

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## SCOPE

### 1 Guideline title

Lower limb peripheral arterial disease: diagnosis and management

#### 1.1 *Short title*

Lower limb peripheral arterial disease

### 2 The remit

The Department of Health has asked NICE: 'To produce a clinical guideline on the diagnosis and management of lower limb peripheral arterial disease in adults'.

### 3 Clinical need for the guideline

#### 3.1 *Epidemiology*

- a) About 20% of people older than 60 have peripheral arterial disease, although only a quarter of these have symptoms. The incidence of peripheral arterial disease is high among people who smoke, people with diabetes, and people with coronary artery disease. Asymptomatic peripheral arterial disease is common in people with diabetes.
- b) Even in the absence of symptoms, a reduced blood pressure at the ankle signifies an increased risk of cardiac and cerebrovascular morbidity and mortality.
- c) Peripheral arterial disease causes pain in the leg on walking (claudication) and occurs in around 5% of people over 60. Symptoms become severe and progressive in approximately 20%

of these people. Peripheral arterial disease may progress to critical limb ischaemia, with constant and intractable pain preventing sleep, often with ulceration or gangrene of the foot. People with critical limb ischaemia are at risk of losing their leg if they don't receive treatment, and a high proportion present for emergency care. Around 1–2% of people with claudication eventually undergo amputation, although the risk is higher (about 5%) in people with diabetes.

### **3.2 Current practice**

- a) The management of peripheral arterial disease remains controversial. Treatments include watchful waiting, medical management, exercise training, endovascular treatment and surgical reconstruction.
- b) Mild symptoms are managed in primary care, but people experiencing more severe symptoms that decrease quality of life are referred to secondary care. Some people may require investigation and treatment for risk factors and associated diseases. A small number of people require invasive treatment.
- c) Reduced Ankle Brachial Pressure Index (ABPI) is an independent predictor of cardiac and cerebrovascular morbidity and mortality and may help to identify people who would benefit from secondary prevention with aspirin, statins and angiotensin-converting enzyme (ACE) inhibitors. Treatments for secondary prevention are less commonly offered to people with peripheral arterial disease than to those with other cardiac and cerebrovascular risk factors.
- d) People with intermittent claudication are often advised to exercise. Supervised exercise programmes are thought to improve walking distance and quality of life. However, access to supervised exercise classes is variable, and many are not funded by the NHS.

- e) Drug treatments for claudication include those used for secondary prevention and those used specifically for the treatment of symptoms (including cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate). Both ramipril and atorvastatin are believed to improve walking distances in people with claudication.
- f) Other non-invasive treatments include the application of intermittent pneumatic compression to the calf and foot, and herbal remedies such as *Ginkgo biloba*.
- g) People with severe symptoms that are inadequately controlled are often referred to secondary care for assessment for endovascular or surgical revascularisation. In recent years there has been a move away from invasive investigation by catheter angiography to non-invasive investigation by duplex ultrasonography, magnetic resonance angiography or computed tomography angiography. Treadmill walking tests and segmental pressures are other commonly used investigations.
- h) Endovascular treatments include balloon angioplasty, endovascular stents and a range of new adjunct or alternative treatments and techniques. The new treatments include drug-eluting stents, modified balloons, laser angioplasty, atherectomy, cryotherapy and brachytherapy.
- i) Surgical reconstruction may be carried out to unblock or bypass occluded or narrowed arteries. Procedures include aorto-bifemoral, femoro-popliteal and femoro-distal bypass and common femoral endarterectomy. The risks and outcomes of these vary according to the nature of the procedure, the presenting symptoms, comorbidities, and the site and extent of the disease. The current trend is toward less invasive treatment.
- j) There is a need for a guideline on lower limb peripheral arterial disease to resolve the considerable uncertainty and variations in practice resulting from rapid changes in diagnostic methods, the

emergence of new endovascular treatments and organisational changes in the provision of vascular services associated with the emergence of new subspecialties in vascular surgery and interventional radiology.

## **4 The guideline**

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

### **4.1 Population**

#### **4.1.1 Groups that will be covered**

- a) Adults aged 18 and older.
- b) People who present with symptoms of lower limb peripheral arterial disease, including intermittent claudication, ischaemic rest pain, and/or tissue loss.
- c) People without symptoms of peripheral arterial disease (for example, those with venous ulceration) who have abnormal ankle/brachial pressure index (ABPI)
- d) Subgroups based on ethnicity, socioeconomic factors, age or comorbidities (including people with diabetes), for which differences in management and outcome are identified.

#### **4.1.2 Groups that will not be covered**

- a) Children and young people aged 17 and younger.
- b) Adults who have acute ischaemia of the lower limb.

## **4.2 Healthcare setting**

- a) All NHS settings where people present with, or undergo treatment for, symptomatic or asymptomatic peripheral arterial disease.

## **4.3 Clinical management**

### **4.3.1 Key clinical issues that will be covered**

- a) Diagnosis, for example using Ankle Brachial Pressure Index.
- b) Drug treatments and other interventions, for managing symptoms and for secondary prevention (for example statins and antiplatelet therapy). Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.
- c) Assessment for intervention (for example, using duplex ultrasonography, magnetic resonance angiography or computed tomography angiography).
- d) Supervised exercise programmes as an alternative or adjunct to medical management, endovascular or surgical treatment.
- e) Endovascular treatments (for example, angioplasty and stents) compared with surgery.
- f) Patient information.
- g) The management of pain associated with critical ischaemia, including methods of pain relief and indications for amputation.

### **4.3.2 Clinical issues that will not be covered**

- a) Acute ischaemia of the lower limb.
- b) Methods of amputation.

- c) Rehabilitation after amputation.
- d) Management of diabetic foot problems (see section 5).
- e) Use of topical treatments and dressings.

#### **4.4 *Main outcomes***

- a) Mortality.
- b) Health-related quality of life using measures such as EQ-5D, SF-36 and the Walking Impairment Questionnaire.
- c) Walking distance.
- d) Limb salvage rates.
- e) Graft and vessel patency (primary and secondary).
- f) Re-intervention rates.
- g) Re-admission rates.
- h) Adverse events.
- i) Pain intensity scale.
- j) Cardiovascular morbidity

#### **4.5 *Economic aspects***

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

## **4.6 Status**

### **4.6.1 Scope**

This is the final scope.

### **4.6.2 Timing**

The development of the guideline recommendations will begin in September 2010.

## **5 Related NICE guidance**

### **5.1 Published guidance**

- Lipid modification. NICE clinical guideline 67 (2008). Available from [www.nice.org.uk/guidance/CG67](http://www.nice.org.uk/guidance/CG67)
- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE technology appraisal guidance 159 (2008). Available from [www.nice.org.uk/guidance/TA159](http://www.nice.org.uk/guidance/TA159)
- Preventing the uptake of smoking by children and young people. NICE public health guidance 14 (2008). Available from [www.nice.org.uk/guidance/PH14](http://www.nice.org.uk/guidance/PH14)
- Promoting physical activity in the workplace. NICE public health guidance 13 (2008). Available from [www.nice.org.uk/guidance/PH13](http://www.nice.org.uk/guidance/PH13)
- Smoking cessation services. NICE public health guidance 10 (2008). Available from [www.nice.org.uk/guidance/PH10](http://www.nice.org.uk/guidance/PH10)
- Physical activity and the environment. NICE public health guidance 8 (2008). Available from [www.nice.org.uk/guidance/PH8](http://www.nice.org.uk/guidance/PH8)
- Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia. NICE technology appraisal guidance 132 (2007). Available from [www.nice.org.uk/guidance/TA132](http://www.nice.org.uk/guidance/TA132)
- Varenicline for smoking cessation. NICE technology appraisal guidance 123 (2007). Available from [www.nice.org.uk/guidance/TA123](http://www.nice.org.uk/guidance/TA123)
- Obesity. NICE clinical guideline 43 (2006). Available from [www.nice.org.uk/guidance/CG43](http://www.nice.org.uk/guidance/CG43)

- Four commonly used methods to increase physical activity. NICE public health guidance 2 (2006). Available from [www.nice.org.uk/guidance/PH2](http://www.nice.org.uk/guidance/PH2)
- Brief interventions and referral for smoking cessation in primary care and other settings. NICE public health guidance 1 (2006). Available from [www.nice.org.uk/guidance/PH1](http://www.nice.org.uk/guidance/PH1)
- Statins for the prevention of cardiovascular events. NICE technology appraisal guidance 94 (2006). Available from [www.nice.org.uk/guidance/TA94](http://www.nice.org.uk/guidance/TA94)
- Clopidogrel and modified-release dipyridamole in the prevention of occlusive vascular events. NICE technology appraisal guidance 90 (2005). Available from [www.nice.org.uk/guidance/TA90](http://www.nice.org.uk/guidance/TA90)
- Type 2 diabetes – footcare. NICE clinical guideline 10 (2004). Available from [www.nice.org.uk/guidance/CG10](http://www.nice.org.uk/guidance/CG10)
- Guidance on the use of patient-education models for diabetes. NICE technology appraisal guidance 60 (2003). Available from [www.nice.org.uk/guidance/TA60](http://www.nice.org.uk/guidance/TA60)

## **5.2 Guidance under development**

NICE is currently developing the following related guidance (details available from the NICE website):

- Percutaneous atherectomy of femoro-popliteal arterial lesions with plaque excision devices. NICE interventional procedure guidance. Publication expected Autumn 2010.
- Diabetic foot problems. NICE clinical guideline. Publication expected March 2011.
- Endovascular repair for popliteal aneurysms. NICE interventional procedure guidance. Publication expected Spring 2011.
- Cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate for the treatment of intermittent claudication in people with peripheral arterial disease. NICE technology appraisal guidance. Publication expected June 2011.
- Type 2 diabetes: preventing pre-diabetes among adults in high-risk groups. NICE public health guidance. Publication expected June 2011.



- Hypertension. Update of NICE clinical guidelines 18 and 34. Publication expected August 2011.
- Type 2 diabetes: preventing the progression from pre-diabetes to type 2 diabetes among high-risk groups. NICE public health guidance. Publication expected May 2012.

## **6 Further information**

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website

([www.nice.org.uk/GuidelinesManual](http://www.nice.org.uk/GuidelinesManual)). Information on the progress of the guideline will also be available from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).