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EXERCISE TRAINING FOR INTERMITTENT CLAUDICATION

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Abstract

Objective—To provide an overview of evidence regarding exercise therapies for patients with lower extremity peripheral artery disease.

Methods—This manuscript summarizes the content of a lecture delivered as part of the 2016 Crawford Critical Issues Symposium.

Results—Multiple randomized clinical trials demonstrate that supervised treadmill exercise significantly improves treadmill walking performance in people with PAD and intermittent claudication symptoms. A meta-analysis of 25 randomized trials demonstrated a 180 meter increase in treadmill walking distance in response to supervised treadmill exercise interventions, compared to a non-exercising control group. Supervised treadmill exercise has been inaccessible to many patients with PAD because of lack of medical insurance coverage. However, in 2017 the Centers for Medicaid and Medicare Service issued a proposed decision memorandum to support health insurance coverage of 12 weeks of supervised treadmill exercise for patients with walking impairment due to PAD. Recent evidence also supports home-based walking exercise to improve walking performance in people with PAD. Effective home-exercise programs incorporate behavioral change interventions such as a remote coach, goal setting, and self-monitoring. Supervised treadmill exercise programs preferentially improve treadmill walking performance, while home-based walking exercise programs preferentially improve corridor walking, such as the six-minute walk test. Clinical trial evidence also supports arm or leg ergometry exercise to improve walking endurance in people with PAD. Treadmill walking exercise appears superior to resistance training alone for improving walking endurance.

Conclusion—Supervised treadmill exercise significantly improves treadmill walking performance in people with PAD by approximately 180 meters, compared to no exercise. Recent evidence suggests that home-based exercise is also effective, and preferentially improves over ground walking performance, such as the six-minute walk test.

Lower extremity peripheral artery disease (PAD) now affects 8.5 million people in the United States and more than 200 million worldwide.[1,2] While most people with PAD will not develop critical limb ischemia, people with PAD have greater functional impairment, more rapid functional decline, and faster mobility loss than those without PAD.[3–7] PAD

related functional impairment is associated with increased rates of hospitalization, nursing home placement, and mobility loss.[8–10] Identifying and implementing interventions to improve functional performance and prevent functional decline are important priorities in the care of patients with PAD and intermittent claudication.

Few medications have been identified that meaningfully walking performance in people with PAD. Only two medications, cilostazol and pentoxifylline, are FDA approved for treating PAD-associated walking impairment. Furthermore, benefits from cilostazol are modest. Cilostazol improves treadmill walking performance in people with PAD and intermittent claudication by approximately 25 to 40%.[11–13] Recently published clinical practice guidelines for PAD recommend against pentoxifylline due to lack of efficacy.[14]

Supervised Treadmill Exercise for Peripheral Artery Disease

A large body of evidence from randomized clinical trials demonstrates that supervised treadmill exercise significantly and substantially improves pain free and maximal treadmill walking distance in people with PAD.[14–16] Fakhry et al. published a meta-analysis of 25 randomized clinical trials of supervised walking therapy, including 1054 PAD patients with intermittent claudication.[16] The 25 included studies were published between 1996 and 2012, ranged from four to 104 weeks in duration, and compared a supervised treadmill exercise intervention to a control group that did not receive an exercise intervention. Results demonstrated that supervised treadmill exercise was associated with a 180 meter greater increase in maximal treadmill walking distance, compared to the control group. Supervised treadmill exercise was also associated with a 128 meter greater increase in pain-free treadmill walking distance, compared to the control group.[16] In summary, randomized clinical trials consistently demonstrate that supervised treadmill exercise improves total treadmill walking distance and pain-free treadmill walking distance in people with PAD who have intermittent claudication.[16] Supervised treadmill exercise has also been shown to improve treadmill walking performance and six-minute walk distance in PAD patients who have atypical ischemic leg symptoms other than intermittent claudication.[17]

Despite its benefits, supervised treadmill exercise has been inaccessible to many PAD patients with intermittent claudication. Lack of access to supervised exercise among people with PAD and intermittent claudication is in part due to lack of medical insurance coverage. For example, the Center for Medicare and Medicaid Services has traditionally not provided coverage for supervised exercise for people with PAD and intermittent claudication. Many private medical insurance companies also do not provide healthcare coverage for supervised treadmill exercise for patients with PAD. Without medical insurance coverage, many patients with PAD are not able to afford participation in supervised treadmill exercise programs. In addition, traveling to an exercise center three times weekly for supervised exercise is burdensome, especially for PAD patients who are older and have limited mobility. Even when supervised exercise is provided to PAD patients without costs, such as in a research program many PAD patients decline participation.[18]

A recent report summarized refusal rates by potential participants in 23 clinical trials of supervised exercise in people with PAD. Of 1,541 potential participants without critical limb

ischemia who had sufficient ischemic symptoms to be eligible for inclusion in supervised exercise studies, 769 (50%) reported lack of interest or simply refused participation in supervised exercise and an additional 295 (19%) reported that attending supervised exercise was too inconvenient.[18] Overall, 69% of eligible PAD participants refused participation in supervised exercise. In summary, this systematic review demonstrated that even when supervised exercise was available without cost to the participant with PAD, approximately 2/3 of people with PAD declined participation.

Medical Insurance Coverage for Supervised Exercise for Intermittent Claudication

In early 2017, the Center for Medicare and Medicaid Services (CMS) released a proposed decision memorandum regarding coverage of supervised exercise therapy for symptomatic peripheral artery disease.[19] The memorandum stated that evidence is sufficient to cover supervised exercise therapy for beneficiaries who have PAD with symptoms of intermittent claudication. The memorandum further indicated that CMS was considering coverage of supervised exercise therapy that consisted of three exercise sessions per week of 30–60 minutes of exercise for up to 12 weeks. The exercise program proposed for coverage by CMS must be located in a hospital or outpatient hospital setting and delivered by qualified personnel trained in basic and advanced life support and also in exercise therapy for PAD.[19] The exercise program must be carried out under direct supervision by a physician. This memorandum suggests that CMS may be providing coverage for supervised exercise in the near future.

Home Based Walking Exercise for Peripheral Artery Disease

Home-based exercise programs have the potential to be more accessible and acceptable to patients with PAD than supervised exercise programs, which require travel to the medical center three times daily and can be costly if medical insurance does not pay. However, until recently home-based walking exercise was considered not effective for PAD patients. For example, 2006 American Heart Association/American College of Cardiology clinical practice guidelines concluded that there was no evidence to support advising people with PAD to “go home and walk.”[20] This 2006 conclusion was based on several small studies of home-based exercise in PAD patients with claudication that did not incorporate behavioral change techniques.[21–23]

Since 2011, three randomized clinical trials have demonstrated that home-based exercise can improve walking performance in people with PAD.[24–26] In the first of these randomized trials, Gardner et al randomized 119 men and women with PAD and intermittent claudication to one of three groups for twelve weeks: supervised treadmill exercise, home-based walking exercise, or a control group.[26] Participants randomized to supervised treadmill exercise attended exercise sessions three times weekly and walked for up to 40 minutes at each exercise session. Participants randomized to home-based exercise used activity monitors to monitor their home exercise and were instructed to walk three times per week at a self-selected pace, working up to 45 minutes of walking exercise per session. PAD participants were instructed to wear the step counter during exercise sessions and also to

record their walking exercise activity on a log. Every two weeks, participants in the home-exercise group returned to the medical center where they reviewed their walking exercise progress with a study investigator, using the activity monitor data and the exercise log. The investigator provided feedback and instructions for walking exercise for the next two weeks. At 12 week follow-up, the groups randomized to supervised treadmill exercise and home-based walking exercise each significantly improved their pain-free and maximal treadmill walking performance, compared to the control group (Table 1). There were no significant differences in the degree of improvement in pain-free or maximal treadmill walking time between the supervised treadmill exercise group and the home-based exercise group. Neither exercise group improved their Walking Impairment Questionnaire (WIQ) score, compared to the control group. Quality of life, measured by the Short Form 36 Physical Functioning questionnaire improved by 9 points in the supervised exercise group and by 8 points in the home-based exercise group. The change in the SF-36 PF score was statistically significant in the supervised exercise group compared to the control group, but not in the home-based exercise group, compared to the control group.[26] The trial had a 23% drop-out rate overall and a 28% drop-out rate in the home-based exercise group. The high drop-out rate in the home-exercise group may represent difficulties with adherence to home-based exercise in people with PAD.

In the second randomized trial, Gardner et al randomized 180 participants with PAD and intermittent claudication to supervised treadmill exercise, home-based walking exercise, vs. an attention control light resistance training group for 12 weeks.[24] Participants randomized to supervised exercise were asked to walk for exercise on the treadmill three days per week, working up to 40 minutes per session, and walking to maximal ischemic leg pain. Participants randomized to home exercise were asked to walk for exercise at a self-selected pace three days weekly, working up to 45 minutes per session. PAD participants in the home-exercise group used an exercise step monitor to track their walking exercise activity. PAD participants in the home-exercise group walked at a self-selected pace during exercise sessions. PAD participants in the home-based exercise program returned at one-week follow-up and subsequently at four, eight, and twelve- week follow-up. At each follow-up session, a study investigator reviewed the exercise data measured by the step-counter and provided feedback. Instructions were provided for exercise activity during the next four weeks. Participants randomized to the attention control group engaged in resistance training, predominately involving the upper extremities. At 12-week follow-up, the supervised exercise group increased their maximal treadmill walking time by 192 seconds, the home-based walking exercise group increased their maximal treadmill walking time by 110 seconds, and the control group increased their walking time by 22 seconds (Table 1).[24] At 12 week follow-up, the supervised exercise group increased their pain-free treadmill walking time by 170 seconds, the home-based walking exercise group increased their pain-free treadmill walking time by 104 seconds, and the control group increased their pain-free walking time by 17 seconds (Table 1). At 12-week follow-up, distance achieved in the six-minute walk increased by 15 meters in the supervised exercise group, by 45 meters in the home-based exercise group, and by 4 meters in the control group. Each exercise group improved the six-minute walk distance significantly more than the control group. The supervised treadmill exercise group improved the peak treadmill walking time significantly

more than the home-based exercise group, but the home-based exercise group improved the six-minute walk significantly more than the supervised treadmill exercise group. This trial underscores the phenomenon in which treadmill walking exercise interventions that train participants on the treadmill achieve greater gains on the treadmill outcome measure, while home-based walking exercise interventions in which participants train by walking over ground achieve greater gains in the six-minute walk test (i.e. a corridor walking test).[27] Since corridor walking more closely simulates over ground walking, home based exercise programs may have an advantage over supervised treadmill exercise programs with regard to improving walking in daily life for people with PAD.

A third randomized trial of home-based exercise, the Group Oriented Arterial Leg Study (GOALS), tested the ability of a Group Mediated Cognitive Behavioral (GMCB) intervention to help patients with PAD adhere to a home-based walking exercise program, thereby improving their walking performance.[25] The GOALS trial is the only randomized clinical trial of home-based exercise that enrolled PAD participants both with and without symptoms of intermittent claudication. The GOALS trial randomized 192 participants with PAD to either a GMCB intervention or an attention control group for six-months.[25] The GMCB intervention employed methods that included social cognitive behavioral change theory and group support. During the first six months of GOALS, PAD participants in the intervention group met weekly at the medical center with other PAD patients and a facilitator. The facilitator led discussions regarding goal setting, self-monitoring, and overcoming obstacles to exercise adherence. At six-month follow-up, participants in the GMCB home-based exercise intervention group significantly improved their six-minute walk performance (primary outcome measure), pain-free treadmill walking time, and maximum treadmill walking time relative to the control group (Table 1). The intervention group had a 53.5 meter greater increase in six-minute walk performance, a 1.01 minute greater increase in maximal treadmill walking time, and a 1.02 minute greater increase in pain-free treadmill walking time than the control group. The GMCB home-based exercise intervention also significantly improved physical activity levels and the WIQ distance score, compared to the control group. After the six-months of weekly on-site sessions, between months 7–12 after randomization, participants in the GOALS intervention received telephone calls from the facilitator, weekly, bi-weekly, and then monthly. The benefits of the GMCB home-based exercise intervention on six-minute walk persisted at 12-month follow-up, six months after the final on-site study intervention.[27] Participants randomized to the GMCB intervention were also less likely to experience mobility loss, defined as becoming unable to either walk up and down a flight of stairs or walk ¼ mile, at 6-month and at 12-month follow-up, compared to the control group.[28] Among participants without mobility impairment at baseline, rates of mobility loss were 6.3% in the GMCB intervention group vs. 26.5% in the control group at 6-month follow-up. Among those without mobility impairment at baseline, rates of mobility loss were 5.2% in the GMCB intervention vs. 18.5% in the control group at 12-month follow-up. In addition to being the only randomized trial to study a home-based exercise intervention in PAD participants both with and without intermittent claudication, GOALS is the longest randomized trial to demonstrate benefits of home-based exercise in patients with PAD. However, a fourth randomized trial of home-based exercise demonstrated no benefit of home-based walking exercise in patients with

PAD.[29] Collins et al randomized 145 participants with PAD and diabetes to a behavioral intervention vs. an attention control group for six months. The behavioral intervention consisted of an individualized counseling session at baseline, followed by one walking session per week with an instructor and other patients with PAD at an exercise center and three days of walking at home, working up to 50 minutes of exercise per session. Participants in the intervention also received bi-weekly telephone calls, in which an instructor reviewed their walking progress and provided feedback. The attention control group received biweekly calls from a study investigator during which the participant and study investigator discussed glucose control, blood pressure, and cholesterol levels during the previous month. At six month follow-up, there were no differences in treadmill walking performance between the home-based intervention vs. the control group (Table 1). The reasons for the lack of efficacy of the home based walking exercise in this trial are unclear.[29] However, only participants who intended to begin a walking exercise program were eligible and randomized. It is conceivable that even participants in the attention control group began exercising, which may explain the improvement that occurred in each of the two groups.

Practical aspects of prescribing exercise for patients with PAD

Prior to prescribing a home-based exercise program, PAD patients should complete a baseline treadmill cardiac stress test.[20] The purpose of the stress test is to identify coronary ischemia that may develop during a new walking exercise program. A regular treadmill exercise stress test is sufficient to evaluate most PAD patients for coronary ischemia prior to initiating a new exercise program. PAD patients whose baseline treadmill exercise stress test shows no evidence of coronary ischemia may proceed with exercise therapy. PAD patients whose baseline treadmill exercise stress test indicates coronary ischemia should undergo additional evaluation and treatment prior to initiating an exercise intervention.

Implementing a supervised treadmill exercise program

In a supervised treadmill exercise program, patients with PAD walk for exercise in a supervised setting at least three times weekly. The exercise program should be tailored for the individual patient. PAD patients starting an exercise program for the first time often need to begin with just 10 minutes of walking exercise per exercise session. Based on current evidence, PAD patients should be advised to walk to near maximal leg pain, although some preliminary evidence suggests that walking only to the onset of ischemic leg pain may also be beneficial.[16] Patients with PAD should be advised to walk at a speed that elicits leg ischemia symptoms within ten minutes. They should be advised that stopping to rest is acceptable and typical for patients with PAD. Once leg pain subsides during a rest, the PAD patient should be advised to resume walking again. Many patients with PAD may start with just 10 to 15 minutes of walking exercise per session, and the duration of exercise should be increased by five minutes each week, until the PAD patient is walking at least 30 minutes per session. Participants able to walk more than 30 minutes per session should be encouraged to increase their walking exercise duration up to 45 to 50 minutes per session. Patients with PAD should be reminded that it is acceptable to stop and rest as necessary in response to ischemic leg pain. Patients who are able to walk continuously for exercise for 10 minutes or

more without stopping to rest should have the intensity of the treadmill exercise increased, either by increasing the treadmill speed or by increasing the treadmill grade.

Implementing a home-based walking exercise

Growing evidence demonstrates that home-based exercise improves walking performance in patients with PAD. Clinical practice guidelines state that home-based exercise is a reasonable intervention for patients with PAD who do not have access to home-based exercise.[14,30] Advantages of home-based exercise include that it is less burdensome and more convenient for people with PAD to walk in their neighborhood or even within their home environment than to travel to a supervised exercise center. Home-based walking exercise preferentially improves over-ground walking, such as that typically encountered in daily life.[24,25,31,32]

Home based exercise programs that have been effective for PAD patients have used activity monitors and/or incorporated principles of behavioral change theory. Behavioral change methods include goal-setting, monitoring progress, and presence of a ‘coach’ to whom the patient reports on progress. Patients with PAD engaged in home-based exercise should be advised to write down walking exercise goals and record their walking exercise activity each week. This information should be reviewed periodically by a coach or a clinician who can provide feedback to the patient. Successful home-based programs have incorporated coach contact with the participant as infrequently as monthly.[24]

Alternative exercise strategies for peripheral artery disease

Upper and lower extremity ergometry for PAD

Few exercise modalities other than walking exercise have been extensively studied in people with PAD. However, upper and lower limb ergometry have been shown to improve walking performance in people with PAD and intermittent claudication in several randomized trials.[33–35] For example, Zwierska et al randomized 104 participants with PAD into an upper limb aerobic ergometry intervention, a lower limb aerobic ergometry intervention, or a non-exercise control group for six months.[33] The exercise interventions took place twice per week and consisted of two minutes of arm (or leg) cranking ergometry exercise followed by two minutes of rest for a total of ten cycles (i.e. 20 minutes of exercise at each session). At 6-month follow-up, the maximal walking distance, measured by a shuttle-walk protocol, increased by 29% in the upper limb ergometry group and by 31% in the lower limb ergometry group. Peak oxygen uptake also improved in the two exercise groups, suggesting that improved cardiovascular fitness may have contributed to the improved walking endurance. Subsequent randomized trials have also demonstrated benefit of upper and lower extremity ergometry as important exercise modes for people with PAD.[34,35]

Resistance training for PAD

Lower extremity resistance training has been evaluated in several randomized clinical trials of participants with PAD.[17,36,37] Two randomized trials demonstrated significant improvement in maximal treadmill walking time following six months of strength-training interventions.[17,36] In the largest trial of resistance training for PAD, 156 participants with

PAD were randomized to supervised treadmill exercise, supervised resistance training, or a control group for 6-months. At six-month follow-up, supervised treadmill exercise achieved a statistically significant and clinically meaningful improvement in six-minute walk performance, while supervised lower extremity resistance training did not achieve significantly greater improvement in six-minute walk performance than an attention control group (+ 35.9 meters vs attention control and +12.4 meters vs. attention control, respectively).[17] Nonetheless, improvements in maximal treadmill walking distance were significantly better in both the supervised treadmill exercise (+3.44 minutes, 95% CI= 2.05 to 4.84 minutes) and in the supervised resistance training group (+1.90 minutes, 95% CI=0.49 to 3.31 minutes), compared to the attention control group. Collectively, these data suggest that lower extremity resistance training may improve walking endurance as measured by maximal treadmill walking distance.

Conclusions

Clinical trial evidence consistently demonstrates that supervised treadmill exercise significantly improves treadmill walking performance in people with PAD. Home-based walking exercise is also beneficial for patients with PAD and improves corridor walking, such as the six-minute walk test, to a greater degree than treadmill walking exercise. If the Center for Medicare and Medicaid services proceeds with providing coverage for supervised treadmill exercise, this benefit will increase the accessibility of supervised exercise to many more patients with PAD in the United States. However, home-based walking exercise may be an alternative therapeutic option for individuals who find travelling for supervised exercise too burdensome.

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Table 1

Randomized Clinical Trials of Home-based Exercise in Peripheral Artery Disease Published Since 2011

Study and Year Published	Sample Size	Duration (months)	Groups	Primary Results	Additional Observations
Gardner et al 2011	119	3	Supervised treadmill exercise. Home-based walking exercise. Control group (received advice to walk)	The supervised treadmill exercise group improved their peak treadmill exercise time by 215 seconds +173, the home-based walking exercise group improved their peak treadmill walking time by 124 seconds + 193, and the control group declined by 10 seconds. Each exercise group also improved their time to treadmill onset of claudication (+165 seconds, +134 seconds, −16 seconds, respectively). Improvements in each exercise group were statistically significant compared to the control group, but the exercise groups were not significantly different from each other.	There was a 23% dropout rate overall. The Walking improvement questionnaire did not significantly change in each exercise group, compared to the control group.
Gardner et al 2014	180	3	Supervised treadmill exercise. Home-based walking exercise. Control group	The supervised treadmill exercise group improved their peak treadmill exercise time by 192 seconds +190, the home-based walking exercise group improved their peak treadmill walking time by 110 seconds + 193, and the control group declined by 22 + 159 seconds. Each exercise group also improved the time to onset of claudication pain on the treadmill (+170 seconds, +104 seconds, +17 seconds, respectively). The supervised treadmill exercise group improved their six-minute walk distance by 45 meters, the home-based exercise group improved their six-minute walk by 15 meters, and the control group improved by four meters.	Participants randomized to supervised treadmill exercise had significantly greater improvement in treadmill walking compared to home-based exercise. Participants randomized to home-based exercise had greater improvement in six-minute walk compared to those randomized to supervised exercise.
McDermott et al 2013	192	6 months (primary outcomes) 12 months (secondary and exploratory outcomes)	A Group Mediated Cognitive Behavioral (GMCB) intervention designed to increase home-based exercise vs. an attention control group.	The six-minute walk (primary outcome) increased by 42.4 meters in the intervention group and declined by 11.1 meters in the control group at six-month follow-up. In addition, the intervention group increased maximal treadmill walking time by 1.01 minutes, compared to the control group and increased the Walking Impairment Questionnaire (WIQ) distance and speed scores by 11.1 and 10.4 points, respectively, relative to the control group.	Benefits in the intervention group regarding improved six-minute walk were attenuated but remained statistically significantly better than the control group at 12-month follow-up, 6 months after the final intervention on-site visit.
Collins et al 2011	145	6 months	Home-based exercise vs. attention control	Participants randomized to the intervention increased their maximal treadmill walking distance by 24.5 meters, and those randomized to the attention control group increased their maximal treadmill walking distance by 39.2 meters.	An eligibility criterion included the intention to begin an exercise program in the next six months, which may have resulted in greater improvement in the control group than otherwise anticipated.

Table 2

Characteristics of effective supervised and home-based walking exercise

	Supervised Treadmill Exercise	**Home-based walking exercise**
Walking exercise frequency	Three times per week	3 to 5 times per week
Duration per session	30 to 50 minutes	40 to 50 minutes
Additional requirements/Helpful additions	On-site exercise physiologist or other qualified staff person to supervise the session. Participant must be willing to attend sessions at an exercise facility three times weekly.	Behavioral techniques including goal setting, self-monitoring, and an activity monitor.
Outcome measures	Most effective at improving treadmill walking performance	Most effective at improving corridor or over ground walking, such as the six-minute walk test.
Medical insurance coverage	May be covered in the future by Centers for Medicare and Medicaid	Not currently paid for by medical insurance.

programs for peripheral artery disease

Table 3

Exercise Modalities for Peripheral Artery Disease

Exercise Method	Overview of Exercise Intervention	Summary of Benefits
Supervised treadmill exercise	Three times weekly treadmill exercise in a supervised setting. Most thoroughly investigated form of exercise for peripheral artery disease.	Significantly improves treadmill walking performance and six-minute walk performance. Variable improvement in physical activity and patient perceived walking ability.
Home-based walking exercise	Walking exercise at home 3 to 5 times per week, using behavioral change modalities including goal setting and self-monitoring	Significantly improves the six-minute walk and improves treadmill walking performance, physical activity, and patient reported measures of walking ability.
Upper and lower extremity ergometry	Ten sets of two minutes of upper or lower extremity ergometry conducted twice weekly for six months.	Significantly improves pain-free and treadmill walking endurance.
Lower extremity resistance training	Lower extremity repetitions of knee extension, leg press, hip flexion exercises in a supervised setting conducted three times weekly.	Significant improves treadmill walking performance, but does not significantly improve the six-minute walk. Improves treadmill walking performance to a lesser degree than supervised treadmill exercise. Improves patient reported measures of stair climbing and some aspects of walking ability.