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The effects of exercise training on walking function and perception of health status in elderly patients with peripheral arterial occlusive disease

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Abstract. Tsai JC, Chan P, Wang CH, Jeng C, Hsieh MH, Kao PF, Chen YJ, Liu JC (Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan). The effects of exercise training on walking function and perception of health status in elderly patients with peripheral arterial occlusive disease. *J Intern Med* 2002; **252:** 448–455.

Objective. To determine the effects of 12-week exercise programme on ambulatory function, free-living daily physical activity and health-related quality of life in disabled older patients with intermittent claudication.

Design. Prospective, randomized controlled trial.

Setting. University Medical Center and Veterans Affairs Medical Center, Taipei, Taiwan.

Subjects. Thirty-two of 64 patients with Fontaine stage II peripheral arterial occlusive disease (PAOD) were randomized to exercise training and 32 to usual care control. Five patients from the exercise group and six patients from the control group dropped out, leaving 27 and 26 patients, respectively, completing the study in each group.

Interventions. Twelve weeks of treadmill exercise training.

Main outcome measures. Treadmill walking time to onset of claudication pain and to maximal claudication pain, 6-min walk distance, self-reported ambulatory ability and perceived health-related quality of life (QOL).

Results. Compliance of exercise programme was 83% of the possible sessions. Exercise training increased treadmill walking time to onset of claudication pain by 88% ($P < 0.001$), time to maximal pain by 70% ($P < 0.001$), and 6-min walk distance by 21% ($P < 0.001$).

Subjects. Perception of health-related QOL improved from 12% to 178% in the exercise group. These improvements were significantly better than the changes in the control group ($P < 0.05$).

Conclusions. Significant improvements in claudication following 12-week exercise training in elderly PAOD patients were observed. Increase in treadmill walking time to maximal claudication pain in these patients translated into the improvement of perceived physical health, which enabled the patients to become more functionally independent.

Keywords: exercise training, intermittent claudication, peripheral arterial occlusive disease, quality of life, treadmill.

Introduction

Peripheral arterial occlusive disease (PAOD) is a leading cause of morbidity in elderly persons because of ambulatory limitations associated with intermittent claudication [1]. Symptomatic PAOD is common in western industrialized countries [2]. 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 [3–6]

results in a sedentary lifestyle [7], self-perceived ambulatory dysfunction [8] and lower health-related quality of life (QOL) [9]. Patients who have ischaemic pain at rest or limb-threatening ischaemia may undergo intervention therapy (e.g. percutaneous transluminal angioplasty or peripheral arterial bypass). 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 [10]. Consequently, interventions should focus on improving ambulatory function to maintain functional independence in PAOD patients with intermittent claudication.

The impact of improved claudication symptoms following exercise rehabilitation on quantitative measures of ambulatory function in the community setting is not well known. Because a low level of daily physical activity is an independent risk factor for coronary heart disease incidence and mortality [11–13], increased free-living daily physical activity in PAOD patients following exercise rehabilitation may improve their poor prognosis for long-term survival [14–16].

The purpose of this prospective, randomized controlled trial was to determine whether a 12-week progressive treadmill exercise rehabilitation programme was more effective than nonexercise usual care in improving ambulatory function, self-reported ambulatory ability and health-related QOL in older PAOD patients functionally limited by intermittent claudication.

Materials and methods

All patients lived independently at home and had Fontaine Stage II PAOD [17], defined by the following criteria: (1) a positive Rose questionnaire for intermittent claudication [18], and (2) an ankle/brachial systolic blood pressure index (ABI) of ≤ 0.95 [8, 19]. The self-reported duration of intermittent claudication in years and the number of blocks walked before claudication pain were recorded. Patients were excluded from participation for the following reasons: (1) rest pain; (2) history of exertional angina; (3) exercise tolerance limited by leg pain of nonvascular origin (e.g. arthritis, orthopaedic pain) and by factors other than intermittent claudication (e.g. dyspnoea, fatigue, dizziness); (4) surgery related to PAOD during the preceding 3 months; (5) myocardial infarction within the preceding 3 months and (6) unstable claudication symptoms during the preceding 3 months. The procedures used in this study were approved by the institutional review board at the Taipei Medical University. A written informed consent was obtained from each patient before this investigation. Data were collected before and after the 12-week exercise training programme.

Treadmill exercise test

Patients performed a progressive, graded treadmill protocol (2 mph, 0% grade with 2% increase every 2 min) until maximal claudication pain. The severity of claudication pain experienced by the patient was recorded on a scale of 0–4 with 0 = no pain, 1 = onset claudication, 2 = mild, 3 = moderate and 4 = severe pain [20]. The time walked to onset of claudication pain (score 1 out of a possible range of 0–4), and time to maximal claudication pain (score 4) for each subject were measured. During treadmill tests, each subject was fitted with a 12-lead electrocardiogram system. Arm blood pressures were monitored every 2 min. The exercise test was terminated if any subject exhibited >1 mm ST-segment change, significant dysrhythmias, an appropriate blood pressure response to increasing workloads, or reported a score of maximal claudication pain. In this study, all subjects reached a maximal level of claudication pain that limited exercise during the graded treadmill test.

Six-minute walk test

Each patient was administered a 6-min walk test by two trained technicians twice within 1 week. Each technician administered the 6-min walk test blinded from the results of the other. Two cones were placed 20 m apart in a marked corridor. Patients were instructed to walk as many laps around the cones as possible and to inform the technician when the onset of claudication occurred. A calibrated electronic pedometer (Omron Health Care Corporation, Vernon Hills, IL, USA) was worn on the hip of each patient to obtain the total number of steps taken during the test. The technician stood at the centre of the 20-m course and provided encouragement every 2 min. Patients were permitted to stop walking during the test if their claudication became intolerable, but the time continued to run during the rest

period. Patients who stopped walking because of claudication pain were encouraged to continue walking as soon as possible. The technician recorded the total distance walked and total number of steps taken during the rest. Using these procedures, we have established high intertechnician reliability in our laboratory; the intraclass correlation coefficient (R) for the 6-min walk measurements ranged between 0.93 and 1.00, and the coefficient of variation (CV) ranged between 0.5% and 1.5%.

Ankle/brachial index (ABI) test

Patients refrained from smoking and drinking caffeinated beverages during the morning of testing. Ankle systolic blood pressure and brachial systolic blood pressure were measured, and ABI was calculated as ankle systolic pressure/brachial systolic pressure.

The patients rested supine for 10 min under standardized laboratory condition before the ABI measurement. The ankle systolic blood pressure was obtained in the posterior tibial and dorsalis pedis arteries of both legs by a Parks Medical Electronics, Inc. nondirectional Doppler flow detector (Model 810 A, Aloka, Tokyo, Japan), a pencil probe (9.3 MHz), and standard size ankle blood pressure cuffs (10 cm width). The artery yielding the highest pressure in the more severely diseased leg was used for the ankle systolic blood pressure. The test–retest R and CV values were 0.95% and 11.8% for ankle systolic pressure and 0.95% and 12.8% for ABI using this methodology [4].

Brachial blood pressures and heart rate were measured from both arms with a Critikon Dinamap Vital Signs Monitor (Parks, Model 1846, TX, USA), using a standard adult size blood pressure cuff (14 cm width). Brachial systolic pressure, diastolic pressure and heart rate were recorded from the arm yielding the higher systolic pressure. In a subsample of 44 participants tested twice in our laboratory within 2 weeks, the test–retest R and CV values were 0.82% and 11.4% for systolic pressure, 0.83% and 8.7% for diastolic pressure, and 0.84% and 11.8% for heart rate [21, 22].

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 [23]. A scale ranging between 0 and 100 assesses each aspect; a score of 0 represents inability and a score of 100 represents no difficulty in performing the task. The WIQ has been widely used in PAOD population to examine the effect of exercise rehabilitation on patients' functional status [23, 24].

Quality of life

Health-related QOL was assessed with the Medical Outcomes Study Short-Form 36 (MOS SF-36) Chinese version [25, 26]. The MOS SF-36 is a reliable and valid generic instrument that includes the following eight multi-item subscales that assess the physical and mental health components of QOL: physical function, role limitations caused by physical problems (role limitations/physical), general health, bodily pain, social function, role limitations caused by emotional problems (role limitations/emotional), mental health and vitality. Respondents were asked to evaluate their own health during the past 30 days. Each domain of these scales is scored from 0 (poorest health) to 100 (optimal health). The psychometric properties of the MOS SF-36 have been examined extensively and support its validity and reliability [25–27]. The MOS instrument also has been widely used in studies to evaluate multiple aspects of life function in PAOD population [8, 10, 24].

Exercise training protocol

Patients in the exercise group performed the treadmill exercise three times each week until 12 weeks. Exercise training began with 5 min of warm-up and ended with 5 min of cool down. During exercise, patients' heart rate and 12-lead electrocardiogram were continuously monitored to detect any exercise-induced dysrhythmias. Arm blood pressure values and claudication pain scores were collected every 5 min Exercise intensity started from 2 mph, 0% grade, with 1% grade increase every 10 min if patients reported a claudication pain score below 2. Patients were encouraged to exercise up to 30 min with their claudication pain scores between 2 and 3 (pain levels between mild and moderate).

Statistical analyses

Descriptive data are given as mean ± SD for baseline variables. For treatment effects, Wilcoxon sign rank test or Mann–Whitney *U* nonparametric tests were used. The absolute change compared with baseline was used for the analysis of treatment effect for each group as well as for the comparison between groups. Correlations were analysed as Spearman's rank correlations. $P < 0.05$ in two-sided tests were regarded as statistically significant.

Results

The mean age of the patients in this study was 76.2 years. The baseline clinical characteristics and ambulatory function were comparable in both the groups (Table 1). Baseline characteristics of the five exercise and six controls who withdrew after randomization were also similar to the patients who completed the study. Body mass index did not differ significantly between the exercise and control groups (23.6 ± 2.0 vs. 23.0 ± 3.0 kg m^{-2}) and did not change with the intervention.

The mean compliance rate in the 27 exercises was 82 ± 16% (SD), with 22 patients attending at least 80% of the sessions. The skewed nature of data towards 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 programme. There were no complications during the exercise sessions or in the control patients that could be attributed to participation in the study.

The exercise training programme increased time to onset of claudication pain and to maximal pain during treadmill tests by an average of 88% and 70% ($P < 0.001$), respectively. These improvements were significantly better than those observed in the controls (Table 2). The total 6-min walk distance increased by 21% ($P < 0.05$) in the exercise group, these changes were also significantly better than in the controls (Table 2). In the exercise group, the change in the 6-min walk distance correlated with the change in time to onset of claudication pain ($r = 0.48$, $P < 0.05$) and time to maximal pain ($r = 0.53$, $P < 0.001$).

The baseline scores on the three WIQ subscales were similar between the two groups (Table 1). The exercise group reported significant higher scores on the distance, speed and stair subscales on the WIQ after the training programme. The changes in speed and stair subscales were most remarkable and were significantly different from the changes in the controls (Table 2).

Individual subscales of the MOS SF-36 were also analysed for each patient. There were no significant differences in all subscores of the MOS SF-36 between the two groups at baseline. In comparison with the baseline data, the exercise group reported significantly higher scores on five subscales of the

Table 1 Baseline clinical characteristics of patients with peripheral arterial occlusive disease and intermittent claudication who completed the study

Variable	Exercise group ($n = 27$)	Control group ($n = 26$)
Gender (% male)	81%	85%
Age (years)	76.3 ± 3.8	76.1 ± 3.7
Duration of intermittent claudication (years)	3.8 ± 1.2	3.9 ± 1.0
Ankle/brachial index	0.7 ± 0.1	0.7 ± 0.1
Systolic blood pressure (mm Hg)	130.7 ± 12.6	132.4 ± 19.0
Diastolic blood pressure (mm Hg)	73.5 ± 9.5	76.0 ± 7.5
Ambulatory function		
Six-minute walk distance (m)	216.5 ± 32.7	218.0 ± 65.7
Time to onset of pain (min)	3.3 ± 3.1	2.9 ± 2.6
Time to maximal pain (min)	7.4 ± 3.9	7.2 ± 3.2
Self-reported ambulatory ability		
WIQ distance (%)	58.8 ± 13.7	63.1 ± 12.8
WIQ speed (%)	53.0 ± 12.3	60.9 ± 13.1
WIQ stairs (%)	75.4 ± 20.0	80.6 ± 19.0

Values are percentage of patients for gender and the remaining variables are mean ± SD in each category.

Table 2 Ambulatory functions in patients with peripheral arterial occlusive disease and intermittent claudication before and after randomization into 12 weeks of exercise training ($n = 27$) or usual care control ($n = 26$)

	Exercise group		Control group		Between group
Variable	Pretest	Post-test	Pretest	Post-test	*P*-value
Ambulatory function					
Six-minute walk distance (m)	216.5 ± 32.7	261.8 ± 36.8***	218.0 ± 64.7	221.2 ± 68.7	0.04*
Time to onset of pain (min)	3.3 ± 3.1	6.2 ± 2.7***	2.9 ± 2.6	3.2 ± 3.4	0.01*
Time to maximal pain (min)	7.4 ± 3.9	12.5 ± 3.7***	7.2 ± 3.2	7.6 ± 3.8	<0.001***
Self-reported ambulatory ability					
WIQ distance (%)	58.8 ± 13.7	64.3 ± 20.3*	63.1 ± 12.8	66.3 ± 7.3	0.18
WIQ speed (%)	53.0 ± 12.3	68.0 ± 12.5*	60.9 ± 13.1	61.6 ± 12.2	<0.001***
WIQ stairs (%)	75.4 ± 20.0	89.2 ± 11.5***	80.6 ± 19.0	76.4 ± 21.0	<0.001***

Values are mean ± SD, $^{*}P < 0.05$, $^{***}P < 0.001$. Between group *P*-value are pretest–post-test differences between exercise and control groups.

Table 3 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 12 weeks of exercise training

	Exercise group		Control group		Between group
Variable	Pretest	Post-test	Pretest	Post-test	*P*-value
Physical function	39.5 ± 0.1	58.0 ± 10.6***	49.2 ± 11.5	48.0 ± 9.6	<0.001***
Role limitations/Physical	22.5 ± 30.0	62.5 ± 31.7**	22.9 ± 19.8	33.3 ± 16.3	0.04*
Bodily pain	64.8 ± 15.9	81.5 ± 18.4*	71.1 ± 20.4	77.3 ± 17.8	0.03*
General health	54.0 ± 13.4	64.8 ± 0.1*	57.5 ± 11.6	56.4 ± 16.0	0.02*
Mental health	70.9 ± 14.6	80.1 ± 0.1	77.6 ± 9.4	78.7 ± 6.6	0.08
Role limitations/emotional	83.3 ± 36.0	93.3 ± 21.1	90.0 ± 0.2	91.0 ± 3.2	0.12
Social function	76.3 ± 20.8	85.0 ± 17.5	78.1 ± 26.7	82.3 ± 15.5	0.23
Vitality	54.5 ± 15.2	70.0 ± 12.9***	60.8 ± 16.2	63.8 ± 2.1	0.02*

Values were obtained from the Medical Outcomes Study Short-Form 36 and are presented as mean ± SD, $^{*}P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$, Between group *P*-value are pretest–post-test differences between exercise and control groups.

MOS SF-36 following the 12-week exercise training programme (Table 3). The improvements in the physical health component (physical function, role limitations caused by physical problems, bodily pain and general health) were more pronounced than that in the mental health component on the MOS SF-36. The improvements in perceived physical function and bodily pain subscores correlated well with the increase in time to maximal claudication pain ($r = 0.66$ and 0.65, $P < 0.05$). No changes in all subscores of the MOS SF-36 were observed in the controls during the study period (Table 3).

Discussion

Patients with intermittent claudication have an impact on walking ability that may limit their function to meet the personal or social demands of daily living. A structured exercise programme helps to improve exercise performance and possibly, functional status in PAOD patients [8, 10]. Preliminary results in a study by Regensteiner *et al.* [24] also suggested that a supervised treadmill training programme was more effective for improving exercise performance than an unsupervised, home-based programme. In our study, treadmill walking was used as the mode of training to enhance patients' walking ability. Training intensity was set to the workload that brought on mild to moderate claudication pain in the patients.

The primary findings of this study were that 12 weeks of exercise training increased the time to onset of claudication pain by 88% and to maximal claudication pain by 70%. These improvements in ambulatory function translated into an increase in

6-min walk distance. Patients with claudication rarely need to walk at the intensity attained during a maximal, graded treadmill test. Thus a 6-min walk test provides more clinically relevant information on the benefits of exercise training in allowing these patients with PAOD to perform activities of daily living.

Different mechanisms appear to explain the exercise-mediated increase in ambulatory function. 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. However, exercise-mediated improvements in peripheral circulation in PAOD patients with intermittent claudication is not a consistent finding, as some studies report an increase [29–32], although others report no change in perfusion [33–35]. The better energy utilization in the calf may be the factor which contributes to a delay in the development of claudication, therefore, manifested by increased distances walked.

Furthermore, exercise training improved the self-reported QOL as assessed by the MOS SF-36 and the disease-specific WIQ instrument. This study demonstrates that exercise training improves ambulatory function, perceived walking ability and health related QOL in older PAOD patients with intermittent claudication, and supports current recommendations for exercise training in this patient population [28]. This finding is also partially compatible with the significant increase of 24% to 28% gains in self-reported physical functioning following exercise programmes found in smaller samples of claudicatants [8].

Exercise training resulted in significant changes in health related QOL, especially the increase in physical health components on the MOS SF-36 survey. However, changes in the mental health components on the MOS SF-36 were less remarkable than that in the physical health components amongst our subjects. Several factors may account for this result. In our cohort of chronically ill PAOD patients, ambulatory dysfunction may be the most important factor influencing self-perceived health-related QOL. It is also possible that the perceived improvements in the mental health component of QOL may lag behind the improvements in ambulatory function achieved at 12 weeks. Regensteiner and colleagues [8] found that a supervised treadmill training programme improved the functional status in PAOD, with 24 weeks of training more effective than 12 weeks. In our study, training profits were obvious even in the 12 weeks of training. Further studies are needed to confirm what training duration can be most beneficial for patients with PAOD.

In our study, the majority of patients were men aged 65 or older (male:female ratios were approximately 8:1). One explanation for this discrepancy in male:female ratios may be the higher prevalence rate for PAOD in man. Another plausible explanation is that men with symptomatic claudication are more likely to obtain medical attention than women [36]. None of the baseline characteristics of our patients, except for age ($r = -0.47$, $P < 0.05$), were independent predictors of the change in 6-min walk distance in response to an exercise training programme. Consequently, PAOD patients with intermittent claudication who are not excluded because of severe coronary artery disease, dyspnoea, and poorly controlled blood pressure are capable of increasing their treadmill walking time to onset and to maximal claudication pain following exercise, regardless of gender, laterality of intermittent claudication, duration of claudication symptoms and cardiovascular disease risk factors. Furthermore, previous study suggests that baseline measures of claudication distances, perceived ambulatory function, ABI and calf perfusion, and body composition did not predict response [37]. This suggests that all PAOD patients with intermittent claudication, who can safely exercise from a clinical, cardiopulmonary, and orthopaedic standpoint, should be considered as candidates for a treadmill walking programme to improve their symptomatology.

In summary, the primary findings of this prospective, randomized controlled trial are that a 12-week programme of exercise training effectively improves ambulatory function by increasing time to onset and to maximal claudication pain, and 6-minutes walk distance in older patients with PAOD functionally limited by claudication. These functional gains translated into increased perceived physical function, which enabled these patients to become more functionally independent. Therefore, exercise training should be considered as part of standard medical care for older patients limited by intermittent claudication.

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