# Appendix 7a London Choosing Wisely

## Draft Policy Template: Varicose Veins

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft for T&amp;F 1</td>
<td>25/04/18</td>
<td>Initial Draft</td>
</tr>
<tr>
<td>Revised version post T&amp;F 1</td>
<td>15/05/18</td>
<td>Criteria for commissioning drafted Rationale for commissioning completed Governance Statement completed Evidence updated to include new study specified by T&amp;F group Appendix 2 updated to reflect LCW policy</td>
</tr>
<tr>
<td>Revised version</td>
<td>07/06/18</td>
<td>Amendments made to criteria for commissioning following comments from T&amp;F group</td>
</tr>
<tr>
<td>Revised version</td>
<td>25/06/18</td>
<td>Amendments made to criteria for commissioning following further comments and discussion with T&amp;F Chair</td>
</tr>
<tr>
<td>Revised version</td>
<td>02/08/2018</td>
<td>Amendments to layout of commissioning criteria &amp; advice to primary care section, following 30/03/18 LCW Steering group</td>
</tr>
<tr>
<td>Revised version</td>
<td>20/08/18</td>
<td>Text added to methods section following discussion at July Steering group meeting.</td>
</tr>
</tbody>
</table>
**Pan-London Commissioning Recommendation**

**Overview** – full details within policy document

<table>
<thead>
<tr>
<th>Clinical Description</th>
<th>Commissioning decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No visible or palpable varicose veins*</td>
<td>Treatment <strong>NOT</strong> funded</td>
</tr>
<tr>
<td>Visible telangiectasia or reticular veins</td>
<td></td>
</tr>
<tr>
<td>Visible or palpable varicose veins:</td>
<td>Treatment is funded <strong>only</strong> if the criteria in box 1 OR 2 are met:</td>
</tr>
<tr>
<td></td>
<td>1) One documented episode of superficial thrombophlebitis above the knee (referred urgently) or two documented episodes of superficial thrombophlebitis below the knee.</td>
</tr>
<tr>
<td></td>
<td>2) Swelling (oedema) due to varicose veins, above the ankle in the affected leg. <strong>AND</strong> Patient experiences severe daily symptoms (such as pain, heaviness, soreness or burning) that affect activities of daily living.</td>
</tr>
<tr>
<td>Skin damage due to varicose veins e.g. varicose eczema, lipodermatosclerosis</td>
<td></td>
</tr>
<tr>
<td>Healed venous leg ulcer (a break in the skin below the knee taking more than 2 weeks to heal)</td>
<td>Treatment <strong>will be</strong> funded</td>
</tr>
<tr>
<td>Active venous leg ulcer (a break in the skin below the knee not healed within 2 weeks)</td>
<td></td>
</tr>
</tbody>
</table>

* Identified through diagnostic tests but not causing symptoms

**Prepared By**
London Choosing Wisely, Commissioned by NHSE

**Approved By**
Varicose Veins Task & Finish Group, London Choosing

**Date Approved**
25/06/2018
<table>
<thead>
<tr>
<th>Wisely</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LCW Steering Board</td>
<td>02/10/2018</td>
</tr>
</tbody>
</table>
Main Policy Document

Policy Statement

London Choosing Wisely (LCW) was commissioned to carry out this work on behalf of all London Clinical Commissioning Groups (CCGs), in order to promote equitable access to certain treatments and the cost-effective use of healthcare resources. All London CCGs will commission the treatment of varicose veins in accordance with the criteria outlined in this document.

In creating this policy, LCW convened a task and finish group focused on developing this policy and has reviewed this clinical condition and the evidence supporting treatment leading to this commissioning decision.

1. Introduction

Varicose veins are common and can affect up to 35% of the population. Whilst in some these are asymptomatic, in others they cause symptoms that adversely affect quality of life (such as pain or lower leg swelling) and less frequently lead to sequelae including skin changes in up to 10% (venous eczema, ulceration) and bleeding in around 3% of cases. Varicose veins are often unsightly and patients sometimes request intervention for cosmetic reasons alone. All London CCGs have published commissioning policies regarding varicose veins and are broadly similar in not routinely commissioning intervention for solely cosmetic reasons. The existing policies differ in the criteria under which varicose veins would be treated. This pan-London policy serves to standardise the criteria for commissioning the treatment of varicose veins in secondary care.

This policy does not cover haemorrhage of varicose veins which is a medical emergency and should be treated accordingly.

2. Key Definitions

Varicose Veins: These are dilated, often palpable veins under the skin with reversed blood flow. They are most commonly found in the legs. They are common and can be symptomatic or asymptomatic.

Endothermal Ablation: Energy from a laser (Endovenous Laser Ablation, EVLA) or high-frequency radio waves (Radiofrequency Ablation, RFA) is used to seal the affected veins.

Foam Sclerotherapy: Foam is injected into the vein under ultrasound (Ultrasound Guided Foam Sclerotherapy, UGFS) which scars the vein and seals it closed.

Ligation & Stripping Surgery: A surgical procedure is undertaken to tie off the affected vein in the leg and then remove it.

3. Aims & Objectives

- To reduce unwarranted variation in access to treatment of varicose veins
- To ensure that the treatment of varicose veins is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness
- To promote the cost-effective use of healthcare resources
4. Criteria for commissioning (inc. exclusions)

This policy only relates to adults over the age of 18 and does not apply to pregnant women.

This policy does not cover haemorrhage of varicose veins which is a medical emergency and should be treated accordingly.

In commissioning interventions for varicose veins, the following classification should be applied at both referral and treatment stage.

<table>
<thead>
<tr>
<th>Clinical Description</th>
<th>CEAP Score</th>
<th>Commissioning decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No visible or palpable varicose veins*</td>
<td>C0</td>
<td>Treatment NOT funded</td>
</tr>
<tr>
<td>Visible telangiectasia or reticular veins</td>
<td>C1</td>
<td>Treatment NOT funded</td>
</tr>
<tr>
<td>Visible or palpable varicose veins</td>
<td>C2 or C3</td>
<td>Treatment is funded only if the criteria in box 1 OR 2 are met:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. One documented episode of superficial thrombophlebitis above the knee (referred urgently) or two documented episodes of superficial thrombophlebitis below the knee.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Swelling (oedema) due to varicose veins, above the ankle in the affected leg. <strong>AND</strong> Patient experiences severe daily symptoms (such as pain, heaviness, soreness or burning) that affect activities of daily living.</td>
</tr>
<tr>
<td>Skin damage due to varicose veins e.g. varicose eczema, lipodermatosclerosis</td>
<td>C4</td>
<td></td>
</tr>
<tr>
<td>Healed venous leg ulcer (a break in the skin below the knee taking more than 2 weeks to heal)</td>
<td>C5</td>
<td>Treatment will be funded</td>
</tr>
<tr>
<td>Active venous leg ulcer (a break in the skin below the knee not healed within 2 weeks)</td>
<td>C6</td>
<td></td>
</tr>
</tbody>
</table>

* Identified through diagnostic tests but not causing symptoms

When treatment is funded according to the above classification the following applies within secondary care:
- Duplex Doppler ultrasound must be performed to confirm diagnosis and plan appropriate treatment

Treatment will be funded according to the following hierarchy:

1. Offer endothermal ablation
2. If endothermal ablation is deemed clinically unsuitable, offer ultrasound guided foam sclerotherapy
3. If ultrasound guided foam sclerotherapy is deemed clinically unsuitable, offer surgery

**Advice to Primary Care Practitioners**

Give people who present with varicose veins information that includes:

- An explanation of what varicose veins are.
- 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, an overview of interventional treatments and the role of compression.

Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

The following lifestyle advice should be offered to all patients with varicose veins:

- Weight loss (if BMI > 30)
- Light to moderate physical exercise
- Smoking cessation

Treatment will **NOT** be funded in the following circumstances:

1. Patients with no symptoms or skin changes associated with venous disease
2. Patients whose concerns are cosmetic including telangiectasia and reticular veins
3. Patients with mild symptoms including itch, ache, mild swelling, minor changes of skin eczema and haemosiderosis
4. Pregnant women presenting with varicose vein should be given information on the effect of pregnancy on varicose veins. Interventional treatment for varicose veins during pregnancy should not be carried out other than in exceptional circumstances. Compression hosiery should be considered for symptom relief of leg swelling associated with varicose veins during pregnancy.

5. **Evidence Summary**

The full evidence review can be found in Appendix 1, with a summary of findings included.
6. Rationale behind Policy Statements

In drafting this commissioning policy, the Task and Finish Group considered the evidence presented, the current position of CCGs both within and outside of London, and their clinical experience.

The Task and Finish group noted that whilst there is some high quality evidence relating to varicose veins, this is mostly focused on the specific efficacy of treatments and not on when to treat patients, the key focus of the commissioning policy.

The Task and Finish group noted that there is no evidence supporting treatment for those in CEAP grades 0-1 as this would constitute purely cosmetic treatment. It was also noted that for CEAP grades 4-6, the more severe end of the spectrum, there was strong evidence to support treatment of varicose veins and this is in alignment with NICE guidelines and many other CCG policies. The Task and Finish group mostly debated CEAP grades 2-3 as this requires most clinical judgement. The group concluded that patients with CEAP of 2 or 3 that meet a number of additional criteria would also be eligible for treatment. This is in alignment with the NICE guidelines.

The group also reviewed the range of scoring systems that exists for varicose veins and noted that none of these are fully suited to be used as commissioning criteria and they are mostly used within research. The group noted that the ‘C’ element of the CEAP classification is broadly most frequently used and is easiest to apply as it gives objective clinical criteria to define stage of varicose vein disease. The group has added additional quality of life criteria around CEAP stages 2 and 3 to make this scale more fit for purpose, and has opted to use clinical descriptions primarily rather than purely refer to CEAP criteria as these are less well known in primary care.

The Task and Finish Group have opted to commission treatment modalities in line with NICE guidelines. There was no additional evidence to suggest a different treatment option should be first line and surgery still represents the last line of treatment. The group noted that new treatments using glue are starting to evolve but do not yet have a strong evidence base and so should not yet feature in the policy, but will likely be added in a future update.

In addition, the Task and Finish Group discussed whether a reference should be made to treat one leg or both legs in the same procedure but it was agreed that there should not be a reference made within the commissioning policy as there are multiple factors that impact on this decision, that should be clinically led.

7. Adherence to NICE Guidelines

This policy adheres to NICE Guideline CG168 – Management of Varicose Veins.

8. Codes for procedures

The following OPCS Codes are covered under this policy. This list is not exhaustive and can be added to at CCG level during implementation of policy.

OPCS4  L831  Crossover graft of saphenous vein
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L832</td>
<td>Subfascial ligation of perforating vein of leg</td>
</tr>
<tr>
<td>L838</td>
<td>Other specified other operations for venous insufficiency</td>
</tr>
<tr>
<td>L839</td>
<td>Unspecified other operations for venous insufficiency</td>
</tr>
<tr>
<td>L841</td>
<td>Combined operations on primary long saphenous vein</td>
</tr>
<tr>
<td>L842</td>
<td>Combined operations on primary short saphenous vein</td>
</tr>
<tr>
<td>L843</td>
<td>Combined operations on primary long and short saphenous vein</td>
</tr>
<tr>
<td>L844</td>
<td>Combined operations on recurrent long saphenous vein</td>
</tr>
<tr>
<td>L845</td>
<td>Combined operations on recurrent short saphenous vein</td>
</tr>
<tr>
<td>L846</td>
<td>Combined operations on recurrent long and short saphenous vein</td>
</tr>
<tr>
<td>L848</td>
<td>Other specified combined operations on varicose vein of leg</td>
</tr>
<tr>
<td>L849</td>
<td>Unspecified combined operations on varicose vein of leg</td>
</tr>
<tr>
<td>L851</td>
<td>Ligation of long saphenous vein</td>
</tr>
<tr>
<td>L852</td>
<td>Ligation of short saphenous vein</td>
</tr>
<tr>
<td>L853</td>
<td>Ligation of recurrent varicose vein of leg</td>
</tr>
<tr>
<td>L858</td>
<td>Other specified ligation of varicose vein of leg</td>
</tr>
<tr>
<td>L859</td>
<td>Unspecified ligation of varicose vein of leg</td>
</tr>
<tr>
<td>L861</td>
<td>Injection of sclerosing substance into varicose vein of leg NEC</td>
</tr>
<tr>
<td>L862</td>
<td>Ultrasound guided foam sclerotherapy for varicose vein of leg</td>
</tr>
<tr>
<td>L863</td>
<td>Injection of glue into varicose vein of leg</td>
</tr>
<tr>
<td>L868</td>
<td>Other specified injection into varicose vein of leg</td>
</tr>
<tr>
<td>L869</td>
<td>Unspecified injection into varicose vein of leg</td>
</tr>
<tr>
<td>L871</td>
<td>Stripping of long saphenous vein</td>
</tr>
<tr>
<td>L872</td>
<td>Stripping of short saphenous vein</td>
</tr>
<tr>
<td>L873</td>
<td>Stripping of varicose vein of leg NEC</td>
</tr>
<tr>
<td>L874</td>
<td>Avulsion of varicose vein of leg</td>
</tr>
<tr>
<td>L875</td>
<td>Local excision of varicose vein of leg</td>
</tr>
<tr>
<td>L876</td>
<td>Incision of varicose vein of leg</td>
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<tr>
<td>L877</td>
<td>Transilluminated powered phlebectomy of varicose vein of leg</td>
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<tr>
<td>L878</td>
<td>Other specified other operations on varicose vein of leg</td>
</tr>
<tr>
<td>L879</td>
<td>Unspecified other operations on varicose vein of leg</td>
</tr>
<tr>
<td>L881</td>
<td>Percutaneous transluminal laser ablation of long saphenous vein</td>
</tr>
<tr>
<td>L882</td>
<td>Radiofrequency ablation of varicose vein of leg</td>
</tr>
<tr>
<td>L883</td>
<td>Percutaneous transluminal laser ablation of varicose vein of leg NEC</td>
</tr>
<tr>
<td>L888</td>
<td>Other specified transluminal operations on varicose vein of leg</td>
</tr>
<tr>
<td>L889</td>
<td>Unspecified transluminal operations on varicose vein of leg</td>
</tr>
</tbody>
</table>

For the following ICD-10 codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I83.0</td>
<td>Varicose veins of lower extremities with ulcer</td>
</tr>
<tr>
<td>I83.1</td>
<td>Varicose veins of the lower extremities with inflammation or specified as inflamed stasis dermatitis NOS</td>
</tr>
<tr>
<td>I83.2</td>
<td>Varicose veins of the lower extremities with both ulcer and inflammation</td>
</tr>
</tbody>
</table>
I83.9 Varicose veins of the lower extremities without ulcer or inflammation

Exceptions (ICD-10); the following in a primary or secondary diagnostic position:

O22.0 Varicose veins of the lower extremity in pregnancy

O87.8 Other venous complications in the puerperium

Equality & Equity Statement

The Equality and Equity Assessments for this policy will be undertaken at CCG level. Please contact the relevant London CCG for further details of their Equality Impact Assessment.

Governance statement

In mid-2017, London’s CCG Chief Officers supported a pan London programme to ensure equitable treatment access for all Londoners that is consistent, clinically appropriate and based on robust evidence that supports improved patient outcomes for certain treatments across London.

NHS England (London) commissioned Healthy London Partnership (HLP) to facilitate the programme management and communications work of the programme, known as ‘London Choosing Wisely’. A London Choosing Wisely Steering Group was formed, chaired by the NHSE (London) Medical Director, Dr Vin Diwakar, and included clinical leaders representing each sustainability and transformation partnership (STP), the clinical leads appointed to the review of each area of care, patient representatives, and public health experts.

The London Choosing Wisely programme specifically looked at the following eight procedures: the surgical removal of benign skin lesions; hip arthroplasty; knee arthroplasty; knee arthroscopy; interventional treatments for back pain; varicose vein procedures; shoulder decompression and cataract surgery.

Six Task and Finish Groups were established to review the evidence and draft the policy documentation for each of the eight identified procedures (with hip and knee policies being considered together). Each group was chaired by a primary care clinical lead, who also sat on the Steering Group. All groups included primary and secondary care clinicians and patient representatives from across the London region and were supported by independent public health experts. Upon consideration of the evidence, the Task and Finish Group drafted and agreed the commissioning policy which was subsequently presented to the Steering Group for approval. The Steering Group’s role was to ensure that a robust and rigorous review process had been carried out and to agree a final draft for each pan London policy.
## London Choosing Wisely

### Guidance and Evidence Review Summary: Varicose Veins

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft for PH Lead</td>
<td>25/04/18</td>
<td>Initial Draft</td>
</tr>
<tr>
<td>Draft for T&amp;F 1</td>
<td>27/04/18</td>
<td>Evidence strengthened where possible to clarify clinical significance of findings.</td>
</tr>
<tr>
<td>Revised version post T&amp;F 1</td>
<td>15/05/18</td>
<td>Additional evidence added</td>
</tr>
<tr>
<td>Revised to include evidence summary here</td>
<td>25/06/18</td>
<td>Based on feedback from earlier policies, to make main policy less lengthy</td>
</tr>
<tr>
<td>Amended</td>
<td>31/07/2018</td>
<td>To include details of search terms from search strategy document, following LCW steering group meeting of 30/07/18</td>
</tr>
<tr>
<td>Amended final version</td>
<td>20/08/18</td>
<td>Text added to methods section following discussion at July Steering group meeting.</td>
</tr>
</tbody>
</table>
# 1.0 Introduction

| (What?) | This guidance and evidence review will focus on treatments for varicose veins and will include endothermal ablation, foam sclerotherapy and surgery. The review does not seek to define the efficacy of each type of treatment in detail, rather to determine criteria to inform decisions about if or when to consider treatment, given that varicose veins occur commonly and may be asymptomatic or minimally symptomatic. **This review does not cover haemorrhage of varicose veins which is a medical emergency and should be treated accordingly.** A list of ICD-10 and OPCS codes relevant to this guidance and evidence review (and ultimately a commissioning policy) are included in Appendix 3. This list is not exhaustive and can be added to at CCG level during implementation of a policy. It is noted that issues around coding of diagnoses and procedures can affect adherence to commissioning policies but this does not negate the need for a policy to state the ICD-10 and OPCS codes included. |
| (Who for?) | The review includes the adult population only (aged 18 and over). |
| (Why is the procedure carried out?) | Varicose veins are common and can affect up to 35% of the population. Whilst in some these are asymptomatic, in others they cause symptoms that adversely affect quality of life (such as pain or lower leg swelling) and less frequently lead to sequelae including skin changes in up to 10% (venous eczema, ulceration) and bleeding in around 3% of cases. Varicose veins are often unsightly and patients sometimes request intervention for cosmetic reasons alone. |
| (Why an issue?) | Most London CCGs have a commissioning policy relating to the treatment of varicose veins. These are similar and no CCG routinely funds treatment of varicose veins for purely cosmetic reasons. However, the criteria whereby treatment would be funded, and which treatments are funded differ between CCGs. Barking, Havering and Redbridge (BHR) do not routinely fund the treatment of varicose veins at all. |
| (Who else does what?) | See Appendix 2 for a detailed table of current CCG policies relating to the treatment of varicose veins. No London CCGs routinely commission treatment of varicose veins for cosmetic reasons. CCGs only commission the procedures if certain criteria are met, but these differ between CCGs. For example, some CCGs require that a duplex ultrasound has shown the extent of truncal reflux before funding whilst other CCGs do not state this criterion. Some CCGs stipulate that foam sclerotherapy is not routinely funded whilst others leave the “choice of surgical intervention at the discretion of the clinician”. Similarly, some CCGs state a requirement for patients to cease smoking ahead of funding varicose vein treatment whilst others do not state this. Through the commissioning positions of the London CCGs are broadly similar, there is potential for patients to not be receiving equal access to treatments across London due to the differing thresholds required to achieve funding. |
2.0 Search strategy:

Core search questions:

1) What are the key clinical criteria (e.g. eczema, ulcers, infection) for which the evidence shows value treating the varicose vein?
2) Does the evidence describe specific parameters of these criteria where therapeutic value is achieved? (e.g. length of time for ulcer to heal, number of episodes of thrombophlebitis)
3) Are there any comorbid conditions for which the evidence shows value treating the varicose vein?
4) Does the evidence provide an appropriate scoring system for severity of varicose veins within clinical practice?
5) Is there an evidence-based treatment hierarchy and if so, what is this? E.g. endothermal ablation, followed by sclerotherapy?

Search Terms:
Varicose veins, varicose veins scoring, long saphenous vein, short saphenous vein, great saphenous vein.
In addition the following interventions will be searched: endothermal ablation, foam sclerotherapy, ligation, stripping, laser ablation.
The evidence review will not, in detail, review the efficacy of these interventions, but will seek to define when intervention is indicated.

2.1 Search Method

In line with the scope agreed for this work, the literature review was intended to focus on collating information across existing CCG policies and reviewing approximately 5 research papers (level 1 policy group). An initial search was undertaken of national guidelines and CCG policies across London. There are NICE guidelines (1) on the management of varicose veins, published in 2013 and reviewed in 2016. As per Appendix 2, most London CCGs commission varicose vein treatment broadly in accordance with these guidelines and cite the NICE guidelines as the source of evidence.

We have identified the key literature providing evidence to this NICE guidance and included these in the review below. To align the above research questions and with the scope of the LCW Programme we have focused on the following chapters from the NICE evidence base:

<table>
<thead>
<tr>
<th>Core search question</th>
<th>Related chapter from NICE evidence base</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) What are the key clinical criteria (e.g. eczema, ulcers, infection) for which the evidence shows value treating the varicose vein?</td>
<td>C.2.1 Factors associated with disease progression</td>
</tr>
<tr>
<td>2) Does the evidence describe specific parameters of these criteria where therapeutic value is achieved? (e.g. length of time for ulcer to heal, number of episodes of thrombophlebitis)</td>
<td>C.2.2 Factors associated with treatment success</td>
</tr>
<tr>
<td>3) Are there any comorbid conditions that would indicate varicose vein intervention?</td>
<td>C.3.2 Duplex vs. No duplex prior to interventional treatment</td>
</tr>
</tbody>
</table>
4) Does the evidence document an appropriate scoring system for severity of varicose veins within clinical practice?  
   Nil directly related

5) Does the evidence document the most appropriate treatment pathway i.e. endothermal ablation, followed by sclerotherapy?  
   C.4.1 Conservative treatment vs. no treatment  
   C.4.2 Compression Vs interventional treatment  
   C.5.1 Stripping surgery vs. foam sclerotherapy  
   C.5.2 Stripping surgery vs endothermal ablation  
   C.5.3 Foam sclerotherapy vs endothermal ablation

This evidence has been graded according to the following table, with Level 1 evidence being of highest quality. Where level 1 evidence exists, we have not reviewed lower quality evidence.

<table>
<thead>
<tr>
<th>Level</th>
<th>Evidence Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Meta-analyses, systematic reviews of randomised controlled trials</td>
</tr>
<tr>
<td>Level 2</td>
<td>Randomised controlled trials</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control or cohort studies</td>
</tr>
<tr>
<td>Level 4</td>
<td>Non-analytic studies e.g. case reports, case series</td>
</tr>
<tr>
<td>Level 5</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

Where a core search question could not be answered using the evidence within the NICE guidelines, the following databases were searched. In addition, these databases were searched for evidence subsequent to the inclusion period for the NICE guidelines:

- NHS Evidence
- Cochrane Library
- PubMed
- British Medical Journal (BMJ) including BMJ Best Practice and BMJ Clinical Evidence
- Royal College of Surgeons
- Vascular Surgery Society

### 2.2 Inclusion / Exclusion Criteria:

**Inclusion:**

- Unlimited date range
- Evidence relating to adults only

**Exclusion:**

- Non English Language papers
- Evidence relating to children
3.0 Summary of findings

The following represents the key evidence used to form the NICE Guidelines on varicose veins.

<table>
<thead>
<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1</td>
</tr>
<tr>
<td>C.2.1 Factors associated with disease progression</td>
<td></td>
</tr>
<tr>
<td>C.2.2 Factors associated with treatment success</td>
<td></td>
</tr>
<tr>
<td>C.3.2 Duplex vs. No duplex prior to interventional treatment</td>
<td>✓</td>
</tr>
<tr>
<td>C.4.1 Compression (conservative) treatment vs. no treatment</td>
<td>✓</td>
</tr>
<tr>
<td>C.4.2 Compression (conservative) vs. interventional treatment</td>
<td>✓</td>
</tr>
<tr>
<td>C.5.1 Stripping surgery vs. foam sclerotherapy</td>
<td>✓</td>
</tr>
<tr>
<td>C.5.2 Stripping surgery vs endothermal ablation</td>
<td>✓</td>
</tr>
<tr>
<td>C.5.3 Foam sclerotherapy vs endothermal ablation</td>
<td>✓</td>
</tr>
</tbody>
</table>

The following level of evidence was identified within the NICE 2016 guidelines surveillance. None of the new evidence had an impact on the NICE guidelines.

<table>
<thead>
<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found between 2013-2016</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1</td>
</tr>
<tr>
<td>C.2.1 Factors associated with disease progression</td>
<td></td>
</tr>
<tr>
<td>C.2.2 Factors associated with treatment success</td>
<td></td>
</tr>
<tr>
<td>C.3.2 Duplex vs. No duplex prior to interventional treatment</td>
<td>No additional evidence was added during the NICE Guideline review pertaining to these chapters</td>
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<tr>
<td>C.4.1 Compression (conservative) treatment vs. no treatment</td>
<td>✓</td>
</tr>
<tr>
<td>C.4.2 Compression (conservative) vs. interventional treatment</td>
<td>✓</td>
</tr>
<tr>
<td>C.5.1 Stripping surgery vs. foam sclerotherapy</td>
<td>✓</td>
</tr>
<tr>
<td>C.5.2 Stripping surgery vs endothermal ablation</td>
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</tbody>
</table>
C.5.3 Foam sclerotherapy vs endothermal ablation

The following evidence level has been identified since the 2016 publication of the NICE Guideline surveillance.

<table>
<thead>
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<th>Summary of highest grade of evidence found between 2013-2016</th>
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<tbody>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>Additional evidence post-2016 NICE guideline surveillance</td>
</tr>
</tbody>
</table>

**Classification of Findings**

**CEAP Classification**: Clinical Severity, Aetiology, Anatomical Location, Pathophysiology

There are a number of grading systems used to group patients with varicose veins together, including the CEAP classification. Not all aspects of the classifier are used, however most evidence uses C1-6 as a grading system and thus a measure of outcomes in varicose veins treatment. Further scoring systems are described in search question 4 below.

- **C0** = No visible or palpable varicose veins
- **C1** = Telangiectasia / reticular veins
- **C2** = Visible/palpable varicose veins (symptomatic or asymptomatic)
- **C3** = Swelling (oedema) due to varicose veins (venous oedema)
- **C4** = Skin damage due to varicose veins (e.g. varicose eczema, atrophie blanche)
- **C5** = Healed venous leg ulcer
- **C6** = Active venous leg ulcer

Similar to the NICE guidelines, this review will refer to the CEAP classification as a descriptor for stasis or progression of varicose vein disease to match outcomes described in the RCTs. CEAP was not designed to be used as a measure of clinical change, or to provide referral criteria and thus may not represent the best way of measuring the condition. This concern is also documented within the NICE guideline (1).

**Findings**

1. What are the key clinical criteria (e.g. eczema, ulcers, infection) for which the evidence shows value treating the varicose vein?
2. Does the evidence describe specific parameters of these criteria where therapeutic value is achieved? (e.g. length of time for ulcer to heal, number of episodes of thrombophlebitis)
3. Are there any comorbid conditions that would indicate varicose vein intervention?

The first three search questions have been grouped into one summary of findings as these are mostly addressed by the same evidence and serve to answer the same question – when should varicose veins be treated?
The 2013 NICE Clinical guidelines (1) states that patients with the following criteria should be referred to a vascular service for consideration of treatment:

- Symptomatic primary or symptomatic recurrent varicose veins. (Symptomatic is described as associated with troublesome lower limb symptoms such as pain, swelling, heaviness, or itching, typically linked to periods of standing)
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
- A healed venous leg ulcer

In patients who fulfil these criteria, the guidelines recommend treatment if a duplex ultrasound confirms the diagnosis of varicose veins with truncal reflux (1). There is no level 1 or level 2 evidence to answer this research question or support the NICE guideline. The NICE guideline was formed from a number of level 3, case control studies. One study (8) comparing 120 subjects with varicose veins and open or healed venous leg ulcers, with 120 control subjects with varicose veins and no history of venous ulcers showed that patients with skin changes (including lipodermatosclerosis (odds ratio [OR] 8.90, 95% confidence interval [CI] 1.44-54.8), corona phlebectatica (OR 4.52, 95% CI 1.12-7.07)) of chronic venous disease and deep vein incompetence were most at risk of future ulceration (i.e. moving from C2-4 to C5-6). The same study also found the risk to be higher in patients who are obese (higher BMI (OR 1.08, 95% CI 1.01-1.15)), smoke, have restricted ankle movement and reduced calf muscle pump function.

A historical cohort study (9) with 290 participants (n = 1,978 in total, but 290 with C2 disease at baseline) in Germany also found obesity to be a main risk factor for progression of vascular disease (from C2 to C3-6), alongside age and a subjective “swelling feeling” in the legs lasting 4 weeks at baseline. This was also true for a subjective feeling of “leg tension” and “leg heaviness” lasting 4 weeks at baseline. Pain during prolonged walking and itching in the 4 weeks before baseline were not associated with disease progression however these last conclusions were highly uncertain. The first criterion in the NICE guideline ‘Symptomatic primary or symptomatic recurrent varicose veins’ is subject to interpretation. A footnote is included by NICE which describes these as “troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).” (1) The evidence for this criterion as stated above is of low quality.

A case-control study (10) describes most factors typically associated with worsening chronic venous disease are in fact due to this population’s greater age. The study reports the following are risk factors for CVD: Older age, male sex, obesity, history of phlebitis, history of serious leg injury and a prior deep vein thrombosis (DVT) either clinical or subclinical. A history of phlebitis increased the risk 25.7 fold. This study had an unclear methodology as it described subjects and controls as having varicose veins ‘with chronic venous insufficiency (CVI)’ or ‘without CVI’, rather than specific CEAP classifications.

A prospective cohort study (11) described prior parity and obesity (body mass index>29kg/m2) as independent predictors of greater probability of having Sapheno-Femoral Junction (SFJ) reflux at 6.6 year follow up after treatment for varicose veins.

One non-randomised trial (12) presented a result that is not included as a criterion within the NICE guideline and serves to answer research question 2 in presenting specific parameters by which therapeutic value is achieved. The study showed that a larger great saphenous vein diameter measured before treatment (by duplex ultrasound examination) was associated with treatment failure in both patients treated by foam sclerotherapy (odds ratio 1.68, 95% CI 1.24-2.27, P < .0008) and those treated by laser
ablation (odds ratio 1.91, 95% CI 1.02-3.59, P < .0428). A similar conclusion was drawn from a single-unit study post-intervention in 807 legs (13) of foam sclerotherapy alone showing that those with larger diameter saphenous veins may warrant alternative treatment options. As measurement of the great saphenous vein diameter is unlikely to be possible in primary care settings, this may be of more relevance to decision making in secondary care.

The full NICE guidelines comment that the evidence to determine markers of disease progression is scarce and of low quality. Many are case-control studies and so rely on participant recall to determine their risk-factor status. The guideline development group (GDG) made the recommendations based upon the limited evidence and consensus. The GDG comment that the decision to refer patients with symptomatic varicose veins was mainly based on the evidence found when reviewing the interventional treatments (research question 5). Whilst these studies did not include subgroup analysis of the treatment effect by baseline CEAP stage or baseline symptomology, the majority of patients within the studies were C2 or C3 at baseline and thus the results were assumed applicable to patients with this stage of disease.

In order to address the search question about key clinical criteria for which evidence shows value in treating varicose veins, the evidence that formed the NICE guideline has been reviewed. This states that for patients with the any of the criteria described in the guideline (stated above), treatment is recommended if a duplex ultrasound confirms the diagnosis of varicose veins with truncal reflux (1). The evidence to support this guideline is derived from one main RCT (level 2) involving 343 legs with a number of follow up points on the same set of patients. The initial RCT in 2005 (15) found that duplex ultrasound prior to treatment led to a lower number of patient-reported ‘worse operated legs’ after 2 years. In addition the study showed a lower incidence of the need for or actual re-operation after two years in the duplex group (two legs, 1.4%) vs the no-prior duplex group (14 legs, 8.8%) (p=0.002). The follow up study in 2011 (16) showed a similar result with a lower incidence of reoperation in the group that underwent duplex ultrasound imaging prior to intervention (15/194 vs. 38/194 legs) (p=0.001). Both studies also found a lower incidence in saphenofemoral or saphenopopliteal incompetence in the group who underwent imaging prior to treatment at 2 years (19 legs, 15% vs. 53 legs, 41.1%) (p<0.001) and at 7 years (14% vs. 46%) (p<0.001). In addition, the original 2005 study (15) described that duplex examination prior to treatment actually suggested a different surgical procedure in 26.5% of the subject legs. The GDG noted that it would not be possible to assess suitability for the hierarchy of treatment (described in search question 5) without duplex ultrasound prior to treatment.

In the 2016 NICE Surveillance Update, no new evidence was added to answer these research questions.

Following the publication of the NICE Surveillance Update no new evidence was found directly pertaining to these research questions. New evidence was found relating to search question 5, described below.

4. Does the evidence document an appropriate scoring system for severity of varicose veins within clinical practice?

As described in the introduction, there are a number of scoring systems in use within research to report primarily on progression of varicose veins. There has been discussion around whether there is a place for scoring within the referral pathway of varicose veins, especially as to whether scoring should be based on leg symptoms, clinical criteria, quality of life measurements or haemodynamic criteria.

<table>
<thead>
<tr>
<th>CEAP</th>
<th>Clinical Aetiological, Anatomical, Pathophysiological</th>
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<tbody>
<tr>
<td>VCSS</td>
<td>Venous Clinical Severity Score</td>
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</table>
AVVQ | Aberdeen Varicose Vein Questionnaire
---|---
CIVIQ | Chronic Venous Insufficiency quality of life Questionnaire
CXVUQ | Charing Cross Venous Ulceration Questionnaire
VEINES-QoL/Sym | VEnous INsufficiency Epidemiological and Economic Study – Quality of Life/Symptoms
VVSymQ® | Varicose Vein Symptom Questionnaire

More details of the most commonly used ones (CEAP, VCSS and AVVQ) are included in Appendix 3. The most frequently used of these is the CEAP classification which scores clinical severity, aetiology, anatomical position and pathophysiology, however, most often within the literature reviewed here, only the ‘C’ clinical severity score is used. The NICE guidelines (1) comment on the use of the CEAP classification within the literature and note that this was not designed as a measure of clinical change or referral criteria so caution should be exercised. A rapid desk-based review of commissioning policies in England (using the Google search engine) identified some commissioning policies and pathways of other CCGs, some of which use the CEAP classification (advising referral for CEAP 4-6 only) and some do not use any formal scoring system, rather the list of criteria describe in the NICE guideline and above in search question 1. The evidence described below in relation to this search question does not provide a conclusive answer and serves to support discussion within the Task and Finish Group regarding the relative benefits, risks and challenges in implementing a Pan-London scoring system for treatment thresholds.

One single-centre prospective study (18) aimed to determine which pre-treatment severity characteristic (AVVQ, VCSS and VFI (Venous filling index), CEAP) were related to the greatest improvement in QoL as a result of treatment. All of these factors improved at 3 month follow up (P<0.0005) confirming that treatment for varicose veins is of benefit to most patients. There was no significant correlation in AVVQ improvement when compared to baseline VCSS, VFI or CEAP, indicating that these parameters are of limited use in predicting which patients would most benefit in QoL from intervention. However, comparing AVVQ improvement from 3 weeks to 3 months the results show significant (P<0.0005) improvement compare to pre-treatment AVVQ, indicating that patients with an initially poor QoL benefited the most from treatment, not necessarily those with a higher VCSS or VFI score. The authors conclude that the baseline AVVQ was the best predictor in identifying patients who improve the most after intervention. Clinical severity, CEAP classification or hemodynamic severity were not helpful in predicting improvements. As the aim of elective treatment is improvement in QoL, it is worth considering the use of the AVVQ over other scoring systems when rationing patients with uncomplicated varicose veins.

A cross-sectional study (19) asked 284 patients on the waiting list for varicose vein treatment to complete the Short Form 12 (SF-12) and a non-validated questionnaire related to symptoms of chronic venous insufficiency including pain, ache, itching, tingling, crap, restless legs, a feeling of swelling and heaviness. The study found that physical and mental health related quality of life (HRQL) is significantly worse (p=0.011) in patients with symptomatic varicose veins, but has no correlation to the CEAP clinical grade of disease. The authors conclude that therefore, rationing of varicose vein treatment to those with CEAP 4-6 only excludes patients who would benefit from an improved quality of life. This study raises the similar question of what are the suitable criteria that can be used to ration a treatment whose key aim is to improve quality of life.

One prospective cohort study (20) assessed the feasibility of using an online AVVQ (either completed at home or immediately prior to their outpatient appointment) to guide referral to vascular specialists. Patients completed the AVVQ before seeing a consultant vascular surgeon who then assigned the patient a VCSS and CEAP grade. The
A study found that AVVQ correlated with the consultant’s VCSS score (P<0.01) and CEAP grade (p<0.01). To account for reproducibility and bias a cohort of patient redid the AVVQ score prior to surgery, which were found to be in close agreement (p<0.01).

Another prospective observational study (21) compared anatomical, haemodynamic and clinical outcomes (duplex ultrasonography, digital photoplethysmography, VCSS, CEAP, SF12) with disease-specific quality-of-life tools (AVVQ, Specific Quality-of-life and Outcome Response-Venous (SQOR-V)) in patients undergoing treatment for varicose veins. The two disease-specific quality-of-life tools (AVVQ and SQOR-V) showed a strong positive correlation (p<0.001) and a weaker correlation with the SF12 and VCSS (p<0.001). There was no correlation between the AVVQ and photoplethysmography (P=0.606) and weak correlation with AVVQ and anatomical reflux. The authors conclude that anatomical and haemodynamic measures correlated poorly with functional outcomes preoperatively and after intervention.

5. Does the evidence document the most appropriate treatment pathway i.e. endothermal ablation, followed by sclerotherapy?

The prime purpose of this guidance and evidence review was to assess clinical criteria or co-morbidities that might impact on the decision of when to refer for treatment in this common condition, not the choice of a specific treatment modality. Current NICE guidelines recommend a hierarchy of treatment hierarchy summarised below, and the rationale for advising interventional treatments over conservative ones is described.

The NICE Guideline (1) states that for people with confirmed varicose veins and truncal reflux (on duplex ultrasound)

1) Offer endothermal ablation
2) If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy
3) If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.

The guidance adds that patients should not be offered compression hosiery to treat varicose veins unless interventional treatment is unsuitable. The NICE guidelines do not directly state if compression hosiery should be used whilst awaiting interventional treatments.

5.1 Conservative Treatment (Compression) Vs. No Treatment

There were 3 RCTs included within the NICE evidence base comparing compression hosiery to no treatment. In the most recent of these, a 2003 multi-centre randomised, double blind crossover study (22), the authors concluded that wearing graduated elastic compression stockings during a 15-day period results in the improvement in the symptoms of early-stage chronic venous disease with no significant difference in compliance between the two groups. There are limitations of this study, notably, this study was carried out on only female patients.

In the 2016 NICE Surveillance update, an additional RCT (23) was identified. This 2014 RCT, also only conducted on female subjects looked at the effects of using Kinesio taping-compression techniques, rather than hosiery. The authors concluded that this improves symptoms (heaviness, claudication, swelling, muscle cramps) and peripheral venous flow, and may also have a placebo effect on pain, in post-menopausal women with CVI. This is the only trial considering the taping technique and considering the small size (n=120) and limited cohort (post-menopausal women only) no update was made to NICE guidance at this time, pending further evidence.

No new level 2+ evidence was found pertaining to this since the 2016 update to NICE guidelines.
5.2 Conservative treatment (Compression) Vs. Interventional treatments

As above, the NICE guidelines state that patients should not be offered compression hosiery to treat varicose veins unless interventional treatment is unsuitable, that is to say that interventional treatments are more effective than conservative management of varicose veins. The NICE guideline does not cover the use of compression treatment as an interim measure whilst on the waiting list for interventional therapy.

The evidence supporting this NICE guideline came from two publications from the same RCT, both of which only compared compression therapy to stripping surgery alone, and not to endothermal ablation or foam sclerotherapy. The first RCT (24) involved 246 patients referred to vascular outpatient clinics at two large NHS hospitals. The results showed a significant quality of life benefit and improvement in symptoms in patients undergoing surgery at two year follow up. The parallel REACTIV trial (25) added that surgery was a cost-effective treatment of varicose veins when measured using quality-adjusted life years (QALY) and incremental cost-effectiveness ratios (ICER), with an ICER well below the threshold normally considered appropriate for the funding of treatments within the NHS.

In the 2016 NICE Surveillance Update, an additional RCT (26) randomised 153 patients with C2 and C3 varicose vein disease to receive either compression stockings (n=77) or stripping surgery (n=76). After 2 years the Venous Clinical Severity Score decreased from 4.6 to 3.5 in the compression group (p<0.01) and from 4.8 to 0.9 in the surgery group (p<0.001), Venous Segmental Disease Score (VSDS) improved from 7.7 to 7.0 in the compression group and from 8.2 to 0.9 in the surgery group (p<0.0001), and health-related quality of life (HRQoL) improved significantly in the surgery group and remained unchanged in the compression group.

No new level 2+ evidence was found pertaining to this since the 2016 update to NICE guidelines.

5.3 Stripping Surgery Vs Foam Sclerotherapy

In general, RCTs that have reported on the effectiveness of different treatment options use reflux as a key outcome measure, alongside need for further treatment, both in the short-term and long-term. Patient reported outcome measures and quality of life indicators are also often reported.

There were a number of RCTs addressing these treatment modalities. The most recent RCT used by the NICE guidelines, published in 2012 (27), was a multi-centre randomised trial involving 430 subjects, comparing efficacy and costs of ultrasound guided foam sclerotherapy (UGFS) and surgery. The results showed that the two-year probability of recurrence (defined as reflux combined with venous symptoms) was similar in both groups (p = 0.407) and reflux irrespective of symptoms was significantly more frequent in the UGFS group (35%) versus the surgery group (21%) (p=0.003). The study reported mean direct hospital costs per 2 years per patient to be €774 for UGFS and €1824 for surgery.

In the 2016 NICE surveillance review a further RCT (28) was noted, comparing the three-year outcomes of foam sclerotherapy, surgical stripping and endovenous laser ablation (EVLA) across 580 legs. The original study was included in the full NICE guideline in 2013 and presented similar results. At three years, eight (6.8%) (EVLA), 31 (26.4%) (UGFS) and 8 (6.5%) (Surgery) veins had recanalised or had failed stripping procedures (P<0.01). Within three years from treatment 14 (12.5%) (EVLA), 37 (32.6%) (UGFS) and 18 (15.5%) (Surgery) legs had to be retreated (p<0.01). Venous Clinical Severity Score (VCSS) and Aberdeen Quality of Life (QoL) scores improved
significantly in all three groups, but with no difference between the groups. The authors conclude that all treatment modalities were efficacious and provide similar improvements in patient report outcomes, however foam sclerotherapy led to more than double the instances of recanalization and reoperation. The justification for the NICE guideline will be described toward the end of this research question.

### 5.4 Stripping Surgery Vs Endothermal Ablation

A 2013 multicentre, three-arm parallel trial (29) compared ligation and stripping surgery, laser ablation or laser ablation with ligation and primarily reported reflux recurrence at the SFJ (after two years), as well as pain and discomfort (after two months). In the surgery group 32.7% presented with post-operative pain after one day, 3.3% in the laser ablation group and 50% in the ablation and ligation group (P=0.0069). The NICE Surveillance update in 2016 presented the findings of the two year follow up study (29) which showed no significant difference in clinical recurrence during the 6 years post therapy. Post-operative decline and subsequent progression through CEAP class was also parallel in all groups. The authors concluded that whilst clinical recurrence appears with the same frequency in all three treatment modalities, the pathological mechanism differs, with EVLA leading to most reflux into the GSV and development of side branches, and surgery leading to more recurrence independent of the SFJ.

A number of other studies were included in the NICE 2016 update, the full review and justification for which is included within Appendix 1 (references 30-39). NICE concluded that the evidence did not change the guideline’s treatment hierarchy.

### 5.5 Foam Sclerotherapy Vs Endothermal ablation

The most recent level 2 evidence included within the original NICE guidelines was a 2012, single-centre RCT (40) comparing the cost and clinical effectiveness of EVLA vs. UGFS in 100 legs at 3 weeks and 3 months. No significant differences were demonstrated in outcomes (measured using VCSS, AVVQ) between the two groups at three months, however UGFS outperformed EVLA in cost, treatment duration and pain. The authors conclude that UGFS is 3.15 times cheaper than EVLA (£230.24 vs £724.72) with comparable clinical effectiveness when basing costing on consumables, staff pay and overheads per individual time treatment. The authors also note that 56% of the UGFS group required additional foam vs 6% required further treatment in the ablation group.

The 15-month follow up to this study was reviewed as part of the 2016 NICE surveillance update. The study (42) presented that EVLA was more effective at occluding the GSV than UGFS (95.5% vs. 67.4%) however both techniques were equally effective at abolishing global venous reflux. During the 15 months follow up period, 41% of the UGFS group and 20% of the EVLA group received adjuvant treatment. There was no statistical difference in patient reported quality of life metrics between the groups.

A number of other studies were included in the NICE 2016 update, the full review and justification for which is included within Appendix 1 (references 41-44). Two key RCTs included in the surveillance update were trial reports of the National Institute for Health Research (NIHR) CLASS trial (43, 44). These studies report that at 6 months the health gain achieved (reported using the AVVQ) in those treated with foam sclerotherapy was significantly lower than those who underwent surgery, but similar to those undergoing EVLA (p=0.006). There was no statistical difference between the three groups for general QoL measures (EQ-5D, SF-36) and no difference in VCSA between the three groups. Secondary outcome measures showed greater health gains at 6 weeks in the EVLA group Vs foam sclerotherapy (p=0.005), there were fewer procedural complications in the EVLA group (1%) than after foam (7%) and surgery (8%)
and participants returned to a wide range of behaviours more quickly following foam or EVLA vs surgery (p<0.05). The cost-effectiveness analysis showed that foam sclerotherapy has the highest probability of being considered cost-effective, with EVLA being less costly and generating more QALYs than surgery. Markov modelling was used to provide estimated 5-year cost effectiveness suggesting that EVLA had the highest probability of being cost effective at conventional thresholds, followed by foam and then surgery. The authors conclude that EVLA should be considered as the treatment of choice for suitable patients given the 6-month clinical outcomes and estimated 5 year cost-effectiveness.

5.6 Additional evidence post 2016 surveillance update on all treatment modalities

There have been a number of publications following the surveillance update, the highest quality of which have been reviewed below and more detail can be found in Appendix 1.

A 2016 Cochrane Database Systematic Review (45) compared the effectiveness of EVLA, radiofrequency ablation (RFA) and UGFS with surgery in the treatment of short saphenous varicose veins (SSV). The review cited three RCTs and the authors conclude that moderate to low evidence exists to suggest that recanalization or persistence of reflux at six weeks and reflux at one year are less frequent with EVLA vs. surgery. The quality of evidence relating to the outcomes of UGFS to surgery was deemed too low to be certain. Another 2016 systematic review (47) focused on the incidence of recurrence of varicose veins after surgery (REVAS) after EVLA vs ligation and stripping surgery. The study appraised seven RCTs and concluded that there was no difference in the incidence of REVAS between laser ablation and surgery, but the causes of recurrence are different between the groups.

A systematic review and meta-analysis published in 2018 (48) also sought to compare long-term outcomes of EVLA vs surgery, specifying a minimum of 5-year follow ups. Overall, nine RCTs were included in the review totalling 2,185 legs of which 1,352 were included in 5-year or more follow up. There was no statistically significant difference in recurrence rate when comparing EVLA and conventional surgery and no significant difference when comparing radiofrequency ablation (RFA) with surgery or EVLA. Both EVLA and RFA were considered as effective as surgery in treating saphenous vein incompetence. Another 2018 systematic review (49) found a moderate level of evidence to report that RFA is as effective as surgery or EVLA and a low level of evidence to report that there were fewer major and minor complications of RFA vs surgery. This was derived from 15 literature reviews, 22 new primary studies and 1 good-practice guideline. The limited sample sizes and lack of standardisation of the outcome led to the low-moderate grading of evidence.

Another 2018 systematic review (50) included 10,034 patients across 53 RCTs, of which 16 were good quality, 28 fair quality and 9 poor quality. A meta-analysis was undertaken to evaluate stripping surgery compared to RFA and revealed no difference in short-term bleeding or reflux recurrence at 1-2 year. Meta-analysis comparing stripping surgery and EVLA also revealed no difference in long-term symptoms score or quality of life at 2 years. The authors concluded that more high-quality studies, with improved heterogeneity in populations and therapies and outcomes was required to determine comparative effectiveness and guide policy. The final meta-analysis presented here (51) was published in 2017 and compared EVLA to RFA looking at efficacy, recurrence and complications. 12 studies were included with a total of 1,577 patients. 3-day and 10-day pain scores, 1 month and 1 year quality of life scores as well as occlusion, thrombophlebitis, haematoma formation and recanalization following RFA was no different to following EVLA (not statistically significant) but RFA was associated with lower overall complication rates.
The Task and Finish Group cited an additional RCT (52), published only one week before the Task and Finish Group met that compares 450 patients with venous leg ulcers across 20 UK hospitals, randomized into those with venous reflux treated with endovenous ablation within 2 weeks of randomization (early-intervention group) and those with venous reflex treated with compression therapy and endovenous ablation after the ulcer healed or 6 months after randomization (deferred-intervention group). The study showed that time to ulcer healing and the number of patients with healed ulcers was better in the early-intervention group (hazard ratio for ulcer healing, 1.38; 95% confidence interval [CI], 1.13 to 1.68; P=0.001). In addition, the median time to ulcer healing was 56 days (95% CI, 49 to 66) in the early-intervention group and 82 days (95% CI, 69 to 92) in the deferred-intervention group. The rate of ulcer healing at 24 weeks was 85.6% in the early-intervention group and 76.3% in the deferred-intervention group. There was also a higher medial number of ulcer-free days in the early-intervention group during the first year after trial enrolment (306 days vs 278 days, p=0.002).

The additional evidence presented since 2016 is unlikely to alter the NICE guideline and similarly, finds all treatment modalities to be effective with endothermal having a slight edge over foam sclerotherapy and surgery both clinically and in cost comparison.
Appendix A – Guidance and evidence review & References

The evidence is presented in the following way:

<table>
<thead>
<tr>
<th><strong>Core Search Questions:</strong></th>
<th>Under this heading the core search questions are restated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NICE Evidence Base Chapter:</strong></td>
<td>Under this heading, evidence used by the NICE Guideline Development Group (GDG) to form the 2013 NICE guidelines is presented.</td>
</tr>
<tr>
<td><strong>Additional evidence presented within NICE Guidelines review - 2016</strong></td>
<td>Under this heading, evidence added to support the NICE Guideline Surveillance update in 2016 is presented.</td>
</tr>
<tr>
<td><strong>Additional evidence review post publication of NICE guidelines in 2016</strong></td>
<td>Under this heading, evidence found subsequent to the publication of the 2016 NICE Guideline Surveillance update is presented.</td>
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</table>
Note: The NICE guidelines is stated below for reference – the evidence reviewed above includes the key literature that formed the NICE guidance.

NICE carried out a review of the evidence and based their recommendations on the best available evidence whilst acknowledging that a lot more evidence based research was needed.

The evidence review for the guideline showed a lack of high quality evidence on the natural progression of varicose veins. It found that the current evidence for the use of compression hosiery was weak and that the evidence for its use after interventional treatment was unclear.

It also found that most of the research into the optimum treatment for varicose veins involved patients at stage C2 and C3 so little is known of the relative efficacies of the treatments at the more severe stages of the disease.

Guideline
Refer people to a vascular service if they have any of the following:
- Symptomatic primary or symptomatic recurrent varicose veins.
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
- A healed venous leg ulcer.

Assessment and treatment in a vascular service
Assessment
- Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.

Interventional treatment
For people with confirmed varicose veins and truncal reflux:
- Offer endothermal ablation
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.

If incompetent varicose tributaries are to be treated, consider treating them at the same time.

Non-interventional treatment
Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

Management during pregnancy
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.
<table>
<thead>
<tr>
<th>NICE IPG8: Radiofrequency ablation of varicose veins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Published Sept 2003, Review Jan 2013</td>
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<tr>
<td>Symptomatic venous insufficiency is common, affecting 1-15% of adult men and 20-25% of adult women. Saphenous vein insufficiency is the most common form of venous insufficiency in patients presenting with symptoms, which include pain, oedema, fatigue, varicose veins and venous ulcers. Radiofrequency ablation of varicose veins involves heating the wall of the vein using a bipolar generator and catheters with sheathable electrodes. The saphenous vein is accessed above or below the knee either percutaneously via an intravenous cannula/venipuncture sheath or via a small incision. The catheter is manually withdrawn at 2.5-3cm/minute, and the vein wall temperature is maintained at 85°C. Current evidence on the safety and efficacy of radiofrequency ablation of varicose veins appears adequate to support the use of this procedure as an alternative to saphenofemoral ligation and stripping, provided that the normal arrangements are in place for consent, audit and clinical governance.</td>
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<tr>
<th>NICE IPG52: Endovenous laser treatment of the long saphenous vein</th>
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<tr>
<td>Published March 2004, Review Jan 2012</td>
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<tr>
<td>Under ultrasound guidance and local anaesthesia, a catheter is placed into the long saphenous vein. A laser fibre is passed through it and positioned below the saphenofemoral junction. An anaesthetic agent is then injected, and the fibre is slowly withdrawn while energy from a diode laser (810 or 940 nm wavelength) is applied in short pulses. This is repeated along the entire length of the vein until the long saphenous vein is closed from the saphenofemoral junction to the point of access. Current evidence on the safety and efficacy of endovenous laser treatment of the long saphenous vein appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. Current evidence on the efficacy of this procedure is limited to case series with up to 3 years follow-up. Clinicians are encouraged to collect longer-term follow-up data.</td>
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<tr>
<th>IPG440: Ultrasound-guided foam sclerotherapy for varicose veins</th>
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<tr>
<td>Published Feb 2013,</td>
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<tr>
<td>Small valves inside the veins help blood flow properly through them. Varicose veins develop when these valves do not work properly, allowing blood to collect in the veins. This enlarges them and causes the valves to deteriorate further. Varicose veins commonly occur in the legs. Many people have no symptoms, but if they do, these can include heaviness, aching, throbbing, itching, cramps or tiredness in the legs. In severe cases, patients may have skin discolouration or inflammation, or skin ulcers. Foam sclerotherapy involves mixing a chemical with air or another gas to produce a foam, which is injected into the affected vein using ultrasound imaging to monitor its progress. This causes scarring of the inside of the vein so that it becomes blocked. Sometimes patients may need more than one injection to block the vein. Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that patients are warned of the small but significant risks of foam embolization, this procedure may be used with normal arrangements for clinical governance, consent and audit. During the consent process, clinicians should inform patients that there are reports of temporary chest tightness, dry cough, headaches and visual disturbance, and rare but significant complications including myocardial infarction, seizures, transient ischaemic attacks and stroke.</td>
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<table>
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<tr>
<th>IPG526: Cyanoacrylate glue occlusion for varicose</th>
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<tbody>
<tr>
<td>Published</td>
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<tr>
<td>Current evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</td>
</tr>
</tbody>
</table>
| 6 | **IPG 557: Endovenous mechanochemical ablation for varicose veins**  
Published May 2016 | Endovenous mechanochemical ablation for varicose veins combines mechanical ablation with the use of sclerosing agents to close veins without the need for tumescent anaesthesia (infusion of a large volume of dilute local anaesthetic around and along the entire length of vein to be treated).

Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure provided that standard arrangements are in place for consent, audit and clinical governance. Clinicians are encouraged to collect longer-term follow-up data. |
|---|---|
| 7 | **IPG37: Transilluminated powered phlebectomy for varicose veins**  
Published Jan 2004, Reviewed 2012 | Current evidence on the safety and efficacy of transilluminated powered phlebectomy for varicose veins includes small numbers of patients and is of limited quality. It does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. |
Core Search Questions:
1) What are the key clinical criteria (e.g. eczema, ulcers, infection) for which the evidence shows value treating the varicose vein?
2) Does the evidence describe specific parameters of these criteria where therapeutic value is achieved? (e.g. length of time for ulcer to heal, number of episodes of thrombophlebitis)
3) Are there any comorbid conditions that would indicate varicose vein intervention?

NICE Evidence Base Chapter: C.2.1 Factors associated with disease progression

<table>
<thead>
<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found</th>
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<tbody>
<tr>
<td>C.2.1 Factors associated with disease progression</td>
<td>![Level 3 Icon]</td>
</tr>
</tbody>
</table>

The following are the level 3 literature most relevant to answering the research questions

8 Robertson L, Lee AJ, Gallagher K et al.

**Evidence Level: 3 – Case Control Study**

**BACKGROUND/OBJECTIVE:**
Identifying which patients with varicose veins are at risk of progressing to more severe forms of chronic venous disease could help in assigning clinical priorities and targeting appropriate treatments. The aim of this study was to determine, in subjects with varicose veins, the characteristics of venous disease and other factors associated with an increased risk of ulceration.

**METHODS:**
One hundred twenty subjects with varicose veins and an open or healed venous leg ulcer were compared with 120 controls with varicose veins and no history of venous ulcer on this case control study. Subjects were recruited from hospital settings and primary care. Each subject completed a questionnaire on lifestyle and medical history and underwent an examination comprising of clinical classification of venous disease (CEAP), duplex scanning, quantitative digital photoplethysmography, and measurement of dorsiflexion. Multiple logistic regression analyses and calculation of receiver operating characteristic (ROC) curves were performed to identify the combination of factors which most accurately predicted which patients with varicose veins will develop leg ulcers.

**RESULTS:**
An increased risk of ulceration was associated with the severity of clinical venous disease, especially with the presence of skin changes ($P < .0001$). Other significant risk factors included history of deep vein thrombosis (DVT) ($P = .001$), higher body mass index (BMI) ($P = .006$), smoking ($P = .009$), and reflux in the deep veins ($P = .0001$). Ulceration was associated with reduced volume of blood displaced as reflected by photoplethysmography and a limited range of ankle movement (not wholly due to the effects of an active ulcer).
Multivariate analyses showed that skin changes including lipodermatosclerosis (odds ratio [OR] 8.90, 95% confidence interval [CI] 1.44-54.8), corona phlebectatica (OR 4.52, 95% CI 1.81-11.3) and eczema (OR 2.87, 95% CI 1.12-7.07), higher BMI (OR 1.08, 95% CI 1.01-1.15), and popliteal vein reflux (OR 2.82, 95% CI 1.03-7.75) remained independently associated with increased risk of ulceration while good dorsiflexion of the ankle (OR 0.88, 95% CI 0.81-0.97) and an effective calf muscle pump (OR 0.96, 95% CI 0.92-0.99) remained protective factors. ROC curve analyses indicated that a model based on clinical observation of skin changes, duplex scanning for popliteal reflux, and calf muscle pump tests would be the most accurate in determining which patients with varicose veins develop leg ulcers.

CONCLUSIONS: The results of this study confirm that, in patients with varicose veins, those with skin changes of chronic venous insufficiency and deep vein incompetence are at greatly increased risk of ulceration. However, the risks may also be increased in those who smoke, are obese, and have restricted ankle movement and reduced calf muscle pump power.

**9**


**Evidence Level: 3 – Prospective Cohort Study**

**BACKGROUND**
Chronic venous disorders (CVD) are among the most common diseases in Germany. In the Bonn Vein Study I (BVS I), conducted in 2000, 3072 participants of the general population of the city of Bonn and two rural townships, aged 18 to 79 years, took part in this study (1350 men, 1722 women). Participants were selected via simple random sampling from the registries of residents. In this follow-up study 6.6 years later, the same population was investigated again. The aim was to identify the incidence and risk factors of progression of pre-existing CVD. In addition, incidence and progression of venous symptoms were documented.

**METHODS**
From May 2007 to September 2008, we contacted all participants of BVS I and invited them for a reinvestigation. The participants answered a standardized questionnaire and were examined by clinical means and by duplex ultrasound in the same way as in BVS I.

**RESULTS**
The response at follow up after 6.6 years was 84.6%. We reinvestigated 1978 participants. The prevalence for varicose veins (VV) rose from 22.7% to 25.1% and for CVD from 14.5% to 16%. Participants with C-Class C2 as a maximum at BVS I increased to higher C-classes in 19.8% (nonsaphenous VV) and in 31.8% (saphenous VV). In a multivariate analysis, the main risk factors for were age, obesity, and arterial hypertension.

**CONCLUSIONS**
These results show a high incidence of progression of CVD to higher C-classes.

**10**


**Evidence Level: 3 – Case control study**

**PURPOSE:**
Most epidemiologic studies on chronic venous insufficiency (CVI) are cross-sectional surveys that suggest potential risk factors by describing their population. However, these relationships could be due to the CVI population's older age. We performed a dual case-control study with multivariate analysis to address this issue.

**METHODS:**
Ninety-three patients with venous ulcers, 129 patients with varicose veins (VV), and 113 general population control patients from two hospitals were interviewed by use of a standardized questionnaire covering medical history, patient demographics, medications, and lifestyle questions. Univariate and multivariate analyses were used to compare the groups.

RESULTS:
Univariate analyses showed CVI to be characterized by several factors, many of which were found to be age related after multivariate analysis. Age-adjusted relationships for CVI include male sex and obesity. Histories of serious leg injury or phlebitis were important associations resulting in a 2.4-fold and 25.7-fold increase in risk for CVI, respectively. After adjusting for age, subjects with VV tend to be younger and female, to more frequently have a history of phlebitis, and to report a family history of VV more frequently than control subjects.

CONCLUSIONS:
Many of the previously suggested associations found with CVI are in reality due to this population's greater age. Patients with CVI are older, male, obese, have a history of phlebitis, and have a history of serious leg injury. These results suggest that a prior deep vein thrombosis, either clinical or subclinical, may be a predisposing factor for CVI.

NICE Evidence Base Chapter: C.2.2 Factors associated with treatment success

The following are the level 3 literature most relevant to answering the research questions


Evidence Level: 3 – Prospective observational study.

OBJECTIVE:
To identify patient and physician-controlled treatment variables that might predict the persistence or redevelopment of saphenofemoral junction (SFJ) reflux.

METHODS:
Thirteen European centers, with substantial lower extremity venous disease practices, examined their experience with SFJ ligation and GSV stripping for primary varicose veins in patients followed for > or =2 years, entering their data into a protocol-driven matrix that stipulated duplex Doppler imaging as an essential component of follow-up examinations and required a complete review of all peri-operative examinations, as well as all operative procedure and anesthesia notes. Matrix entries were centrally audited for consistency and credibility, and queried for correction or clarification before being accepted into the study database. Presence or absence of Doppler-detectable SFJ reflux...
was the dependent variable and principal outcome measure.

RESULTS:
Among 1,638 limbs, 315 (19.2%) had SFJ reflux. After adjustment for follow-up length and inputting for missing values, multivariable analysis identified seven significant predictors. Ultrasonic groin mapping (odds ratio [OR], 0.28; 95% confidence interval [CI], 0.20 to 0.40) and <3-cm groin incisions at or immediately below the groin crease (OR, 0.50; 95% CI, 0.32 to 0.78) were both uniquely associated with diminished probability of follow-up SFJ reflux. Prior parity (OR, 2.69; 95% CI, 1.45 to 4.97), body mass index >29 kg/m² (OR, 1.65; 95% CI, 1.12 to 2.43), <3-cm suprainguinal incisions (OR, 3.71; 95% CI, 1.70 to 5.88), stripping to the ankle (OR, 2.43; 95% CI, 1.71 to 3.46), and interim pregnancy during follow-up (OR, 4.74; 95% CI, 2.47 to 9.12), were each independent predictors of a greater probability of having SFJ reflux.

CONCLUSIONS:
The findings suggest that ultrasound groin mapping, reticence for short suprainguinal or longer groin incisions and extended stripping, and counseling women about the effect of future pregnancy are prudent clinical choices, especially for obese or previously parous patients.

Evidence Level: 3 – non randomised trial

BACKGROUND:
Great saphenous vein (GSV) reflux is the most frequent form of venous insufficiency in symptomatic patients and is commonly responsible for varicose veins of the lower extremity. This non-randomized prospective controlled study was designed to test the hypothesis that 1) endovenous laser treatment is more effective than foam sclerotherapy in the closure of the refluxing GSV (as measured by degree of great saphenous vein reflux and venous clinical severity score changes) and 2) to record the associated complications of echo-guided endovenous chemical ablation with foam and endovenous laser therapy for the treatment of great saphenous vein reflux and to further identify risk factors associated with treatment failure.

METHODS:
Between January 1, 2006 and June 25, 2006, patients seeking treatment of varicose veins at a private practice of vascular medicine were assessed for the study. Inclusion criteria were: 1) presence of great saphenous vein reflux and 2) C2-6, Epr, A s, according to the CEAP classification. The selected patients consented into the study and were allowed to choose between foam (53 patients) or laser (45 patients) treatment. Duplex examinations were performed prior to treatment and at seven and 14 days, four weeks, six months, and one year after treatment. Venous clinical severity score was assessed pre-treatment and at one year post-procedure.

RESULTS:
The cohorts showed no statistically significant differences in age, sex, clinical and anatomical presentation, great saphenous vein diameter, and venous clinical severity score before the treatments. After one year follow up, occlusion of the great saphenous vein was confirmed in 93.4% (42/45) of limbs studied in the laser group and 77.4% (41/53) of limbs in the foam group (P < .0465). Venous clinical severity score significantly improved in both groups (P < .0001). Procedure associated pain was higher in the laser group (P < .0082). Induration, phlebitis, and ecchymosis were the most common complications. Logistical regression and subgroups analysis shown that a larger great saphenous vein diameter measured before treatment was associated with treatment failure in the foam (odds ratio 1.68, 95% CI 1.24-2.27, P < .0008) and in the laser group (odds ratio 1.91, 95% CI 1.41-2.60, P < .0008).
**CI 1.02-3.59, P < .0428.** A 90% treatment success is predicted for veins <6.5 mm in the foam group versus veins <12 mm in the laser group.

**CONCLUSIONS:**

Overall, endovenous laser ablation achieved higher occlusion rates than echo-guided chemical ablation with foam after one year follow-up. Matching the patient to the technique based on great saphenous vein diameter measured before treatment may assist in boosting the treatment success rate to >90%. A larger patient cohort followed and compared over a longer period of time would be required to confirm these findings.

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<tr>
<th>13</th>
<th>Evidence Level: 3 – Prospective observational study</th>
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**OBJECTIVE:**

To estimate medium-term success after a technique for ultrasound-guided sclerotherapy for superficial chronic venous disease.

**DESIGN:**

A prospective study in a single unit with ultrasound surveillance after treatment.

**MATERIALS:**

Results after 1189 treatment sessions for 807 venous saphenous veins and related tributaries or non-saphenous tributaries in 489 patients.

**METHODS:**

Univariate life table analysis determined primary and secondary success rates. Multivariate Cox regression analysis detected covariates that affected outcome.

**RESULTS:**

Primary and secondary success rates at 36 months for all veins were 52.4% (95%CI 46-58%) and 76.8% (95%CI 71-82%). Cox regression analysis for primary success for all veins showed significantly worse results for saphenous veins compared to tributaries (HR 3.72 - 95%CI 1.9 to 7.3). Cox regression for all saphenous veins showed independently worse results for patients less than 40 years of age (HR 2.16 - 95%CI 1.27-3.66), small compared to great saphenous veins (HR 1.58 - 95%CI 1.11-2.24), veins greater than 6mm diameter compared to smaller veins (HR 2.22 - 95%CI 1.40-3.50), liquid compared to foam sclerotherapy (HR 2.20 - 95%CI 1.28-3.78), lower volumes of sclerosant compared to volumes greater than 12 ml (HR 0.51 - 95%CI 0.33-0.81) and highly diluted compared to concentrated sclerosant (HR 2.05 - 95%CI 1.21-3.46) with worse results using highly diluted or undiluted 3% sclerosant compared to a 1.5% concentration. There were no significant differences for primary success for saphenous veins for date of procedure, sex, side, primary or recurrent varicose veins, or commercial type of sclerosant.

**CONCLUSIONS:**

Ultrasound-guided sclerotherapy gives satisfactory results if it is accepted that treatment may need to be repeated to achieve secondary success. Results provide a basis for further research to explore factors that might affect outcome. Younger patients with larger diameter saphenous veins may warrant alternative forms of treatment, particularly for small saphenous reflux.

| 14 | Evidence Level: 3 – Prospective cohort study |

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BACKGROUND AND OBJECTIVE: Superficial venous surgery for CEAP 2 disease leads to an improvement in disease-specific quality of life (QoL) in the short term. However, which factors influence the magnitude of this improvement, how surgery affects QoL in patients with CEAP 4 to 6 disease, and whether this improvement is durable are not known. The objective of this study was to identify patient, operative, and surgeon factors that might influence the change in disease-specific QoL in the 2 years after superficial venous surgery.

METHODS: This prospective study was comprised of 203 unselected, consecutive patients with CEAP 2 to 6 disease who underwent saphenous with or without subfascial endoscopic perforator surgery and who completed the Aberdeen Varicose Vein Symptoms Severity Score (AVVSSS) before surgery and at 4 weeks, 6 months, and 2 years after surgery. Univariate and multivariate analyses were performed.

RESULTS: At baseline, recurrent and ulcer (CEAP 5 and 6) diseases were associated with a higher (worse) AVVSSS. Surgery was associated with a significant improvement in median (interquartile range [IQR]) AVVSSS: baseline, 17.8 (11.8 to 27.2); 4 weeks, 13.8 (7.9 to 21.3); 6 months, 9.6 (4.2 to 15.8); and 2 years, 8.1 (4.0 to 14.7). One hundred seventy-five patients (86%) at 6 months and 177 patients (87%) at 2 years reported an improvement in AVVSSS. Postoperative AVVSSS at both 6 months and 2 years was most significantly influenced by preoperative score (P < .0001). After adjustment for baseline AVVSSS, the following factors were identified in multivariate analysis as having a significant and independent positive (+) or negative (-) impact on AVVSSS: at 6 months, (-) recurrent disease (P = .009), (-) CEAP 4 disease (P = .026); and at 2 years, (+) long saphenous surgery (P = .02), (-) CEAP 5 disease (P = .030).

CONCLUSION: In this unselected series, saphenous surgery with or without subfascial endoscopic perforator surgery led to an improvement in disease-specific QoL in 87% of patients out to 2 years. Although univariate analysis results suggested that many baseline factors might be associated with outcome, multivariate analysis results suggested that only surgery for recurrent disease and for CEAP 4/5 disease remained as significant negative, and only long saphenous surgery as significant positive, independent prognostic factors. These data provide evidence of the medium-term clinical effectiveness of venous surgery across the full spectrum of CEAP clinical grades, show the importance of multivariate analysis, and reemphasize the importance of minimization of recurrence.

NICE Evidence Base Chapter: C.3.2 Duplex vs. No duplex prior to interventional treatment

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<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found</th>
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<td>C.3.2 Duplex vs. No duplex prior to interventional treatment</td>
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There is one key RCT with a number of follow up studies that informs the NICE guidelines on the need for duplex scans prior to interventional treatment. Only the first (2005) and last (2011) publications have been included.
**Evidence Level: 2 – RCT**

**BACKGROUND:**
Duplex imaging is used increasingly for preoperative evaluation of varicose veins, but its value in terms of the long-term results of surgery is not clear. 

**METHODS:**
Patients with primary varicose veins were randomized to operation with or without preoperative duplex imaging. Reoperation rates, clinical and duplex findings were compared at 2 months and 2 years after surgery.

**RESULTS:**
Two hundred and ninety-three patients (343 legs) had varicose vein surgery after duplex imaging (group 1; 166 legs) or no imaging (group 2; 177 legs). In 44 legs (26.5 per cent), duplex examination suggested a different surgical procedure than had been considered on clinical grounds; the procedure was changed accordingly for 29 legs. At 2 months, incompetence was detected at the saphenofemoral or saphenopopliteal junction (or both) in 14 legs (8.8 per cent) in group 1 and in 44 legs (26.5 per cent) in group 2 (P < 0.001). At 2 years, two legs (1.4 per cent) had undergone or were awaiting reoperation in group 1, and 14 legs (9.5 per cent) in group 2 (P = 0.002). In the remainder, major incompetence was found in 19 legs (15.0 per cent) in group 1 and in 53 (41.1 per cent) in group 2 (P < 0.001).

**CONCLUSION:**
Routine preoperative duplex examination led to an improvement in results 2 years after surgery for patients with primary varicose veins.

**Evidence Level: 2 – RCT**

**BACKGROUND:**
Routine preoperative duplex examination led to an improvement in results 2 years after surgery for primary varicose veins. The aim of the present study was to evaluate the impact of preoperative duplex imaging after 7 years, in relation to other risk factors for varicose vein recurrence.

**METHODS:**
Patients with primary varicose veins were randomized to operation with (group 1), or without (group 2) preoperative duplex imaging. The same patients were invited to attend follow-up with interview, clinical examination and duplex imaging. Quality of life (QoL) was measured with the Short Form 36 questionnaire.

**RESULTS:**
Some 293 patients (343 legs) were included initially; after 7 years 227 were interviewed, or their records reviewed: 114 in group 1 and 113 in group 2. One hundred and ninety-four legs (95 in group 1 and 99 in group 2) were examined clinically and with duplex imaging. Incompetence was seen at the saphenofemoral junction and/or saphenopopliteal junction in 14 per cent of legs in group 1 and 46 per cent in group 2 (P < 0.001). QoL was similar in both groups. After a mean follow-up of 7 years (and including patients who underwent surgery after the review), 15 legs in group 1 needed reoperation and 38 in group 2 (P = 0.001).

**CONCLUSION:**
Routine preoperative duplex imaging improved the results of surgery for primary varicose veins for at least 7 years.
Core Search Questions:
1) What are the key clinical criteria (e.g. eczema, ulcers, infection) for which the evidence shows value treating the varicose vein?
2) Does the evidence describe specific parameters of these criteria where therapeutic value is achieved? (e.g. length of time for ulcer to heal, number of episodes of thrombophlebitis)
3) Are there any comorbid conditions that would indicate varicose vein intervention?

Additional evidence presented within NICE Guidelines review - 2016
Nil added by NICE relevant to these research questions

Additional evidence review post publication of NICE guidelines in 2016

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<th>Summary of highest grade of evidence found</th>
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<td>Level 1</td>
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<td>Additional evidence review post publication of NICE guidelines in 2016</td>
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NHS Evidence
See PubMed section below – all relevant articles were linked to PubMed

Cochrane Library
Nil related to the research questions found

PubMed
17
Ismail L, Normahani P et al.

**Evidence Level: 1 – Systematic Review**

**OBJECTIVE:**
The association between pregnancy and the development of varicose veins is uncertain. We aimed to determine whether a history of pregnancy is associated with the development of varicose veins.

**METHODS:**
We performed a systematic literature search using the databases of PubMed, Embase, Robert Koch-Institut, and Cochrane Central and the references of included papers. Eligible studies were all epidemiologic observational studies in which the outcome "varicose veins" and pregnancy history were assessed. The quality of each study was evaluated on the basis of the Dutch Cochrane review checklist and by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement. For our meta-analysis, a random effects model was applied to pool odds ratios and 95% confidence intervals across studies.

**RESULTS:**
We found nine eligible studies enrolling 17,109 women. Pregnancy was associated with a significant risk increase in developing varicose veins. The results of our meta-analysis suggest that the odds for women with a history of pregnancy in developing varicose veins significantly increases by 82% (odds ratio, 1.82; 95% CI, 1.43-2.33) compared with women with no history of pregnancy. As expected for epidemiologic observational studies, the
heterogeneity was considerably high ($I(2) = 81\%$).

**CONCLUSIONS:**
Our meta-analysis strongly supports the hypothesis that there is a **significant and strong association between a history of pregnancy and varicose veins**. However, qualitative and quantitative differences among studies were evident and were also reflected in a considerably high heterogeneity.

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<th>Source</th>
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<tr>
<td>British Medical Journal (BMJ) including BMJ Best Practice and BMJ Clinical Evidence</td>
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<tr>
<td>Royal College of Surgeons</td>
<td>Nil related to the research questions found</td>
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<tr>
<td>Vascular Surgery Society</td>
<td>Nil related to the research questions found</td>
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**Core Search Questions:**
4) Does the evidence document an appropriate scoring system for severity of varicose veins?

**NICE Evidence Base Chapter**: Nil directly related to the research questions

The NICE Clinical Guidelines state:
Attempts to group like people together have been attempted with classifications such as the CEAP grading system. This provides a method of classifying varicose veins, providing information on the clinical severity, aetiology, anatomical location and pathophysiology of varicose veins. The clinical severity aspect of CEAP classification (for example, C1-C6) is used throughout the document, to match the outcomes used in the included randomised controlled trials.

However, the GDG recognise the limitations of using the clinical severity classification as an outcome measure, as it was not designed to be used as a measure of clinical change, or to provide referral criteria, and there is uncertainty about how the stages interact with each other.

**Additional evidence presented within NICE Guidelines review - 2016**

Nil added by NICE relevant to this research question

**Additional evidence review related to the research question**

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<td>Additional evidence review post publication of NICE guidelines in 2016</td>
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**18 Lattimer CR, Kalodiki E, Azzam M et al (2013)**

**Evidence Level: 3 – Prospective Cohort Study**

**ABSTRACT**
Rationing treatment of varicose veins (VVs) is of importance in countries with a public health service and limited funds. This study examines why and how the Aberdeen varicose vein questionnaire (AVVQ) can be used in achieving rationing. Baseline assessments prior to endovenous treatment included the venous clinical severity score (VCSS), venous filling index (VFI), and the refluxing great saphenous vein (GSV) diameter. Absolute change in the AVVQ defined improvement. There was no significant correlation in AVVQ improvement compared to baseline VCSS, VFI, GSV diameter or when patients were divided into mild and severe disease (C2,3 vs C4-6) or laser ablation versus foam sclerotherapy. However, AVVQ improvement significantly correlated at 3 weeks (n = 84) and 3 months (n = 70) with their baseline values \((r = .5\) and \(r = .585\), \(P < .0005\) (Spearman). In conclusion, patients with an initial poor quality of life may benefit most from endovenous treatment, irrespective of other baseline severity assessments.

**CONCLUSIONS**
On the basis of this study, the baseline AVVQ seemed to be the best predictor in identifying those patients who
improve the most after VV intervention. Clinical severity, CEAP classification, hemodynamic severity, or treatment type did not seem to make much difference. Since the aim of elective treatment is improvement in the QoL, it may be prudent to prioritize the use of this questionnaire over other baseline severity assessments for rationing patients with uncomplicated VVs.

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<th>Evidence Level: 3 – Cross-Sectional Study</th>
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<tr>
<td><strong>Abstract</strong></td>
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<td><strong>OBJECTIVES:</strong></td>
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<tr>
<td>To determine the relationship between lower limb symptoms and generic health-related quality of life (HRQL) in patients with varicose veins (VV).</td>
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<tr>
<td><strong>METHODS:</strong></td>
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<tr>
<td>284 patients on the waiting list for VV treatment completed the Short Form-12 (SF12) and a questionnaire asking about the presence of lower limb symptoms commonly attributed to venous disease (pain or ache, itching, tingling, cramp, restless legs, a feeling of swelling, and heaviness).</td>
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<td><strong>RESULTS:</strong></td>
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<tr>
<td>Median age was 57 years (interquartile range 45-67); 100 (35%) were male, and 182 (64%) had CEAP clinical grade 2 or 3 disease. Jonckheere-Terpstra test for trend revealed that both physical (P &lt; .0005) and mental (P = .001) HRQL worsened as the reported number of symptoms increased. Patients reporting tingling (P = .016, Mann-Whitney U test), cramp (P = .001), restless legs (P &lt; .0005), swelling (P &lt; .0005), and heaviness (P &lt; .0005) had a significantly worse physical HRQL than those who did not. Mental HRQL was also significantly worse in patients with tingling (P = .010), cramp (P = .008), restless legs (P = .040), swelling (P = .001), and heaviness (P = .035). These significant relationships remained, and pain was also correlated with worse physical HRQL (P = .011), when linear regression was performed to control for CEAP clinical grade, age and sex.</td>
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<tr>
<td><strong>CONCLUSIONS:</strong></td>
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<tr>
<td>Physical and mental HRQL is significantly worse in VV patients with lower limb symptoms irrespective of the clinical stage of disease. This observation confirms that VV are not primarily a cosmetic problem and that NHS rationing of treatment to those with CEAP C4-6 disease excludes many patients who would benefit from intervention in terms of HRQL. Generic HRQL instruments also allow comparison with interventions for other chronic conditions.</td>
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<table>
<thead>
<tr>
<th>Evidence Level: 3 – Prospective Cohort Study</th>
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<tbody>
<tr>
<td><strong>ABSTRACT</strong></td>
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<tr>
<td><strong>OBJECTIVES</strong></td>
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<tr>
<td>To determine the feasibility and reliability of an online patient completed Aberdeen Varicose Vein Questionnaire (AVQV) as a tool to guide specialist referral.</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
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<tr>
<td>This was a prospective qualitative and quantitative study. One hundred and six patients completed an online questionnaire. Some 43 (40%) completed the AVQV questionnaire at home and 63 (60%) did it immediately before their appointment.</td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
</tr>
<tr>
<td>Venous Clinical Severity Score (VCSS) and CEAP grades were assigned by a consultant vascular surgeon. In 11 patients, the questionnaire was repeated at the time of surgery to assess reproducibility and bias.</td>
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</table>
### RESULTS

The AVVQ correlated with the specialist's VCSS scores (Spearman coefficient 0.795; \( p < 0.01 \)) and similarly with CEAP grade (\( p < 0.01 \), ANOVA test). AVVQ was reproducible with close agreement (Spearman coefficient 0.89; \( p < 0.01 \)) between both 1st AVVQ score of 21.61 (sd 10.26; range 6.12–40.14) and 2nd AVVQ score of 21.03 (sd 10.50 range 4.51–42.57). Patients' feedback about the online AVVQ was positive.

**Conclusions**

An online questionnaire is acceptable to patients, correlates with clinical findings and using a threshold value could be used by healthcare Commissioners to guide varicose vein referrals.

### Evidence Level: 3 – Prospective Cohort Study

**OBJECTIVE:**

The wide variety of outcome measures to evaluate patients with varicose veins poses significant difficulties when comparing clinical trials. In addition, the relationship between different outcome measures is poorly understood. The aim of this study was to compare anatomical, hemodynamic, and clinical outcomes with disease-specific quality-of-life tools in patients undergoing treatment for varicose veins.

**METHODS:**

Patients undergoing treatment for symptomatic veins in a single unit were studied. Assessments included duplex ultrasonography, digital photoplethysmography, evaluation of Venous Clinical Severity Scores and CEAP scores, generic (Short Form 12 [SF12]) and disease-specific (Aberdeen Varicose Vein Questionnaire [AVVQ], and Specific Quality-of-life and Outcome Response-Venous [SQOR-V]) questionnaires. Patients were reviewed at 6 weeks when hemodynamic, clinical, and quality-of-life assessments were repeated. The relationships between these outcomes were assessed.

**RESULTS:**

The AVVQ showed a strong positive correlation with the SQOR-V (Spearman coefficient 0.702; \( p < .001 \)) and weaker, but significant correlations with the SF12 physical and mental component scores and the Venous Clinical Severity Score (VCSS) (\( p < .001 \), \( p = .019 \), and \( p < .001 \), respectively, Spearman correlation). No correlations were observed between the AVVQ and photoplethysmography results (Spearman coefficient -0.042; \( p = .606 \)), and weak correlations were observed with the AVVQ and anatomical reflux. At 6 weeks, functional, clinical, and hemodynamic measurements were all responsive to changes following interventions; however, correlations observed between changes in disease-specific quality-of-life and generic, clinical, and hemodynamic outcomes were weak.

**CONCLUSIONS:**

Both the AVVQ and SQOR-V questionnaires are sensitive and responsive disease-specific questionnaires, which correlate with generic and clinical outcomes to some extent. Anatomical and hemodynamic measurements correlated poorly with functional outcomes both preoperatively and following interventions.

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**Shepherd AC, Gohel MS, Lim CS, Davies AH.**

A study to compare disease-specific quality of life with clinical anatomical and hemodynamic assessments in patients with varicose veins.

Core Search Questions:
5) Does the evidence document the most appropriate treatment pathway i.e. endothermal ablation, followed by sclerotherapy?

NICE Evidence Base Chapter: C.4.1 Conservative treatment vs. no treatment

<table>
<thead>
<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found</th>
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<tr>
<td>C.4.1 Conservative treatment vs. no treatment</td>
<td>[✓]</td>
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</table>

The following is the highest level evidence within the NICE guidelines. Lower level evidence is not presented here but can be found in the full NICE guidelines referenced above. Where more than one study exists within the evidence level, the most recently published will be presented here.


Evidence Level: 2 - RCT

AIM:
The aim of this study was to compare the efficacy of Class 1 (10-15 mmHg at the ankle) compression stockings with that of reference stockings of identical appearance during the early stages of chronic venous disease (CVD).

METHODS:
A prospective multi-center randomized double blind crossover study was conducted on 2 groups of female patients presenting with CVD with a CEAP classification of C1-3SEp As1-5. The efficacy of Class 1 compression stockings was evaluated with respect to global painful discomfort (visual analog scale), each symptom of CVD, the daily behavior of the patient, changes in the volume of the legs, and the functioning of the venous pump (D-PPG). The compliance level of each patient was measured by the number of days that she wore the stockings for at least 6 hours, and tolerance was measured by the reporting of ensuing undesirable events.

RESULTS:
A total of 125 patients were included in the study and were analyzed for intent to treat. Highly significant differences favoring Class 1 compression stockings were noted with respect to both global painful discomfort and each symptom of CVD with the exception of paresthesia. The relief of symptoms that resulted from the use of the Class 1 compression stockings was twice that which resulted from the use of the reference stockings. Differences that favored the Class 1 compression stockings were also observed with respect to 2 quality-of-life factors (mood and daily work activity). Good compliance in the use of the stockings was reported for 95% of the patients, and tolerance was higher for the Class 1 compression stockings group than for the reference group.

CONCLUSION:
The regular wearing of Class 1 graduated elastic compression stockings during a 15-day period results in a significant improvement in the symptomatology of early-stage chronic venous disease, i.e., in the relief of global painful
discomfort as well as in quality-of-life criteria. A high level of patient compliance in the wearing of the stockings was achieved in this study.

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<tr>
<th>Added to NICE evidence base in 2016 review of the guidelines: NICE Verdict – Relevant but does not alter guidelines</th>
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<tr>
<td><strong>23</strong> Aguilar-Ferrandiz ME, Castro-Sanchez AM, Mataran-Penarrocha GA et al. (2014)</td>
</tr>
<tr>
<td>A randomized controlled trial of a mixed Kinesio taping-compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency. Clinical Rehabilitation 28:69-81</td>
</tr>
<tr>
<td><strong>Evidence Level: 2 - RCT</strong></td>
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<tr>
<td><strong>OBJECTIVES:</strong> To investigate the effect of a mixed Kinesio taping treatment in women with chronic venous insufficiency.</td>
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<tr>
<td><strong>DESIGN:</strong> A double-blinded randomized clinical trial.</td>
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<td><strong>SETTING:</strong> Clinical setting.</td>
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<td><strong>PARTICIPANTS:</strong> One hundred and twenty postmenopausal women with mild-moderate chronic venous insufficiency were randomly assigned to an experimental group receiving standardized Kinesio taping treatment for gastrocnemius muscle enhancement and ankle functional correction, or to a placebo control group for simulated Kinesio taping. MAIN OUTCOMES VARIABLES: Venous symptoms, pain, photoplethysmographic measurements, bioelectrical impedance, temperature, severity and overall health were recorded at baseline and after four weeks of treatment.</td>
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<tr>
<td><strong>RESULTS:</strong> The 2 x 2 mixed model ANCOVA with repeated measurements showed statistically significant group * time interaction for heaviness (F = 22.99, p = 0.002), claudication (F = 8.57, p = 0.004), swelling (F = 22.58, p = 0.001), muscle cramps (F = 7.14, p = 0.008), venous refill time (right: F = 9.45, p = 0.023; left: F = 14.86, p = 0.001), venous pump function (right: F = 35.55, p = 0.004; left: F = 17.39 p = 0.001), extracellular water (right: F = 35.55, p = 0.004; left: F = 23.84, p = 0.001), severity (F = 18.47, p = 0.001), physical function (F = 9.15, p = 0.003) and body pain (F = 3.36, p = 0.043). Both groups reported significant reduction in pain.</td>
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<tr>
<td><strong>CONCLUSION:</strong> Mixed Kinesio taping-compression therapy improves symptoms, peripheral venous flow and severity and slightly increases overall health status in females with mild chronic venous insufficiency. Kinesio taping may have a placebo effect on pain.</td>
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NICE Evidence Base Chapter: C.4.2 Compression Vs interventional treatment

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<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found</th>
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<tr>
<td>C.4.2 Compression Vs interventional treatment</td>
<td>Level 1</td>
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<table>
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<tr>
<th>Evidence Level: 2 - RCT</th>
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| **24** Michaels JA, Brazier JE, Campbell WB, MacIntyre JB, Palfreyman SJ, Ratcliffe J.  
Randomised clinical trial comparing surgery with conservative treatment for uncomplicated varicose veins.  
British Journal of Surgery 2006; 93: 175181 |
| **BACKGROUND:**  
Surgical treatment of medically uncomplicated varicose veins is common, but its clinical effectiveness remains uncertain.  
**METHODS:**  
A randomized clinical trial was carried out at two large acute National Health Service hospitals in different parts of the UK (Sheffield and Exeter). Some 246 patients were recruited from 536 consecutive referrals to vascular outpatient clinics with uncomplicated varicose veins suitable for surgical treatment. Conservative management, consisting of lifestyle advice, was compared with surgical treatment (flush ligation of sites of reflux, stripping of the long saphenous vein and multiple phlebectomies, as appropriate). Changes in health status were measured using the Short Form (SF) 6D and EuroQol (EQ) 5D, quality of life instruments based on SF-36 and EuroQol, complications of treatment, symptomatic measures, anatomical extent of varicose veins and patient satisfaction.  
**RESULTS:**  
In the first 2 years after treatment there was a significant quality of life benefit for surgery of 0.083 (95 per cent confidence interval (c.i.) 0.005 to 0.16) quality-adjusted life years (QALYs) based on the SF-6D score and 0.13 (95 per cent c.i. 0.016 to 0.25) based on the EQ-5D score. Significant benefits were also seen in symptomatic and anatomical measures.  
**CONCLUSION:**  
Surgical treatment provides symptomatic relief and significant improvements in quality of life in patients referred to secondary care with uncomplicated varicose veins. |

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<th>Evidence Level: 2 - RCT</th>
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</table>
| **25** Michaels JA, Campbell WB, Brazier JE, MacIntyre JB, Palfreyman SJ, Ratcliffe J, Rigby K.  
Randomised clinical trial, observational study and assessment |
| **OBJECTIVES:**  
To establish the cost-effectiveness of surgery and sclerotherapy for the treatment of varicose veins.  
**DESIGN:**  
Randomised controlled trials (RCTs) were carried out for conservative treatment, sclerotherapy and surgery for varicose veins. An economic analysis was carried out alongside the randomised trial. Economic modelling was
of costeffectiveness of the treatment of varicose veins (REATIV trial).

undertaken based on the primary data collection and a literature review (database searches undertaken in April 2000 and updated in March 2001).

SETTING:
Primary data collection was from a large district general hospital and a teaching hospital both in England over a 2-year period from January 1999. Cost-effectiveness analysis and economic modelling were carried out using an NHS perspective.

PARTICIPANTS:
A total of 1009 patients were recruited.

INTERVENTIONS:
Thirty-four patents were randomised in Group 1 (minor varicose veins with no reflux, randomised between conservative treatment and sclerotherapy), 77 in Group 2 (moderate varicose veins with reflux, randomised between surgery and sclerotherapy) and 246 in Group 3 (severe varicose veins with reflux, randomised between conservative treatment and surgery). The remaining 652 patients formed the observational part of the study.

MAIN OUTCOME MEASURES:
The cost-effectiveness analysis was based on NHS treatment costs for the 2002--3 financial year, and utilities based on the Short Form 6D (SF-6D) preference-based health measure. For the clinical trial, the outcome measures were health-related quality of life (HRQoL) [Short Form with 36 Items (SF-36), EuroQol quality of life questionnaire (EQ-5D), visual analogue scale (VAS) and standard gamble], symptomatic relief, anatomical extent (for which a new classification was developed and validated), patient satisfaction and the incidence of complications.

RESULTS:
Of the RCTs, only the Group 3 trial was large enough to provide clear results. This showed that surgical treatment produced better results than conservative treatment in terms of HRQoL, symptomatic relief, anatomical extent and patient satisfaction. Clinical outcomes of surgery and sclerotherapy showed significant improvement in the extent of varicose veins, symptomatic and HRQoL parameters. Cost-effectiveness analysis based on the Group 3 trial showed that surgery produced an estimated discounted benefit of 0.054 quality-adjusted life-year (QALY) over a 2-year period, with an additional discounted cost of pound 387.45, giving an incremental cost-effectiveness ratio (ICER) of pound 7175 per QALY. Economic modelling suggested that surgery produced a still greater benefit when considered with a 10-year time horizon, with an ICER of pound 1936 per QALY. Injection sclerotherapy produced an incremental benefit of approximately 0.044 QALY at a cost of pound 155 when compared with conservative treatment, giving an ICER of pound 3500 per QALY. When surgery was compared with sclerotherapy, surgery produced greater benefit with a lower ICER (showing extended dominance).

CONCLUSIONS:
Standard surgical treatment of varicose veins by saphenofemoral ligation, stripping and multiple phlebectomies is a clinically effective and cost-effective treatment for varicose veins, with an ICER well below the threshold normally considered appropriate for the funding of treatments within the NHS. Injection sclerotherapy also appears to be cost-effective, but produces less overall benefit, with a higher ICER than surgery for patients with superficial venous reflux. In minor varicose veins without reflux, sclerotherapy is likely to provide a small average benefit with acceptable cost-effectiveness. Research is needed into methods for accurate and acceptable utility evaluations for conditions with relatively minor effect on HRQoL and also for a validated and standardised method of classification for varicose veins.
OBJECTIVE:
Superficial venous reflux and varicose veins are common. The aim of this randomized controlled trial was to assess effectiveness of compression therapy compared with surgery for superficial venous reflux.

METHODS:
153 patients with CEAP class C2-C3 and superficial venous reflux were randomized to receive either conservative treatment (compression stockings) (n = 77) or surgery (n = 76). Clinical examination including duplex ultrasound (DUS) was performed at entry and 1 and 2 years after randomization (compression group) or surgery (surgery group). Venous Clinical Severity Score without compression stockings (VCSS-S), Venous Segmental Disease Score (VSDS), Venous Disability Score (VDS), and health-related quality of life (HRQoL) were assessed at entry and at the follow-ups. Data were analysed on an intention-to-treat basis and according to the actual treatment performed.

RESULTS:
At 2 years, 70/76 patients in the surgery group and 11/77 patients in the compression group had been operated on. VCSS-S decreased from 4.6 to 3.5 in the compression group (p < .01) and from 4.8 to 0.6 in the surgery group (p < .001). VSDS decreased from 7.7 to 7.0 in the compression group and from 8.2 to 0.9 in the surgery group (p < .0001). HRQoL did not change in the compression group, but improved significantly in the surgery group.

CONCLUSION:
The surgical elimination of non-complicated superficial venous reflux is an effective treatment when compared with providing compression stockings only.

NICE Evidence Base Chapter: C.5.1 Stripping surgery vs. foam sclerotherapy

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<tr>
<th>Related chapter from NICE evidence base</th>
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<tr>
<td>C.5.1 Stripping surgery vs. foam sclerotherapy</td>
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The following is the highest level evidence within the NICE guidelines. Lower level evidence is not presented here but can be found in the full NICE guidelines referenced above. Where more than one study exists within the evidence level, the most recently published will be presented here.
27 Shadid N, Ceulen R, Nelemans P. et al. 
Randomised clinical trial of ultrasound guided foam sclerotherapy versus surgery for the incompetent great saphenous vein. 
British Journal of Surgery, 2012 Aug;99(8): 1062-70

Evidence Level: 2 - RCT

BACKGROUND: 
New minimally invasive treatment modalities, such as ultrasound-guided foam sclerotherapy (UGFS), are becoming more popular. In a multicentre randomized controlled non-inferiority trial, the effectiveness and costs of UGFS and surgery for treatment of the incompetent great saphenous vein (GSV) were compared.

METHODS: 
Patients with primary great saphenous varicose veins were assigned randomly to either UGFS or surgical stripping with high ligation. Recurrence, defined as reflux combined with venous symptoms, was determined on colour duplex scans at baseline, 3 months, 1 year and 2 years after initial treatment. Secondary outcomes were presence of recurrent reflux (irrespective of symptoms), reduction of symptoms, health-related quality of life (EQ-5D(™)), adverse events and direct hospital costs.

RESULTS: 
Two hundred and thirty patients were treated by UGFS and 200 underwent GSV stripping. The 2-year probability of recurrence was similar in the UGFS and surgery groups: 11·3 per cent (24 of 213) and 9·0 per cent (16 of 177) respectively (P = 0·407). At 2 years, reflux irrespective of venous symptoms was significantly more frequent in the UGFS group (35·0 per cent) than in the surgery group (21·0 per cent) (P = 0·003). Mean(s.d.) hospital costs per patient over 2 years were €774(344) per patient for UGFS and €1824(141) for stripping.

CONCLUSION: 
At 2-year follow-up, UGFS was not inferior to surgery when reflux associated with venous symptoms was the clinical outcome of interest. UGFS has the potential to be a cost-effective approach to a common health problem.

Added to NICE evidence base in 2016 review of the guidelines: NICE Verdict – Relevant but does not alter guidelines


Evidence Level: 2 - RCT

INTRODUCTION: 
This study compares the outcome 3 years after treatment of varicose veins by endovenous laser ablation (EVLA), radiofrequency ablation, ultrasound-guided foam sclerotherapy (UGFS), or surgery by assessing recurrence, Venous Clinical Severity Score (VCSS), and quality of life (QOL).

METHODS: 
A total of 500 patients (580 legs) were randomized to one of the three endovenous treatments or high ligation and stripping of the great saphenous vein (GSV). Follow-up included clinical and duplex ultrasound examinations and VCSS and QOL questionnaires. Kaplan-Meier (KM) life-table analysis was used. P values below .05 were considered statistically significant.

RESULTS: 
At 3 years, eight (KM estimate, 7%), eight (KM estimate, 6.8%), 31 (KM estimate, 26.4%), and eight (KM estimate, 6.5%) of GSVs recanalized or had a failed stripping procedure (more than 10 cm open refluxing part of the treated GSV; CLF, EVLA, UGFS, and stripping, respectively; P < .01). Seventeen (KM estimate, 14.9%), 24 (KM estimate, 20%), 20 (KM estimate, 19.1%), and 22 (KM estimate, 20.2%) legs developed recurrent varicose veins (P = NS). The patterns of reflux and location of recurrent varicose veins were not different between the groups. Within 3 years after treatment, 12 (KM estimate, 11.1%), 14 (KM estimate, 12.5%), 37 (KM estimate, 31.6%), and 18 (KM
(estimate, 15.5%) legs were retreated in the CLF, EVLA, UGFS, and stripping groups, respectively (P < .01). VCSS, SF-36, and Aberdeen QOL scores improved significantly in all the groups with no difference between the groups. CONCLUSIONS: All treatment modalities were efficacious and resulted in a similar improvement in VCSS and QOL. However, more recanalization and reoperations were seen after UGFS.

NICE Justification: The new evidence is a longer term follow-up of an RCT that was included in the guideline. The findings of this 3-year report show that all four treatment modalities were effective and resulted in similar improvements in severity scores and quality of life. These results are similar to the results at 1 year that were included in the guideline. In addition, this review question (comparing stripping surgery with foam sclerotherapy) is linked to the other four review questions below on interventional treatment (one question comparing stripping surgery with endothermal ablation, one question comparing foam sclerotherapy with endothermal ablation; and two questions comparing treatment options for tributary veins), with the recommendation on interventional treatment in the guideline coming from an overall consideration of the evidence from these five review questions. Therefore, this new evidence is unlikely to change the direction of the current recommendation (1.3.2) which prescribes the following sequence for people with confirmed varicose veins and truncal reflux: 1) endothermal ablation 2) ultrasound-guided foam sclerotherapy, if endothermal ablation is unsuitable 3) surgery, if ultrasound-guided foam sclerotherapy is unsuitable.

**NICE Evidence Base Chapter: C.5.2 Stripping surgery vs endothermal ablation**

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<tr>
<th>Related chapter from NICE evidence base</th>
<th>Summary of highest grade of evidence found</th>
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<tr>
<td>C.5.2 Stripping surgery vs endothermal ablation</td>
<td>![Level 2 - RCT]</td>
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</table>

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**29 Flessenkremp I, Hartmann M, Stenger D, Roll S.**

Endovenous laser ablation with and without high ligation compared with high ligation and stripping in the treatment of great saphenous varicose veins: initial results of a

**Evidence Level: 2 - RCT**

**OBJECTIVES:** To compare reflux recurrences at the saphenofemoral junction after endovenous laser ablation (EVLA) with or without high ligation with high ligation and stripping (HL/ST) of the great saphenous vein (GSV) in patients with varicosity of the GSV. Design Multicentre, randomized, three-arm, parallel trial. Material and Methods Patients with varicosity of the GSV were randomized to one of three groups: HL/ST, laser ablation (980 nm) or a combination of laser ablation with high ligation (EVLA/HL). Patients were examined clinically and by ultrasound pre- and postoperatively and after two months. The primary endpoint of this ongoing study is the inguinal venous reflux (IVR).
multicentre randomised controlled trial. Phlebology 2013 Feb 28(1):16-23

in the proximal section of the GSV after two years. We present data after two months. Secondary endpoints include postoperative ecchymosis, pain or discomfort, saphenous syndrome. Groups were compared by chi-squared test.

**RESULTS:**
A total of 449 patients were randomized; mean age 48 years and 71.2% were women. Postoperative ecchymosis developed among 69.2% in the HL/ST group, in 50.4% of the EVLA group and in 50.3% of the EVLA/HL group (P = 0.0007). Postoperative pain after one day occurred in 32.7% in the HL/ST group. Discomfort occurred after surgery in 37.3% in the EVLA group, and in 50.0% in the EVLA/HL group (P = 0.0069). Early postoperative nerve saphenous syndrome developed in 0.6% in the HL/ST group, in 3.7% in the EVLA group and in 6.1% in the EVLA/HL group (P = 0.0341). After two months, IVR persisted in 38 cases (8.5%) in the laser group, in 10 (2.2%) in the EVLA/HL group and none in the HL/ST group (P = 0.6800).

**CONCLUSIONS:**
After two months IVR was more often seen in both EVLA groups compared with the HL/ST group. There were significantly more postoperative ecchymosis in the HL/ST. Postoperative pain occurred significantly more often in the EVLA/HL group. Peri- and postoperative data showed significant differences between the three groups. For definitive results concerning the primary endpoint of IVR the later follow-up has to be waited for.

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**Added to NICE evidence base in 2016 review of the guidelines: NICE Verdict – Relevant but does not alter guidelines**

<table>
<thead>
<tr>
<th>Evidence Level: 2 – RCT – multiple RCTs referenced here</th>
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<tbody>
<tr>
<td>The following is reproduced from the NICE Surveillance Evidence Decision Matrix: Appendix A</td>
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<tr>
<td>Two publications of one UK NIHR HTA-funded multi-centre-RCT (the CLASS trial) (Brittenden J et al, 2015 and 2014) compared the clinical and cost-effectiveness of surgery, foam sclerotherapy and laser ablation (n=798). Results at 6 months revealed that the health gain achieved in the Aberdeen Varicose Vein Questionnaire (AVVQ) with foam sclerotherapy was significantly lower than with surgery, but was similar to that achieved with laser ablation. There were no significant differences between the three groups in generic QoL measures. Cost-effectiveness analysis suggested that, at 5 years, laser ablation would be most cost-effective at conventional thresholds, followed by foam sclerotherapy and surgery. There were significantly fewer procedural complications in the laser ablation group than after foam and surgery. There were no differences in VCSS between the three treatments. Truncal ablation rates were similar for surgery and laser ablation, with rates for both being significantly higher than for foam sclerotherapy.</td>
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<tr>
<td>A cost-effectiveness study (Tassie E et al, 2014) of the CLASS trial found that at 6 months, foam sclerotherapy and laser ablation were cheaper than surgery on the average, and were even cheaper when costs associated with the use of the operation theatre were included. Foam sclerotherapy produced fewer quality-adjusted life years (QALYs), whereas laser ablation produced additional QALYs. Extrapolating to 5 years, laser ablation was associated with increased costs and QALYs compared with foam sclerotherapy, and generated cost savings and QALY gain compared with surgery. However, laser ablation was the most cost-effective</td>
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treatment strategy when a threshold of £20 000 per QALY gained was used. A multi-centre RCT (Flessenkamper et al, 2013) comparing surgery and laser ablation with and without high ligation, for varicosity of the great saphenous vein (n=449) found significantly more reflexive side-branches in the laser ablation groups, but no significant differences for recurrences and sonographic reflux between groups. There was also significantly more matting and postoperative restrictions, lymphatic oedema and sensory disturbance of the saphenous nerve in the two laser groups compared with surgery. One RCT (Mozafar M. et al, 2014) of laser ablation of the great saphenous vein (GSV) compared to surgery (n=65) found similar occlusion rates in both groups at the 18-month follow-up. There were significant reductions in median CEAP scores in both groups after 1 week and for the rest of the study. The Aberdeen Varicose Vein Symptom Severity score was significantly lower in the laser ablation group at the 12- and 18-month follow-ups. There was no significant difference in patient satisfaction in both groups. One RCT (Nandhra S. et al, 2015) of conventional surgery versus laser ablation for small saphenous varicose veins (n=106) found no significant difference in clinical recurrence, sensory disturbance or any quality of life domain in the two groups, but laser ablation was significantly better than surgery in eliminating axial reflux. A 5-year follow-up data of an RCT (Kalteis M. et al, 2015) comparing high ligation and stripping with high ligation and laser ablation of the great saphenous vein (n=100) found high patient satisfaction as well as significant improvements for both groups in CEAP-C class, VCSS, and the CIVIQ2 quality of life score. There was no difference in recurrence rates or rates of reopened or residual incompetent GSV between the two groups. A 5-year follow-up of an RCT included in the guideline (Rasmussen L. et al, 2013) comparing laser ablation with open surgery in patients with great saphenous vein incompetence (n=121 patients, 137 legs) found no significant differences between the groups in the number of open refluxing segments of 5 cm or more, clinical recurrence, reoperations, VCSS, Aberdeen VVSS or SF-36 quality of life scores. One RCT (Roopram AD. et al, 2013) of laser ablation versus surgery in the treatment of small saphenous vein incompetence (n=175) found a much higher residual incompetence, higher rates of surgical site infection, longer operation time and significantly more neurological complications in the surgery group compared to laser ablation at 6 weeks. the laser ablation group experienced more pain after one week of treatment compared to surgery, however, both interventions resulted in less pain after 6 weeks. There was no significant difference between the groups for quality of life but there was quicker return to work and better appreciation of the scar after laser ablation. One RCT (Yang L et al., 2013) of endovenous microwave ablation (EMA) with high ligation versus conventional surgery alone (n=not reported in abstract) revealed complete occlusion of varicose veins, lower rate of recurrence, shorter operative time, less bleeding and smaller incisions with EMA than with surgery. There were no significant differences in AVVQ and VCSS scores between the groups although both groups had significant improvements in these scores.

Following treatment. There were a few skin burns in the EMA group but there were fewer sensory changes and bruises.

**NICE Evidence Base Chapter: C.5.3 Foam sclerotherapy vs endothermal ablation**

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<th>Related chapter from NICE evidence base</th>
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<td>C.5.3 Foam sclerotherapy vs endothermal ablation</td>
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The following is the highest level evidence within the NICE guidelines. Lower level evidence is not presented here but can be found in the full NICE guidelines referenced above. Where more than one study exists within the evidence level, the most recently published will be presented here.

Lattimer CR, Azzam M, Kalodiki E, et al

Cost and effectiveness of laser with phlebectomies compared with foam sclerotherapy in superficial venous insufficiency. Early results of a randomised controlled trial. Eur J Vasc and Endovasc Surg 2012; 43: 594600

**Evidence Level: 2 - RCT**

**OBJECTIVES:**
Quantify endovenous laser ablation (EVLA) with concurrent phlebectomies and ultrasound-guided foam sclerotherapy (UGFS) in cost and effectiveness at 3 weeks and 3 months.

**DESIGN:**
Single-centre, prospective, randomised controlled trial.

**PATIENTS:**
One hundred patients (100 legs), C(2-6), age 21-78, M:F 42:58, with primary varicose veins received either EVLA under local anaesthetic or UGFS.

**METHODS:**
Assessments included duplex, Aberdeen varicose vein questionnaire (AVVQ), venous clinical severity score (VCSS), venous filling index (VFI), visual analogue 7-day pain score and analgesia requirements. Additional treatments with UGFS were performed, if required. Micro-costing, using individually timed treatments, was based on consumables, staff pay and overheads.

**RESULTS:**
Changes in AVVQ, VCSS and VFI values (3 months) did not demonstrate any significant difference between groups. At 3 months, the above-knee GSV occlusion rate (without co-existing reflux) was not significantly different between the groups (74% vs 69%; EVLA vs UGFS; P = .596). Of the 9 haemodynamic failures in each group, 7 EVLA patients and 4 UGFS patients had co-existing cross-sectional above-knee GSV occlusion at some point. However, UGFS significantly outperformed EVLA in cost, treatment duration, pain, analgesia requirements and recovery.
CONCLUSIONS:
UGFS is 3.15 times less expensive than EVLA (£230.24 vs £724.72) with comparable effectiveness but 56% (versus 6%) required additional foam.

### Added to NICE evidence base in 2016 review of the guidelines: NICE Verdict – Relevant but does not alter guidelines

#### Evidence Level: 2 – RCT - multiple RCTs referenced here

The following is reproduced from the NICE Surveillance Evidence Decision Matrix: Appendix A

A 3-year follow up of an RCT included in the guideline (Rasmussen L et al, 2013) comparing four treatments for varicose great saphenous veins - surgery, foam sclerotherapy, laser ablation and radiofrequency ablation (n=500, 580 legs) found significantly more treatment failures and reoperations following UGFS compared to the other treatments. There were no significant differences between groups for recurrence, with similar patterns of reflux and location of recurrent varicose veins between the groups. All four treatments improved VCSS and quality of life, with no significant differences between the groups.

A 15-month follow up of an RCT included in the guideline (Lattimer CR et al, 2013) comparing laser ablation (accompanied by surgical removal of tributary veins) with foam sclerotherapy of the truncal vein only (n=100, 100 legs) found that occlusion of the great saphenous vein was more effective with laser ablation compared to foam sclerotherapy. However, both methods were equally effective at abolishing global venous reflux. Reductions in VCSS, AVVQ and the saphenous treatment score were significant compared to baseline, but there were no significant differences between the groups.

Two publications of one UK NIHR HTA-funded multicentre-RCT (the CLASS trial) (Brittenden J et al, 2015 and 2014) compared the clinical and cost-effectiveness of surgery, foam sclerotherapy and laser ablation (n=798). Results at 6 months revealed that the health gain achieved in the Aberdeen Varicose Vein Questionnaire (AVVQ) with foam sclerotherapy was significantly lower than with surgery, but was similar to that achieved with laser ablation. There were no significant differences between the three groups in generic QoL measures. Cost-effectiveness analysis suggested that, at 5 years, laser ablation would be most cost-effective at conventional thresholds, followed by foam sclerotherapy and surgery. There were significantly fewer procedural complications in the laser ablation group than after foam and surgery. There were no differences in VCSS between the three treatments. Truncal ablation rates were similar for surgery and laser ablation, with rates for both being significantly higher than for foam sclerotherapy. A cost-effectiveness study6 of the CLASS trial found that at 6 months, foam sclerotherapy and laser ablation were cheaper than surgery on the average, and were even cheaper when costs associated with the use of the operation theatre were included. Foam sclerotherapy produced fewer quality-adjusted life years (QALYs), whereas laser ablation produced additional QALYs. Extrapolating to 5 years, laser ablation was associated with increased costs and QALYs compared with foam sclerotherapy, and generated cost savings and QALY gain compared with surgery. However, laser ablation was the most cost-effective treatment strategy when a threshold of £20 000 per QALY gained was used.

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**42** Lattimer CR, Kalodiki E, Azzam M et al. (2013) Interim results on abolishing reflux alongside a randomized clinical trial on laser ablation with phlebectomies versus foam sclerotherapy. International Angiology 32:394-403.


Core Search Questions:
5) Does the evidence document the most appropriate treatment pathway i.e. endothermal ablation, followed by sclerotherapy?

Additional evidence review post publication of NICE guidelines in 2016

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<td>Additional evidence review post publication of NICE guidelines in 2016</td>
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Only Level 1 evidence has been presented below.


**Evidence Level: 1 – Systematic Review**

**BACKGROUND:**
Short (or small) saphenous vein (SSV) varices occur as a result of an incompetent sapheno-popliteal junction, where the SSV joins the popliteal vein, resulting in reflux in the SSV; they account for about 15% of varicose veins. Untreated varicose veins may sometimes lead to ulceration of the leg, which is difficult to manage. Traditionally, treatment was restricted to surgery or conservative management. Since the 1990s, however, a number of minimally invasive techniques have been developed; these do not normally require a general anaesthetic, are day-case procedures with a quicker return to normal activities and avoid the risk of wound infection which may occur following surgery. Nerve injury remains a risk with thermal ablation, but in cases where it does occur, the injury tends to be transient.

**OBJECTIVES:**
To compare the effectiveness of endovenous laser ablation (EVLA), radiofrequency ablation (RFA) and ultrasound-guided foam sclerotherapy (UGFS) versus conventional surgery in the treatment of SSV varices.

**SEARCH METHODS:**
The Cochrane Vascular Information Specialist searched the Specialised Register (last searched 17 March 2016) and the Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 2). We searched clinical trials databases for details of ongoing or unpublished studies.

**SELECTION CRITERIA:**
We considered all randomised controlled trials (RCTs) comparing EVLA, endovenous RFA or UGFS with conventional surgery in the treatment of SSV varices for inclusion.

**DATA COLLECTION AND ANALYSIS:**
We independently reviewed, assessed and selected trials that met the inclusion criteria; any disagreements were resolved by discussion. We extracted data and used the Cochrane's tool for assessing risk of bias. When the data permitted, we performed either fixed-effect meta-analyses with odds ratios (ORs) and 95% confidence intervals (CIs) or random-effects meta-analyses where there was moderate to significant heterogeneity.

**MAIN RESULTS:**
We identified three RCTs, all of which compared EVLA with surgery; one also compared UGFS with surgery. There were no trials comparing RFA with surgery. The EVLA versus surgery comparison included 311 participants: 185 received EVLA and 126 received surgery. In the UGFS comparison, each treatment group contained 21 people. For several outcomes in the EVLA comparison, only a single study provided relevant data; as a result, the current review is limited in its ability to demonstrate meaningful results for some planned outcomes. The quality of evidence according to GRADE was moderate to low for the outcome measures in the EVLA versus surgery comparison, but low for the UGFS versus surgery comparison. Reasons for downgrading in the EVLA versus surgery comparison were risk of bias (for some outcomes, the outcome assessors were not blinded; and in one study the EVLA-surgery allocation of 2:1 did not appear to be prespecified); imprecision (data were only available from a single small study and the CIs were relatively wide); indirectness (one trial reported results at six months rather than one year and was inadequately powered for SSV varices-only analysis). Reasons for downgrading in the UGFS versus surgery comparison were imprecision (only one trial offered UGFS and several participants were missing from the analysis) and a limitation in design (the study was inadequately powered for SSV participants alone).

For the EVLA versus surgery comparison, recanalisation or persistence of reflux at six weeks occurred less frequently in the EVLA group than in the surgery group (OR 0.07, 95% CI 0.02 to 0.22; I² = 51%; 289 participants, 3 studies, moderate-quality evidence). Recurrence of reflux at one year was also less frequent in the EVLA group than in the surgery group (OR 0.24, 95% CI 0.07 to 0.77; I² = 0%; 119 participants, 2 studies, low-quality evidence). For the outcome clinical evidence of recurrence (i.e. presence of new visible varicose veins) at one year, there was no difference between the two treatment groups (OR 0.54, 95% CI 0.17 to 1.75; 99 participants, 1 study, low-quality evidence). Four participants each in the EVLA and surgery groups required reintervention due to technical failure (99 participants, 1 study, moderate-quality evidence). There was no difference between the two treatment groups for disease-specific quality of life (QoL) (Aberdeen Varicose Veins Questionnaire) either at six weeks (mean difference (MD) 0.15, 95% CI -1.65 to 1.95; I² = 0%; 265 participants, 2 studies, moderate-quality evidence), or at one year (MD -1.08, 95% CI -3.39 to 1.23; 99 participants, 1 study, low-quality evidence). Main complications reported at six weeks were sural nerve injury, wound infection and deep venous thrombosis (DVT) (one DVT case in each treatment group; EVLA: 1/161, 0.6%; surgery 1/104, 1%; 265 participants, 2 studies, moderate-quality evidence). For the UGFS versus surgery comparison, there were insufficient data to detect clear differences between the two treatment groups for the two outcomes recanalisation or persistence of reflux at six weeks (OR 0.34, 95% CI 0.06 to 2.10; 33
participants, 1 study, low-quality evidence), and recurrence of reflux at one year (OR 1.19, 95% CI 0.29 to 4.92; 31 participants, 1 study, low-quality evidence). No other outcomes could be reported for this comparison because the study data were not stratified according to saphenous vein.

**AUTHORS' CONCLUSIONS:**

Moderate- to low-quality evidence exists to suggest that recanalisation or persistence of reflux at six weeks and recurrence of reflux at one year are less frequent when EVLA is performed, compared with conventional surgery. For the UGFS versus conventional surgery comparison, the quality of evidence is assessed to be low; consequently, the effectiveness of UGFS compared with conventional surgery in the treatment of SSV varices is uncertain. Further RCTs for all comparisons are required with longer follow-up (at least five years). In addition, measurement of outcomes such as recurrence of reflux, time taken to return to work, duration of procedure, pain, etc., and choice of time points during follow-up should be standardised such that future trials evaluating newer technologies can be compared efficiently.


**Evidence Level: 1 – Systematic Review**

**BACKGROUND:**

Varicose veins can affect quality of life. Patient-reported outcome measures (PROMs) provide a direct report from the patient about the impact of the disease without interpretation from clinicians or anyone else. The aim of this study was to examine the quality of the psychometric evidence for PROMs used in patients with varicose veins.

**METHODS:**

A systematic review was undertaken to identify studies that reported the psychometric properties of generic and disease-specific PROMs in patients with varicose veins. Literature searches were conducted in databases including MEDLINE, up to July 2016. The psychometric criteria used to assess these studies were adapted from published recommendations in accordance with US Food and Drug Administration guidance.

**RESULTS:**

Nine studies were included which reported on aspects of the development and/or validation of one generic (36-Item Short Form Health Survey, SF-36®) and three disease-specific (Aberdeen Varicose Vein Questionnaire, AVVQ; Varicose Veins Symptoms Questionnaire, VVSymQ®; Specific Quality-of-life and Outcome Response - Venous, SQOR-V) PROMs. The evidence from included studies provided data to support the construct validity, test-retest reliability and responsiveness of the AVVQ. However, its content validity, including weighting of the AVVQ questions, was biased and based on the opinion of clinicians, and the instrument had poor acceptability. VVSymQ® displayed good responsiveness and acceptability rates. SF-36® was considered to have satisfactory responsiveness and internal consistency.

**CONCLUSION:**

There is a scarcity of psychometric evidence for PROMs used in patients with varicose veins. These data suggest that AVVQ and SF-36® are the most rigorously evaluated PROMs in patients with varicose veins.


**Evidence Level: 1 – Systematic Review**

**BACKGROUND:**

Recurrence of varicose veins after surgery (REVAS) for saphenous incompetence has been well described after

**METHODS:**
We searched databases (January 1, 2000 through July 1, 2014) for published RCTs evaluating EVA treatment of great saphenous vein (GSV) incompetence that employed endovenous laser ablation or radiofrequency ablation. RCTs were eliminated that (1) did not have follow-up of at least 2 years, (2) did not obtain postoperative duplex scans, (3) did not clearly report the incidence of recurrent varicosities after GSV ablation, and (4) treated the small saphenous or anterior accessory saphenous veins.

**RESULTS:**
Of the 68 studies screened, 20 RCTs that employed EVA of the GSV were identified. Eight had a follow-up of at least 2 years, but one was eliminated because of lack of information on both the site and cause of REVAS. The resultant seven RCTs provided eight comparisons (one study compared both types of EVA to a comparator arm): three used radiofrequency ablation, and five employed endovenous laser ablation. Overall recurrent varicose veins developed in 125 limbs after EVA (22%), with no difference in the incidence vs the L&S group (22%) based on the number of limbs available at the time of the development of recurrence for both groups, but this incidence is dependent on the length of follow-up after the initial treatment. The two studies with serial follow-up showed an approximate doubling of REVAS over time for both EVA and L&S. By contrast, the cause of REVAS was different between the two methods. Neovascularization occurred in only two limbs (2%) after EVA vs 18 (18%) in the L&S group. Recanalization was the most common cause of REVAS for EVA (32%; 40 of 125 limbs), followed by the development of anterior accessory saphenous vein incompetence (19%; 23 of 125 limbs). In contrast to other reports, incompetent calf perforating veins were an infrequent cause of REVAS (7%; eight of 125).

**CONCLUSIONS:**
There is no difference in the incidence of REVAS for EVA vs L&S, but the causes of REVAS are different with L&S, which has important implications for treatment.

**Evidence Level: 1 – Systematic Review & Meta-Analysis**

**BACKGROUND:**
Early studies have demonstrated that endovenous therapy for varicose veins is associated with a faster recovery and lower complication rates compared with conventional therapy. More than one million procedures have been performed worldwide. The objective of this study was to determine long-term efficacy of currently available endovenous therapy methods for varicose veins compared with conventional surgery (saphenofemoral ligation and stripping of great saphenous vein [GSV] with or without multiple avulsions) in management of GSV-related varicose veins.

**METHODS:**
In July 2017, we searched MEDLINE, Cumulative Index to Nursing and Allied Health Literature, Embase, Scopus, Cochrane Library, and Web of Science without date or language restriction for relevant randomized controlled trials (RCTs). Bibliographies of included studies were also searched for additional studies. RCTs comparing conventional
surgery and endovenous therapy for treating lower extremity varicose veins with 5 years or more of follow-up were selected. Data extraction and quality assessment were performed independently by two review authors, and any disagreements were resolved by consensus or by arbitration of a third author. Cochrane RevMan 5 was used for analysis.

RESULTS:
At time of data extraction, long-term follow-up was available for endovenous laser therapy (EVLT), radiofrequency ablation (RFA), and ultrasound-guided foam sclerotherapy. Included in the review were nine RCTs. The RCTs included 2185 legs; however, only 1352 legs were followed up for 5 years (61.9%). There was no statically significant difference in recurrence rate in comparing EVLT with conventional surgery in treating GSV incompetence (36.6% vs 33.3%, respectively; pooled risk ratio, 1.35; 95% confidence interval, 0.76-2.37; P = .3). Also, no significant difference was determined for recurrence rate in comparing RFA with surgery or EVLT.

CONCLUSIONS:
Although the analysis showed that EVLT and RFA are as effective as conventional surgery in treating saphenous venous insufficiency, the number of patients available for analysis was too small for definitive conclusions to be drawn.


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| **BACKGROUND:**
| Since the 1990s, new techniques for the treatment of varicose veins have emerged, including radiofrequency ablation (RFA) and laser treatment. We performed a study to compare the safety, efficacy and outcomes of RFA compared to those of open surgery and laser ablation for the treatment of varicose veins. We also carried out a cost analysis of RFA compared to open surgery to assess whether RFA could help free up operating room time by being performed in an outpatient context. |
| **METHODS:**
| We conducted a systematic literature review (publication date May 2010-September 2013 for articles in English, January 1991-September 2013 for those in French). We used several checklists to measure the quality of the studies. We also collected data on costing. |
| **RESULTS:**
| The literature search identified 924 publications, of which 38 were retained for analysis: 15 literature reviews, 1 good-practice guideline and 22 new primary studies. The overall level of evidence was low to moderate owing to the limited sample sizes, lack of information on patient characteristics and lack of standardization of the outcome measures. However, the results obtained are consistent from study to study. In the short and medium term, RFA is considered as effective as open surgery or laser treatment (moderate level of evidence) and presents fewer major and minor complications than open surgery (low level of evidence). Radiofrequency ablation can be performed on an outpatient basis. We calculated that RFA would be about $110-$220 more expensive per patient than open surgery. |
| **CONCLUSION:**
| Radiofrequency ablation is a valuable alternative to open surgery and would free up operating room time in a context of low accessibility. |

50 Evidence Level: 1 – Systematic Review
BACKGROUND: Chronic lower extremity venous disease (LECVD) is twice as prevalent as coronary heart disease, and invasive therapies to treat LECVD accounted for an estimated $290 million in Medicare expenditures in 2015. Despite increasing use of these invasive therapies, their comparative effectiveness is unknown.

METHODS: We conducted a systematic review and meta-analysis of treatments for patients (symptomatic and asymptomatic) with lower extremity varicosities and/or lower extremity chronic venous insufficiency/incompetence/reflux. We searched PubMed, Embase, and the Cochrane Database of Systematic Reviews for relevant English-language studies published from January 2000 to July 2016. We included comparative randomized controlled trials (RCTs) with >20 patients and observational studies with >500 patients. Short-, intermediate-, and long-term outcomes of placebo, mechanical compression therapy, and invasive therapies (surgical and endovascular) were included. Quality ratings and evidence grading was performed. Random-effects models were used to compute summary estimates of effects.

RESULTS: We identified a total of 57 studies representing 105,878 enrolled patients, including 53 RCTs comprised of 10,034 patients. Among the RCTs, 16 were good quality, 28 were fair quality, and 9 were poor quality. Allocation concealment, double blinding, and reporting bias were inadequately addressed in 25 of 53 (47%), 46 of 53 (87%), and 15 of 53 (28.3%), respectively. Heterogeneity in therapies, populations, and/or outcomes prohibited meta-analysis of comparisons between different endovascular therapies and between endovascular intervention and placebo/compression. Meta-analysis evaluating venous stripping plus ligation (high ligation/stripping) compared with radiofrequency ablation revealed no difference in short-term bleeding (odds ratio [OR]=0.30, 95% CI 0.16 to 5.38, P=.43) or reflux recurrence at 1-2 years (OR=0.76, 95% CI 0.37 -1.55, P=.44). Meta-analysis evaluating high ligation/stripping versus endovascular laser ablation revealed no difference in long-term symptom score (OR 0.02, 95% CI -0.19 to 0.23, P=.84) or quality of life at 2 years (OR 0.06, 95% CI -0.12 to 0.25, P=.50).

CONCLUSIONS: The paucity of high-quality comparative effectiveness and safety data in LECVD is concerning given the overall rise in endovascular procedures. More high-quality studies are needed to determine comparative effectiveness and guide policy and practice.
12 reported studies with a combined total of 1577 patients were included. Vein ablated length (SMD: 0.37, 95% CI: 0.04 to 0.77), 3 days pain scores (SMD: 11.25, 95% CI: 3.42 to 25.92) and 10 days (SMD: 0.79, 95% CI: 0.48 to 2.05), 1 month quality of life (SMD: 0.09, 95% CI: 0.28 to 0.10) and 1 year (SMD: 0.04, 95% CI: 0.21 to 0.13), occlusion (OR: 1.05, 95% CI: 0.41 to 2.73), thrombophlebitis (RR: 1.03, 95% CI: 0.56 to 1.92), haematoma (OR: 1.55, 95% CI: 0.54 to 4.45) and recanalization (OR: 0.68, 95% CI: 0.43 to 1.09) following RFA showed no difference when compared with EVLA. These results were not statistically significant. RFA was associated with the lower overall complication (OR: 3.49, 95% CI: 1.36 to 8.96) in patients with varicose veins compared to the EVLA treatment.

CONCLUSION: EVLA and RFA seem to be the same safe and effective on clinical efficacy (vein ablated length, 3 days and 10 days pain scores, 1 month and 1 year quality of life, occlusion, thrombophlebitis, haematoma and recanalization). Data on RFA seems to having potential benefits from reducing risk of overall complication than EVLA, which is needed by large high-quality prospective randomized trials.

Evidence Level: 2 – RCT – Specific new evidence added by T&F Group


BACKGROUND
Venous disease is the most common cause of leg ulceration. Although compression therapy improves venous ulcer healing, it does not treat the underlying causes of venous hypertension. Treatment of superficial venous reflux has been shown to reduce the rate of ulcer recurrence, but the effect of early endovenous ablation of superficial venous reflux on ulcer healing remains unclear.

METHODS
In a trial conducted at 20 centers in the United Kingdom, we randomly assigned 450 patients with venous leg ulcers to receive compression therapy and undergo early endovenous ablation of superficial venous reflux within 2 weeks after randomization (early-intervention group) or to receive compression therapy alone, with consideration of endovenous ablation deferred until after the ulcer was healed or until 6 months after randomization if the ulcer was unhealed (deferred-intervention group). The primary outcome was the time to ulcer healing. Secondary outcomes were the rate of ulcer healing at 24 weeks, the rate of ulcer recurrence, the length of time free from ulcers (ulcer-free time) during the first year after randomization, and patient-reported health-related quality of life.

RESULTS
Patient and clinical characteristics at baseline were similar in the two treatment groups. The time to ulcer healing was shorter in the early-intervention group than in the deferred-intervention group; more patients had healed ulcers with early intervention (hazard ratio for ulcer healing, 1.38; 95% confidence interval [CI], 1.13 to 1.68; P=0.001). The median time to ulcer healing was 56 days (95% CI, 49 to 66) in the early-intervention group and 82 days (95% CI, 69 to 92) in the deferred-intervention group. The rate of ulcer healing at 24 weeks was 85.6% in the early-intervention group and 76.3% in the deferred-intervention group. The median ulcer-free time during the first year after trial enrollment was 306 days (interquartile range, 240 to 328) in the early-intervention group and 278 days (interquartile range, 175 to 324) in the deferred-intervention group (P=0.002). The most common procedural complications of endovenous ablation were pain and deep-vein thrombosis.

CONCLUSIONS
Early endovenous ablation of superficial venous reflux resulted in faster healing of venous leg ulcers and more time free from ulcers than deferred endovenous ablation. (Funded by the National Institute for Health Research Health
## Appendix 2 – Current CCG policies

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### Commissioning Position

**Intervention, including open surgery (ligation and stripping), endovenous laser ablation, and radiofrequency ablation is appropriate only for significant and intractable symptoms and signs including:**

- Not routinely funded

**Cosmetic Varicose Veins**

This procedure is not routinely funded by the NHS NCL and will only be considered for funding if the criteria below are met and evidenced. This guidance applies to each leg individually. The techniques that are normally approved are open surgery (ligation and stripping) and the endovenous techniques endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) using VNUS Closure system. Sclerotherapy will not normally be funded. Factors to be taken into account when selecting the most appropriate treatment include local equipment, clinical assessment (including vein tortuosity)

**Clinical threshold SWL CCGs fund this procedure when all of the following criteria (1 - 4) are met.**

**Treatment may be given providing the below criteria are fulfilled.**

- Asymptomatic and Mild Varicose Veins
  - Asymptomatic and mild varicose veins present as a few isolated, raised palpable veins with little or no associated pain, discomfort or skin changes. They should be managed in primary care and patients offered advice and information. South East London CCGs do not routinely commission surgery for asymptomatic and mild varicose veins. Therefore surgical treatment for patients presenting to primary care with mild or asymptomatic varicose veins will only be funded under exceptional clinical circumstances.

**NHS NWL CCGs will only fund varicose vein surgery if a patient has at least one of the below presentations. The choice of surgical intervention, namely, foam sclerotherapy, endothermal ablation or laser ablation for long saphenous veins and surgical stripping will be left to the discretion of the clinician.**

- No visible or palpable varicose veins and visible telangiectasia and reticular veins (CO, C1) – treatment not funded.

This policy only relates to adults over the age of 18 and does not apply to pregnant women.
### Criteria for Commissioning

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<tr>
<td>• Symptomatic primary or symptomatic recurrent varicose veins, unresolved by at least 6 months conservative management (exercise, elevation)</td>
<td>A healed venous ulceration secondary to venous stasis. OR Healed venous ulcers in patients that cannot tolerate compression stockings for clinical reasons. OR Significant haemorrhage from a ruptured superficial varicosity (serious enough to warrant transfusion or admission) ALTERNATIVELY After an unsuccessful six month trial of conservative management (compression stockings AND exercise AND daily elevation several times a day) when varicosities result in either: recurrent documented thrombophlebitis (two or more episodes) OR persistent skin changes (eczema, pigmentation or lipodermatosclerosis)</td>
</tr>
<tr>
<td>1. Patient has confirmed varicose veins. AND 2. Patient had a duplex ultrasound that shows truncal reflux NB. Date of duplex ultrasound that shows truncal reflux will need to be provided on the Tickbox form. AND 3. Patient has at least one of the following: a) Primary or recurrent varicose veins causing significant functional impairment that impacts on activities of daily living* (Venous Clinical Severity Scoring of 9 or more is also accepted) OR b) Skin changes including: varicose eczema, lipodermatosclerosis or a venous ulcer, which took over 2 weeks to heal OR c) At least two episodes of</td>
<td>1. There is documented evidence of at least one of the following: a. Varicose eczema b. Lipodermatosclerosis or a venous ulcer c. A venous ulcer that has taken over two weeks to heal d. One or more episodes of documented superficial thrombophlebitis e. A major episode of bleeding from a varicosity. AND 2. The patient has followed the above pathway AND 3. The diagnosis of varicose veins has been confirmed and there is evidence of truncal reflux AND 4. The patient has a normal BMI, or there is evidence that NICE guidance on measures to lose weight have been followed over a period of at least one year. AND 5. There is documented evidence that the patient is aware of the complications and limitations of the treatment</td>
</tr>
<tr>
<td>Presentations</td>
<td>• Symptomatic primary or symptomatic recurrent varicose veins. • Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency. • Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence. A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks) A healed venous leg ulcer.</td>
</tr>
</tbody>
</table>

*Venous Clinical Severity Scoring (VCSS) is a validated method for assessing the severity of venous disease, incorporating symptoms and signs of venous disease into a single numerical score. A score of 9 or more indicates a severe level of venous disease.

NB. Date of duplex ultrasound that shows truncal reflux will need to be provided on the Tickbox form.
OR
- persistent aching, heaviness, itching or swelling severely affecting the patient’s quality of life (for example the patient is unable to stand throughout the day for their job or they are woken regularly at night by severe discomfort

superficial thrombophlebitis OR
d) A major episode of bleeding from the varicosity.
AND
4. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

or recurrent varicose veins.

or recurrent varicose veins.

and thigh.

OR

Oedema above the ankle in the affected leg.

Patients with skin damage due to varicose veins e.g. varicose eczema (C4), healed venous leg ulcer (a break in the skin below the knee taking more than 2 weeks to heal) (C5) and active venous leg ulcer (a break in the skin below the knee not healed within 2 weeks) (C6) – treatment funded

Additional policy stipulations

Proposed new policy statement from 2017
1. Stable BMI under 30 (stable defined as below 30 for 3 consecutive months prior to referral)
2. 6 consecutive months conservative management prior to referral, defined as (a) Light to moderate exercise; and (b) daily elevation two or three times a day.

Criteria for treatment:
1. Patients experiencing

SWL CCG do not routinely fund the following:
- Patients with no symptoms or skin changes associated with venous disease
- Patients whose concerns are cosmetic including telangiectasia and reticular veins
- Patients with mild symptoms including itch, ache, mild

Asymptomatic and Mild Varicose Veins
Asymptomatic and mild varicose veins present as a few isolated, raised palpable veins with little or no associated pain, discomfort or skin changes. They should be managed in primary care and patients offered advice and information. This will include:
- An explanation of varicose veins, possible causes, and the likelihood of progression.
- Treatment options aimed at symptom relief and an explanation of the limited role of compression therapy. Compression hosiery for

Note: Patients who smoke should have attempted to stop smoking 8 to 12 weeks before referral to reduce the risk of surgery and the risk of post-surgery complications. Patients should be routinely offered referral to smoking cessation services to reduce these surgical risks.

When treatment is funded according to the above classification the following applies within secondary care:
- Duplex Doppler ultrasound must be performed to confirm diagnosis and plan appropriate treatment

Treatment will be funded according
spontaneous bleeding (not including spontaneous bruising) should be referred urgently 2. A documented history of superficial vein thrombosis and suspected venous incompetence 3. Trophic skin changes 4. Lipodermatosclerosis, healed leg ulceration 5. Varicose eczema associated with varicose veins (Varicose Eczema is common in patients with varicose veins and not usually an indication on its own for surgical intervention) 6. Venous leg ulceration with evidence of varicose veins 7. Skin changes indicative of ulceration Varicose vein procedures are not otherwise commissioned.

Interventional treatment should be in line with NICE guidance which identifies endothermal ablation as the first line intervention where suitable.

For individuals who meet the criteria with one limb and have symptomatic varicose veins on their other limb; simultaneous bilateral intervention is supported. A separate procedure for the symptomatic limb is not commissioned.

Do not offer compression swelling, minor changes of skin eczema and haemosiderosis
• Pregnant women presenting with varicose veins should be given information on the effect of pregnancy on varicose veins. Interventional treatment for varicose veins during pregnancy should not be carried out. Conservative treatment: Patients should have received 6 months of conservative treatment (listed below) before referral and will not normally be accepted for interventional treatment without evidence that conservative treatment has failed: Patients should lose weight loss if their BMI is raised Taking up light to moderate exercise Avoidance of prolonged immobility Patients should also be advised to stop smoking – in symptomatic varicose veins should not be offered unless interventional treatment is unsuitable.
• 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. 
• Advice on symptom relief, which should include advice on weight loss, the benefit of light to moderate physical activity, avoiding activities that make symptoms worse (standing for long periods) and when and where to seek further help. Moderate to Severe Varicose Veins Moderate varicose veins present as local or generalised dilatation of subcutaneous veins with associated pain or discomfort and slight ankle swelling. Severe varicose veins may present with phlebitis, ulceration and haemorrhage. People should be referred to a vascular service if they have any of the following: 
• Bleeding varicose veins (immediate referral).
• Symptomatic (veins found in association with troublesome lower limb symptoms - typically pain, aching, discomfort, swelling, heaviness and itching) primary or symptomatic recurrent varicose veins where other causes of these symptoms can be ruled out. 
• Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
• Superficial vein thrombosis to the following hierarchy:
  1. Offer endothermal ablation
  2. If endothermal ablation is deemed clinically unsuitable, offer ultrasound guided foam sclerotherapy
  3. If ultrasound guided foam sclerotherapy is deemed clinically unsuitable, offer surgery
The following lifestyle advice should be offered to all patients with varicose veins:
• Weight loss (if BMI>30)
• Light to moderate physical exercise
• Smoking cessation

Treatment will NOT be funded in the following circumstances:
1. Patients with no symptoms or skin changes associated with venous disease
2. Patients whose concerns are cosmetic including telangiectasia and reticular veins
hosiery UNLESS interventional treatments are not suitable.

NCL CCGs will not fund treatment in the following circumstances:

1. Patients with no symptoms or skin changes associated with venous disease
2. Patients whose concerns are cosmetic including telangectasia and reticular veins
3. Patients with mild symptoms including itch, ache, mild swelling, minor changes of skin eczema and haemosiderosis
4. Pregnant women presenting with varicose vein should be given information on the effect of pregnancy on varicose veins. Interventional treatment for varicose veins during pregnancy should not be carried out other than in exceptional circumstances.

Compression hosiery should be considered for symptom relief of leg swelling associated with varicose veins during pregnancy.

There are seven grades of increasing clinical severity listed below. For the initial assessment of a patient, the clinical severity assessment can be simple observation and does not need special tests:

- C0 No evidence of venous disease
- C1 Superficial spider veins reticular veins only
- C2 Simple varicose veins only
- C3 Ankle oedema of venous origin (not foot oedema)
- C4 Skin pigmentation in the gaiter area (lipodermatosclerosis, varicose eczema)
- C5 A healed venous ulcer
- C6 An open venous ulcer.

Pregnancy
Particular attention should be paid to the conservative management of varicose veins in primary care during pregnancy. So in addition to the

3. Patients with mild symptoms including itch, ache, mild swelling, minor changes of skin eczema and haemosiderosis
4. Pregnant women presenting with varicose vein should be given information on the effect of pregnancy on varicose veins. Interventional treatment for varicose veins during pregnancy should not be carried out other than in exceptional circumstances. Compression hosiery should be considered for symptom relief of leg swelling associated with varicose veins during pregnancy.
| conservative management listed above these should be considered: Give pregnant women presenting with varicose veins advice on varicose veins Do not carry out interventional treatment for varicose veins during pregnancy | the vein or ligation (tying off the vein)) • If incompetent varicose tributaries are to be treated, consider treating them at the same time. Treatment outside the criteria outlined will not be funded unless there are exceptional circumstances and approval has been gained via the Individual Funding Request (IFR) process. Interventional treatment for varicose veins in pregnancy will not be funded unless exceptional circumstances apply and agreement is sought via the IFR process. |
Appendix 3

Full Classification Criteria:

CEAP:

- **Clinical**
  - C₆: No clinical signs
  - C₅: Small varicose veins
  - C₄: Large varicose veins
  - C₃: Edema
  - C₂: Skin changes without ulceration
  - C₁: Skin changes with healed ulceration
  - C₀: Skin changes with active ulceration

- **Etiology**
  - E₆: Congenital
  - E₅: Primary
  - E₄: Secondary (usually due to prior DVT)

- **Anatomy**
  - A₆: Superficial veins
  - A₅: Deep veins
  - A₄: Perforating veins

- **Pathophysiology**
  - P₆: Reflux
  - P₅: Obstruction

*Early application of compression should be performed to correct swelling and progressive scarring and to initiate the healing process by improving the venous microcirculation.*


Venous Clinical Severity Score (VCSS):

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score 0</th>
<th>Score 1 (mild)</th>
<th>Score 2 (moderate)</th>
<th>Score 3 (severe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>None</td>
<td>Occasional; no use of analgesics</td>
<td>Daily; occasional use of non-narcotic analgesics</td>
<td>Constant use of narcotic analgesics</td>
</tr>
<tr>
<td>Varicose veins</td>
<td>None</td>
<td>Few, scattered</td>
<td>Multiple</td>
<td>Extensive</td>
</tr>
<tr>
<td>Edema</td>
<td>None</td>
<td>Evening, ankle only</td>
<td>Afternoon, above ankle</td>
<td>Morning above ankle</td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td>None</td>
<td>Limited</td>
<td>Diffuse over lower third of leg</td>
<td>Wide distribution</td>
</tr>
<tr>
<td>Inflammation and cellulitis</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Induration</td>
<td>None</td>
<td>Focal</td>
<td>Less than lower third of leg</td>
<td>Entire lower third of leg or more</td>
</tr>
<tr>
<td>Active ulcers — no.</td>
<td>0</td>
<td>2</td>
<td>3–12</td>
<td>&gt;2</td>
</tr>
<tr>
<td>Duration of active ulceration — mo</td>
<td>&lt;3</td>
<td>2–6</td>
<td>Not healed at &gt;12</td>
<td></td>
</tr>
<tr>
<td>Diameter of active ulcer — cm</td>
<td>&lt;2</td>
<td>Most days</td>
<td>Constant</td>
<td></td>
</tr>
<tr>
<td>Use of stockings</td>
<td>None</td>
<td>Occasional</td>
<td>Constant</td>
<td></td>
</tr>
</tbody>
</table>

*An aggregate score for the limb is calculated by adding the individual component scores. The range of the total score is 0 to 30.


Aberdeen Varicose Vein Questionnaire (AVVQ):
1: Please draw in your varicose veins

Legs Viewed from Behind       Legs Viewed from in Front

2:  In the last 2 weeks for how many days did your veins cause you pain or ache?

<table>
<thead>
<tr>
<th></th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>None at all</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between 1 and 5 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between 6 and 10 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For more than 10 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3:  During the last two weeks, on how many days did you take painkilling tablets for your varicose veins?

<table>
<thead>
<tr>
<th></th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>None at all</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between 1 and 5 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between 6 and 10 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4: In the last two weeks, how much ankle swelling have you had?

<table>
<thead>
<tr>
<th>Option</th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>None at all</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Between 1 and 5 days</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Between 6 and 10 days</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>For more than 10 days</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

5: In the last two weeks, have you worn support stockings or tights?

<table>
<thead>
<tr>
<th>Option</th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, those I bought myself without prescription</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, those prescribed by my doctor which I wear occasionally</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, those prescribed by my doctor which I wear every day</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

6: In the past two weeks, have you had any itching in association with your varicose veins?

<table>
<thead>
<tr>
<th>Option</th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, above the knee only</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, below the knee only</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, above and below the knee</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

7: Do you have purple discolouration caused by tiny blood vessels in the skin, in association with your varicose veins?

<table>
<thead>
<tr>
<th>Option</th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

8: Do you have a rash or eczema in the area of your ankle?

<table>
<thead>
<tr>
<th>Option</th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, but it does not require treatment from a doctor or district nurse</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes, and it requires treatment from a doctor or district nurse</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

9: Do you have a skin ulcer associated with your varicose veins?

<table>
<thead>
<tr>
<th>Option</th>
<th>Right Leg</th>
<th>Left Leg</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
10: Does the appearance of your varicose veins cause you concern

- No
- Yes, their appearance causes me slight concern
- Yes, their appearance causes me moderate concern
- Yes, their appearance causes me a great deal of concern

11: Does the appearance of your varicose veins influence your choice of clothing including tights?

- No
- Occasionally
- Often
- Always

12: During the last two weeks, have your varicose veins interfered with your work/housework or other activities?

- No
- I have been able to work but my work has suffered to a slight extent
- I have been able to work but my work has suffered to a moderate extent
- My veins have prevented me working one day or more

13: During the last two weeks, have your varicose veins interfered with your leisure activities? (including sport, hobbies and social life)

- No
- Yes, my enjoyment has suffered to a slight extent
- Yes, my enjoyment has suffered to a moderate extent
- Yes, my veins have prevented me taking part in any leisure activities