NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Varicose veins in the legs: the diagnosis and management of varicose veins

1.1 Short title

Varicose veins in the legs

2 The remit

The Department of Health has asked NICE: 'To produce a clinical guideline on the management of varicose veins'.

3 Clinical need for the guideline

3.1 Epidemiology

a) Varicose veins are a common condition. They are dilated, often palpable, subcutaneous veins with reversed blood flow and are most commonly located on the lower legs.

b) The Edinburgh Vein Study (1999) showed age-adjusted prevalence rates for varicose veins of 39.7% in men and 32.2% in women. The same study found prevalence rates for chronic venous insufficiency of 9.4% in men and 6.6% in women. In contrast the BONN Vein study II (2010) found lower prevalence rates for varicose veins (25.1%) and higher rates for chronic venous insufficiency (16.0%); it did not identify gender differences.

c) The Framingham Study (1988) conducted in the USA found that the annual incidence of varicose veins was 1.9% for men and 2.6% for women. The incidence was found not to vary within the age range (40–89 years).

d) The age of onset does vary and prevalence rises with age. Varicose veins are common during pregnancy and affect about 40% of pregnant women.

e) The clinical presentation of varicose veins differs and some people are asymptomatic. In the majority of people varicose veins do not cause damage or threat to the limb but are associated with aching, itching, burning, cramps at night, and restless legs. In some people with varicose veins, progression of the condition may result in more severe problems such as skin pigmentation changes, eczema, infection, superficial thrombophlebitis, bleeding, loss of subcutaneous tissue, lipodermatosclerosis and venous ulceration.

3.2 Current practice

a) Current management of varicose veins is controversial and there is considerable variation in clinical practice.

b) There is a lack of consensus about optimum indications for referral and treatment. Suitability for varicose vein treatment is mainly determined by clinical examination and followed by a hand held doppler and/or duplex scan to determine whether venous reflux is present. However, there can be an inconsistent association between the symptoms of varicose veins and their severity or size on examination.

c) There are many clinical grading systems for varicose veins, including CEAP (clinical signs, aetiologic classification, anatomic distribution and pathophysiological dysfunction). However, with most of these there is a lack of agreement as to their usefulness for clinical decision making. Although CEAP is the most widely accepted grading system for varicose veins as a way to determine treatment needs, it is not discriminatory when looking at mild forms of the disease or predicting who would benefit the most from intervention.

d) Treatment options include:

- Conservative treatment – this includes diet, lifestyle advice and compression therapy. These are often used as first-line treatments in primary care.
- Pharmacological treatments for the relief of symptoms. There are none currently licensed for use in the UK.
- Interventional procedures:
  - Surgical treatments – these include ligation (tying off the vein), stripping and avulsion (different ways of removing the vein). These operations can be performed under general, regional or local anaesthesia, depending on the preferences of the surgeon and patient, and on the extent and the complexity of the varicose veins to be treated.
  - Sclerotherapy – injecting a sclerosing (irritating) agent directly into the varicose veins. This can be either as liquid or foam. This causes an inflammatory response that closes off the vein.
  - Thermal ablation – heating the vein from inside (for example using radiofrequency or laser catheters), this causes irreversible damage to the vein and its lining and closes it off.

e) Often several of the above techniques are used in combination. Treatment choice depends on a number of factors; symptoms, severity, patient preference and available medical resources.

f) The lack of clarity over assessment and the perceived similarity in outcomes from the different the interventional therapies have led to considerable variation in the management of varicose veins.

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 (18 and older) with primary or recurrent varicose veins in their legs.

b) The particular needs of pregnant women will be considered.

4.1.2 Groups that will not be covered

a) Children and young people (younger than 18).

b) People with venous malformations.

c) People with varicose veins in places other than their legs.

4.2 Healthcare setting

a) NHS healthcare settings in which varicose veins are managed.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Assessment for referral and treatment, including hand held doppler, duplex scan and clinical grading systems.

b) Conservative treatments, including

- lifestyle advice
- compression therapies.

c) Interventional therapies, for example:

- surgical treatments
- thermal ablation treatments.

d) Information and support needs of patients and carers.

4.3.2 Clinical issues that will not be covered

a) Management of leg ulcers, other than the role of ablative truncal venous interventions.

b) Spider veins (thread veins).

c) Management of pelvic varicose veins unless they are associated with primary or recurrent lower limb varicose veins.

d) Management of varicose veins not located on the legs.

e) Pharmacological treatment.

f) Alternative or complementary treatment.

4.4 Main outcomes

a) Health-related quality of life, using generic validated tools (for example, Medical Outcomes Study Short Form 36, EQ-5D) and disease specific validated tools (for example, Chronic Venous Insufficiency Questionnaire).

b) Patient-assessed symptoms.

c) Physician-reported outcome (venous clinical severity score or venous disability score).

d) Complications from varicose veins (skin ulcer occurrence or changes, haemorrhage, and phlebitis).

e) Adverse events from intervention (including stroke, deep vein thrombosis and neuropraxia).

f) Recurrent varicose veins.

g) Vein reflux and occlusion (blockage) rates.

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 only be 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 2011.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be incorporated

NICE interventional procedure guidance 314 (2009) ‘Ultrasound-guided foam sclerotherapy for varicose veins’ is being updated and we expect that guidance will be available in late 2012. If the updated guidance recommends that the procedure can be used without the need for special arrangements for clinical governance, consent or research, the interventional procedure guidance will be incorporated into the guideline.

This guideline will also incorporate the following NICE guidance.

- Endovenous laser treatment of the long saphenous vein. NICE interventional procedure guidance 52 (2004). Available from www.nice.org.uk/guidance/IPG52
- Transilluminated powered phlebectomy for varicose veins. NICE interventional procedure guidance 37 (2004). Available from www.nice.org.uk/guidance/IPG37
- Radiofrequency ablation of varicose veins. NICE interventional procedure guidance 8 (2003). Available from www.nice.org.uk/guidance/IPG8

5.1.2 Other related NICE guidance

- Promoting physical activity in the workplace. NICE public health guidance 13 (2008). Available from www.nice.org.uk/guidance/PH13
- Smoking cessation services. NICE public health guidance 10 (2008). Available from 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
- Obesity. NICE clinical guideline 43 (2006). Available from 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
- 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
- NICE referral advice recommendations database [online]. Available from www.nice.org.uk/usingguidance/referraladvice/index.jsp

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). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).