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From the Society for Vascular Surgery

Medical management of claudication

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ABSTRACT

Peripheral artery disease (PAD) is common and associated with significant morbidity and mortality. Optimal medical management of PAD is required for each patient, irrespective of the decision regarding lower extremity revascularization. The goals include reducing cardiovascular morbidity and mortality and improving quality of life. The approach should consist of aggressive and individualized risk factor modification including smoking cessation, antiplatelet therapy, a statin, and an angiotensin-converting enzyme inhibitor. Exercise is critical for cardiovascular health and highly effective for improving claudication symptoms. Cilostazol may be considered for symptomatic treatment in certain patients. (J Vasc Surg 2017; 1-6.)

Peripheral artery disease (PAD) affects >8 million Americans.¹ PAD negatively affects the quality and length of life among those affected. The goals of the medical treatment of PAD focus on two areas: helping patients "live longer" by reducing cardiovascular morbidity and mortality and helping patients "feel better" by improving quality of life. The cornerstones of the medical management of PAD include risk factor modification, medications, such as statins and antiplatelet therapy, and exercise.² In addition, cilostazol may be considered for treatment of claudication symptoms, although adverse side effects can be limiting.

RISK FACTOR MODIFICATION

Smoking cessation. The effect of smoking in PAD is enormous, both in scope and effect. Up to 80% of patients with PAD are current or former smokers.³ The risk of death, myocardial infarction (MI), and amputation is reported to be higher with continued smoking. Smoking cessation in PAD patients may reduce disease progression and may increase walking distance.⁴ Smoking after lower extremity bypass increases the risk of graft failure by at least threefold; however, smoking cessation may restore the patency rates to the level of nonsmokers.⁵

The patient with claudication is often uniquely motivated to quit smoking after learning that (1) the leg

symptoms could improve with smoking cessation, and (2) the disease will worsen with continued smoking. If the symptoms can improve with simply quitting smoking without any further medical or surgical intervention, then smoking cessation should always be the first step.⁶

Varenicline (Chantix; Pfizer Inc, Mission, Kan) is the most effective medication on the market for smoking cessation. It is a partial agonist (it both agonizes and blocks) α -4- β -2 nicotinic acetylcholine receptors, and by doing so, relieves withdrawal symptoms and simultaneously prevents further nicotine binding, which then partially blocks the reinforcing effects of nicotine.⁷ Varenicline is more effective than bupropion and more effective than nicotine replacement therapy. The United States Food and Drug Administration (FDA) recently removed the black-box warning for the psychiatric side effects of varenicline. The EAGLES (Study Evaluating The Safety And Efficacy Of Varenicline and Bupropion For Smoking Cessation In Subjects With And Without A History Of Psychiatric Disorders) study (n = 8144) showed no increase in neuropsychiatric adverse events attributable to varenicline or bupropion relative to nicotine patch or placebo.8 The same study found varenicline was more effective than placebo, nicotine patch, and bupropion; bupropion and the nicotine patch were also more effective than placebo.8

Originally, practitioners would tend not to prescribe varenicline until patients were "ready to quit," partly because the medication is to be started ~1 week before the patient's proposed quit date. More recent evidence suggests that perhaps patients should be prescribed varenicline even if they are not immediately ready to quit because it will still increase smoking cessation rates. Table I offers a basic approach to smoking cessation in the vascular patient. The five "A's" of smoking cessation are Ask, Advise, Assess, Assist, and Arrange. For providers who prefer not to provide pharmacologic treatment or counseling, another approach is Ask, Advise, and Refer. Partnerships between vascular surgery and vascular medicine can help to achieve this goal. The

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Author conflict of interest: The spouse of E.V.R. is employed by MedImmune, which is owned by AstraZeneca, and owns stock in AstraZeneca.

Presented at the Society for Vascular Surgery 2016 Vascular Annual Meeting, National Harbor, MD, June 8-11, 2016.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

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Table I. Approach to smoking cessation: The 5 A's^a

| Explanation | Example |
|--|--|
| Ask every patient at every single visit if he or she uses any tobacco products (including electronic cigarettes or smokeless tobacco). Implement a system in the office for universal identification. | Do you smoke? Do you use smokeless tobacco like snuff or chew? Do you use electronic cigarettes (vaping)? |
| Advise every patient to quit at every visit. Use clear, strong, and personalized advice. | You need to quit smoking as soon as possible to help keep your leg arteries open. |
| Assess the patient's willingness to quit. | Do you want to quit? Are you ready to quit? |
| Assist the patient by helping to set a quit date and providing medication and counseling and resources. For patients who have recently quit, discuss any challenges and the importance of preventing relapse. | What quit date would work for you? (Suggest an upcoming holiday or birthday or anniversary). Prescribe varenicline. Provide hotline information such as 1-800 QUIT NOW and the Smoking Cessation Patient Page from Vascular Medicine. ⁶ |
| Arrange for follow-up contact (office visit or phone call or email), ideally within the first week after the quit date. | Call the patient to check in. Set a delayed message in MyChart ^b reminding the patient of the quit date. |
| | Ask every patient at every single visit if he or she uses any tobacco products (including electronic cigarettes or smokeless tobacco). Implement a system in the office for universal identification. Advise every patient to quit at every visit. Use clear, strong, and personalized advice. Assess the patient's willingness to quit. Assist the patient by helping to set a quit date and providing medication and counseling and resources. For patients who have recently quit, discuss any challenges and the importance of preventing relapse. Arrange for follow-up contact (office visit or phone call or email), ideally within the first week after the quit |

important message is that the benefits of smoking cessa-

important message is that the benefits of smoking cessation greatly exceed any risks associated with pharmacologic treatment.¹⁰

Hypertension. Hypertension should be treated according to current published guidelines to lower the risk of cardiovascular events. Guidelines from the Eighth Joint National Committee advised a target blood pressure of <140/90 mm Hg if the patient has diabetes or chronic kidney disease or is aged <60 years. 11 Otherwise, the target from the Eighth Joint National Committee was <150/90 mm Hg. The more recent SPRINT (Systolic Blood Pressure Intervention Trial) study has led to a more aggressive approach to blood pressure lowering.¹² SPRINT compared the benefit of treatment of systolic blood pressure to a target of <120 mm Hg with treatment to <140 mm Hg among patients at high risk for cardiovascular events but without diabetes. The lower target resulted in lower rates of major cardiovascular events and death from any cause, although with an increased risk of adverse events.¹² The ideal target blood pressure for patients with atherosclerotic vascular disease remains an active topic of debate.

Angiotensin-converting enzyme (ACE) inhibitors are an excellent choice for the treatment of hypertension in the setting of PAD and reduce cardiovascular risk beyond simply lowering blood pressure. The HOPE (Heart Outcomes Prevention Evaluation) study randomized 9297 high-risk patients (including 4051 patients with PAD) to ramipril (10 mg/d) vs placebo.¹³ At a mean follow-up of 4.5 years, a relative risk reduction of 22% was seen in the ramipril group (14.0%) compared with the placebo group (17.5%) for the composite end-point of MI, stroke, or cardiovascular death.¹³ A subset of the HOPE trial, the SECURE trial (Study to Evaluate Carotid Ultrasound

changes in patients treated with Ramipril and vitamin E; n=732) showed a delay in the progression of carotid intimal medial thickness by carotid ultrasound imaging.¹⁴

The ONTARGET (Ongoing Telmisartan Alone and in Combination with Ramipril Global Endpoint Trial) study demonstrated that telmisartan, an angiotensin-receptor blocker (ARB), was equivalent to ramipril in prevention of cardiovascular events, including in the subgroup of patients with PAD.¹⁵ Thus, current guidelines support the use of ACE inhibitors or ARBs to reduce the risk of cardiovascular events in patients with lower extremity PAD.¹

Of note, β -blockers are not contraindicated in PAD patients. A meta-analysis of 11 randomized trials showed that β -blockers do not adversely affect walking capacity or claudication symptoms. However, β -blockers are not first-line for treatment of hypertension but are commonly used for other indications such as heart failure, atrial fibrillation, or secondary prevention after MI.

Diabetes. Diabetes is a major risk factor for PAD and increases the risk of poor outcomes among PAD patients.¹⁷ Patients with diabetes and PAD require a comprehensive and multidisciplinary care plan to include nutrition, weight management, podiatry, ophthalmology, endocrinology, and medications for glycemic control.¹ For many years, the accepted target hemoglobin A_{1c} was <7%. Recently, the trend has shifted to a more individualized approach to glycemic control. For example, a more relaxed goal may be safer in older patients on insulin. Glycemic control has more effect on microvascular complications than on macrovascular complications and is particularly vital among patients with critical limb ischemia.

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