Exercise training for intermittent claudication

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ABSTRACT

Objective: The objective of this study was to provide an overview of evidence regarding exercise therapies for patients with lower extremity peripheral artery disease (PAD).

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 exercise interventions compared with a nonexercising 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 Medicare and Medicaid Services issued a 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, whereas home-based walking exercise programs preferentially improve corridor walking, such as the 6-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.

Conclusions: Supervised treadmill exercise significantly improves treadmill walking performance in people with PAD by approximately 180 meters compared with no exercise. Recent evidence suggests that home-based exercise is also effective and preferentially improves over-ground walking performance, such as the 6-minute walk test. (J Vasc Surg 2017;■:1-9.)

Lower extremity peripheral artery disease (PAD) now affects 8.5 million people in the United States and >200 million worldwide.[1,2] Whereas 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 to prevent functional decline are important priorities in the care of patients with PAD and intermittent claudication.

Few medications have been identified that meaningfully improve walking performance in people with PAD. Only two medications, cilostazol and pentoxifylline, are Food and Drug Administration 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 because of lack of efficacy.[14]

SUPERVISED TREADMILL EXERCISE FOR PAD

A large body of evidence from randomized clinical trials demonstrates that supervised walking exercise significantly and substantially improves pain-free and maximal treadmill walking distance in people with PAD.[14-16] Fakhry et al[16] published a meta-analysis of 25 randomized clinical trials of supervised walking exercise, including 1054 PAD patients with intermittent claudication. The 25 included studies were published between 1996 and 2012, ranged from 4 to 104 weeks in duration, and compared a supervised walking exercise intervention with a control group that did not receive an exercise intervention. Results demonstrated that supervised walking exercise was associated with a 180-meter greater increase in maximal treadmill walking distance compared with the control group. Supervised walking exercise was also associated with a 128-meter greater increase in pain-free treadmill walking distance compared with the control group.[16] In summary, randomized

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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 6-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. Before 2017, the Centers for Medicare and Medicaid Services (CMS) did not provide coverage for supervised exercise for people with PAD and intermittent claudication. Many private medical insurance companies also have not provided health care 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 1541 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 two-thirds of people with PAD declined participation.

MEDICAL INSURANCE COVERAGE FOR SUPERVISED EXERCISE FOR INTERMITTENT CLAUDICATION

In early 2017, the CMS released a proposed decision memorandum regarding coverage of supervised exercise therapy for symptomatic PAD.[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 to 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. On May 30, 2017, CMS announced that they would provide coverage for supervised exercise for patients with symptomatic peripheral artery disease.

HOME-BASED WALKING EXERCISE FOR PAD

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 weekly 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[26] randomized 119 men and women with PAD and intermittent claudication to one of three groups for 12 weeks: supervised treadmill exercise, home-based walking exercise, or a control group. 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 2 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 2 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 with the control group (Table I). 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