    a. Never.
    b. Seldom (1-2 days).
    c. Sometimes (3-4 days).
    d. Often (5-7 days).
14. Do you feel that you can walk better today than you could before you entered the vascular rehabilitation exercise program?
    a. Yes.
    b. No.

If yes, do you think you can walk better as a result of the vascular exercise program? Please describe.

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