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Exercise Therapy for Claudication: Latest Advances

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Opinion statement

Peripheral artery disease (PAD) creates a significant national and international healthcare burden. A first line treatment for PAD is supervised walking exercise in hospitals and clinics. Specifically, supervised walking exercise seeks to improve the classic symptom associated with PAD, intermittent claudication (IC), which is characterized by cramping, aching and pain of the muscles in the lower extremities during walking. While effective, supervised walking exercise is often not prescribed or utilized due to a number of treatment barriers such as lack of transportation to clinical centers and lack of insurance reimbursement. Walking exercise in community settings is an option that has gained attention due to the limitations of supervised walking exercise, as community walking is generally more convenient in terms of a patient's schedule and may circumvent potential barriers such as treatment cost and transportation difficulties. However, more research is needed to improve the effectiveness of community-based walking programs since far less is known about the optimal structure of such programs. Other exercise therapy options are becoming available for PAD patients in addition to walking exercise. These modalities include but are not limited to leg and arm ergometry, polestriding and resistance training. These exercise therapy options have not to date been as well validated as supervised walking exercise. However, they may potentially be used in the event supervised walking exercise is not feasible or patient preference warrants an alternative exercise strategy.

Keywords

Peripheral Artery Disease; Walking Exercise; Physical Activity; Supervised Training; Community-Based Exercise; Polestriding; Cycle Ergometry; Arm Ergometry; Strength Training; Plantar Flexion; Quality Of Life; Patient-Reported Outcomes

Introduction

It is estimated that peripheral artery disease (PAD) affects up to 10% of the worldwide population and the prevalence increases to as high as 20% among patients 70 years of age and older [1–4]. Atherosclerotic PAD is characterized by significant narrowing of the arteries in the legs due to the development of plaque. The stenoses and/or occlusions of the peripheral arteries lead to decreased blood flow to the muscles of the legs resulting in a range of leg symptoms. The severity of the associated symptoms are highly variable and range from complete lack of symptoms, to atypical symptoms, to leg pain with exertion, and finally to the most severe form, critical limb ischemia (CLI), which is characterized by rest pain in the legs and feet as well as potential tissue and limb loss [5–7]. For patients with mild and moderate levels of PAD, the primary symptom often reported is intermittent

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claudication (IC), described as pain, aching, fatigue and/or cramps in the calves, thighs and/or buttocks which is induced by walking and relieved by rest [4]. Thus, individuals with IC are often sedentary and may avoid most forms of ambulation. This behavior ultimately decreases functional capacity, leading to poor patient-reported outcomes which are strongly associated with an increased risk of premature mortality [8].

A primary treatment option for PAD patients with IC, and often considered the gold standard therapy, is a program of supervised walking exercise training which is typically a 3 month program performed in a hospital or healthcare clinic [9,10]. These programs consist of intermittent bouts of walking interspersed with periods of rest when moderate to severe leg pain manifests [11]. A supervised exercise program typically improves overall walking ability by allowing the PAD patient to walk for longer periods of time and by increasing distance and/or time at which claudication symptoms first appear while walking [12,13]. However, supervised exercise programs are underutilized possibly due to lack of reimbursement from insurance companies, a lack of local training centers, and the need for PAD patients to travel to a facility frequently over an extended period of time. Thus community walking programs have recently gained attention as a potential option for treating IC. Using the patient's living environment may be a valid setting in which to promote walking exercise. However, the effectiveness of this type of program for improving PAD patients' walking ability has not been well established [14]. Given the current state of the US healthcare system for treating PAD (i.e., lack of reimbursement for supervised training), development of exercise programs conducted in the community setting merits more attention. However, the design of these programs has not been standardized as with supervised exercise programs. Often, researchers (and clinicians) have just recommended that patients with PAD "go home and walk." Such studies have not generally resulted in significant improvement in walking ability and patient-reported outcomes. More recently, there have been better designed studies that provide more effective ways of getting patients to exercise in the community. Specifically programs using established supervised walking guidelines that monitor PAD patients in the community over the course of an intervention and provide direct feedback on how to improve walking ability may be beneficial.

There are a number of other exercise based methods for treating IC in addition to walking programs. Therapies under development primarily consist of using different modes of exercise including: 1) leg ergometry and arm ergometry, 2) polestriding and 3) resistance training. The evidence is not as robust for improving health outcomes using these modalities as it is for supervised exercise, at least in part because they have only been recently developed. However, there may be instances where these alternative exercise therapies merit usage in the clinical setting or if patient preference warrants their use, for example, using arm ergometry exercise for PAD patients who are unable to walk, such as among those with toe or lower limb amputation. The purpose of this review is to evaluate the current literature for exercise therapy to treat PAD patients. Table 1 provides a brief review of the advantages and disadvantages of each type of exercise therapy available for patients with PAD and IC.

TREATMENT

- The goals of exercise therapy for PAD patients should, in most cases, be to improve walking ability, with the most common endpoint assessed being peak walking time (PWT) or peak walking distance, as well as claudication onset time (COT) or claudication onset distance. Other pertinent outcomes for evaluating impact of exercise among PAD patients include patient-reported outcomes assessed by questionnaires such as the disease-specific Walking Impairment Questionnaire (WIQ) or the Medical Outcomes Study 36-item short form questionnaire (SF-36), a quality of life measure [15,16]. Although all types of exercise are beneficial for

general cardiovascular health, supervised walking has been preferred for PAD patients and will result in physiological adaptations specifically leading to improvement in walking outcomes.

Exercise therapy for claudication

Supervised walking exercise

Supervised walking exercise has been well validated as an effective treatment for walking impairment due to PAD [4,11,17]. Supervised walking in hospitals and health-care clinics is considered the gold standard (IA) treatment for patients with PAD and IC according to the ACC/AHA practice guidelines for the management of PAD [9]. In a meta-analysis of randomized controlled trials, Watson et al. [18] concluded that supervised exercise training improved PWT of PAD patients who experienced IC by 50–200%. Patient-reported outcomes have been shown to improve as well [17,19], which is important as the patient's perception of health following treatment may guide therapy decisions. Additionally, exercise training improves the cardiovascular system and risk factors as well as local skeletal muscle adaptations [12,13,20] indicating this type of therapy as a primary option for PAD patients.

Recently, the multicenter Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) trial evaluated the primary outcome of PWT for PAD patients with IC randomized into 3 separate groups: 1) supervised walking plus optimal medical therapy, 2) endovascular revascularization plus optimal medical therapy and 3) optimal medical therapy alone [17]. Results indicated that at the 6 month follow-up time point, the primary endpoint of PWT improved the most in the supervised walking group compared to revascularization and optimal medical therapy alone (+5.8 vs. +3.7 vs. +1.2 minutes). COT values improved similarly in the supervised walking group and revascularization group and both were higher than optimal medical therapy group patient outcomes (+3.0 vs. +3.6 vs. +0.7 minutes). Disease-specific patient-reported outcomes assessed by the WIQ and Peripheral Artery Questionnaire [21] improved in both the supervised walking and revascularization treatment groups with the greatest improvements in the revascularization group.

Usage—Patients typically walk on a motorized treadmill until limited by the development of moderate IC (3 or 4 on the Claudication Symptom Rating Scale which ranges from 1 = no pain to 5 = severe pain). Each bout of walking is then followed by a rest period to allow the leg pain to subside after which the patient resumes walking. The walking/rest sessions continue until the patient reaches 35 to 50 minutes of total combined time, and completes at least three sessions•week^{-1}, for a total duration of 3 to 6 months. However, recently, Gardner et al. [22] found that adherence rates may in fact be better with programs that are only 2 months in duration.

Special points—It is not uncommon for patients to continue having residual claudication following revascularization [23] potentially due to initial sub-optimal clinical success rates (e.g., patency), restenosis, multi-vessel disease, or new symptoms in the opposing leg if bilateral revascularization was not performed. However, for patients where IC has resolved, ratings of perceived exertion (RPE) using the Borg 15 Category RPE Scale or OMNI Perceived Exertion Scales can be used to regulate exercise intensity at a moderately hard level [24,25], which has been used successfully in previous exercise training programs for asymptomatic PAD patients [26]. This method may be a better alternative to using moderate intensity prescriptions based on age-predicted exercise heart rate responses as many PAD patients are prescribed medications (e.g., beta-blockers) that may affect heart rate during exercise.

Cost/cost-effectiveness—Treesak et al. [27] examined cost-effectiveness of 3 and 6 months of supervised **e**xercise training and endovascular therapy in patients who experienced claudication. Findings indicated that at 3 months, endovascular therapy was more effective clinically than exercise training as evidenced by improvements in peak walking distance [27]. However, outcomes at 6 months indicated that exercise training provided more gains in walking distance (137 meters) and less cost per meter gained ($61 less) than endovascular therapy.

Community-based walking exercise

Studies employing general advice by physicians and healthcare providers to exercise have proven largely ineffective for PAD patients, and patients given this advice have often served as the control group in clinical trials [28–30]. A meta-analysis of supervised exercise programs and unsupervised exercise programs in home and community settings revealed that supervised exercise therapy has a far greater clinical benefit compared with non-supervised community regimens [14]. However, recent studies have begun to emerge using more intensive structured interventional components in settings outside of clinics to create more effective programs in the community. Gardner et al. [31] conducted a 12 week intervention employing supervised exercise training, community exercise training and a non-exercising control arm for patients with IC. Compliance to exercise was monitored with a piezoelectric activity monitor for the supervised exercise group and the community exercise group. Patients were also asked to complete diaries/log books outlining the exercise sessions. The exercise program for the community exercise group consisted of intermittent walking to near-maximal leg pain for 3 days per week. Patients walked and rested initially for 20 minutes over a 2 week period and periodically increased duration by 5 minutes until a total of 45 minutes of walking was reached. Positive improvements for COT and PWT were demonstrated for the supervised exercise group (+165 and +215 seconds, $P < .001$) and the community exercise group (+134 and +124 seconds, $P < .01$) but not for the control group (−16 and −10 seconds). Additionally, patient-reported outcomes assessed with the WIQ and SF-36 both improved for patients in the supervised and community exercise groups but not for the non-exercising control group. Thus there is evidence that structured community exercise programs can be effective.

Usage—Exercise prescription components (duration, intensity, frequency of exercise) for community-based walking exercise should be methodologically similar to supervised exercise programs.

Special points—A limiting factor of community exercise program implementation is that although the established, peer-reviewed guidelines of supervised exercise programs may be prescribed to patients, they may not be feasibly applied in the typical community setting. For example, when a patient experiences IC in the community while walking, there may not be an adequate place to sit and rest. Additionally, issues related to the built environment (e.g., lack of or poor quality sidewalks), weather, and crime/safety concerns may prevent patients from walking in the community for an extended period of time. Thus, this type of therapy for PAD patients is still evolving and warrants additional research.

Cost/cost-effectiveness—A recent Dutch study evaluated the cost-effectiveness of supervised exercise compared to exercise advice without supervision [32]. Findings indicated that the supervised exercise program was more effective (more costly as well) than the exercise advice program for PAD patients. These findings are not surprising, given the ineffectiveness of unsupervised community walking programs where only advice is given to patients. Cost-effectiveness data have not been evaluated with regard to the more recently

developed community based exercise programs which feature some elements of supervised exercise in the community setting.

Leg ergometry

PAD patients with IC have pronounced gait alterations [33] and may have comorbidities such as obesity and other factors that confound walking which may make leg ergometer usage an attractive alternative form of exercise. A number of studies have demonstrated leg ergometry to be an effective approach for improving walking and/or cycling outcomes for PAD patients [34–37]. Additionally, Tuner et al. [38] evaluated absolute claudication time and cardiorespiratory outcomes during incremental cycling and treadmill exercise testing in a group of PAD patients with IC. Results indicated similar absolute claudication time outcomes between the two modalities in addition to significantly higher cardiovascular and metabolic responses during leg ergometry compared to treadmill walking. These findings provide additional support for the use of leg ergometry as it employs functional usage of the lower limbs resulting in specificity to training, inducing both central as well as peripheral vascular and metabolic adaptations. Thus leg ergometry may be a valid approach to improving walking ability for PAD patients although more research is needed to establish the role of this newer therapy for IC.

Usage—Studies using leg ergometry as a treatment modality for PAD patients have generally used similar exercise prescription methods as supervised walking exercise, that is, patients exercise for several minutes to the point of moderate pain then follow with several minutes of rest until a pre-defined exercise/rest duration is reached for each session [34,36,37].

Special points—Leg ergometry seating may be uncomfortable for patients. This may represent a barrier to participating in this type of exercise.

Cost/cost-effectiveness—To date there are no cost-effectiveness studies available for leg ergometer exercise for PAD patients with IC.

Arm ergometry

For those patients who are unable to perform leg exercise such as patients with lower limb amputations or CLI, arm ergometry may be a valid approach for treatment and a number of trials have examined its usage for improving walking ability for patients with IC [35–37,39–41]. In a more recent trial using arm ergometry to treat PAD patients with claudication, Bronas et al. [40] found a significant change in claudication onset distance from baseline to 12 weeks for patients completing an arm ergometer exercise program (+89.6 meters, $P < .01$) which was also similar to patients in a supervised walking program (+106.7 meters) and higher among control patients (+7.3 meters). Additionally, there were no differences in peak walking distances for patients randomized to the arm ergometer exercise program (+181.1 meters) vs. the supervised walking program group (+297.6 meters) but both intervention groups showed more improvement than control patients (+46.3 meters, $P < .05$). These findings are critically important for establishing upper limb exercise as an alternative therapy for PAD patients, as a major barrier to walking exercise is IC.

Usage—Methods for several studies [39,40] have had patients starting at a cadence of 50 revolutions•min^{-1} and 10 W below maximal output achieved during an arm ergometer exercise test. Because patients are not using their lower limbs during arm ergometry and may not experience IC, patients exercise for 2 minutes using an exercise intensity range of 13–15 on the Borg 15 Category Ratings of Perceived Exertion scale. This is followed by 2 minutes of rest for a total duration of 60 minutes and is similar to the walk/rest ratio used for

supervised walking exercise programs. The duration of the exercise portion of the overall session is increased every few weeks with up to 5 minutes of exercise interspersed with 1 minute of rest.

Special points—This type of exercise, while promising, still currently requires supervised support by healthcare providers thus lending itself to the same limitations as supervised walking exercise such as lack of reimbursement for supervision and the need for patients to travel to and attend clinic visits for an extended period of time.

Cost/cost-effectiveness—No studies have addressed cost-effectiveness of arm ergometry for patients with IC.

Polestriding

Polestriding is a type of exercise where patients ambulate with poles for additional upper body motion thereby increasing the central cardiovascular demand. The use of polestriding for treating PAD is intended to elicit a cardiorespiratory response that may not be possible in all patients such as those with severe IC, as the poles used during walking attenuate lower limb pain by redistributing weight to the poles in addition to decreasing the vertical ground reaction forces during walking [42,43]. While there are only a few studies examining this modality for use in PAD, results are promising for treating IC [43–47]. In a sample of n = 77 PAD patients who completed 24 weeks of training, Collins et al. [47] examined the effect on walking ability of polestriding vs. supervised walking. The change in PWT for the supervised walking group at 24 weeks was higher compared to the polestriding group, however the difference was not statistically significant (+170 vs. +127%). Additionally, adherence to exercise sessions over the course of the intervention was similar between groups (polestriding: 73 ± 24 and supervised walking: 73 ± 22%). Thus, polestriding may be a viable alternative to standard walking programs, however, large scale multicenter trials are needed to establish this therapy as a primary treatment for IC.

Usage—According to the recent study by Collins et al. [47], patients exercised initially for 3 times•week^{-1} for 30 minutes at light, moderate and high intensities. Intensity of exercise was based on percentages of maximal heart rate achieved from an initial walking treadmill test. The majority of the exercise time occurred at a moderate intensity of 60% of time, compared to 20% each at light and high intensities. The goal was to complete 60 minutes of exercise by the end of the intervention at the following intensities: 1) light intensity for 10% of total time, 2) moderate intensity for 35% of total time, 3) high intensity at 50% of total time, and 4) very high intensity for 5% of total time.

Special points—Patients may need an extensive familiarization session for polestriding exercise as the movement may be difficult initially.

Cost/cost-effectiveness—Not studied

Resistance training

Resistance training is comprised of several different types of exercise including plantar flexion and upper and/or lower body endurance and strength training. Plantar flexion exercise consists of patients being in a seated or recumbent position and actively moving the foot in a plantar and dorsi flexion motion against a resistive pedal. Several trials have examined this mode of exercise for improving walking ability in PAD [48–50]. Recently, Tebbutt et al. [48] randomized PAD patients (n = 42) to an unsupervised intervention group consisting of 12 weeks of plantar flexion (also advice to walk at home) and a control group that received only advice to walk at home. Results indicated an improvement in median

claudication onset distance and peak walking distance for patients enrolled in the intervention group (+20 and +40 meters) but not for those in the control group (+0 and −50 meters). However, it should be noted that the study was discontinued prematurely, resulting in an interim analysis that determined the variance of outcomes were too high and thus significant differences were not found. Although a considerable amount of research is needed to determine the effectiveness and successful implementation of plantar flexion exercise, this recent study is promising as this type of modality does bypass barriers to walking exercise. For example, in patients with orthopedic issues such as knee arthritis, this could be an option as the knee joint is not involved directly in moving the resistive pedal. However, in the event of iliac arterial disease, where the patient may experience buttock claudication with ambulation, this modality may not be an optimal treatment option.

Other resistance training studies have evaluated the effect of strength training consisting of dynamic movement using the upper and/or lower limbs to determine if walking ability is improved in PAD patients [13,26,50–55]. Recently, Meneses et al. [52] compared the effects on claudication onset distance and peak walking distance following a supervised upper and lower body resistance exercise program or a supervised walking program in patients with IC. There were significant improvements in walking ability pre and post intervention for both the resistance training group (claudication onset distance: +182 meters, $P < .01$; peak walking distance: +172 meters, $P < .001$) and the supervised walking group (claudication onset distance: +132 meters, $P < .01$; peak walking distance: +173 meters, $P < .001$) but no differences were observed between groups. McDermott et al. [26] found that a 6 month lower extremity resistance training program for patients with and without IC significantly improved PWT compared to patients randomized to a control group (+2.41 vs. +0.51 minutes, $P = .009$). Additionally, the resistance training group demonstrated greater median improvements compared to the control group for the physical component score of the SF-36 (+10.0 vs. +5.0, $P = .04$) as well as WIQ distance scores (+8.52 vs. +0.25, $P = .03$) and stair climbing scores (+12.5 vs. +0.0, $P = .02$). Thus, these studies as well as the others cited demonstrate resistance training to be a potentially useful mode of exercise for PAD patients.

Usage—The methods for the few studies examining plantar flexion exercise for improving walking ability in PAD and IC generally consists of one leg performing exercise at a given time, with patients exercising and then resting which is similar to the walk/rest concept used in supervised walking exercise. For dynamic strength training, exercise prescription methods are variable and dependent on the desired outcome (maximal strength gains vs. muscular endurance improvement), although many studies have used a standard exercise prescription consisting of 2 or 3 sets, ranging from 5 to 30 repetitions with several minutes of rest in between sets and using RPE to regulate exercise intensity [26,51,52].

Special points—The cardiovascular system may not be impacted to as great an extent as seen in walking programs. Thus resistance exercise may be used as a complementary part of the exercise prescription given that the cardiovascular system is adversely effected in PAD.

Cost/cost-effectiveness—Resistance training for PAD has not been studied directly or in comparison with other treatments with regard to cost or cost-effectiveness. However an early study in assessing the effectiveness of resistance training to improve walking ability of PAD patients concluded that the modest benefits demonstrated could not allow for a recommendation that resistance training is a cost-effective approach for treating PAD and IC [13].

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Table 1

Summary of advantages and disadvantages of various exercise therapy options for peripheral artery disease patients with intermittent claudication

Exercise Modality	Advantages	Disadvantages
supervised walking	- rated class IA by the ACC/AHA PAD practice guidelines [9] - effective strategy for improving PWT, COT and patient-reported outcomes [18] - patient safety assured in hospital settings	- lack of insurance reimbursement [56] - transportation to clinics may not be available for patients, additionally costly or inconvenient - long term adherence problematic due to short duration of most supervised programs (3 months)
community walking	- walking exercise in community settings more specific to activities of daily living than supervised walking and non-weight bearing modalities (e.g., leg ergometry) - bypasses many of the barriers associated with supervised exercise - lower cost [32]	- rated class IIB (as unsupervised exercise) by the ACC/AHA PAD practice guidelines [9] - ineffective when clinicians provide only advice to exercise - numerous social and built environment barriers to performing community-based walking such as crime and poor sidewalks [57]
leg ergometry	- able to induce IC thus providing specific training to affected lower limbs in addition to central cardiovascular adaptations [38] - potential alternative for patients with gait abnormalities limiting walking	- not assessed by ACC/AHA PAD practice guidelines - many leg ergometers are uncomfortable for seating [58] - no studies in community settings, thus similar barriers for implementation as supervised walking programs
arm ergometry	- alternative for patients who are high risk for wounds such as those with CLI - effective for improving central cardiorespiratory adaptations of patients otherwise limited in ability to exercise [40]	- not assessed by ACC/AHA PAD practice guidelines - lack of specificity for local level muscular adaptations due to inactive lower limbs - studies needed examining implementation in community settings because supervision is required
polestriding	- may be viable alternative for patients with balance issues - maintains upright weight-bearing nature of walking exercise however poles decrease lower limb loading [59] thus attenuating IC and increasing central cardiorespiratory demand and improvement	- not rated by ACC/AHA PAD practice guidelines - patients' may be unfamiliar with the ski like motion required, thus adoption may be difficult - differences in technique and/or fitness level may result in a wide range of walking improvement [46] - patients may be uncomfortable walking with poles in community settings [45]
resistance training	- plantar flexion resistance exercise can be performed while seated which may be more comfortable for patients - resistance training improves other health outcomes such as increased bone mineral density and muscular strength [55]	- not rated by ACC/AHA PAD practice guidelines - plantar flexion exercise focuses on the muscles of the calf thus patients with IC in the thighs or buttocks will not derive benefit from this modality - unlikely to be as beneficial for the cardiovascular system as walking exercise

ACC American College of Cardiology; *AHA* American Heart Association; *CLI* critical limb ischemia; *COT* claudication onset time; *IC* intermittent claudication; *PAD* peripheral artery disease; *PWT* peak walking time