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3	Varicose veins in the legs: the diagnosis
4	and management of varicose veins
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7	NICE guideline
8	Draft for consultation, February 2013
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	If you wish to comment on this version of the guideline, please be aware that
	all the supporting information and evidence is contained in the full version.
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1 Introduction

2 Varicose veins are dilated, often palpable, subcutaneous veins with reversed 3 blood flow. They are most commonly found in the legs. Estimates of the 4 prevalence of varicose veins vary. Visible varicose veins in the lower limbs are estimated to affect at least a third of the population. Risk factors for 5 6 developing varicose veins are unclear, although prevalence rises with age and 7 they often develop during pregnancy. In some people, varicose veins are 8 asymptomatic or cause only mild symptoms, but in others, they cause pain, 9 aching or itching and can have a significant effect on their quality of life. 10 Varicose veins may become more severe over time and can lead to 11 complications such as changes in skin pigmentation, bleeding or venous 12 ulceration. It is not known which people will develop more severe disease but 13 it is estimated that 3-6% of people who have varicose veins in their lifetime 14 will develop venous ulcers.

- 15 There are several options for the management of varicose veins, including:
- 16 advice and reassurance

17 • compression hosiery

interventional treatments (endothermal ablation, foam sclerotherapy and
 surgery).

In 2009/10, there were 35,659 varicose veins procedures carried out in the
NHS. These interventions increase workload and costs substantially. There is
no definitive system for identifying which patients will benefit the most from
interventional treatment and no established framework within the NHS for the
diagnosis and management of varicose veins. This has resulted in wide
regional variations in the management of varicose veins in the UK.

27 product characteristics to inform decisions made with individual patients.

1 Patient-centred care

- This guideline offers best practice advice on the care of adults aged 18 years
 and over with varicose veins in the legs.
- 4 Patients and healthcare professionals have rights and responsibilities as set
- 5 out in the <u>NHS Constitution for England</u> all NICE guidance is written to
- 6 reflect these. Treatment and care should take into account individual needs
- 7 and preferences. Patients should have the opportunity to make informed
- 8 decisions about their care and treatment, in partnership with their healthcare
- 9 professionals. If someone does not have the capacity to make decisions,
- 10 healthcare professionals should follow the <u>Department of Health's advice on</u>
- 11 consent, the code of practice that accompanies the Mental Capacity Act and
- 12 the supplementary code of practice on deprivation of liberty safeguards. In
- 13 Wales, healthcare professionals should follow <u>advice on consent from the</u>
- 14 Welsh Government.
- 15 NICE has produced guidance on the components of good patient experience
- 16 in adult NHS services. All healthcare professionals should follow the
- 17 recommendations in <u>Patient experience in adult NHS services</u>.

1 Strength of recommendations

2 Some recommendations can be made with more certainty than others. The 3 Guideline Development Group makes a recommendation based on the trade-4 off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline 5 6 Development Group is confident that, given the information it has looked at, 7 most patients would choose the intervention. The wording used in the 8 recommendations in this guideline denotes the certainty with which the 9 recommendation is made (the strength of the recommendation).

- 10 For all recommendations, NICE expects that there is discussion with the
- 11 patient about the risks and benefits of the interventions, and their values and
- 12 preferences. This discussion aims to help them to reach a fully informed
- 13 decision (see also 'Patient-centred care').

14 Interventions that must (or must not) be used

- 15 We usually use 'must' or 'must not' only if there is a legal duty to apply the
- 16 recommendation. Occasionally we use 'must' (or 'must not') if the
- 17 consequences of not following the recommendation could be extremely
- 18 serious or potentially life threatening.

19 Interventions that should (or should not) be used – a 'strong'

20 recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

26 Interventions that could be used

- 27 We use 'consider' when we are confident that an intervention will do more
- 28 good than harm for most patients, and be cost effective, but other options may
- 29 be similarly cost effective. The choice of intervention, and whether or not to
- 30 have the intervention at all, is more likely to depend on the patient's values Varicose veins in the legs: NICE guideline DRAFT (February 2013)

- 1 and preferences than for a strong recommendation, and so the healthcare
- 2 professional should spend more time considering and discussing the options
- 3 with the patient.

4

Terms used in this guideline

- 2 Symptomatic varicose veins Veins found in association with troublesome
- 3 lower-limb symptoms (typically pain, aching, discomfort, swelling, heaviness,
- 4 and itching) that are thought to be caused by superficial venous reflux and for
- 5 which no other more likely cause is apparent
- 6 **Vascular service** A team of healthcare professionals who have the skills to

7 undertake a full clinical and duplex ultrasound assessment and provide a full

8 range of treatment

9 Key priorities for implementation

- 10 The following recommendations have been identified as priorities for
- 11 implementation.

12 Referral to a vascular service

- 13 Refer people to a vascular service if they have:
- 14 symptomatic primary or recurrent varicose veins **or**
- 15 lower-limb skin changes (such as pigmentation or eczema)
- 16 thought to be caused by chronic venous insufficiency.
- 17 Refer people to a vascular service if they have:
- 18 a venous leg ulcer (a break in the skin below the knee that
- 19 has not healed within 2 weeks) **or**
- 20 a healed venous leg ulcer.

21 Assessment and treatment in a vascular service

- Consider using duplex ultrasound to confirm the diagnosis and plan
- 23 treatment for people with suspected primary or recurrent varicose veins.
- Offer interventional treatment to people with confirmed varicose veins and
- 25 truncal reflux as follows:

26

- Offer endothermal ablation.

- 1 - If endothermal ablation is not suitable or is declined, offer ultrasound-guided foam sclerotherapy¹. 2 - If ultrasound-guided foam sclerotherapy is unsuitable or is 3 declined, offer surgery. 4 If incompetent varicose tributaries are to be treated, consider 5 treating them at the same time. 6 7 Offer compression hosiery only if interventional treatment is not suitable or is declined. 8
- 9

¹Recommendation linked to <u>Ultrasound-guided foam sclerotherapy for varicose veins</u> (IPG440). Varicose veins in the legs: NICE guideline DRAFT (February 2013)

1 **1 Recommendations**

2 The following guidance is based on the best available evidence. The <u>full</u>

3 guideline [hyperlink to be added for final publication] gives details of the

4 methods and the evidence used to develop the guidance.

- 5 All recommendations relate to adults aged 18 years and over.
- 6 **1.1**

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Information for people with varicose veins

- 7 1.1.1 Give people who present with varicose veins information that8 includes:
 - an explanation of what varicose veins are
- 10 possible causes of varicose veins
- the likelihood of progression and possible complications,
 including deep vein thrombosis, skin changes, leg ulcers,
 bleeding and thrombophlebitis. Address any misconceptions the
 person may have about the risks of developing complications
- treatment options, including symptom relief, compression and a
 brief overview of interventional treatments
- 17 lifestyle changes that may help, for example:
 - weight loss (for guidance on weight management, see <u>Obesity</u> [NICE clinical guideline 43])
- 20 light to moderate physical activity (for example, walking or
 21 swimming)
- avoiding factors that are known to make their symptoms
 worse if possible (for example, some people find prolonged
 standing or hot baths make their symptoms worse)
 - when and where to seek further medical help.
- 26 1.1.2 When discussing treatment for varicose veins at the vascular
 27 service, tell the person:
- what treatment options are available
- the expected outcomes and possible adverse events of each
 treatment option
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1		 that new varicose veins may develop after treatment
2		 that they may need more than 1 session of treatment
3		 that the chance of recurrence after treatment for recurrent
4		varicose veins is higher than for primary varicose veins.
5	1.2	Referral to a vascular service
6	1.2.1	Refer people with bleeding varicose veins to be seen by a
7		vascular service immediately or within 24 hours.
8	1.2.2	Refer people with a recent history of minor bleeding from varicose
9		veins to be seen by a vascular service within 2 weeks.
10	1.2.3	Refer people to a vascular service if they have:
11		 symptomatic primary or recurrent varicose veins or
12		 lower-limb skin changes (such as pigmentation or eczema)
13		thought to be caused by chronic venous insufficiency.
14	1.2.4	Refer people with superficial vein thrombosis (characterised by the
15		appearance of hard, painful veins) and suspected superficial
16		venous incompetence to a vascular service.
17	1.2.5	Refer people to a vascular service if they have:
18		 a venous leg ulcer (a break in the skin below the knee that has
19		not healed within 2 weeks) or
20		 a healed venous leg ulcer.
21	1.3	Assessment and treatment in a vascular service
22	1.3.1	Consider using duplex ultrasound to confirm the diagnosis and to
23		plan treatment for people with suspected primary or recurrent
24		varicose veins.
25	1.3.2	Offer interventional treatment to people with confirmed varicose
26		veins and truncal reflux as follows:
27		Offer endothermal ablation.

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1		If endothermal ablation is not suitable or is declined, offer
2		ultrasound-guided foam sclerotherapy ² .
3		 If ultrasound-guided foam sclerotherapy is unsuitable or is
4		declined, offer surgery.
5		If incompetent varicose tributaries are to be treated, consider
6		treating them at the same time.
7	1.3.3	Offer compression hosiery only if interventional treatment is not
8		suitable or is declined.
9	1.3.4	Do not offer compression bandaging or hosiery for more than
10		7 days after completion of interventional treatment for varicose
11		veins.
12	1.4	Management during pregnancy
12 13	1.4 1.4.1	<i>Management during pregnancy</i> Give pregnant women presenting with varicose veins information
13		Give pregnant women presenting with varicose veins information
13 14	1.4.1	Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.
13 14 15	1.4.1	Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins. Do not carry out interventional treatment for varicose veins during
13 14 15 16	1.4.1 1.4.2	Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.Do not carry out interventional treatment for varicose veins during pregnancy other than in exceptional circumstances.
13 14 15 16 17	1.4.1 1.4.2	Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.Do not carry out interventional treatment for varicose veins during pregnancy other than in exceptional circumstances.Consider compression hosiery for symptom relief of leg swelling
13 14 15 16 17 18	1.4.1 1.4.2 1.4.3 2	Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.Do not carry out interventional treatment for varicose veins during pregnancy other than in exceptional circumstances.Consider compression hosiery for symptom relief of leg swelling associated with varicose veins during pregnancy.

- 22 patient care in the future. The Guideline Development Group's full set of
- 23 research recommendations is detailed in appendix N of the <u>full guideline</u>
- 24 [hyperlink to be added for final publication]

² Recommendation linked to <u>Ultrasound-guided foam sclerotherapy for varicose veins</u> (IPG440). Varicose veins in the legs: NICE guideline DRAFT (February 2013)

1 2.1 Natural history of varicose veins

2 In people with varicose veins at CEAP (Clinical, etiological, anatomical and

3 pathophysiological) stage C2 or C3, what are the factors that influence

4 progression of the disease to CEAP stages C5 or C6?

5 Why this is important

The evidence review for the guideline showed a lack of high-guality evidence 6 7 on the progression of varicose veins from CEAP stage C2 or C3 to more 8 serious varicose veins disease. A large observational prospective cohort 9 study, similar to the Framingham or BONN veins studies, should be 10 undertaken. The study should recruit patients with C2 and C3 disease and 11 follow the progress of their disease over a number of years. Consideration 12 should be given to including a genetic component in the study because 13 genetic factors have not been studied on a large scale. The results of such a 14 study should help to more accurately identify which patients are at risk of 15 developing more serious disease so that interventions can be offered at an 16 early stage to those who will benefit most.

17 2.2 Compression as a management option

18 What is the clinical and cost effectiveness of compression hosiery versus no 19 compression for managing symptomatic varicose veins?

20 Why this is important

- 21 Compression hosiery is widely used as first-line treatment for symptomatic
- 22 varicose veins. In some areas of the UK, a period of hosiery use is a
- 23 precursor to referral to secondary care.
- 24 Discomfort and difficulty in application may cause people to stop wearing
- 25 compression hosiery or wear it only occasionally. The current evidence for the
- 26 benefit of compression hosiery is weak. There is little evidence of an impact
- 27 on symptom relief or an improvement in quality of life. It is therefore not
- 28 possible to calculate the cost effectiveness of compression hosiery.
- 29 A multicentre trial randomising compression hosiery versus no compression in
- 30 patients with symptomatic varicose veins is needed. The trial should evaluate

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1 quality of life, including symptom reduction, and measure adherence with

2 compression hosiery. In addition, the trial should investigate the impact of

3 compression on disease progression and the need for subsequent

4 intervention.

5 2.3 Compression after interventional treatment

6 What is the clinical and cost effectiveness of compression hosiery after

- 7 interventional treatment for varicose veins compared with no compression
- 8 hosiery? If there is benefit, how long should compression hosiery be worn for?

9 Why this is important

10 The benefit of compression after interventional treatment for varicose veins is

11 unclear. A well conducted multicentre randomised controlled trial (RCT) of

12 compression hosiery after each of the 3 main interventional treatments would

13 help determine whether compression hosiery is beneficial, and if so, what type

14 of compression is best and how long it should be worn for. There should be 6

15 RCT arms, 1 arm with compression and 1 arm without in each of 3 patient

16 groups:

- 17 patients who have had endothermal ablation
- 18 patients who have had ultrasound-guided foam sclerotherapy
- 19 patients who have had surgery.
- 20 Each arm should have subgroups for compression type and duration.

21 Adherence to treatment with compression hosiery and the effect of adherence

- 22 on effectiveness should also be evaluated. A cost-effectiveness analysis
- 23 should be performed. If compression hosiery is beneficial, such a trial should
- help improve quality of life for people with varicose veins and reduce the
- 25 longer-term need for retreatment.

26 **2.4** Truncal treatment with or without concurrent

27

tributary treatment

- 28 What is the clinical and cost effectiveness of concurrent phlebectomies for
- 29 varicose tributaries during truncal endothermal ablation for varicose veins
- 30 compared with:

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- 1 truncal endothermal ablation without concurrent phlebectomies
- truncal endothermal ablation with subsequent phlebectomies, if needed, 6-
- 3 12 weeks later.

4 Why this is important

Conventional truncal stripping under general anaesthetic involves
synchronous phlebectomies of varicose tributaries, and in ultrasound-guided
foam sclerotherapy truncal and tributary veins are treated concurrently. In
contrast, endothermal ablation may be performed alone to obliterate truncal
incompetence, or synchronously with phlebectomies, and current practice
varies.

11 Synchronous tributary treatment ensures a single treatment episode, and the 12 removal of all symptomatic varicosities leads to a better immediate quality of 13 life, but this takes longer and thus may be associated with increased 14 morbidity. Deferred tributary treatment may reduce morbidity, and also mean 15 that some patients do not need tributary treatment (or need fewer tributary 16 treatments on smaller veins). However, it involves 2 interventions for patients 17 who need tributary treatment. Omitting tributary treatments entirely ensures a 18 single treatment episode, but it is unclear whether remaining varicosities will 19 persist and impair quality of life.

At present, there is limited evidence from 1 small-scale (n=50) study on the use and timing of tributary treatments after truncal endothermal ablation treatment. There is a need for practice to be based on empirical evidence from a large and sufficiently powered RCT comparing all 3 main intervention options (no tributary treatment, concurrent tributary treatment and delayed tributary treatment).

26

27

2.5 Interventional treatment for people with CEAP stage C6 disease (leg ulcers) and varicose veins

28 Does the early interventional treatment of superficial venous reflux together 29 with compression therapy improve wound healing and result in greater cost

- 1 effectiveness compared with compression therapy alone in patients with
- 2 chronic venous ulceration?

3 Why this is important

- 4 Chronic venous leg ulcers are a common major cause of morbidity. Quality of
- 5 life for patients with venous leg ulcers is substantially reduced by discomfort
- 6 and social isolation resulting from odour and wound discharge. The social and
- 7 personal impact of chronic venous leg ulceration is therefore considerable.
- 8 Only 1 study has been completed in which surgery and compression were
- 9 compared with compression alone. This showed improvement in the rates of
- 10 ulcer recurrence. It would now be suitable to consider endovenous
- 11 interventional techniques which, being a minimally invasive procedure, are
- 12 more acceptable to patients.
- 13 At present, ulceration is often managed with compression, despite poor
- 14 success rates. A high-quality, large-scale randomised trial evaluating
- 15 outcomes after early interventional treatment compared with compression
- 16 therapy is needed.

3 Other information

18 **3.1 Scope and how this guideline was developed**

- 19 NICE guidelines are developed in accordance with a <u>scope</u> that defines what
- 20 the guideline will and will not cover.

How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see section 4), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in <u>The guidelines manual</u>.

1 3.2 Related NICE guidance

- 2 Details are correct at the time of consultation on the guideline (February
- 3 2013). Further information is available on <u>the NICE website.</u>
- 4 Published
- 5 General
- 6 Patient experience in adult NHS services. NICE clinical guidance 138
- 7 (2012).

8 **Condition-specific**

- 9 <u>Ultrasound-guided foam sclerotherapy for varicose veins</u>. NICE
- 10 interventional procedure guidance 440 (2013).
- Promoting physical activity in the workplace. NICE public health guidance
 13 (2008).
- 13 <u>Smoking cessation services</u>. NICE public health guidance 10 (2008).
- Physical activity and the environment. NICE public health guidance 8
 (2008).
- 16 Obesity. NICE clinical guideline 43 (2006).
- 17 Four commonly used methods to increase physical activity. NICE pubic
- 18 health guidance 2 (2006).
- 19 Brief interventions and referral for smoking cessation. NICE public health
- 20 guidance 1 (2006).
- 21 Endovenous laser treatment of the long saphenous vein. NICE
- 22 interventional procedure guidance 52 (2004).
- 23 Transilluminated powered phlebectomy for varicose veins. NICE
- 24 interventional procedure guidance 37 (2004).
- <u>Radiofrequency ablation of varicose veins</u>. NICE interventional procedure
 guidance 8 (2003).
- 27

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