Peripheral artery disease (PAD) refers to chronic narrowing or atherosclerosis of the lower extremities and represents a spectrum of disease severity from asymptomatic disease to intermittent claudication (IC), to critical limb ischemia (CLI). PAD has a similar atherosclerotic process to coronary artery disease and shares similar risk factors: male gender, age, diabetes, smoking, hypertension, high cholesterol, and renal insufficiency. PAD is known to be associated with a reduction in functional capacity and quality of life as well as an increased risk for myocardial infarction (MI), stroke, and death; it is also a major cause of limb amputation. Therefore, the general goals of treatment for PAD are cardiovascular protection, relief of symptoms, preservation of walking and functional status, and prevention of amputation. The optimal treatment for PADâ€"with specific emphasis on the comparative effectiveness of treatment optionsâ€"is not known. The backbone of treatment for PAD is smoking cessation, risk factor modification, dietary modification, and increased physical activity. There are three main treatment options for improving functional status and other clinical outcomes in patients with PAD: (1) medical therapy, (2) exercise training, and (3) revascularization. The treatment options offered to PAD patients depend on whether the patient is asymptomatic or symptomatic (with either IC or CLI). The KQs considered in this comparative effectiveness review were: KQ 1. In adults with PAD, including asymptomatic patients and symptomatic patients with atypical leg symptoms, IC, or CLI: a. What is the comparative effectiveness of aspirin and other antiplatelet agents in reducing the risk of adverse cardiovascular events, functional capacity, and quality of life? b. Does the effectiveness of treatments vary according to the patientâ€™s PAD classification or by subgroup (age, sex, race, risk factors, or comorbidities)? c. What are the significant safety concerns associated with each treatment strategy? Do the safety concerns vary by subgroup (age, sex, race, risk factors, comorbidities, or PAD classification)? KQ 2. In adults with symptomatic PAD (atypical leg symptoms or IC): a. What is the comparative effectiveness of exercise training, medications (cilostazol, pentoxifylline), endovascular intervention (percutaneous transluminal angioplasty, atherectomy, or stents), and/or surgical revascularization (endarterectomy, bypass surgery) on outcomes including cardiovascular events, amputation, quality of life, wound healing, analog pain scale score, functional capacity, repeat revascularization, and vessel patency? b. Does the effectiveness of treatments vary by use of exercise and medical therapy prior to invasive management or by subgroup (age, sex, race, risk factors, comorbidities, or anatomic location of disease)? c. What are the significant safety concerns associated with each treatment strategy? Do the safety concerns vary by subgroup (age, sex, race, risk factors, comorbidities, anatomic location of disease)? KQ 3. In adults with CLI due to PAD: a. What is the comparative effectiveness of endovascular intervention (percutaneous transluminal angioplasty, atherectomy, or stents) and surgical revascularization (endarterectomy, bypass surgery) for outcomes including cardiovascular events, amputation, quality of life, wound healing, analog pain scale score, functional capacity, repeat revascularization, and vessel patency? b. Does the effectiveness of treatments vary by subgroup (age, sex, race, risk factors, comorbidities, or anatomic location of disease)? c. What are the significant safety concerns associated with each treatment strategy (e.g., adverse drug reactions, bleeding, contrast nephropathy, radiation exposure, infection, and periprocedural complications causing acute limb ischemia)? Do the safety concerns vary by subgroup (age, sex, race, risk factors, comorbidities, or anatomic location of disease)?

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