PoleStriding Exercise and Vitamin E for Management of Peripheral Vascular Disease

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[1]Research and Development Service, [2]Nursing Service, [3]Medical Service, [4]Surgical Service, and [5]Cooperative Studies Program Coordinating Center at VA Hospital, Hines, IL; [6]College of Nursing at University of Illinois Chicago, Chicago, IL; and [7]Departments of Medicine and [8]Surgery, Stritch School of Medicine at Loyola University, Maywood, IL

ABSTRACT

COLLINS, E. G., W. E. LANGBEIN, C. OREBAUGH, C. BAMMERT, K. HANSON, D. REDA, L. C. EDWARDS, and F. N. LITTOOY. PoleStriding Exercise and Vitamin E for Management of Peripheral Vascular Disease. *Med. Sci. Sports Exerc.*, Vol. 35, No. 3, pp. 384–393, 2003. **Purpose:** The purpose of this investigation was to evaluate the efficacy of PoleStriding exercise (a form of walking that uses muscles of the upper and lower body in a continuous movement similar to cross-country skiing) and vitamin E (α-tocopherol) to improve walking ability and perceived quality of life (QOL) of patients with claudication pain secondary to peripheral arterial disease (PAD). **Methods:** Fifty-two subjects were randomized into four groups: PoleStriding with vitamin E ($N = 13$), PoleStriding with placebo ($N = 14$), vitamin E without exercise ($N = 13$), and placebo without exercise ($N = 12$). The dose of vitamin E was 400 IU daily. Only the PoleStriding with vitamin E and PoleStriding with placebo groups received PoleStriding instruction and training. Assignment to vitamin E or placebo was double blind. Subjects trained three times weekly for 30–45 min (rest time excluded). Individuals in vitamin E and placebo groups came to the laboratory biweekly for ankle blood-pressure measurements. **Results:** Results of this randomized clinical trial provide strong evidence that PoleStriding significantly ($P < 0.001$) improved exercise tolerance on the constant work-rate and incremental treadmill tests. Ratings of perceived claudication pain were significantly less after the PoleStriding training program ($P = 0.02$). In contrast, vitamin E did not have a statistically significant effect on the subjects' ratings of perceived leg pain ($P = 0.35$) or treadmill walking duration ($P = 0.36$). Perceived distance and walking speed (Walking Impairment Questionnaire) and perceived physical function (Rand Short Form-36) improved in the PoleStriding trained group only ($P < 0.001$, 0.022 and 0.003, respectively). **Conclusion:** PoleStriding effectively improved the exercise tolerance and perceived QOL of patients with PAD. Little additional benefit to exercise capacity was realized from vitamin E supplementation. **Key Words:** ANTIOXIDANTS, PERIPHERAL ARTERIAL DISEASE, EXERCISE

Patients with atherosclerotic peripheral arterial disease (PAD) of the lower extremities are subject to periods of intermittent claudication caused by the formation of atherosclerotic plaques that narrow or occlude arteries. This condition results in an inadequate blood flow causing ischemic muscle pain. This potentially debilitating problem can affect an individual's quality of life (QOL) by limiting daily physical activities thus affecting ability to work, personal and social relationships, and independence.

Vitamin E supplements have been investigated as a treatment for intermittent claudication. Vitamin E is a fat-soluble vitamin present in many foods. It is postulated that vitamin E acts as an antioxidant by protecting polyunsaturated fatty acids and other oxygen-sensitive substances such as vitamin A and ascorbic acid from oxidation. Most have found that vitamin E decreases platelet aggregation (7). The results of studies analyzing the effects of vitamin E on PAD have been mixed. Previous investigators have reported improvements in walking distance of 78–243% and others no changes (25,30).

Numerous investigators have studied the effects of exercise on the walking capacity of persons with PAD. Reports of improvement in pretraining walking distance range from 25 to 183% (4,8–12). All studies, many of which did not use random assignment of subjects, report an increase in exercise capacity and a posttraining decrease of intermittent claudication pain during walking or the ability to walk further before reaching exercise-limiting pain (4,12,13,17,19,20,25,26). Two studies showed that functional capacity and daily activity level improve after exercise training (8,9,18,19).

Few investigators have studied QOL in patients with PAD (2,8,9,18–20). Researchers have reported significant associations between decreased walking ability and low physical function scores on QOL instruments (2). More research is needed, however, before drawing any conclusions regarding the effects of improved walking capacity on the QOL in this population.

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The purpose of this clinical trial was to determine the efficacy of utilizing PoleStriding (see Rehabilitation/Conditioning Protocol for a description of PoleStriding) and/or α-tocopherol (vitamin E) for increasing exercise tolerance, improving QOL, and daily activity level in individuals with peripheral arterial disease. The institution's Human Studies Subcommittee (IRB) approved the study.

RESEARCH METHODS

Overview of research plan. A prospective, randomized clinical trial with a two-by-two factorial double-blind (vitamin E variable only) design was used in this investigation. Because the patient's walking ability was limited by PAD, patients who satisfied the inclusion criteria, completed a history and physical exam, and gave their written informed consent completed a symptom limited maximal wheelchair exercise test to screen for cardiovascular disease (5). In the event that the electrocardiogram was positive, the patient was not included in the program unless appropriate follow-up testing (coronary angiography, dipyridamole thallium treadmill test) was completed, and a cardiologist cleared him/her to do so. After this initial screening test, baseline testing was completed. Baseline testing consisted of at least two symptom-limited, maximal, incremental treadmill tests, a constant work-rate treadmill test, measurement of ankle-brachial indices, and completion of the Medical Outcomes Study/RAND Corporation's 36-item short-form Walking Impairment Questionnaire and Physical Activity Recall Questionnaire. The treadmill and QOL testing was repeated by all subjects at 4, 8, 12, 16, and 24 wk. Metabolic and hemodynamic measures were taken before, during, and after the treadmill test. Oxygen uptake was determined using the 2900 Metabolic Measurement Cart (SensorMedics Corporation, Yorba Linda, CA). Before and after each test, the analyzers were calibrated with reference gases and room air. Serum vitamin E levels were monitored at baseline, 12 and 24 wk. Investigators were blind to the vitamin E levels until the study was completed. Randomization, using permuted blocks, was computer generated. Exercise and control assignments were in sealed envelopes that were opened at the time the patient was randomized.

After baseline testing, subjects were randomized into four groups: PoleStriding exercise with vitamin E (PS+VitE), PoleStriding exercise with placebo (PS+placebo), vitamin E without exercise (VitE), and placebo without exercise (placebo). The dose of vitamin E was 400 IU daily. Only the PS+VitE and PS+placebo groups received PoleStriding instruction and training. Individuals in the VitE and placebo groups came to the laboratory biweekly for ankle-brachial index (ABI) measurements.

ABI for the most severely affected leg was assessed before exercise, after 15 min supine rest, and again within 120–150 s after exercise, and every 2 min until the subject's ABI returned to the preexercise level. With the subject resting comfortably in a supine position, Doppler ultrasound was used to measure the systolic pressure in the right arm and then the right ankle (posterior tibial and dorsalis pedis arteries). The same procedure was performed on the left side. The ABI was calculated by dividing the highest ankle pressure (dorsalis pedis or posterior tibial) in the affected leg by the highest systolic arm pressure. The baseline site for measuring the ABI was kept consistent for each individual for the remainder of the study.

Before each test, subjects were asked to look over the Borg scale (3). After the subject indicated that he/she was familiar with the scale, a technician reviewed instructions for the determination of rating of perceived exertion (RPE) and rating of perceived pain (RPP). During exercise, the subject's perception of claudication pain severity was determined every 60 s.

To establish a stable baseline for treadmill testing, subjects completed the incremental treadmill test protocol at least twice. If the duration on the two baseline incremental treadmill tests was within 10%, the subject continued with other baseline testing. In the event that the duration was greater than 10% between the two initial treadmill tests, the subjects' maximal metabolic values ($\dot{V}O_2$, $mL \cdot kg^{-1} \cdot min^{-1}$) were compared. If the maximal $\dot{V}O_2$ was within 5%, the subject proceeded with the next battery of baseline tests. However, if the variation in measures of both duration and $\dot{V}O_2$ were greater than the 10% and 5% limits, the subject completed a third test.

Subject selection and screening. Subjects were recruited from the Peripheral Vascular and Outpatient Clinics at the Department of Veterans Affairs Hospital where the study was conducted, referrals from local physician groups, and responses to advertisements in local media. A total of 1065 individuals were screened for participation in the study. The four primary factors that precluded participation were presence of comorbid conditions (36%), did not have peripheral arterial disease (21%), refusal to travel to the research laboratory (9%), and "pseudo volunteers" or individuals who indicate interest in participating but failed to respond to follow-up calls and/or did not come for scheduled appointments (7%). Individuals selected to participate in the study were male or female with a current diagnosis of PAD, a history of intermittent claudication, and an ABI <0.95 at rest and/or <0.85 after exercise (10). Pain from intermittent claudication must have been the primary limiting factor to maximal exercise performance during a treadmill test. If a patient was currently taking any of the following drugs, vitamin E, Coumadin, or pentoxifylline, he/she was excluded from the study.

Incremental Symptom-Limited Treadmill Test protocol. A new treadmill protocol was developed for the present study. The protocol had ramp characteristics with small increases in percent grade that occur every 30 s, and after the first 6 min, speed was increased every 3 min. Exercise began at 0% grade and a speed of 2.9 $km \cdot h^{-1}$. The protocol was designed so that the metabolic requirements increased by 1 MET every 3 min (METs were estimated using the equation published in *Guidelines for Exercise Testing and Prescription*) (14).

Constant Work-Rate Treadmill Test protocol. Subjects completed a constant work-rate treadmill test at baseline and 1, 3, and 6 months. Treadmill speed and grade were held constant at 2.9 $km \cdot h^{-1}$ and 12%, respectively; no metabolic measures were taken during this test. During the baseline test, subjects walked until forced to stop by intermittent claudication pain. Walking time was recorded. Subjects' ABI were determined at rest, before exercise, and during recovery. In addition, heart rate, RPP, RPE, blood pressure, duration, and distance were measured during the constant work-rate treadmill test.

Psychometric testing. A trained member of the research team administered all interviews intended to determine subjects' perceived QOL and functional status.

Medical outcomes study/RAND Corporation's 36-item short-form (SF-36). The SF-36 has been widely used (28). The SF-36 is comprised of eight subscales (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health). Scores on all of the subscales have high reliability and stability when administered to groups of medically stable individuals (29).

Walking Impairment Questionnaire (WIQ). The WIQ assesses a subject's self-reported difficulty in walking a defined distance (1/2 or less, 1, 2, or 3 city blocks) and speed (walking one block slowly, at an average speed, or quickly, or running or jogging one block). Responses to the 18 questions are ranked on a 0–3 scale (0 = did not do, 3 = no difficulty) (18). The WIQ has been shown to be a reliable and valid measure of walking impairment in the PAD population (18). Summary scores were obtained for the six walking distance and four speed questions.

PAD Physical Activity Recall Questionnaire (PAR). The PAR was used to evaluate energy expenditure for all waking hours of the previous week. The PAR assesses all forms of physical activity associated with occupation, leisure time, and maintaining a household (22). Subject responses to the interviewer's questions were quantified in METs and reported in MET hours per week.

Placebo and vitamin E (α-tocopherol) protocol. Subjects received 400 IU of vitamin E orally daily or an identical placebo (oil only) capsule (vitamin E and placebo capsules were provided by the Henkel Corporation, La-Grange, IL). Compliance with the study drug treatment was monitored in two ways: patient self-report and measured vitamin E levels. Vitamin E levels were obtained at baseline and 3 and 6 months. Investigators did not receive the measured vitamin E levels until the study ended.

Rehabilitation/conditioning protocol. PoleStriding is a form of walking that uses muscles of the upper and lower body in a continuous movement similar to cross-country skiing. EXERSTRIDER® walking poles (EXERSTRIDER Products Inc., Madison, WI) were individually sized according to the subject's height. The EXERSTRIDER poles are similar to those used in cross-country skiing but have rubber tips and modified hand grips designed to provide a better platform for the hand during the push phase of poling. The use of PoleStriding by individuals with peripheral arterial disease may have some mechanical and physiological advantages. Wilson et al. (31) demonstrated that the use of walking poles enable the individual to walk at increased speed and stride length with reduced vertical ground and knee joint reaction forces. Theoretically, with the longer period of time the leg muscles are relaxed between the "toe off" to "heel strike" phase of the recovering leg (nonweight bearing), individuals using good poling mechanics may have better perfusion of the leg muscles (15). Moreover, there may be less tension created in the antigravity muscles contracting to balance forces due to the reduced effect of ground reaction forces on the leg. As a result, the accumulation of metabolic by-products may be slowed, thus extending the period of time the muscles of the lower legs can perform aerobically (15).

PoleStriding instruction/orientation lasted approximately 1 h and included a videotape (21), demonstration, and practice. After this introductory session, PoleStriding instruction was provided during every training session as needed and continued throughout training. Initial training intensity and duration was based on information obtained from both the wheelchair and treadmill exercise tests. Training intensity ranged from 70 to 80% of measured maximal HR. Duration of training sessions, not including rest intervals, was 45–60 min, three times weekly for 24 wk. An exercise interval could be stopped earlier than planned if a participant's rating of perceived claudication pain on the Borg scale was 5.0 or more severe. Gradually, exercise intervals were increased in length while rest intervals were shortened. The intensity of training was varied by the amount of upper body effort used during poling, increasing or decreasing walking speed, combined changes in walking speed and poling effort, the amount of time allowed for rest intervals, and changes in terrain. Frequent measures of HR and RPE served as indicators of exercise strain.

For the first 3 months, nonexercising subjects were seen biweekly by the study staff and monthly thereafter. This was done to control for potential bias in subject measurements caused by the amount of attention one group received over the other. During each visit body weight, heart rate, BP, and ABI were measured, a PAR completed, and drug compliance assessed. Data obtained from these visits were used for clinical purposes only.

Statistical analysis. The baseline walking endurance time on the symptom-limited incremental treadmill test was determined as the longest time walked on the two treadmill tests that differed by $\leq 10\%$. For continuous measures, such as exercise parameters and QOL, the change from baseline to the end of the study was calculated for each patient. Two-way ANOVA with interaction was performed to determine whether PoleStriding and vitamin E had significant effects on the outcome measures. If the interaction was not significant, then it was dropped from the model. The significance of the PoleStriding exercise and vitamin E main effects and the interaction were tested at $P \leq 0.05$. Note: interaction effects were not significant for any of the models tested. Therefore, all models were retested for main effects only.

TABLE 1. Demographic information for subjects randomized to the PoleStriding with vitamin E (PS+VitE, $N = 13$), PoleStriding with a placebo (PS+placebo, $N = 14$), vitamin E without PoleStriding (VitE, $N = 13$) and placebo without PoleStriding (placebo, $N = 12$) groups.

Parameter	Group Assignment			
	PS+VitE	PS+Placebo	VitE	Placebo
Age (yr)	67.5 ± 5.8	63.6 ± 7.8	67.2 ± 9.4	70.2 ± 8.3
BMI	27.4 ± 4.0	29.7 ± 5.8	27.7 ± 5.8	29.0 ± 5.0
Education (highest grade)	11.8 ± 2.4	12.1 ± 2.9	14.1 ± 2.1	11.8 ± 2.0
Smoking (pack yr)	67.0 ± 44.6	56.0 ± 28.2	48.2 ± 34.1	59.5 ± 37.9
Smoking presently (%)	38.5	35.7	46.2	25.0
Employment status (%)				
Full-time	0	14.3	15.4	8.3
Part-time	15.4	21.4	23.1	0
Seeking employment	15.4	0	7.7	0
Retired	61.5	42.9	53.8	91.7
Disabled	7.7	21.4	0	0
Ethnic background (%)				
Black	0	28.6	7.7	25.0
Caucasian	100	64.3	92.3	75.0
Hispanic	0	7.1	0	0

PS+VitE data include one female subject; PS, PoleStriding; BMI, body mass index [body weight (kg) ÷ height (m^2)].

The slope of the relationship between rating of RPP as well as RPE and time of exercise on the treadmill test was determined for each subject by using linear regression procedures. Differences in derived slopes between PoleStriding and vitamin E were determined using a two-way ANOVA.

RESULTS

Subjects. Seventy-three individuals satisfied the inclusion criteria and gave their written informed consent. Twenty-one subjects did not progress to randomization for the following reasons: baseline stress test was positive for coronary artery disease ($N = 6$), exercise was limited by factor(s) other than claudication ($N = 5$), uncontrolled hypertension ($N = 4$), ongoing treatment for cancer ($N = 2$), time commitment too great ($N = 3$), and developed pancreatitis ($N = 1$). The nonrandomized cohort (mean age = 73 ± 5 yr) was significantly older than those who were eventually randomized to one of the study groups (mean age = 67 ± 8 yr; $P = 0.03$). No other significant differences on major study variables were found. Of this group, 51 men and one woman completed baseline testing and were randomized into one of the four experimental conditions (Table 1). No significant differences were noted between the groups on any of the major demographic variables by using one-way ANOVA or chi-square statistics (age, body mass index, education, employment, pack years of smoking, or current smoking status). Six randomized subjects did not complete the study. Four individuals were withdrawn for medical reasons that included severe exacerbation of osteoarthritis (PS+VitE), psychological instability (PS+placebo), cancer diagnosis (Placebo), and an accident that resulted in rib fractures and carpal tunnel surgery (placebo). One subject (PS+placebo) withdrew immediately after baseline testing was completed (no reason given) and the other (PS+placebo) after 2 months of exercise training (excessive time commitment).

Baseline symptom-limited incremental treadmill exercise testing. Thirty-five (67%) of the subjects satisfied either the duration or the metabolic criteria after two baseline treadmill tests. Seventeen randomized subjects required a third test. The difference between the three tests in these 17 subjects was significant ($F = 6.12$, $P = 0.01$). *Post hoc* pairwise comparisons revealed significant differences between the first and second tests ($P = 0.008$), and the first and third ($P = 0.003$) tests. No significant difference was found between the second and third tests ($P = 0.79$). Of the 52 randomized subjects, the average percent difference in exercise duration on the two qualifying tests was 5.4 ± 3.1%.

Symptom-limited incremental treadmill exercise test. Mean differences in the exercise duration between baseline and 6 months for the four groups during the incremental treadmill test were evaluated. There was a significant PoleStriding exercise effect ($F = 53.9$, $P < 0.0001$) and no significant vitamin E ($F = 0.7$, $P = 0.42$) or interaction ($F = 1.1$, $P = 0.30$) effect. The model was unchanged when retested without the interaction effect (PoleStriding effect, $F = 55.1$, $P < 0.0001$; vitamin E effect, $F = 0.71$, $P = 0.41$). Exercise duration for each group at baseline and 6 months is presented in Table 2. After 6 months of training, the PS+VitE and PS+placebo groups improved their duration

TABLE 2. Means (±SD) for experimental groups at baseline and 6 months for the incremental treadmill test; parameters shown include exercise duration and peak oxygen uptake [$\dot{V}O_2$ ($mL \cdot min^{-1}$)].

Parameter	PS+VitE ($N = 12$)	PS+placebo ($N = 11$)	VitE ($N = 13$)	Placebo ($N = 10$)	*P* PS	*P* VitE
Duration (s)						
Baseline	612 ± 268	639 ± 233	714 ± 321	611 ± 234	—	—
6th month	954 ± 213	934 ± 325	608 ± 319	634 ± 241	<0.0001	0.40
$\dot{V}O_2$ ($mL \cdot min^{-1}$)						
Baseline	1321 ± 195	1379 ± 580	1548 ± 511	1438 ± 348	—	—
6th month	1478 ± 313	1680 ± 656	1472 ± 556	1409 ± 425	<0.0001	0.80

PS, PoleStriding; VitE, vitamin E; since the interaction was not significant, *P* values are presented from the main effects model.

TABLE 3. Means (±SD) for duration walked (s) on the constant work-rate treadmill test for all experimental groups at baseline, 1, 3, and 6 months.

Parameter	PS+VitE (N = 12)	PS+Placebo (N = 11)	VitE (N = 13)	Placebo (N = 10)	P PS	P VitE
Baseline	466 ± 360	804 ± 640	705 ± 951	612 ± 378	—	—
1st month	1051 ± 927	1271 ± 1137	672 ± 629	670 ± 401	0.002	0.88
3rd month	1112 ± 1070	1428 ± 1278	515 ± 276	688 ± 416	0.004	0.89
6th month	1886 ± 1092	2020 ± 1389	664 ± 548	623 ± 531	<0.0001	0.36

PS, PoleStriding; VitE, vitamin E; since the interaction was not significant, P values are presented from the main effects model. Tabled comparisons for PS and VitE were baseline vs 1, 3, and 6 months.

on the treadmill test by 47% and 57%, respectively. Conversely, duration for the VitE group declined by 14% and the Placebo group improved by 1%. By 6 months, measures of peak oxygen uptake increased in both of the PoleStriding groups and not in the nonexercising groups (see Table 2).

Constant work-rate treadmill test. By 6 months, the PS+VitE group increased their baseline time by 1420 s (304%) or 1.13 km on the constant work-rate treadmill test, the PS+placebo group improved their time by 1216 s (151%) or 0.98 km, the VitE group walking time decreased by 41 s (−6%), and the placebo group increased walking time by 11 s (2%) (Table 3). Two-way ANOVA was used to test the effect of the PoleStriding exercise and vitamin E on duration walked on the constant work-rate treadmill test. A change score was computed by calculating the difference in seconds walked from the baseline test to the 6-month test. Because the baseline exercise duration for the PS+VitE group was markedly lower than the other three groups, the model was tested with and without the baseline duration as a covariate. The interaction effect between PoleStriding and vitamin E was also tested. Both baseline duration and the interaction effect were not significant. Therefore, the model utilized for subsequent data analyses did not include either of these factors. PoleStriding training significantly affected duration ($F = 29.42$, $P < 0.001$), whereas vitamin E had no effect on duration walked during the constant work-rate treadmill test ($F = 0.84$, $P = 0.36$).

Arterial blood flow in the legs. Resting preexercise ABI and 2-min postexercise ABI for the constant work-rate treadmill test were recorded at baseline and 1, 3, and 6 months (see Table 4). There was no PoleStriding training effect on resting ABI ($P = 0.87$) or the 2-min postexercise ABI ($P = 0.29$). Likewise, there was no vitamin E effect for the resting ABI ($P = 0.20$) or the 2-min postexercise ABI ($P = 0.39$).

Rating of perceived leg claudication pain. The slope of the relationship between perceived leg pain and exercise time during the incremental treadmill test was determined for each subject using the least squares method. At baseline, the average of the slopes of the regression lines for perceived leg pain in the four groups were equivalent (see Table 5). After 6 months, there was a significant main effect change for exercise and no vitamin E effect. In Figure 1, the average ratings of perceived leg pain given by subjects in the four groups at baseline and 6 months during the treadmill test have been plotted.

Following identical procedures as used with RPP, the slope of the relationship between RPE and exercise time during the treadmill test was determined for each subject. Likewise, there was a significant main effect for exercise and no significant effect from vitamin E (see Table 5).

Health-related QOL. A significant PoleStriding effect was found in the SF36 when comparing changes in baseline with 6-month values on the physical function subscale only. No significant interaction or vitamin E effects were found on any of the subscales (Table 6).

WIQ. At baseline, group differences for perceived ability to walk and ability to walk at greater speed were not significant (Table 7). There was a significant PoleStriding effect and no significant effect from vitamin E supplementation. There was no significant interaction effect. The increase in perceived walking distance correlated directly with the change in time walked on the treadmill ($r = 0.42$, $P = 0.007$) but not perceived physical function or overall physical activity.

PAR. Total active MET hours were computed using the PAR (Table 8). MET hours were computed by multiplying the number of active hours by their associated MET value. Differences in the average change in MET hours from baseline to the average MET hours from 1 to 6 months for

TABLE 4. Resting ankle-brachial index (ABI) means (±SD) pre and 2 min postexercise on the constant work-rate treadmill test for all experimental groups at baseline, 1, 3, and 6 months.

Parameter	PS+VitE (N = 12)	PS+Placebo (N = 11)	VitE (N = 13)	Placebo (N = 10)	P PS	P VitE
Resting ABI						
Baseline	0.72 ± 0.20	0.55 ± 0.27	0.63 ± 0.15	0.77 ± 0.10	—	—
1st month	0.67 ± 0.23	0.56 ± 0.18	0.62 ± 0.17	0.75 ± 0.17	0.89	0.87
3rd month	0.71 ± 0.13	0.64 ± 0.26	0.67 ± 0.18	0.78 ± 0.11	0.46	0.86
6th month	0.69 ± 0.15	0.73 ± 0.30	0.63 ± 0.12	0.82 ± 0.17	0.87	0.20
Two-minute ABI						
Baseline	0.26 ± 0.20	0.20 ± 0.19	0.28 ± 0.22	0.35 ± 0.23	—	—
1st month	0.28 ± 0.17	0.25 ± 0.24	0.26 ± 0.16	0.39 ± 0.34	0.56	0.46
3rd month	0.27 ± 0.16	0.39 ± 0.26	0.36 ± 0.20	0.38 ± 0.14	0.49	0.93
6th month	0.32 ± 0.21	0.40 ± 0.31	0.21 ± 0.19	0.44 ± 0.19	0.29	0.39

PS, PoleStriding; VitE, vitamin E; ABI, ankle-brachial index; since the interaction was not significant, P values are presented from the main effects model. All comparisons above were made between the noted time period and baseline.

TABLE 5. Slopes of regression lines for ratings of perceived pain and ratings of perceived exertion on exercise time.

	Rating of Perceived Pain			Rating of Perceived Exertion		
	Baseline	6 months	% Δ	Baseline	6 months	% Δ
PS+Vit E	0.92 ± 0.68	0.43 ± 0.21	53*	0.78 ± 0.64	0.32 ± 0.15	59**
PS+placebo	0.67 ± 0.40	0.42 ± 0.41	37*	0.62 ± 0.46	0.34 ± 0.25	45**
VitE	0.89 ± 0.86	0.83 ± 0.48	7	0.86 ± 0.86	0.78 ± 0.63	9
Placebo	0.69 ± 0.34	0.66 ± 0.46	3	0.57 ± 0.41	0.64 ± 0.34	12

* Main effect change for exercise, $P = 0.02$; vitamin E effect, $P = 0.33$; ** Main effect change for exercise, $P = 0.016$; vitamin E effect, $P = 0.26$.

the four groups were compared. A significant main effect for PoleStriding was found on the PAR, but no significant change was associated with vitamin E. The interaction effect was not significant. Supervised exercise sessions were not included in the measurement of physical activities accounted for in the PAR.

Adherence and compliance. Subjects' adherence to the supervised training sessions was high; absences were mainly caused by illness. The mean compliance to the exercise sessions in the 27 PoleStriders was 88 ± 23% with 21 subjects attending at least 70% of the supervised exercise sessions. Blood levels of vitamin E were measured at baseline and 3 and 6 months to monitor subjects' compliance with the study drug regimen. The difference between the baseline levels of vitamin E in subjects randomized to receive the study drug and those to receive a placebo were small 11.6 ± 5.2 $mg \cdot L^{-1}$ and 12.9 ± 4.6 $mg \cdot L^{-1}$, respectively. By 6 months, this difference increased from −1.3

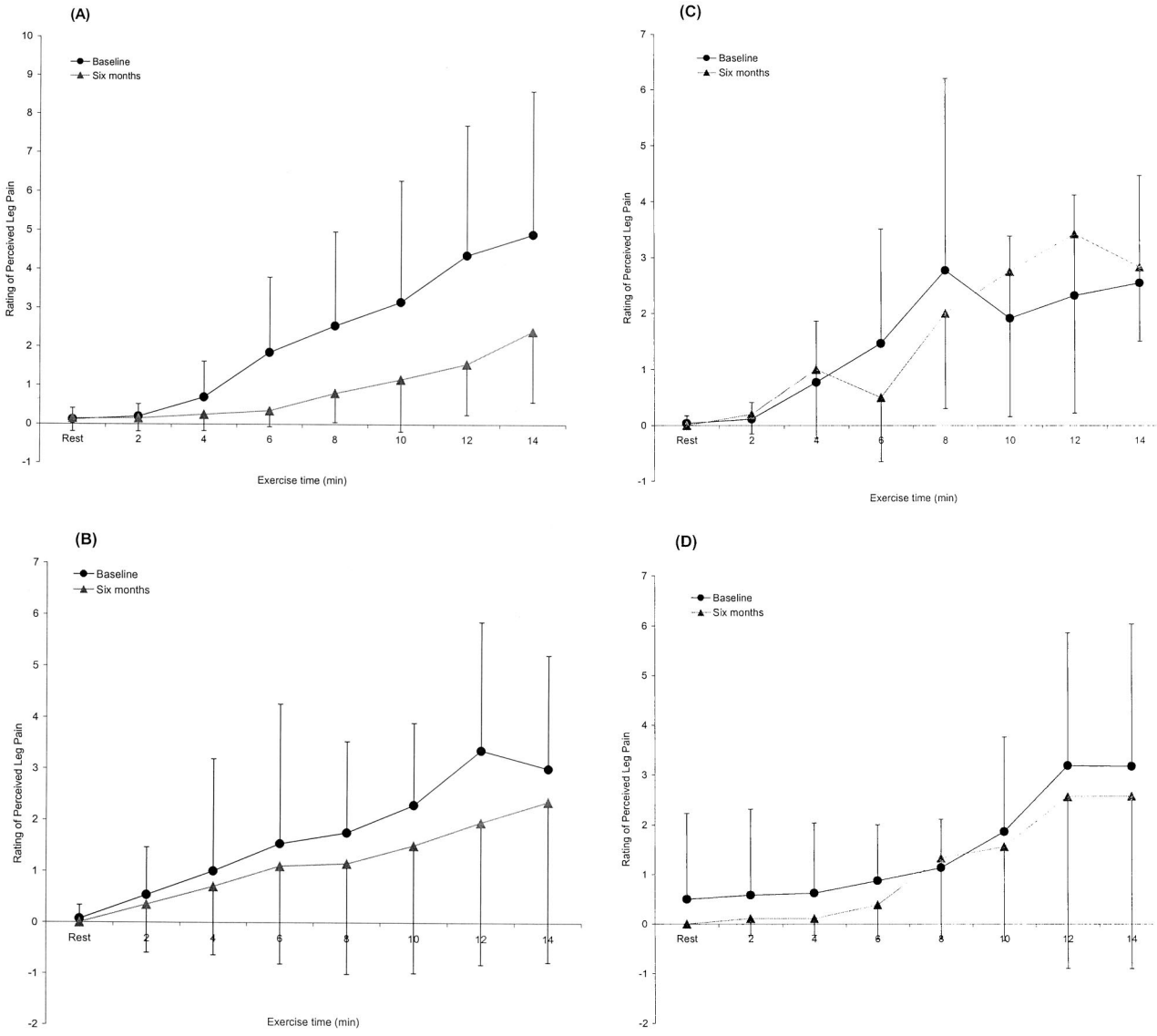

FIGURE 1—Mean rating of perceived leg pain during the incremental workload treadmill test for subjects in each of the four study groups. A. PoleStriding + vitamin E group; B. PoleStriding + placebo group; C. vitamin E only group; D. placebo group. Rating of perceived leg pain at baseline and 24 wk are plotted on exercise time up to 14 min.

TABLE 6. SF-36 subscales means (±1SD) for experimental groups at each measurement time period.

Subscale	PS+VitE (N = 12)	PS+Placebo (N = 11)	VitE (N = 13)	Placebo (N = 10)	P PS	P VitE
Physical function						
Baseline	50.4 ± 22.6	52.5 ± 22.3	43.1 ± 15.6	46.7 ± 21.5		
6th month	75.0 ± 17.8	66.1 ± 26.9	45.8 ± 16.8	50.0 ± 19.7	0.003	0.99
Role physical						
Baseline	55.8 ± 48.0	53.6 ± 43.7	48.1 ± 43.9	45.8 ± 45.0		
6th month	85.0 ± 26.9	55.6 ± 41.0	52.1 ± 44.5	20.0 ± 28.3	0.07	0.23
Body pain						
Baseline	58.6 ± 18.0	55.9 ± 21.8	49.5 ± 21.0	59.7 ± 16.5		
6th month	69.5 ± 19.1	60.4 ± 20.5	53.4 ± 21.3	49.0 ± 16.1	0.12	0.25
General health						
Baseline	63.6 ± 15.7	60.3 ± 18.1	52.9 ± 21.0	59.8 ± 19.4		
6th month	76.8 ± 10.1	60.6 ± 24.3	49.5 ± 20.2	57.5 ± 12.6	0.14	0.82
Vitality						
Baseline	61.9 ± 15.9	45.0 ± 20.2	51.5 ± 16.4	53.3 ± 13.5		
6th month	66.0 ± 13.3	57.2 ± 15.4	54.2 ± 17.7	57.0 ± 17.2	0.23	0.12
Social function						
Baseline	58.5 ± 32.4	50.0 ± 30.4	64.6 ± 27.9	53.3 ± 31.4		
6th month	72.0 ± 27.0	67.8 ± 33.8	65.8 ± 28.4	43.0 ± 17.1	0.25	0.82
Role emotional						
Baseline	79.5 ± 37.4	57.1 ± 47.9	56.4 ± 41.7	80.5 ± 26.4		
6th month	83.3 ± 28.3	63.0 ± 45.5	75.0 ± 37.9	53.3 ± 39.1	0.54	0.10
Mental health						
Baseline	79.7 ± 15.0	65.1 ± 24.9	76.9 ± 16.1	79.3 ± 18.1		
6th month	81.2 ± 10.0	75.1 ± 21.0	80.0 ± 14.2	74.4 ± 15.8	0.43	0.71

PS, PoleStriding; VitE, vitamin E; because the interaction was not significant, P values are presented from the main effects models.

$mg \cdot L^{-1}$ to 7.7 $mg \cdot L^{-1}$. Vitamin E levels steadily increased in the VitE group but not in the placebo group (Fig. 2). A graphic test using 95% confidence intervals of the difference in vitamin E between the two groups at baseline and 6 months revealed no difference between groups at baseline, but there was an apparent but not conclusive difference at 6 months (Fig. 3). Therefore, a procedure that utilizes the confidence interval to determine the difference between independent means was used. The resulting 95% confidence interval, 0.25–15.2, did not include zero, thereby indicating that the difference in the mean vitamin E level for the two groups at 6 months was significant. Additionally, the graphic analysis verifies that the difference in the measured levels of vitamin E at baseline and 6 months in the VitE group was significant. In the placebo group, the difference in vitamin E at baseline and 6 months was clearly not significant (Fig. 3). In this investigation, subjects' compliance with the drug protocol was extremely important. These data provide sufficient evidence to conclude that the subjects did adhere reasonably well to the study drug regimen and that the conclusions drawn from the analyses of the research hypotheses were minimally impacted by any outliers who failed to comply fully.

DISCUSSION AND IMPLICATIONS

The results of this randomized, double-blind control clinical trial provide strong evidence that PoleStriding significantly improved exercise tolerance. In addition, ratings of perceived claudication pain were significantly less after the PoleStriding training program. In contrast, vitamin E did not have a statistically significant effect on the subjects' ratings of perceived leg pain or treadmill walking duration.

In the well-publicized CHAOS trial, which was designed to evaluate the relationship between α-tocopherol (vitamin E) and nonfatal myocardial infarction and cardiovascular mortality, there was a significant increase in serum level of vitamin E in the treatment but not the placebo group (effect size of 1.7) (27). Similarly, there was a significant increase and large effect size (1.96) in the serum levels of vitamin E in the treated subjects in the present investigation. Mean vitamin E levels in the subjects receiving a placebo decreased slightly, and the effect size (0.18) was small. In this study, the investigators theorized that vitamin E would have a positive effect on exercise tolerance in persons with intermittent claudication due to both its antioxidant and antiplatelet adhesion and aggregation properties. However, vitamin E alone or combined with exercise did not have a

TABLE 7. Walking Impairment Questionnaire subscales (distance and speed) means (±1SD) for the experimental groups at each measurement time period.

Subscale	PS+VitE (N = 12)	PS+Placebo (N = 11)	VitE (N = 13)	Placebo (N = 10)	P PS	P VitE
Distance						
Baseline	0.22 ± 0.16	0.35 ± 0.30	0.30 ± 0.21	0.38 ± 0.30		
6th month	0.66 ± 0.25	0.58 ± 0.33	0.26 ± 0.28	0.36 ± 0.34	<0.0001	0.43
Speed						
Baseline	0.26 ± 0.12	0.29 ± 0.19	0.28 ± 0.20	0.28 ± 0.20		
6th month	0.44 ± 0.17	0.50 ± 0.20	0.27 ± 0.17	0.33 ± 0.32	0.02	0.15

PS, PoleStriding; VitE, vitamin E; because the interaction was not significant, P values are presented from the main effects models.

TABLE 8. Physical Activity Recall Questionnaire means (±SD) total MET·h for the experimental groups at each measurement time period.

	PS+VitE (N = 12)	PS+Placebo (N = 11)	VitE (N = 13)	Placebo (N = 10)	P PS	P VitE
Baseline	130.4 ± 66.8	117.2 ± 53.0	143.7 ± 79.5	137.2 ± 51.9		
6th month	138.1 ± 58.5	146.5 ± 70.2	121.4 ± 53.9	137.2 ± 63.5	0.04	0.42

PS, PoleStriding; VitE, vitamin E; MET·h, hours active × METs of activity.

significant effect on treadmill walking endurance. The absence of a meaningful contribution of vitamin E to changes in exercise tolerance in these patients may have resulted from one or more of the following: (i) insufficient time was allowed for the vitamin E to exert a large enough antioxidant effect to be detected by the measurements used in this study; (ii) the dose of vitamin E used in this study was not sufficient to influence the antiplatelet adhesion and aggregation activities to the extent that there was a significant improvement in blood flow to the exercising leg muscles; (iii) vitamin E supplementation in humans has little or no effect on exercise performance (1,16,17,23,24,30); and (iv) vitamin E has little effect on existing atherosclerotic lesions in the leg, rather, as has been previously suggested, the effect is on the lipid composition of atheromatous plaques and not on their volume (27).

A large and significant improvement was found in walking duration on the incremental treadmill test for those assigned to the PoleStriding groups. These results are similar although not identical to previously published reports. One important difference in the methodology between this and previous studies should be noted. Most trials did not establish a stable treadmill test performance at baseline before proceeding with their intervention. In the present investigation, there were 17 subjects (33%) who required a third test to establish a stable baseline. Results of a one-way ANOVA for repeated measures of the difference between the three tests in these 17 subjects were significant between the first and third tests. No significant difference was found between the second and third tests. This finding strongly suggests that when subjects with PAD are given only one test at baseline, investigators may be underestimating the individual's true initial walking ability probably due to unfamiliarity with the treadmill. In the present study, investigators used the subject's best performance on the baseline tests as the baseline measure.

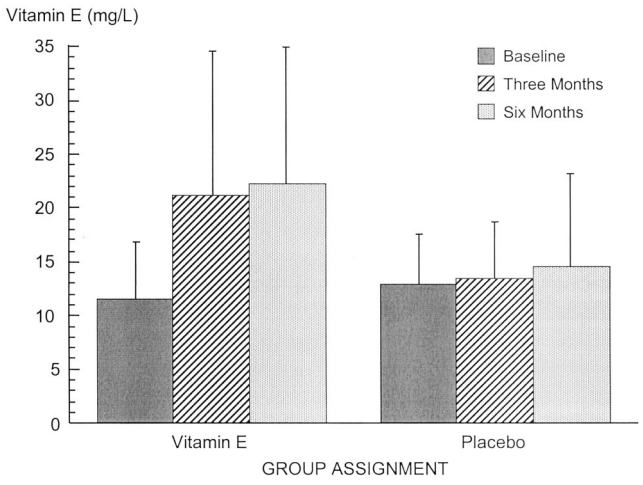

FIGURE 2—Serum level of vitamin E at baseline and 3 and 6 months in subjects randomized to receive vitamin E (PoleStriding with vitamin E, vitamin E only), or placebo (PoleStriding with placebo and placebo only).

QOL has not been investigated to a great extent in the PAD population. Investigators have assumed that improvements in blood flow and/or walking distance translate into improvements in an individual's QOL. Additional work is required to validate these assumptions. The Feinglass group (6) reported an average physical function score on the SF-36 of 48.8 ± 22.5 in 555 persons with PAD. At baseline, the overall present study sample had a comparable score of 47.6 ± 20.3. This physical function score is similar to subjects with heart failure (47.9 ± 2.7 SEM) (30) and well below a group of 789 persons entering cardiac rehabilitation (62.3 ± 24.2) (30). These data attest to the severe limitations in perceived function experienced by persons with PAD.

Investigators used the Medical Outcomes Study Short-Form 20 (SF-20) to assess QOL in 29 subjects undergoing treadmill walking training for 24 wk (N = 10), strength training for 12 wk (N = 9) then treadmill walking training for 12 wk (N = 6), and control for 12 wk (N = 10) then treadmill walking training plus strength training for 12 wk (N = 6) (19,20). In this study, perceptions of physical function improved in the treadmill-trained group only. The strength training only group reported improved well-being in the first 12 wk and no improvements when they were crossed-over to the treadmill walking group. No significant changes were found in social functioning, role functioning, and overall health scores for any of the groups. In the present study, only the scores on the physical function subscale significantly improved after 6 months of PoleStriding training. No differences were observed on the other subscales when differences were compared between groups. These findings parallel the above observations and confirm subjects' anecdotal accounts as the study progressed. They were feeling better and were able to do more (e.g., shopping without depending on the shopping cart for support, ability to keep up with and play with grandchildren). Sample size may have been a factor in the ability to detect change on the body pain and general health subscales of the SF36. Interestingly, baseline vitality scores for the PS+VitE group was at the normative level at baseline (U.S. norm for vitality subscale 61.0 ± 20.9; PS+VitE group 61.9 ± 15.9) (29). The ability to detect meaningful change is difficult when baseline reports are already at the normative level. This phenomenon was also a factor with the role emotional (PS+VitE and placebo groups) and the mental health (all groups) subscales.

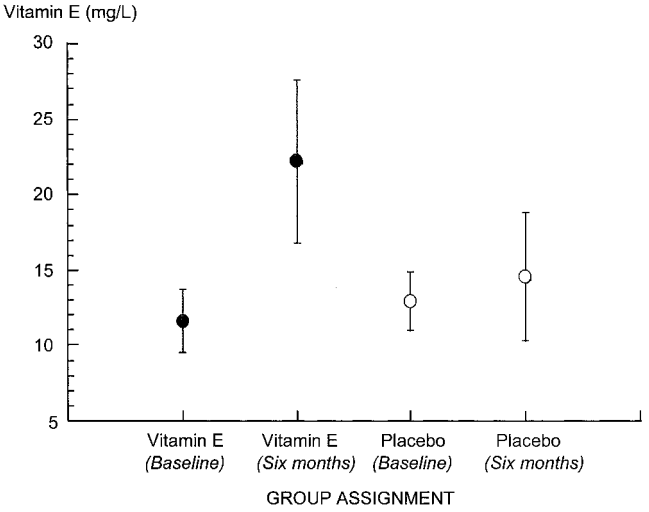

FIGURE 3—Graphic test using 95% confidence intervals of the difference in serum levels of vitamin E in subjects receiving vitamin E and placebo at baseline and 6 months. Differences between groups at baseline were not significant. The difference in confidence intervals at 6 months was significant ($P < 0.05$, see text).

At baseline, the score on the WIQ (0.31 ± 0.25) was virtually the same as that found in a large sample of PAD patients ($N = 555$) (6). Regensteiner et al. (18) reported significant improvements in perceived distance (26.5%) and speed (68%) in 10 persons with PAD who engaged in a 12-wk exercise program. In contrast, after 12-wk training, subjects in the present study reported a 115% improvement in perceived distance and 76% improvement in perceived speed of walking. However, little additional change occurred from 12 to 24 wk. Perceived distance walked increased from a 115% improvement to 121%, and speed declined slightly from 76% to 71% by 6 months. No significant changes were found in the non-PoleStriding groups (at 6 months, perceived distance declined by 9% and speed improved by 7%; these differences were not significant).

In the present study, the focus of training was on distance walked and less on speed. Subjects were encouraged to use the poles to walk as far as possible before stopping due to claudication pain. The present study data provide evidence of this emphasis. Although short bouts of speed play were employed during routine training, subjects were much more interested in how far they had walked on a given day. Subjects anecdotally reported that as long as they were able to keep pace with their spouse or peers during activities of daily living, they were satisfied with the speed of their walking.

The Physical Activity Recall Questionnaire was used to measure physical activity performed within the prior week. Due to potential seasonal effects on volume of and type of physical activity, the MET hours from the 1-month through 6-month time periods were averaged. A significant increase (15%) in the number of MET hours of activity in the PoleStriding group but not in the non-PoleStriding group was found. Improvements in the PoleStriding group were slightly less than that reported by Regensteiner et al. (15% improvement vs 26% improvement) (18). Gardner (8) reported a 38% increase in physical activity as measured by an accelerometer in 31 claudicants randomized to an exercise group; interestingly, self-reported physical activity in this group did not change from pre- to post-exercise. Investigators in the present study concur that the subjects were generally poor historians with regard to recalling the required information. The MET hours reported at baseline in the present study were substantially less (127 MET·h) than that reported by Regensteiner et al. (18) in a similar sample of subjects (155 MET·h). This tendency toward a comparatively lower recall of daily physical activity was observed throughout the course of the study.

Subject compliance with vitamin E was monitored by self-report and vitamin E blood levels. Although subjects were told during the informed consent process that vitamin E levels would be monitored, they were only told that their cholesterol was being checked (a necessary component of testing for vitamin E levels) at the time of phlebotomy. However, the possibility remains that some subjects "prepared" for these blood tests by taking their study medication (vitamin E or placebo) just before the blood draw. The half-life of vitamin E is 13 h with 80–90% being excreted within 7–8 d. Because vitamin E is stored in the adipose tissue, excretion is affected by the amount of adipose tissue present. The use of study pill counts would have provided an additional measure of study drug compliance. The absence of this procedure may have influenced the precision of the assessment of the subjects' compliance with the vitamin E intervention.

Based on qualitative observations, previous biomechanical analysis of walking with poles, and time required to demonstrate significant improvement in walking duration, the investigators posit that PoleStriding exercise may be a more efficacious mode of rehabilitative exercise for persons with PAD than walking without the poles. However, the present study was not designed to test this hypothesis, and the empirical proof is not available at the present time.

CONCLUSIONS

A supervised, 24-wk PoleStriding exercise program for persons with PAD resulted in significant increases in both the measured and perceived distance walked and lower ratings of perceived leg pain at any submaximal treadmill workload. Vitamin E had no significant effect on perceived pain or distance walked in this sample. Potential direction for future study could be comparing the effectiveness of PoleStriding for increasing exercise tolerance against a traditional walking program without poles.

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