11 Varicose Veins and Venous Ulcers*

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1 Summary

Introduction/statement of the problem

Chronic venous disease is the most common vascular condition to affect the lower limb. It covers a wide range of conditions which can be broadly categorised as varicose veins, chronic venous insufficiency and venous ulcers. Venous disease is associated with a large burden of ill-health and it consumes a substantial amount of NHS resources. In the UK each year roughly half a million people consult their general practitioners about varicose veins and associated symptoms. Varicose veins are one of the most common conditions seen in surgical clinics, they make up a significant part of the elective surgery workload and they are responsible for a large proportion of patients on surgical waiting lists in NHS hospitals. Venous ulcer care is a major component of community nursing services. Venous disease has been a Cinderella area of health care, in terms of both research and treatment, though this situation is changing. Moreover, this situation has raised important questions about what conditions the NHS should treat.

Whilst there is lay recognition that a varicose vein is a tortuous twisted vein, a standard definition has not yet been agreed. In addition, the exact pathophysiology surrounding the development of varicose veins remains controversial. Most varicose veins are primary (i.e. arising *de novo*), and whilst there are some recognised predisposing factors, structural abnormalities and abnormal haemodynamic effects which may influence their development, there is no agreement on which of these is the main cause of veins becoming varicose.

Venous ulcers are located at the severe end of the spectrum of chronic venous disorders of the leg. A chronic venous ulcer can be defined as an area of discontinuity of epidermis, persisting for 4 weeks or more and occurring as a result of venous hypertension (increased pressure) and calf muscle pump insufficiency. Venous hypertension is the undisputed initiating factor in venous ulcer development but a detailed understanding of the aetiology of venous ulcers is lacking, not least information on the natural history of varicose veins in relation to venous ulcers.

There appears to be a high degree of acceptance of symptoms of venous disorders of the leg among affected persons, but for around a third of people they do present a significant problem. Symptoms reported by patients presenting with varicose veins include aching pain, tiredness/feelings of heaviness, throbbing, itching and swelling in the lower limbs. Not all varicose veins are associated with symptoms. Cosmetic dissatisfaction with the appearance of varicose veins is probably universal, although the impact it

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has on an individual and his or her lifestyle will be a matter of personal outlook. Few studies of function or quality of life have been carried out for venous disorders of the leg. Those that exist report that patients with varicose veins have a reduced quality of life compared with the general population and that those with venous leg ulcers have a poorer quality of life than age-matched controls.

The management of venous disorders is thought to represent between 1% and 3% of total health care expenditure. In the UK in 2000–01, 107 020 people were admitted to hospital for operations for varicose veins of the lower limb. The management of leg ulcers comprises a significant portion of the workload of community and hospital nurses, general practitioners, dermatologists, surgeons and physicians involved in the care of the elderly. Each ulcer costs around £2000–4000 per annum to treat and the total cost to the National Health Service in 1995 was estimated at £600 million.

Recurrence of varicose veins after treatment is a significant problem to the health service. This occurs in 20–80% of cases treated for primary varicose veins, depending on the definition of recurrence used, length of follow-up and the initial treatment. The rate of occurrence increases with time, with an estimated recurrence rate of around 50% up to 5 years. Approximately 20% of varicose vein surgery is for recurrent disease. Recurrence may be due to inadequate assessment and initial surgery and to the development of new varicose veins. Venous ulcers take time to heal; up to 50% of venous ulcers may be present for 7 to 9 months, between 8% and 34% may be present for more than 5 years, and about 70% of patients have recurrent ulcers.

Sub-categories

No universally accepted classification of chronic venous disease has been agreed and of those classifications that exist, few have been based on objective measurements of abnormal venous pressure/flow. The classification systems used most widely are those developed by Widmer in 1978, Porter in 1988 and the CEAP (clinical signs, etiologic classification, anatomic distribution and pathophysiologic dysfunction) classification presented by the American Venous Forum in 1995. None of these have been formally validated.

The sub-categories to be used in this chapter are as follows:

- **mild discretionary:** asymptomatic, cosmetic/mild discomfort or swelling
- **severe non-discretionary:** severe pain/swelling, skin change (lipodermatosclerosis) without ulcer
- **venous ulcer:** chronic ulceration (healed and active).

Prevalence/incidence

The population distribution of varicose veins has to be put in a context of uncertainty. The many studies that consider the prevalence of varicose veins and venous disorders are difficult to interpret, as:

1. the method of measurement/assessment of varicose veins varies greatly, including the validity of the questionnaires used
2. the comparability is limited by the varying definitions of varicose veins used
3. much of the epidemiological data relates to highly selected groups rather than a cross-section of the general population. The nature of many of the populations studied renders most of these studies of limited value in determining levels of service requirement in the UK.

The prevalence of venous-related oedema and skin changes is not well documented but there is a large number of studies on the prevalence of leg ulceration. Venous ulcers are the commonest cause of leg ulceration. However, as with the studies on varicose veins, the variations between definitions and methodology employed in these studies make it difficult to give a definitive prevalence figure.

The best available data representative of the UK population are from the Edinburgh vein study, carried out between 1994 and 1996. Incorporating the results of this study into the sub-categories defined in the previous section, a prevalence of varicose veins and chronic venous insufficiency (CVI) has been estimated (*see* Table 1). These values underestimate the population prevalence, as the Edinburgh study only included 18- to 64-year-olds and venous disease is commoner in older age groups. In addition, there are no data available on non-Caucasians.

Table 1: Estimated prevalence of varicose veins and CVI (in a population aged 18–64 years).

	Sub-category	Estimated prevalence (%)	
		Male	Female
A	Mild discretionary*	40	31
B	Severe non-discretionary†	8	7
C	Venous ulcer‡	1	1

* Based on the prevalence of trunk varices (Grade 1) and CVI (Grade 1).
† Based on the prevalence of trunk varices (Grade 2–3) and CVI (Grade 2).
‡ VU is both healed and active ulceration (the latter about 0.1–0.25%).

Whilst many risk factors for varicose veins have been postulated (including age, pregnancy, ethnicity, family history, obesity, occupations requiring prolonged standing or sitting, lack of dietary fibre, use of constricting corsets and sitting posture for defecation), the evidence linking most factors to varicose vein development is limited. Age is the most important, but recent studies have not found significant gender differences and an association with obesity seems to be confined to females. If the link with obesity is real, the prevalence of varicose veins could increase with the rising levels of obesity in the UK population.

Services available

Primary prevention

The scope for primary prevention is limited. Specific measures that have been suggested include weight control, reducing the amount of standing, greater physical activity and prophylaxis against deep vein thrombosis (DVT) (e.g. in surgical patients). The use of compression stockings after an acute DVT has been shown to reduce the incidence of CVI and venous ulcer which can occur as a post-thrombosis complication.

Presentation

Many people with varicose veins will choose not to seek any medical advice. People who do go to their general practitioner are primarily concerned about the cosmetic appearance of their veins or present with symptoms associated with varicose veins. Concern about the future course of the veins is also a common underlying reason. Symptoms draw attention to varicose veins but it has been found that varicose veins may not be the cause of the symptom. Women are more likely to consult their GP with varicose veins than men.

The National Institute for Clinical Excellence has published a guide to appropriate referral from general practice to specialist services for varicose veins. The guide emphasises that most varicose veins require no treatment and state that the key role of primary care is to provide reassurance, explanation and education.

Assessment

An initial diagnosis of varicose veins is usually made up of the signs observed by the general practitioner and the symptoms reported by the patient. However, the accuracy of clinical examination in identifying the site of incompetence is poor. Whether a diagnosis of varicose veins then becomes a referral for treatment and/or further assessment at an outpatient clinic depends upon the severity of the signs and symptoms, the likelihood of complications, patient preferences and the supply of treatment options. There is no single test available to provide answers to the many questions that need to be asked to decide if and how to treat varicose veins and other venous disorders of the leg. For this reason a number of specialised investigations have evolved over the years and include non-invasive methods (continuous-wave Doppler ultrasound, duplex scanning, plethysmography, near-infra-red spectroscopy) and invasive methods (phlebography/varicography, foot venous pressure measurements, ambulatory venous pressure). Each technique of investigation has its own advantages and disadvantages, and out of the series of tests available in the vascular laboratory, several methods will measure the same thing. Whatever the method used, the interpretation is open to inter-observer variation and can be expensive and time-consuming. The duplex method has become the investigation of choice, especially for recurrent disease, post-DVT disease, and for CVI or venous ulcer. In the UK it would be unusual for any patient to undergo any test other than a duplex outside a research protocol.

Treatment

The general indications for treatment of varicose veins are to prevent complications related to venous disease, to relieve symptoms and to improve the appearance of the leg. However, there is no national consensus as to which varicose veins should be treated based on site of incompetence, severity, etc. and as to which types of treatment to be offered (*see* below).

Pharmacotherapy

A variety of medications are available for the relief of various individual symptoms, such as heaviness, discomfort, itching, cramps, pain and aching, and swelling.

Compression therapy

Compression is the mainstay of venous ulcer treatment. It acts to reduce vein calibre, capillary filtration and venous reflux and improves venous pumping. These effects increase venous return, improve lymphatic drainage and decrease oedema. Materials used for compression include elastic and inelastic bandages, and elastic stockings. There are many ways of applying compression, such as single layers of bandaging, multiple layers of bandaging, compression stockings or a combination of bandages. Intermittent pneumatic compression is an alternative method.

Sclerotherapy

Sclerotherapy is the injection of an irritant solution into an empty vein, resulting in an endothelial reaction, fibrosis and complete venous destruction. Compression usually accompanies sclerotherapy. Its importance in the sclerotherapy process, the strength of compression and the length of time for which it is applied vary and depend on the technique used. As a mode of treatment, sclerotherapy has been variably popular in Europe and the USA.

Echosclerotherapy

Echosclerotherapy is a modification of sclerotherapy which involves injection of a sclerosing agent into a vein under ultrasound guidance and therefore in real proximity to the leakage point.

Surgical management

The basis of surgery is to ligate (tie off) any incompetent venous connections and/or to strip out (remove) any varicose veins.

The types of operation available to treat varicose veins include:

- phlebectomies (avulsions) of varicosities, ligation of tributaries and local excision of tributaries
- flush ligation of the sapheno-femoral junction, also called high saphenous ligation
- stripping of the long saphenous vein
- sapheno-popliteal junction ligation, also called short saphenous ligation
- stripping of the short saphenous vein (but avoided by most surgeons)
- ligation of the medial lower leg communicating veins
- ligation of other communicating veins (i.e. gastrocnemius, lateral calf, Hunterian and miscellaneous veins)
- operations on recurrent varicose veins.

New technologies and other treatments

Continuous-wave laser systems, such as carbon dioxide lasers and argon lasers, have been tested for their effects on leg veins. Some laser systems show promise as alternative or complementary therapies for telangiectasias. Whilst compression therapy is the main venous ulcer therapy, various other interventions including electrical stimulation, laser therapy and ultrasound have been used in addition to, or in replacement of, compression where the latter is contraindicated. New therapies for varicose veins include radio-frequency ablation and the use of a laser probe to close off the long saphenous vein under ultrasound control.

Configuration of services

Day-case surgery

Day-case surgery for varicose veins has been shown to be economic, safe and effective and to reduce waiting time for surgery. It is now widely accepted as the most appropriate way to treat many patients who need common surgical procedures, and there has been a national drive to increase the percentage of varicose veins dealt with as day cases. However, day-case surgery is disliked by a proportion of patients and in the private sector varicose vein surgery is very rarely carried out as a day case. Patients for whom day surgery may be unsuitable include those with extensive varicosities, those needing open calf perforator surgery, those requiring post-operative bed rest for venous ulcers, and those with pre-existing medical conditions.

Waiting lists

Increasing pressure on surgical resources in terms of inpatient beds and operating-theatre availability has led to increasing waiting lists for varicose veins. A number of waiting-list initiatives have demonstrated

that varicose vein waiting lists can be significantly reduced. Waiting for an operation can result in deterioration in the clinical condition of the patient and considerable morbidity for the patient while they wait.

Management of venous ulcers

There is wide variation in the management of venous leg ulcers with types of care including hospital inpatient care, hospital outpatient clinics, primary care clinics and home visits. The introduction of community ulcer clinics has been shown to significantly improve leg ulcer healing and reduce costs by about £150 000 per 250 000 population per annum.

Current service provision

Data on current service provision are based on hospital episode data from NHS hospitals in England (HES data) from 1990–91 to 2000–01. There were 45 216 main operations for varicose veins in NHS hospitals in England in 2000–01. The rate of surgical treatment for varicose veins increased after 1990–91 until 1995–96 when there were 121 operations per 100 000 population. Since then the rate has declined and is now back at 1990 levels with a rate of 92 per 100 000 population in 2000–01. The rates for treatment for varicose veins are highest amongst females between 35 and 64 years of age. The most notable trend is that the proportion of operations for varicose veins carried out as day surgery has increased considerably, from 19% of operations in 1990–91 to 55% of operations in 2000–01. Other important trends are the increase in waiting times for varicose vein operations and the noticeable decrease in length of stay for those patients admitted as inpatients. There are no routine data on the indications for surgery or on surgery for recurrent disease with which to evaluate the appropriateness of outcomes of surgery.

Similarly, there are no routinely collected data on elective hospital treatment carried out in England and Wales by the independent sector. However, one study found that surgery performed in independent hospitals accounted for 24% of the ligation or stripping operations for varicose veins in England and Wales in 1997–98, and the number of privately-funded operations accounted for 21% of these operations.

As venous ulcers are largely managed in outpatient clinics, there are limited routine data on workload, processes or outcomes of care.

Effectiveness

The effectiveness of the different forms of management for varicose veins and venous ulcers can be assessed by the amount of reduction in the presenting symptoms and signs, and in the long term by the volume of need for further treatment, including that for recurrent disease. The effectiveness of different types of treatment still remains unclear. This is reflected in the large variation in the balance of treatment types between countries (e.g. in drugs, sclerotherapy and surgery). A Task Force on Chronic Venous Disorders of the Leg was established in September 1993 with the purpose of comprehensively evaluating this area of medicine. One of its mandates was to critically review existing scientific evidence on the diagnosis and treatment of the condition. The results of their evaluation are reported in Section 6. Where more current effectiveness data have been identified this information has been included. The Cochrane Peripheral Vascular Disease Group is co-ordinating systematic reviews of many aspects of venous disease management.

Models of care/recommendations

Key features of a venous disease service appear to be as follows:

1 appropriate referral of patients in whom varicosities are presented or suspected (*see* NICE referral advice)
2 availability of appropriate diagnostic assessment tests and staff trained in their use – this includes not only Doppler but also ideally duplex ultrasound
3 trained junior surgical staff and supervision of inexperienced surgical trainees by consultants
4 maximal use of day surgery – wherever possible, varicose vein treatment should be provided in a day-care setting
5 consideration of the opening of elective treatment centres following the model established in South Wales evaluated by Harvey *et al.* – such centres reduced waiting times and increased the volume of varicose vein surgery
6 community venous ulcer clinics with appropriately trained nurses and an optimal flow of patients.

2 Introduction/statement of the problem

Venous disease is the most common vascular condition to affect the lower limb.[1] The term 'chronic venous disorders of the leg' covers a wide range of conditions, including asymptomatic incompetence of venous valves, venous symptoms, telangiectases, reticular veins, varicose veins, oedema, skin changes and leg ulceration. These can be broadly categorised into varicose veins, chronic venous insufficiency (CVI) and venous ulcers. The relationship between these conditions in the general population is illustrated in Figure 1.

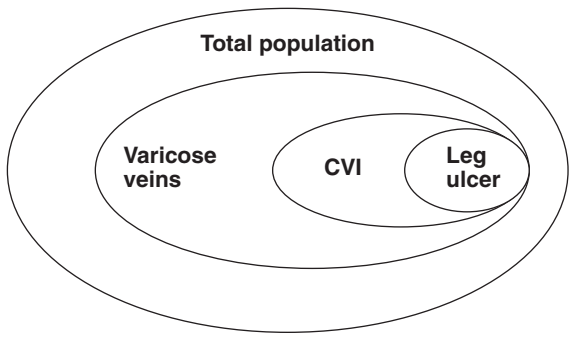

Figure 1: The relationship between varicose veins, chronic venous insufficiency and leg ulceration in the population. *Source*: Callam, 1999.[1]

This chapter addresses varicose veins of the lower limbs but excludes those that may arise as a complication of pregnancy and the puerperium. Varicose veins may be primary or secondary (usually associated with past venous thrombosis affecting the deep and communicating veins).[2] The chapter will also consider other chronic venous disorders of the leg since:

- there is no clear definition of what constitutes a varicose vein

- there is often no differentiation between varicose veins and other more or less severe venous disorders of the leg (especially when considering prevalence and service provision in the literature)
- it is generally believed that varicose veins can progress to venous ulcers
- venous ulcers are an important health problem.

The relevant ICD disease codes and OPCS operation codes can be found in Appendix 1.

An interpretation of the evidence concerning appropriate levels of NHS provision of treatment for varicose veins and other venous disorders of the leg is presented. The broad questions addressed in this analysis are as follows.

- How common are varicose veins and what are the symptoms and complications associated with them?
- What scope is there for the primary prevention of varicose veins?
- When should diagnostic assessment be used and which is the best method?
- Which type of surgery should be used to treat varicose veins to alleviate symptoms and reduce the extent of recurrence? What is the place of other therapies?
- How has varicose vein treatment expanded and what is the current level?
- Is day surgery suitable for varicose vein surgery, and what categories of patient should have day surgery?
- How can the large waiting lists associated with varicose vein surgery be reduced?
- How should services for venous disorders be organised?
- What level and content of provision should a commissioning body accommodate?

Health care needs can be defined in terms of the individual's capacity to benefit from treatment. The problem faced by commissioning authorities when considering treatments for varicose veins and associated conditions is in defining the level of particular treatments that should be provided to permit such benefits to be experienced. The question is therefore not simply whether individuals may benefit, but which individuals with which categories of morbidity should be provided with which specific forms of care. In the light of publicity over new drugs termed 'lifestyle' drugs, such as sildenafil, a decision as to whether the NHS should be funding treatments for less severe venous disorders of the leg such as telangiectases, reticular veins and asymptomatic varicose veins, which may be seen as funding cosmetic surgery, will be questioned.

Varicose veins

In the UK each year roughly half a million people consult their general practitioners about varicose veins and associated symptoms.[3] Varicose veins are one of the most common conditions seen in surgical clinics; they make up a significant part of the elective surgery workload and are responsible for a large proportion of operations on waiting lists in NHS hospitals.[4] The independent sector reduces some of this burden, being responsible for around 24% of surgery for varicose veins.[5] Although it has been suggested in the past that there is a low level of interest in varicose veins in the medical profession,[6] and that operations for varicose veins are seen as low priority and are often performed by the least experienced member of the surgical team, often without supervision,[3] there has been considerable change in the last decade, with varicose veins now being taken on increasingly by interested vascular surgeons.[7]

A standard definition of what constitutes a varicose vein has not yet been agreed. The *Oxford Medical Dictionary* defines them as 'veins that are distended, lengthened and tortuous'.[8] Porter described varicose veins as dilated, palpable subcutaneous veins generally larger than 4 mm.[9] The World Health Organization (WHO) defines them as 'saccular dilatation of the veins which are often tortuous'.[10] However, these definitions, if taken literally, could be restrictive and unhelpful to a commissioner of health care, who will be faced with

conditions that the definition would exclude but which are often referred to under the umbrella heading of varicose veins or, more broadly, venous disease. This is discussed further in the section on sub-categories.

In the absence of a precise definition of varicose veins, it is important to understand broadly what varicose veins are and what causes them. Again, this is the subject of much debate.

Anatomy

Venous blood from the skin and subcutaneous fat in the legs is returned to the heart through veins working against gravity. These veins contain valves to prevent a back-flow of blood. There are three types of vein in the lower limbs, and two of these are important when considering venous disease.

- **Deep veins:** These are the venae comitantes to the tibial arteries – the popliteal, tibial and femoral veins and their tributaries. These veins are found beneath the fascia within the fascial compartments. Almost 90% of all venous blood leaves the legs by the deep veins.[11] The blood is under high pressure due to the effects of the calf and foot muscle pump.
- **Superficial veins:** These drain the skin and subcutaneous fat and are situated beneath the skin in the superficial fascia. They include the long and small saphenous veins and their tributaries. The blood is normally under lower pressure than in the deep system due to the protective effect of one-way valves which are in the perforating veins connecting superficial and deep systems. If these valves become incompetent, pressure rises in the superficial system.

Some venous blood drains towards the deep venous system through perforating veins or via the long or short saphenous veins which join the deep system at the sapheno-femoral junction in the groin and the sapheno-popliteal junction behind the knee. It can also drain directly into the deep venous system or bypass the deep system entirely and enter the pelvis.[12] The deep veins carry more blood at a higher pressure than the superficial veins.

Blood is moved from the leg to the heart primarily by the pumping action of the leg muscles, i.e. by muscular compression. The deep veins are subjected to intermittent pressure both at rest and during exercise from pulsations of the adjacent arteries and contractions of the surrounding muscles, which compress the veins and force blood up the limbs towards the heart. As the muscles surrounding the deep veins relax, the pressure within the deep vein lowers temporarily. This causes venous blood to be drawn from the superficial veins into the deep veins, in turn lowering the superficial venous pressure. Competent valves are required to prevent reflux, and to protect the superficial veins and capillaries from a sudden rise in venous pressure when the muscles contract.

Aetiology

In basic terms, the three components of the venous system of the limb – deep veins, superficial veins and perforating veins – work together. Dysfunction of any of these results in dysfunction of the other two.[11] However, although varicose veins have been recognised for centuries, the exact pathophysiology surrounding the development of varicose veins remains controversial. The vast majority of varicose veins arise *de novo* (i.e. are primary). A minority are secondary to obstruction, e.g. pelvic tumours or post-deep vein thrombosis (DVT). Varicose veins do have some recognised predisposing factors, structural abnormalities and abnormal haemodynamic effects which may influence their development.[13]

Predisposing factors

Predisposing factors for varicose veins are difficult to establish due to the interplay of environmental and genetic elements. Family history of varicose veins, increasing age, female sex (though this is now

questioned), parity, ethnicity and occupation may all be factors in the development of varicose veins. A case also exists for the role of height, weight, smoking (though the evidence is weak) and tight underclothes. Aggravating factors such as a fibre-depleted diet (leading to constipation) and long hours spent standing and sitting have been emphasised, and a recurring hypothesis is that adoption of the 'industrial lifestyle' is the major predisposing factor for development of varicose veins. These risk factors will be discussed further in Section 4.

Structural abnormalities

Valvular deficiency

One school of thought is that varicose veins occur when the valves in the veins are incompetent, i.e. they fail to prevent blood returning to the direction from which it has come, resulting in reflux.[14,15] This leads to enlargement of the vein (in length and width) and tortuosity. The location of incompetence varies. DVT is a common mechanism for the destruction of valves in the deep and perforating veins.[11] DVT is estimated to precede the development of varicose veins in as many as 25% of patients,[16] though more information is needed on the association between DVT and varicose veins.

Valvular incompetence in the superficial veins has been said to contribute to 80% of venous disorders.[17] Although valves in varicose veins are stretched and do become atrophic,[18] some believe this to be secondary to the disease process and at present there appears to be little evidence overall to suggest a role for an inherent valvular abnormality as the main cause of primary varicose veins.[13]

Vein wall abnormalities

A number of studies now support the hypothesis that a change in the vein wall precedes valvular incompetence.[18–22] The suggestion that varicose veins are caused by abnormal collagen metabolism has been the subject of much dispute, and changes in elastin content and an increase in smooth muscle in the vein wall as the cause of varicose veins have been suggested.[13] A study in 1992 found a significantly reduced vein wall elasticity and an increased arterial flow in high-risk limbs compared with normal limbs but no corresponding increase in the incidence of valvular incompetence.[23] This study therefore suggests that the role of the venous valves in the development of varicose veins is secondary to changes in the elastic properties of the vein wall and the rate of arterial flow. However, another study of the wall structure and composition of varicose veins with reference to collagen, elastin and smooth muscle content suggested that varicose veins are a dynamic response to venous hypertension and are not thin-walled structures.[24]

Haemodynamic effects

It is thought that increased and irregular blood flow in the veins causes them to become dilated. In addition, the role of arteriovenous fistula in the development of varicose veins was thought to be a contributory aetiological factor. However, very few believe this and the evidence for these theories is limited and inconclusive.[13]

Chronic venous insufficiency/venous ulcers

CVI is manifested by lower limb oedema and lipodermatosclerosis, i.e. skin changes such as pigmentation, atrophy and eczema. It arises secondary to venous hypertension. The high pressure leads to oedema, and leakage of protein has local inflammatory effects.

A chronic venous ulcer can be defined as an area of discontinuity of epidermis, persisting for four weeks or more and occurring as a result of venous hypertension and calf muscle pump insufficiency.[25] It is easily recognised when it is situated in the 'gaiter' region near the medial malleolus (the protuberance at the lower end of the tibia), and occasionally adjacent to the lateral malleolus (the protuberance at the lower end of the fibula). It has a shallow base with a flat margin and the surrounding skin has features of long-standing venous hypertension, i.e. haemosiderin pigmentation, atrophie blanche, eczema, and dilated venules over the instep of the foot.[26]

Venous ulcers are located at the severe end of the spectrum of chronic venous disorders of the leg (*see* Figure 1). Because of this they occur more often in subjects with other forms of venous diseases such as varicose veins and skin changes.[27] Venous leg ulceration has been reported to account for 70–95% of all leg ulcers,[26,28] and 20–50% of these are said to be a consequence of varicose veins.[29,30] However, there is a general lack of data explaining the way varicose veins develop into venous ulcers, and at what point treatment could be advised as being prophylactic rather than remedial.

Venous hypertension is the undisputed initiating factor in venous ulcer development. More severe venous incompetence is associated with a higher risk of ulceration. The higher the venous pressure, the greater the risk, whether incompetence involves the deep or superficial venous system.[31] The reasons why venous ulcers go on to develop is still an area of debate, but there are three main theories (*see* Box 1).

An important determinant of venous ulcers is the venous hypertension that can arise after deep vein thrombosis, especially if it extends above the knee. Brandjes *et al.* have shown that wearing a compression stocking can reduce the incidence of the post-thrombotic limb.[32] This condition commonly occurs after DVT; in the Brandjes study of DVT it occurred in 60% of the control arm within 2 years.

Box 1: Events which cause venous ulceration – three theories. *Source*: Adapted from Hollinsworth, 1998.[297]

- **Fibrin cuff:**[33] Excessive venous pressure causes large molecules of fibrinogen to leak out into superficial tissues because capillary walls are only one epithelial cell thick. Fibrinogen is then polymerised into fibrin cuffs around capillaries, which prevents oxygen and nutrients from diffusing out from the capillaries, leading to cell death and ulceration.
- **White cell trapping:**[34] Venous hypertension causes white blood cells to become trapped and accumulate in the capillaries of dependent legs (legs which are allowed to hang down in the dependent position for long periods). This leads to capillary occlusion, and the release of proteolytic enzymes and toxic metabolites, which result in local ischaemia and ulceration.
- **A combination of mechanisms:**[35] A cascade of events is initiated by venous hypertension. White blood cells release cytokines which stimulate other cells to synthesise fibrin cuffs. These cuffs inhibit the development of new blood vessels and deprive superficial tissues of oxygen and nutrients, leading to tissue damage and ulceration.

More recently, thrombophilia is being investigated as a risk factor for chronic venous ulceration, with a review of the literature concluding that patients with chronic venous ulceration appear to have a prevalence of thrombophilia much higher than the general population but similar to post-DVT patients.[296] One study investigating the prevalence of thrombophilia in patients with chronic venous leg ulceration found that 41% of these patients had thrombophilia.[79] This rate was 2 to 30 times higher than the rate in the general population but was similar to that reported for patients with DVT. However, in patients with chronic venous ulceration, thrombophilia did not appear to be related to a history of DVT, a pattern of reflux or severity of disease.

The impact of chronic venous disorders of the leg

Impact on health and quality of life

There appears to be a high acceptance of symptoms of venous disorders of the leg among affected people.[36] In around two-thirds of patients who have varicose veins the condition is medically insignificant, i.e. it is seen by the patient as insufficiently important to mention spontaneously in health questionnaires, despite being diagnosable on clinical examination. This acceptance could be put down to the fact that varicose veins are such a widespread disease and in most patients are only a slowly progressing condition.[37] For the remaining patients, varicose veins do present a significant problem,[38] one of which may be concerns about the future impact of the disease.

Symptoms reported by patients presenting with varicose veins include aching pain, tiredness/feelings of heaviness, throbbing, itching and swelling in the lower limbs. The relationship between the visible severity of varicose veins and symptoms is, however, weak. Cosmetic dissatisfaction with the appearance of varicose veins is probably universal, although the extent to which it distresses an individual and affects his or her lifestyle will be a matter of personal outlook.

Varicose veins can sometimes be complicated by haemorrhage and thrombophlebitis. The presence of varicose veins is a risk factor for venous thrombosis during abdominal and pelvic major surgery. The role of thromboprophylaxis in varicose vein surgery is uncertain – these patients are generally younger than major surgery patients, are at risk of bleeding post-operatively, and compression methods cannot be easily applied (at least to the operated limb).

Women are more likely to consult their doctor for varicose veins than men. A study in Edinburgh found that only 10% of men reported a previous doctor's diagnosis of varicose veins, compared with 17% of women. This was despite the fact that these men on examination were subsequently found to have a significantly higher prevalence of lower limb varices than women.[39]

Few studies of function or quality of life have been carried out for venous disorders of the leg. Biland and Widmer reported that 10% of patients with varicose veins were unable to work and 25% demonstrated reduced well-being.[40] Smith *et al.*, using the Aberdeen Questionnaire, found that patients with varicose veins have a reduced quality of life compared with the general population and that this is significantly improved at 6 weeks by operating on them.[41] People with leg ulcers have a poorer perceived quality of life than age-matched controls, mainly because of pain and odour.[42] Studies of patients with venous ulcers in the UK have shown high levels of depression, pain and isolation, with very considerable gains from effective treatment.[43] In some severe cases, venous ulcers may lead to long-term entry into care in nursing or residential homes.[44]

Socio-economic impact

The management of venous disorders is thought to represent between 1% and 3% of total health expenditure, with this estimate not including some supplies, cosmetic products and social costs, such as lost productivity.[27]

In the UK in 2000–01, 107 020 people were admitted to hospital for operations for varicose veins of the lower limb (Hospital Episode Statistic [HES] data).[45] In a study carried out in 1992 in five countries (the UK, France, Spain, Italy and Germany),[38] medical costs of venous disorders as estimated from the total amount of resources used annually for ambulatory care (doctors and nurses, drugs purchased and hospital costs) added up to £300 million for the UK. In Germany, around 2% of all people with varicose veins deemed themselves unfit to work for several weeks each year because of complaints related to the condition.[37] Venous disease also creates longer-term costs in disability and dependence on State-funded invalidity pensions.[44] Invalidity costs stemming from venous disease were 0.4% of the total in the UK in 1992.[38]

The management of leg ulcers comprises a significant portion of the workload of community and hospital nurses, general practitioners, dermatologists, surgeons and physicians involved in the care of the elderly. Each ulcer costs around £2000–4000 per annum to treat,[46] and the total cost to the National Health Service in 1995 was estimated at £600 million per annum.[25] There is also a considerable cost to the patient[47] and carers.

Recurrence following treatment

Recurrent varicose veins are a significant problem, with recurrence reported as occurring in 20–80% of cases treated for primary varicose veins, although this depends on the definition of recurrence employed, the length of follow-up and the initial treatment.[48] The rate of occurrence increases with time. Juhan *et al.* assumed a recurrence rate of around 50% up to 5 years.[49] Approximately 20% of varicose vein surgery is for recurrent disease.[50] The average time between the first and second operation ranges from 6 to 20 years.[48] The reasons commonly cited for recurrence include inadequate assessment, incomplete or inadequate surgery, neovascularisation and the subsequent development of reflux from the deep to superficial venous systems.[51–55] Surgery for recurrent varicose veins is technically more demanding and prolonged.[56]

Venous ulcers are chronic and recurrent.[2] Up to 50% of venous ulcers may be present for 7 to 9 months, between 8% and 34% may be present for more than 5 years, and between 67% and 75% of patients have recurrent ulcers.[57,58] Venous ulcers are the most common type of lower limb ulcer, followed by arterial and neuropathic ulcers. They are commonest in the gaiter area above the ankle.[63]

3 Sub-categories

A classification of varicose veins that is of operational use to commissioning authorities is clearly important. However, there is a lack of a clear and universally accepted classification of varicose veins that is easy to use in practice.[59] There are a number of classification systems for varicose veins that are widely used, but they are usually incorporated into classifications of venous disease and are based on clinical severity (*see* Table 2). Few classification systems use objective measurements.

Widmer's classification[60] presented in 1978 is commonly used but is related only to the clinical appearance of the limb. It has been used in clinical studies of treatments of venous disorders but its validity has never been formally assessed.[27] A committee chaired by Porter in the USA[9] described classifications by anatomic region, clinical severity, physical examination and functional assessment. Again, although this classification has been used in many studies on diagnosis and treatment, it has not been formally validated.[27] The most recent classification system to be published is the CEAP classification presented by the American Venous Forum in 1995. This is based on clinical signs, aetiologic classification, anatomic distribution and pathophysiologic dysfunction (CEAP) (*see* Appendix 2). It was developed to provide a comprehensive, objective classification that could be promoted worldwide.

The ease of application of the CEAP classification and its validity have yet to be formally assessed.[27] However, there has already been some criticism of it.[62] The fact that it is all-encompassing has been deemed unnecessary from a clinical point of view, and also that it has attempted to classify on more than one extreme. In addition, its use for epidemiological research has been questioned, as it describes an individual patient and would therefore give rise to many subgroups.[37] It has been suggested that a working classification of chronic venous disease relating to valvular incompetence and/or obstruction

Table 2: Classification of varicose veins and chronic venous disease of the leg.

Author	Class	Definition
Widmer (1978)[60]		*Varicose veins*
	1	*Hyphenwebs*: intradermal venectasis
	2	*Reticular varices*: dilated tortuous veins, not belonging to the main trunk or its major branches
	3	*Trunk varices*: dilated, tortuous trunks of the long or short saphenous vein and their branches of the first or second order.
		Each category is graded 1–3 according to the degree and extent of tortuosity and prominence.
		Chronic venous insufficiency
		Categorised into grades I, II and III according to the presence of dilated subcutaneous veins, skin changes and ulceration.
Porter (1988)[9]	0	Asymptomatic
	1	Mild, i.e. mild to moderate ankle swelling, mild discomfort, and local or generalised dilation of subcutaneous veins. Usually superficial veins only.
	2	Moderate, i.e. hyperpigmentation of the skin, moderate brawny oedema, and subcutaneous fibrosis. There is usually prominent local or regional dilatation of the subcutaneous veins.
	3	Severe, i.e. chronic distal leg pain associated with ulcerative or pre-ulcerative skin changes, eczematoid changes, and/or severe oedema. Usually involves the deep venous system with widespread loss of venous valvular function and/or chronic deep vein obstruction.
'CEAP' (1995)[61] – Clinical classification	0	No visible or palpable signs of venous disease
	1	Telangiectases or reticular veins (also called spider veins/thread veins/star bursts/matted veins)
	2	Varicose veins
	3	Oedema
	4	Skin changes ascribed to venous disease (e.g. pigmentation, venous eczema, lipodermatosclerosis)
	5	Skin changes (as defined above) in conjunction with healed ulceration
	6	Skin changes (as defined above) in conjunction with active ulceration

alone is required.[62] A proposal for two basic classifications has been put forward by Darke and Ruckley:[62]

1 an index of severity based on symptomatology (this is an adaptation of the CEAP clinical classification) and ulceration which is a guide to deciding priorities of need
2 a classification of simple morphology that can be related to treatment options (*see* Table 3).

The VEINES Task Force (VEnous INsufficiency Epidemiologic and Economic Study), set up in part to review the classification of chronic venous disorders of the leg, proposes a scoring system which also uses the CEAP clinical classification but weighs venous disease according to the probability of future leg ulceration.[27] The Task Force's suggested scoring system is shown in Table 4. Scores reflect the outcome values in individual patients, not the treatment efficacy, so that the maximum value is achieved if the problem is completely cured. The classification purposely mixes symptoms and signs as this is how patients present to their physicians, and does not require the use of investigations that may not be universally available. This system also has still to be assessed for its validity.

Table 3: Classification of venous disease presented by Darke and Ruckley.

Clinical presentation	
Grade 1	Asymptomatic
Grade 2	Cosmetic/trivial pain or swelling
Grade 3	Severe pain/swelling
Grade 4	Skin change (lipodermatosclerosis) without ulcer
Grade 5	Chronic ulceration
Morphology	
1	Primary: 1.1 Superficial incompetence alone (long/short saphenous with or without perforator incompetence) 1.2 Deep incompetence with or without superficial incompetence (without evidence of post-phlebitic damage)
2	Secondary (post-phlebitic/traumatic/obstruction)

Table 4: VEINES Task Force proposed scoring system for chronic venous disorder of the leg.

Class (based on CEAP clinical class)	**Weight**
Symptoms and/or telangiectases	1
Varicose veins	5
Oedema (venous)	10
Skin changes	20
Healed venous ulcer(s)	50
Active venous ulcer(s)	100

Source: Kurz *et al.*[27]

Sub-categories for the Health Care Needs Assessment

The sub-categories used in this chapter are displayed in Table 5 and are based on the above classifications and a similar classification proposed by Krijnen *et al.*[36] For ease of use by commissioners, we have grouped asymptomatic with cosmetic/mild discomfort or swelling, and severe pain/swelling with skin change

Table 5: Sub-categories of varicose veins and venous disease to be used in this chapter.

A	Mild discretionary	• Asymptomatic • Cosmetic/mild discomfort or swelling
B	Severe non-discretionary	• Severe pain/swelling • Skin change without ulcer
C	Venous ulcer	Chronic ulceration (healed and active)

without ulcer, based on the Darke and Ruckley scheme. However, our sub-categorisation is not perfect. A study in Edinburgh[64] has concluded that if decisions to operate on varicose veins are based simply on the nature, severity and chronicity of symptoms, or on the extent and severity of varicosities on clinical examination, they are likely to be unreliable.

4 Prevalence and incidence

This section presents information on the prevalence and incidence of venous disease of the leg gathered from a multitude of studies. It highlights the differing epidemiological terminology, populations studied, assessment methods and definitions used.

Meaningful interpretation of the epidemiological studies on varicose veins requires the following knowledge.

1 The method of measurement/assessment of varicose veins varies greatly. Some studies rely on simple questionnaires completed by the patient,[65,66] a method of data collection liable to error[67] and of little value in most epidemiological studies of varicose disease.[68] Others involve physical examination, photography and the use of continuous-wave Doppler measurement.[69] There can be a lack of precision when diagnosing varicose veins by examination alone, and observation criteria used by different research teams are unlikely to be strictly comparable. The more recent studies are probably easier to interpret as they have new assessment techniques available to them. However, studies in general seldom provide data on the validity of the method used.[70]

   It has been reported that the use of self-assessment questionnaires leads to the lowest prevalence, interviewer-assisted questionnaires result in higher prevalence, while the use of physical examination leads to the highest values.[37]

2 The comparability of population studies estimating the prevalence and incidence of varicose veins is limited by the varying definitions of varicose veins used. As the previous section emphasises, there is a lack of consensus concerning which definition/classification system for venous disease and varicose veins should be used. There were 18 different definitions employed in the prevalence studies identified, ranging from no definition[65,71,72] to a definition using classification of type and severity.[73,74] An important variation is the specific inclusion or omission of hyphenwebs/telangiectasias and small subcutaneous (reticular) veins, both of which could lead to a marked variation in the overall prevalence of varicose veins reported. Even if the same definition is used, considerable variations in the interpretation of the observer/respondent can occur. This problem was highlighted in the 1960s by a WHO expert:

   > *as long as the terminology varies between the different schools and languages, as long as generally acceptable criteria for the clinical diagnosis of primary and secondary varicose veins have not been developed, the data of national surveys as well as of other samples are not comparable.*[10]

3 Many of the epidemiological data relate to highly selected groups rather than a representative sample of the general population. Many studies consider patients or people who probably do not represent the general population in the UK – for example, residents of villages in New Guinea,[75] provincial towns in Tanzania[76] and residents of Cook Island.[77] The age and sex distribution of the populations examined also varied widely. In the majority of studies a minimum age of around 15 to 20 years was used, in others a maximum age was employed, and some studies only included specific age groups. The nature of many of the populations studied renders most of these studies of limited value in determining levels of service requirement in the UK.

Prevalence of varicose veins and other venous disorders of the leg

Callam[78] analysed all studies looking at the prevalence of varicose veins available in 1994 and estimated the prevalence of venous disease in the lower limb (*see* Table 6). This shows that venous disease in the general population is common and that women appear to be affected more than men. It also shows that at the more severe end of the scale only a small percentage of the population is affected.

Table 6: Prevalence of lower-limb venous disease in adults.

Severity	Prevalence (%)	
	Men	Women
Venous disease (all types)*	40–50	50–55
Visible varicose veins†	10–15	20–25
Chronic venous insufficiency‡	2–7	3–7
Chronic venous leg ulceration	0.5–1	1–1.5

Source: Callam.[78]
* Any evidence of venous disease including venectasia.
† Reticular and truncal varicosities.
‡ Hyperpigmentation, eczema and liposclerosis.

A review of the literature to October 2001 has revealed a number of studies published since this review. Some of these are probably more relevant to the UK population. The results of all studies identified by this literature review are tabulated in Appendix 3.

The prevalence studies that are more representative of the UK population are described below.

Prevalence studies: Europe and the USA

National studies

In early national health surveys recording a number of chronic disorders, the prevalence of varicose veins was found to be relatively low. An estimated national prevalence of around 2% was found in a number of surveys among random samples of the population (US National Survey 1961–63, UK Survey of Sickness 1950, the Sickness Survey of Denmark 1952 and the Canadian Sickness Survey of 1950–51).[80] However, the results from these surveys are questionable – the definition of varicose veins was often not stated and the surveys were by questionnaire alone and usually administered by untrained non-medical personnel.[81] This low prevalence is made more questionable by other population and regional surveys and Callam's study,[78] designed specifically to consider prevalence of varicose veins, which have shown higher rates of prevalence.

Regional studies

Ideally, a population study including either the whole population or a stratified random sample defined by age and sex is required to reveal the true prevalence of a disease such as varicose veins.[82] However, regional

surveys that are limited to a specific neighbourhood or city have proved to be of great value in epidemiological research.[37] In addition, unlike the early national surveys, the majority of regional surveys identified are designed primarily for investigating venous disorders rather than a number of diseases.

Regional studies in Europe and the USA identified in a MEDLINE search to October 2001 are listed in Table 7. This information shows a wide variation in the prevalence of varicose veins with reported prevalences between 6% and 85%, depending on the type and severities of varicose vein included in the study and the methodology of the study. Several of the studies indicate that if all types of varicose veins are included, more than half of the adult population is affected,[83] as per Callam above.

Table 7: Regional population studies – Europe and the USA.

Study	Country	Year	Population/setting	Total number	Prevalence of varicose veins		
					Female	Male	Total
Preziosi *et al.*[84]	France	1994–98	Participants of the SUVIMAX cohort. Women 35–60; men 45–60 (representative of the French population for the age range under consideration)	3,065 (1,747 women, 1,318 men)	18.1% – medically diagnosed 12.4% – self-diagnosed	10.8% – medically diagnosed 7.4% – self-diagnosed	
Evans *et al.*[83] Bradbury *et al.*[64]	Scotland	1994–96	Men and women aged 18–64 resident in Edinburgh	1,566 (867 women, 699 men)	Trunk 1: 26% 2 or 3: 6% Hyphenweb 1: 84% 2 or 3: 10% Reticular 1. 85% 2 or 3: 6%	Trunk 1: 33% 2 or 3: 6% Hyphenweb 79% 2 or 3: 6% Reticular 82% 2 or 3: 4%	
Cesarane *et al.*[82]	Italy	1994	Residents of San Valentino, a village in Central Italy, aged 8–94 (mean age 46.3 ± 7)	746 (379 women, 367 males)			About 8% (venous diseases)
Canonico *et al.*[85]	Italy	1991–92	Males and females aged 66–96 (mean 74.2) (a random sample drawn by means of a stratified multi-stage sampling design using electoral rolls)	1,319 (560 men, 759 women)	35.2%	17.0%	362 (27.4%)
Franks *et al.*[65]	England	1989	Patients from general practices in West London aged 35–70	1,338	31.5%	17.5%	25%
Leipniz *et al.*[86]	Germany	1989	Randomly selected from population. Males and females aged 45–65	2,821	29%	14.5%	20.2%

Table 7: Continued.

Study	Country	Year	Population/setting	Total number	Prevalence of varicose veins		
					Female	Male	Total
Laurikka *et al.*[66]	Finland	1989	People born in 1929, 1939 and 1949, i.e. 40, 50 and 60-year-olds	5,568	42%	18%	
Rudofsky[87]	Germany	1988	Community sample. Males and females aged >15 years	14,000			15%
Henry and Corless[88]	Ireland	1986	Random sample of households	4,900			622 (12.7%)
Fischer[89]	Germany	1983	Random sample aged 17–70 (intracutaneous to trunk varices)	4,530			59%
Novo *et al.*[90]	Western Sicily, Italy	1977–79	A sample of the population of the village of Trabia, which mainly comprises farmers, fishermen and a few craftsmen and traders	1,122	46.2%	19.3%	35.2%
Weddell[67]	Wales	1966	Randomly selected from the electoral roll. Males and females aged 15+	289	53% (non-clinical: 36%; clinical: 17%)	37% (non-clinical: 31%; clinical: 6%)	
Coon *et al.*[91]	USA	1959–60 and 1962–65	Residents of Tecumseh, a city in SE Michigan, aged 10 years +	6,389	25.9% (moderate to severe 16.7%)	12.9% (moderate to severe 7.4%)	
Arnoldi[92]	Denmark	1958	Clinic attendees aged >25 years	1,981	38%	18.4%	28%
Lake *et al.*[71]	USA	1942	Males and females over 40 years representing four different types of occupational activity: sitting, standing, walking, climbing	536	73.2%	40.7%	57%

The Edinburgh vein study[39,64,83] is probably the most relevant study to the UK population and will be described in more detail. It looks at the prevalence of varicose veins and chronic venous insufficiency. It considers a wide age range, includes both sexes, defines the classification of chronic venous disease and uses clinical examination in addition to a questionnaire. It does not, however, have any data on non-Caucasians.

The Edinburgh vein study

The primary aim of the study was to conduct a detailed population survey of the prevalence of all grades of venous disease in a randomly selected age-stratified sample of the adult population. It was a cross-sectional survey of men and women aged 18–64 years old resident in Edinburgh. The sample was selected from computerised registers of 12 general practices with catchment areas geographically and socio-economically distributed throughout Edinburgh. There were 1566 participants out of 2912 people who were initially approached, giving a response rate of 53.8%. A follow-up of a sample of 194 non-respondents suggested that participants were more likely to have a history of diagnosed venous disease than the general population. Hence the prevalence figures may be overestimates. Participants were also more likely to be women ($n = 867$) than men ($n = 699$) and from the older age group range (mean age was 44.8 for women and 45.8 for men).

Subjects attended a research clinic or, if they were unable to do this, were visited at home. All participants completed a self-administered questionnaire which was subsequently checked by a member of the research team. The questionnaire asked about the presence of various symptoms often attributed to venous disease. It also recorded personal and occupational details, relevant medical and family history and possible risk factors for venous disease. After completion of the questionnaire both legs were examined. The method of classification of venous disease was adapted from Widmer (*see* Table 2). Trunks were defined as 'dilated, tortuous trunks of the long and short saphenous vein and their branches of the first or second order', reticulars as 'dilated, tortuous subcutaneous veins not belonging to the main trunk or its major branches' and hyphenwebs as 'intradermal varices'. Each of these three groups was subdivided into grades of severity 1–3. In practice, grade 1 trunks ranged from a small, discrete, visible or palpable length of dilated trunk vein to more obvious but not grossly dilated veins, grade 2 trunks were more extensive and/or more grossly dilated trunk varices, and grade 3 trunks were varices at the most severe end of the spectrum.[39] Patients were examined after they had been standing for at least two minutes and varices were graded 1 to 3 accordingly using standard reference photographs. Subjects were also examined for the presence of any pitting ankle oedema, and assessed for CVI. Grade 1 CVI corresponds to malleolar flare, grade 2 CVI corresponds to skin changes, and grade 3 CVI corresponds to healed or active ulceration.

Prevalence of leg symptoms

Women were more likely than men to have lower leg symptoms (*see* Table 8), despite fewer women having trunk varices than men (32% vs. 40% age-adjusted prevalence). The prevalence of symptoms increased with age in both men and women, and this links in with the increased prevalence of varicose veins (all severities) with age.

Table 8: Age-adjusted prevalence (%) of leg symptoms in men and women (Edinburgh vein study).

Leg symptoms	Men ($n = 699$)	Women ($n = 867$)	p-value
Heaviness or tension	16.0	28.6	$\leqslant 0.010$
Feeling of swelling	9.2	23.0	$\leqslant 0.010$
Aching	32.5	53.8	$\leqslant 0.010$
Restless legs	20.0	35.1	$\leqslant 0.010$
Cramps	34.0	42.0	$\leqslant 0.010$
Itching	19.0	25.3	$\leqslant 0.010$
Tingling	16.0	19.8	$\leqslant 0.084$

Source: Bradbury *et al.*[64]

Prevalence of venous disease

Hyphenweb and reticular varices were very common in both sexes (*see* Table 9), although the majority had these varices only to a mild degree. Trunk varices were more common in men than women, the age-adjusted prevalence of trunk varices being 39.7% in men and 32.2% in women. Again, the majority of affected subjects had mild lower limb varices. The figures for varicose veins are higher than Callam's figures, partly due to the detailed physical examination undertaken in the Edinburgh study. However, the prevalence of venous insufficiency is comparable to Callam's figures.

Table 9: Age-adjusted prevalence of grades of varices by sex (Edinburgh vein study).

	Grade	Males ($n = 699$)		Females ($n = 867$)		*p*-value
		%	*n*	%	*n*	
Hyphenweb varices	1	79.2	554	84.4	732	0.260
	2	5.9	44	9.2	76	0.030
	3	0	0	0.6	5	–
Trunk varices	1	33.3	238	26.2	223	0.009
	2	5.4	39	5.6	47	0.888
	3	1.0	7	0.5	4	0.241
Reticular varices	1	81.6	571	85.3	739	0.422
	2	4.0	29	6.4	54	0.042
	3	0	0	0	0	–
CVI	1	6.9	51	5.3	44	0.157
	2	1.3	10	1.1	9	0.607
	3	1.0	8	0.2	2	0.058

Source: Evans *et al.*[39]

Studies of selected populations

Many studies investigate limited age groups, samples of clinic populations or specific occupational groups (*see* Appendix 3). Studies of selected populations can be useful in identifying the risk factors for varicose veins but are limited in estimating the overall prevalence of varicose veins in a population.

Incidence

The incidence of varicose veins is the development of new cases over a period of time in a population. The Framingham study[93] followed up men and women who were living in Framingham, USA. Every 2 years from 1966 over a 16-year period, subjects were examined for varicose veins. Over the 16 years, 396 of 1720 men and 629 of 2102 women who were initially free from varicose veins developed varicose veins. The two-year incidence rate of varicose veins was on average 39.4 per 1000 for men and 51.9 per 1000 for women, i.e. 4–5%. The incidence rate beyond the age of 40 years did not increase with age, suggesting that the relationship between age and prevalence is due to a relatively constant development of new cases as people age.[27]

The 11-year Basel vein follow-up study[94] found that in a group of 660 adult subjects who were free of varicose veins at the initial examination, after 11 years 87% had developed non-relevant varicose veins and 5% relevant varicose veins. Amongst the 510 subjects with relevant varicose veins at entry, 27% developed

deep vein thrombosis or superficial phlebitis and 10% developed venous leg ulcers. Among the subjects with non-relevant varicose veins at entry, these proportions were 8% and 0.8%, respectively.

Risk factors

Risk factors for varicose veins include fixed factors (female sex, age, pregnancy, ethnicity, geographic location, left iliac vein compression by the right iliac artery, family history) and potentially preventable factors (obesity, occupations requiring prolonged standing or sitting, lack of dietary fibre, use of constricting corsets, and sitting posture for defecation).[78] Table 11 summarises the available evidence on risk factors for varicose veins. The VEINES Task Force[27] found that apart from age and sex, evidence linking most factors to varicose vein development is limited, and concluded that the evidence was adequate only for pregnancy and obesity. The findings on the aetiology of primary varicose veins do not suggest that there is large scope for primary prevention.

Sex

It is generally believed that women are more commonly affected by varicose veins than men and most studies have shown a female predominance of varicose veins.[66,67,72,84,85,88,90,91,95–97] In the majority of studies the sex ratio decreases with increasing age. For example, a study in Israel found that in 20–34-year-olds the sex ratio was 6 females:1 male, but in people aged 65–74 this ratio fell to 1.5 females:1 male.[95]

There are a number of exceptions to this rule, notably the Edinburgh vein study (*see* Table 10), which found that there was a significantly higher prevalence of trunk varices in men compared with women,[39] a study in Switzerland[98] where there was no significant difference between the prevalence of varicose veins in men and women, and a study in New Zealand[74] where, although the prevalence of mild and moderate varicose veins was higher in women, gross varicose veins were equally prevalent in men. Higher rates in women might be related to greater self-reporting, especially of less severe varicose veins.

Table 10: Prevalence of trunk varices and CVI by age and sex (Edinburgh vein study).

	Age (years)										***p*-value**
	18–24		**25–34**		**35–44**		**45–54**		**55–64**		
	%	***n***	**%**	***n***	**%**	***n***	**%**	***n***	**%**	***n***	
Trunk varices (all severities)											
Men	20.0	11	15.5	16	36.1	57	42.0	76	61.4	124	0.000
Women	5.3	4	13.9	22	22.6	42	41.9	95	50.5	111	0.000
Total	11.5	15	14.6	38	28.8	99	41.9	171	55.7	235	0.000
Chronic venous insufficiency (all severities)											
Men	–	0	–	0	2.5	4	7.7	14	25.3	51	
Women	1.3	2	1.3	2	3.8	7	7.9	18	12.3	27	

Source: Evans *et al.*[39]

Age

The association between age and prevalence of varicose veins is fairly conclusive. The majority of surveys listed in Table 11 (*see* overleaf) show a steady increase in prevalence of varicose veins with increasing age for all grades of varicosity. The increase, however, was not as significant in the older age groups or was not apparent at all in some studies.[76,97] In addition, the incidence rate flattens in the Framingham study, suggesting that age is a less important risk factor in older ages. The Edinburgh vein study (*see* Table 10) showed that the prevalence of trunk varices increased linearly with age in both sexes, and ranged from 11.5% in the 18–24-year-olds to 55.7% in the 55–64-year-olds when both sexes were combined ($p \leqslant 0.001$).[39] The same trend was found in the prevalence of reticular and hyphenweb varices ($p \leqslant 0.001$).

Varicose veins can be present before adulthood. In a longitudinal study (not presented in Table 11) a cohort of schoolchildren aged 10–12 years was examined. The presence of discrete reticular varices was found in only 10% of the pupils. Four years later this figure had risen to 30%, with a number of children developing stem and branch varices.[99]

The age-related patterns suggest that the prevalence of venous disease will increase as demographic change shifts to an older population.

Pregnancy

It is generally believed that pregnancy leads to varicose veins due to the pressure of the uterus obstructing venous return from the legs. However, this has been refuted, as the majority of varices appear during the initial 3 months when the uterus is not large enough.[100] A hormonal factor is thought to be responsible or the increased circulating volume of blood.

The majority of studies in Table 11 show an association between the onset of varicose veins and pregnancy.[67,71–74,76,77,90,96,101] Women with at least one pregnancy generally had a higher prevalence of all types of varicose veins than women who had no pregnancies.[69,74,84,90,95,97,102,103] Some studies found that parity was only a significant risk factor in younger women.[96,101] With increasing age, the influence of pregnancy on the prevalence of varicose veins is smaller.[69] A study in Switzerland[73] found that when the age factor was excluded no significant association remained between the prevalence of varicose veins and childbirth. In addition, the Tecumseh community health study[91] and a study in Tanzania[76] failed to show a rising prevalence with increasing number of pregnancies.

Ethnicity and Western lifestyle

A striking feature of the epidemiological studies of varicose veins is a marked geographical variation in prevalence rates, suggesting a possible association with ethnic group or with lifestyle factors. Several studies suggest that varicose veins are rare in Africa and other developing countries[75] compared with Western societies.[76,104] A study in Jerusalem[95] showed that men born in North Africa had significantly lower age-adjusted prevalence rates than immigrants from Europe, America and Israel. Other variations shown in different ethnic groups within a country include a higher prevalence in Southern Indian railway workers than in Northern Indian railway workers,[105] a higher prevalence of varicose veins in whites than non-whites in Brazil[97] and a lower prevalence in Southern Europeans than in other Europeans in a study of women in Switzerland.[73] A study comparing female cotton workers in England and Egypt found that the prevalence of varicose veins was significantly higher in English women than in Egyptian women.[101]

The key question is: do Indo-Asians and African Caribbeans in the UK have higher or lower rates of varicose veins than Caucasians? No studies were identified that answer this question, as it is difficult to assess the contributions of genetic predisposition and environmental (e.g. Western lifestyle) influences.

Table 11: A summary of the evidence on risk factors for varicose veins (continued opposite).

Study	Age	Sex	Race	Family	Occupation	Parity	Obesity	Height	Smoking	Other
Edinburgh[39]	Prevalence increases with age ($p = 0.000$)	Mild trunk varices were more prevalent in males ($p = 0.009$). Other varices more prevalent in females (NS)	–	–	–	–	–	–	–	Social class (NS)
Western Sicily[90]	Prevalence increases with age (SNR)	More prevalent in females (SNR)	–	–	–	Increased prevalence in women with one or more babies (SNR)	More prevalent in respondents with a higher relative body weight (SNR)	–	–	Patients suffering constipation showed a higher prevalence (SNR)
Tampere, Finland[66]	Increases with age (SNR)	More prevalent in females (SNR)	–	–	–	–	–	–	–	–
Tecumseh, USA[91]	Increases with age (SNR)	More prevalent in females (SNR)	–	–	–	No correlation	–	–	–	–
Campania, Southern Italy[85]	No correlation ($p = 0.75$)	More prevalent in females ($p = < 0.0001$)	–	–	No relationship between varicose veins and previous occupation	–	More prevalent in female subjects with a higher BMI ($p < 0.0001$). Males – no correlation	–	No correlation	Alcohol consumption – no correlation (women $p = 0.005$, NS in men). Constipation – no correlation
Cardiff, Wales[67]	Prevalence increases with age (SNR)	More prevalent in females	–	–	Varicose veins more prevalent in men and women whose work involved heavy lifting ($p < 0.05$). No correlation with work involving long hours of standing	Increased prevalence with parity ($0.2 < p < 0.3$)	–	–	–	–

Ireland[88]	Prevalence increases with age	More prevalent in females	–	–	Increased prevalence in standing employment	Increased prevalence with number of pregnancies	–	–	–	–
New York[102] (female sample)	–	–	–	Family history ($p < 0.0001$)	Increased prevalence with standing vocation (> 6 hours/ day) ($p < 0.0001$)	Increased prevalence with pregnancy ($p < 0.0001$)	Increased prevalence with obesity (< 20% over ideal weight) ($p < 0.0001$)	–	–	Oral contraceptive use – no correlation
France[84]	Prevalence increases with age (SNR)	More prevalent in females (SNR)	–	–	–	Increased prevalence with parity ($p = 0.007$)	Increased prevalence with increasing BMI ($p = 0.003$)	–	–	–
Turkey[103]	Prevalence increases with age	More prevalent in females than males but NS ($p > 0.005$)	–	Positive family history ($p = 0.001$)	–	Association with at least one pregnancy (S)	No association	No association	No association	–
Czechoslovakia[69] (female sample)	Prevalence increases with age ($p < 0.05$)	–	–	Positive family history ($p < 0.01$)	Increased prevalence in women standing compared to sitting and changing position	Higher prevalence with at least one pregnancy ($p < 0.001$)	Increased prevalence with rising body weight (S)	–	–	Physical activity – NS. Blood pressure – NS
Switzerland[73] (female sample)	Prevalence increases with age ($p < 0.001$)	N/A	Prevalence lower in Southern Europeans than in Central Europeans (S)	–	Prevalence higher in women standing at work but no significant correlation ($p = 0.11$ after removing age factor)	Prevalence increased with number of children born but NS when age factor was excluded	Increased prevalence with increasing body weight but NS when age factor was excluded	No significant association	–	Corsetry – NS
England and Egypt[101] (female sample)	Prevalence increases with age ($p < 0.001$)	N/A	Prevalence higher in England than in Egypt ($p < 0.001$)	Positive family history ($p < 0.001$)	Higher prevalence in women standing (England: $p < 0.001$, Egypt: NS)	Prevalence higher in women who had had children (England: $p < 0.05$, Egypt: $p < 0.01$). Only in 15–34 age group	Increased prevalence with body weight (England: $p < 0.001$, Egypt: NS)	–	–	Constipation – NS. Corsetry – England: $p < 0.001$ or $p < 0.01$ when standardised, Egypt: NS)

Table 11: Continued.

Study	Age	Sex	Race	Family	Occupation	Parity	Obesity	Height	Smoking	Other
Basle, Switzerland[98]	Prevalence increases with age	NS	–	–	–	–	NS	NS	–	–
New York[71]		More prevalent in females (SNR)	–	–	Walkers have higher prevalence than sitters, but NS	–	–	–	–	–
Finland[72]	Prevalence increases with age	More prevalent in females	–	–	No association in occupational groups. Standing S in women ($p < 0.001$)	More prevalent in women who have had children, increasing linearly up to 5 children ($p < 0.001$)	Increased prevalence with increasing body weight and BMI (S)	In women, more prevalent in taller women ($p < 0.001$)	In women, less prevalent in smokers ($p < 0.01$)	–
Western Jerusalem[95]	Prevalence increases with age ($p < 0.001$)	Prevalence higher among women	Prevalence lower in men born in North Africa ($p < 0.01$)	–	Higher prevalence in workers who spend a lot of time standing ($p < 0.01$)	More prevalent with at least one pregnancy ($p = 0.0011$)	More prevalent in heavier groups ($p < 0.00001$)	More prevalent in taller subjects ($p = 0.007$)	No significant association	Corset – more prevalent ($p < 0.01$). Stockings ($p < 0.01$). Inguinal hernia in men ($p = 0.0006$)
New Zealand[74]	Prevalence increases with age	Prevalence higher among women for mild and moderate varicose veins but equally prevalent for gross varicose veins	–	–	–	More prevalent with one or more pregnancies	No association	–	–	–
Japan[96] (female sample)	Prevalence increases with age	Prevalence higher in women	–	–	–	More prevalent with one or more pregnancies but only in younger age groups	No association	No association	No association	–

Tanzania[76]	No association	Prevalence higher in men but NS	–	–	–	No association	–	–	–	–
Brazil[97]	Prevalence increases with age (S) but not after 40 years of age in women	Prevalence higher in women (S)	Prevalence higher in white than non-white (S)	–	No association	Correlation between prevalence and number of pregnancies (S)	–	–	–	Posture adopted for defaecation – no association
India[105] (male sample)	Increasing prevalence with increasing age	–	Prevalence higher in South Indian than North Indian ($p \leqslant 0.001$)	–	No association	–	–	–	No association	–
Amsterdam, The Netherlands[36]	Increasing prevalence with age ($p < 0.0005$)	–	–	–	Large number of years in a standing profession on severity ($p < 0.05$)	–	Increasing prevalence with increasing weight ($p < 0.005$)	–	–	–

S = significant.
NS = not significant.
SNR = significance not reported.
– = not investigated or reported.

Family history

A number of studies have found that the risk of varicose veins was higher in those with affected relatives,[69,101–103] perhaps suggesting a genetic element or shared environmental factors. However, it has been noted that these results should be regarded with caution. In most studies considering a family history, the relatives were not examined. In addition, family members are not good judges of the presence of varicose veins in the rest of the family,[67] and people with varicose veins are more likely to notice this condition in their relatives than individuals without varicose veins.[37]

Body weight and height

Several authors have found an association between weight and body mass and an increased risk of varicose veins. Of the studies in Table 11, a positive correlation with varicose veins was found in seven studies[69,72,84,90,95,101,102] and no correlation was found in three of the studies.[69,74,96] In a further study, the higher the body mass index, the more prevalent varicose veins were in women, but there was no association in the male participants.[85] In a female population in Switzerland, although there was an increased prevalence of varicose veins with increasing body weight, this was not significant when the age factor was excluded.[73] The rising prevalence of obesity in Western countries may lead to a greater burden of venous disease.

A number of studies reported an association between body height and varicose veins.[72,95] The mini-Finland study showed a smoothly graded increase in prevalence with increasing height.[72] However, more studies found no correlation between height and varicose veins.[73,96,98,103]

Occupation

A person's occupation has been put forward as a possible risk factor for varicose veins. A standing occupation has been indicated in some studies as a significant risk factor for varicose veins,[69,72,88,95,101,102] although this has been found to be insignificant in other studies[71,73] and refuted in yet others.[67,105] Work involving heavy lifting was significantly related to the presence of varicose veins in one study.[67] A number of studies show no correlation between occupation and the prevalence of varicose veins.[71,85,97] A review of venous insufficiency at work concluded that there are undoubted risk factors in the workplace but recommended further research in this area.[106]

Other risk factors

Smoking

A correlation between cigarette smoking and varicose veins was found among men in the Framingham study,[93] but other studies have shown no relationship between cigarette smoking and varicose veins.[85,95,96,103] In one study varicose veins were less prevalent in women who smoked.[72]

Constipation

A diet deficient in fibre has been implicated as a major factor in the causation of varicose veins.[107] It is thought that fibre-depleted diets lead to constipation, and the subsequent straining to produce a stool produces high intra-abdominal pressure which is transmitted to the leg veins and progressively dilates

them.[76] A positive correlation was shown between constipation and the prevalence of varicose veins in one study[90] but not in others.[85,101]

Constricting undergarments

The role of corsets in the development of varicose veins was investigated in a number of studies[73,95,101] and was found to be significant in two of them.[95,101]

Social class

In the Edinburgh vein study there was no obvious relationship between social class (classified by occupation) and the age- and sex-adjusted prevalence of trunk varices.[39]

Post-thrombotic limb

Post-thrombotic limb is the term used to describe venous insufficiency when there is evidence of previous deep vein thrombosis (DVT). Studies have reported frequencies of the syndrome in between 5% and 100% of patients having an acute DVT, especially when the DVT extends proximal to the popliteal fossa. This can be reduced by using a compression stocking post-DVT.[32]

Prevalence of oedema and skin changes (chronic venous insufficiency)

The prevalence of venous-related oedema and skin changes is not well documented. In Tecumseh, USA,[91] 37% of women and 3.0% of men had skin changes. The prevalence increased markedly with age from 1.8% in women aged 30–39 years to 20.7% in women over 70 years of age. The marked gender difference was not demonstrated by the Edinburgh study,[39] which found that 1.1% of women and 1.3% of men had skin changes (hyper- or de-pigmented areas, with or without corona phlebectatica), but again the prevalence increased with age. Under the age of 35 years, CVI (all severities) was extremely rare in women and did not occur at all in men, but it increased to 12.3% in women and 25.2% in men in the oldest age group investigated (55–64 years).

CVI is more common if varicose veins are more severe – if both deep and superficial systems are involved, if both long and short saphenous veins are varicose and if there is below-knee involvement.

Prevalence of venous ulcers

There have been many studies on the prevalence of leg ulceration but, as with the studies on varicose veins, the variations between definitions and methodology employed in these studies make it difficult to give a definitive prevalence figure. A review by Callam[108] of the prevalence of chronic leg ulceration in Western countries concluded that active chronic leg ulceration has a point prevalence of 0.1–0.2% of the adult population and approximately 1% of the population will suffer from leg ulceration at some time in their lives. Studies by Nelzen agree with this figure, suggesting that the prevalence of healed ulcer is 2 to 4 times higher than that of active ulcers and that the prevalence of both together in the population is around 1%.[109–111]

The sex ratio (M:F) is generally thought to be 1:2 to 1:3 at all ages,[27] but the Edinburgh study[39] found that 1% of men and 0.2% of women had grade 3 CVI (i.e. healed or active ulceration). The prevalence of venous ulcers increases consistently with age,[109–114] with chronic leg ulceration being relatively

uncommon below the age of 60,[112] unlike varicose veins. The annual incidence rate in the population over 45 years of age was estimated at 3.5 per 1000 in one retrospective study.[115]

Health service utilisation data

Primary care: morbidity statistics from general practice (1991–92)

The results from the Fourth National Study of Morbidity Statistics from General Practice[116] can be used to estimate the incidence and prevalence of varicose veins and venous ulcer as they present to general practitioners (GPs) in the community (*see* Table 12) and therefore the potential workload of a typical primary care trust (PCT). The study, carried out in 1991–92, presents data on the level and detail of morbidity seen in general practice and covers a 1% sample of the population of England and Wales (502 493 patients, 468 042 person-years at risk). These people were on the list of 60 practices volunteering to take part. The prevalence estimates include all severities of varicose veins covered by ICD-9 code 454 (*see* Appendix 1), and include venous ulcers.

The data from the study reflect the main trends and information gathered from the prevalence studies mentioned earlier, particularly the higher presentation rates in females. They also show the strong prevalence age gradient that continues up to the over-75s.

The data suggest that for a typical PCT ($n = 100\,000$) there would be around 1770 people in the PCT with varicose veins (with or without venous ulcer), around 1250 cases presenting with varicose veins for the first time each year and around 2540 consultations with a doctor for varicose veins (with or without venous ulcer) each year. The prevalence suggested by these data does appear to be lower than in most of the prevalence studies. However, it should be recognised that the figures in the GP study are only based on people who present to their general practitioner and do not include those who do not see their GP for their complaint (i.e. they do not describe population rates). As mentioned earlier, a significant proportion of people with varicose veins do not present to primary care.

Table 12: Results from the Fourth National Study of Morbidity Statistics from General Practice.

Varicose veins of lower extremities (ICD 454*)		**Age group (years) and sex**								
		Total	**0–4**	**5–15**	**16–24**	**25–44**	**45–64**	**65–74**	**75–84**	**85 and over**
Patients consulting (rates [prevalence] per 10,000 person-years at risk)	Male	58	1	1	10	31	97	197	232	232
	Female	119	1	1	33	96	186	263	307	244
	Total	177	2	2	43	127	283	460	539	476
New and first ever episodes (rates per 10,000 person-years at risk)	Male	40	0	1	8	24	70	123	166	119
	Female	85	1	1	27	75	138	177	193	158
	Total	125	1	2	35	99	208	300	359	277
Consultations with doctor (rates per 10,000 person-years at risk)	Male	95	0	1	14	42	177	296	432	368
	Female	169	3	1	37	111	270	431	482	364
	Total	254	3	2	51	153	447	727	914	732

*This code includes varicose veins with ulcers and inflammation.

Summary

The best available data likely to be representative of the population in England and Wales appear to be those from the Edinburgh vein study (albeit a Scottish study, but recent and population based). Incorporating the results of this study into the sub-categories defined in the previous section, a prevalence of varicose veins and CVI has been estimated (*see* Table 13). This estimate is likely to be low if applied to the whole population, as the population in the Edinburgh study was limited to 18–64-year-olds. Other studies have indicated that there is a strong age gradient which continues up to the over-75s age group.

Table 13: Estimated prevalence of varicose veins and CVI (population aged 18–64 years).

		Estimated prevalence (%)	
		Male	**Female**
A	Mild discretionary*	40	31
B	Severe non-discretionary†	8	7
C	Venous ulcer‡	1	1

* Based on the prevalence of trunk varices (Grade 1) and CVI (Grade 1).
† Based on the prevalence of trunk varices (Grade 2–3) and CVI (Grade 2).
‡ Both healed and active ulceration (latter about 0.1–0.25%).

5 Services available and their costs

The services and treatment options available to a person in the general population who has varicose veins and related diseases will depend on:

- the nature of the patient's complaints and expectations. What is their perception of the severity of the condition? How important is the cosmetic appearance to them? Do they know what treatments are available to them, the side-effects of these treatments and the levels of recurrence? Are they willing to undergo these treatments?
- the clinical severity of the varicose veins and venous ulcer(s)
- the cause of the varicose veins/venous ulcer(s) and the site of incompetence (which guides treatment)
- the policies of local health providers
- waiting lists which reflect supply and demand
- diagnostic facilities and expertise.

Corbett[117] stated that in terms of providing services to a population there are two important considerations: the proportion of patients who are likely to require surgery for symptoms, and whether varicose vein surgery plays any part in preventing ulceration in old age. The latter is debatable, as indicated in Section 4.

Figure 2 summarises the various service options likely to be used by patients with chronic venous disease of the lower limb. At any point of the referral process, patients may decide to circumvent long NHS waiting times and seek private treatment.

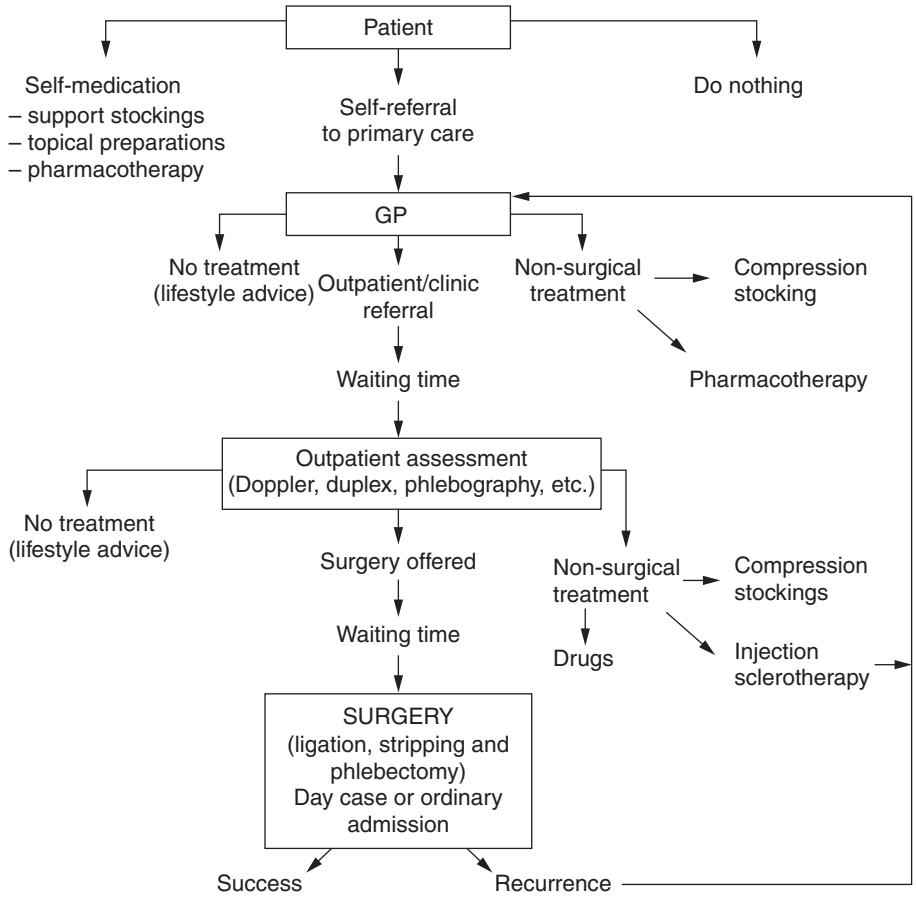

Figure 2: Flow chart illustrating points of decision making in the treatment of chronic venous disease.

Primary prevention

The VEINES Task Force concluded that the evidence on associated risk factors for varicose veins was only adequate for pregnancy and obesity.[27] There are also thought to be some risks with occupations involving much standing (*see* Section 4). Specific measures suggested to help prevent the development of varicose veins include weight control, reducing the amount of standing in certain jobs, and greater physical activity.[69] The use of a prophylaxis to prevent DVT in high-risk situations (e.g. hospitalised medical and surgical patients) and the use of compression stockings following definite DVT to prevent post-thrombotic limb are discussed elsewhere.

Initial contact with health care services

Many people with varicose veins will choose not to seek any medical advice. When they do, a significant proportion of patients seek an opinion because they are primarily concerned about the cosmetic appearance of their veins.[64] Concern about the future course of the varicose veins (fear of thrombosis, ulcers and

concern about family history of vein problems) is an additional common underlying reason for presentation.[7] Many will also present with symptoms associated with varicose veins (this will be commoner at secondary care level). Aching, heaviness and swelling were the most frequent reasons for presentation among both men and women in a survey of 229 patients referred over a 10-month period to two vascular surgeons for management of varicose veins.[118] Cosmetic concerns accounted for a total of 26% of presentations to the vascular surgeons (33% of women and 8% of men).

Symptoms draw attention to varicose veins but it has been found that varicose veins may not be the cause of the symptom.[64] Sisto *et al.*[72] showed a statistically significant association between varicose veins and osteoarthritis of the knee, which commonly coexist.

Women are more likely to consult their GP with varicose veins than men.[116] In line with this a frequent finding of studies looking at the prevalence of treatment of varicose veins is that treatment for the latter is more prevalent in women than in men.[119] One study[72] reported that 53% of affected women had received surgical treatment compared to 29% of affected men.

Assessment

An initial diagnosis of varicose veins is usually made up of the signs observed by the general practitioner and the symptoms reported by the patient. Whether a diagnosis of varicose veins then becomes a referral for treatment and/or further assessment at an outpatient clinic depends upon the severity of the signs and symptoms, the likelihood of complications, patient preference and the local provision of treatment. Indications considered appropriate for further investigation by surgeons responding to a survey of members of the Vascular Surgical Society in 1999[120] were suspected deep venous disease (90%), recurrent varicose veins (83%), past history of deep venous thrombosis or fracture (81%), skin damage or ulceration (57%), suspected sapheno-popliteal reflux (63%) and all varicose veins (7%).

The continuous-wave Doppler ultrasound (hand-held Doppler) is rarely used at the time of the clinical examination to assist in this initial diagnosis. In fact no UK medical school expects final-year students to be skilled in the use of hand-held Doppler for assessment of varicose veins.[121]

The National Institute for Clinical Excellence has published a guide to appropriate referral from general practice to specialist services for varicose veins. The guide emphasises that most varicose veins require no treatment and says that the key role of primary care is to provide reassurance, explanation and education. Table 14 outlines the referral advice for referral to a specialist service in patients in whom varicosities are present or suspected.

There is no single test available to provide answers to the many questions that need to be asked to decide if and how to treat varicose veins and other venous disorders of the leg.[123] For this reason a number of specialised investigations have evolved over the years (*see* Table 15). These are used to objectively assess the presence and amount of venous outflow obstruction and the presence and amount of venous reflux in the superficial, communicating and deep venous system. The tests will help the assessor/surgeon answer the following questions.[124]

1 Are the symptoms of which the patient complains attributable to venous disease and, if not, what other pathological processes may be involved?
2 Is the patient's pattern of venous disease amenable to surgery and, if so, what operation should the patient have? For this the sites of incompetence and whether the deep system is involved need to be accurately identified, especially in the context of CVI or ulceration.

The selection of the appropriate tests will depend on the local facilities, the clinical presentation and the severity of the symptoms.[123] A survey of members of the Vascular Surgical Society[120] found that 65% of

Table 14: Referral advice for patients in whom varicosities are present or suspected.

Referral timings	Condition
Patient is seen immediately (within a day)	Patient is bleeding from a varicosity that has eroded the skin
Patient is seen urgently (max. 2-week wait recommended)	Patient has bled from a varicosity and is at risk of bleeding again
Patient is seen soon	Patient has an ulcer which is progressive and/or painful despite treatment
Patient has a routine appointment	Patient has an active or healed ulcer and/or progressive skin changes that may benefit from surgery
	Patient has recurrent superficial thrombophlebitis
	Patient has troublesome symptoms attributable to their varicose veins, and/or they and their GP feel that the extent, site and size of the varicosities are having a severe impact on quality of life

Source: National Institute for Clinical Excellence.[122]

Table 15: Methods of assessment for venous disease.

Non-invasive	Invasive
Continuous-wave Doppler ultrasound	Phlebography/varicography
Duplex scanning	Foot venous pressure measurements
Plethysmography (strain-gauge/air/photo)	Ambulatory venous pressure
Near-infra-red spectroscopy	

surgeons routinely use hand-held Doppler in the assessment of varicose veins. Duplex scanning was used as the first-line investigation by 83%, venography or varicography by 10% and plethysmography by 1%. Facilities for duplex scanning were available to 97% of respondents, venography to 94%, plethysmography to 32% and ambulatory venous pressure measurements to 16%. For most cases, duplex has become the investigation of choice, especially for recurrent disease or venous ulcer/CVI cases, though there are no cost-effectiveness data to support this.

The less invasive tests detect and quantify obstruction and reflux, and define the locality of the abnormality. They have lower risks associated with them, are well tolerated and are readily repeatable. The more invasive tests are not usually necessary for simple varicose veins. However, they may be needed when there is uncertainty over whether the varicose veins are primary or secondary to deep vein damage,[99] or if there is a history of calf perforator incompetence or surgery.

There are no perfect tests of venous physiological function.[80] Each technique of investigation has its own advantages and disadvantages, and out of the series of tests available in the vascular laboratory, several methods will measure the same thing. Whatever the method used, the interpretation is open to inter-observer variation and can be expensive and time-consuming.[125] Belcaro *et al.* stated that the optimum useful information can be obtained using only three instruments: the Doppler, duplex scanning (preferably with colour-flow imaging) and air plethysmography.[126] In the UK, it is unusual for a patient to undergo any test other than a duplex outside a research protocol.[127]

Description of assessment methods

Clinical examination

Traditionally, the requirement for surgery for varicose veins was based on a full history and clinical examination,[128] although this rarely happens. Inspection and palpation (which can include the cough/thrill test, the tap test and the tourniquet test) constitute the clinical examination.

Continuous-wave Doppler ultrasound

The accuracy of the clinical examination has been improved by the additional use of continuous-wave Doppler ultrasound (CWDU) examination,[51] commonly referred to as hand-held Doppler and sometimes pocket Doppler.[129] Its use has become routine in outpatient clinics for screening because it is quick, inexpensive and non-invasive.[123] CWDU emits a continuous beam of ultrasound waves that detect red blood cells moving within the targeted vein.[11] The principle behind Doppler ultrasonography is that the frequency of signals reflected from the moving red blood cells shifts in proportion to the velocity of the cells. The output from a CWDU is normally presented as an audible signal, so that a sound is heard whenever there is movement of blood in the vessel being examined.[130] CWDU is used for detecting reflux at the sapheno-femoral and sapheno-popliteal junction.[131,132] Its main function is to detect incompetence of valves between the deep venous system and the superficial veins. CWDU is particularly useful in the examination of obese legs where the results of a tourniquet test are more difficult to interpret.

Duplex scanning

Duplex scanning combines an image and a Doppler signal. Colour units indicate flow from the heart in red and toward the heart in blue.[11] Colour flow duplex scanning has become the 'gold standard' varicose vein assessment technique,[56,133] speeding up the assessment procedure and improving its accuracy.[123,134] This non-invasive technique allows the operator to locate and identify specific structures using real-time imaging and then obtain information on the presence, direction and velocity of blood flow from a specific location or vessel within the image.[135] The femoral, popliteal, deep calf and perforating veins can be specifically and individually tested as well as determining the involvement of the long and short saphenous veins and their tributaries.[123] It has also been suggested that colour duplex should be the investigation of choice for patients presenting with recurrent varicose veins.[136] Duplex scanning has been recommended for all patients with varicose veins,[6,137,138] but the feasibility of this has been questioned due to time and cost implications.[138,139] It has been suggested that duplex scanning be used selectively on primary varicose veins, reducing the workload of the vascular laboratory without compromising patient care.[140,141] There are few diagnostic evaluation studies on which to base practice.

Plethysmography (strain gauge/air/photo/foot volumetry)

The term plethysmography describes several techniques used to measure volume changes. A plethysmograph consists of a mechanism to sense displacement. Sensors include air-filled, water-filled, mechanical, light, capacitance and electrical impedance devices.[11] These techniques attempt to quantify the physiological significance of Doppler findings and are only very rarely required for clinical purposes.

Near-infra-red spectroscopy

Near-infra-red spectroscopy is a relatively new non-invasive technique that allows measurement of changes in deoxygenated haemoglobin and oxygenated haemoglobin in tissue.[142] It is currently mainly used as a

research tool for the assessment of ambulatory venous function in the leg as a whole and the severity of CVI in patients with primary varicose veins. An advantage of the technique is that it can be used to assess venous insufficiency during exercise.

Phlebography/varicography

Phlebography is the term used to refer to X-ray contrast imaging, which used to be the only method available for examining the venous system. It used to play an important role in the management of patients with secondary or recurrent varicose veins.[2] Earlier contrast media were associated with frequent side-effects because of their hyperosmolarity, but the introduction of low-osmolarity contrast media has significantly improved patient comfort and safety, reducing the risk of contrast-induced thrombophlebitis. The technique should be tailored to the diagnostic problem, and the site of injection of contrast will depend on the clinical problem to be clarified.[135] Specific phlebographic techniques include:

- *ascending phlebography*, where the contrast medium is injected into a foot vein. This technique investigates the state of deep veins and detects incompetent communicating/perforating veins[2]
- *varicography*, where the superficial veins are directly injected with contrast medium and the channels it takes on its way to the deep system of veins in the legs or to the groin and perineum are screened.[135,143] This technique investigates the site, extent and connections of superficial and deep varices[2]
- *descending phlebography*,[144] where contrast medium is injected into the femoral vein and the amount of reflux towards the periphery is assessed and graded.[145] This technique is performed to show abnormal reflux in the deep or long saphenous vein.[2]

Phlebography is not necessary in the majority of cases but would be considered if the ultrasound examinations (CWDU or duplex) had not provided all the information required for a decision to be made. The disadvantages of phlebography are that it is invasive, costly and non-repeatable, it exposes the patient to radiation and there is potential for complications.

Ambulatory venous pressure examination

This test measures the net effect of all the abnormalities that affect venous haemodynamics. Venous pressure is measured by inserting a needle in a vein on the dorsum of the foot with the patient standing. Pressures are recorded during a ten tiptoe exercise test. The ambulatory venous pressure (AVP) is defined as the lowest pressure reached during the exercise.[126] Ambulatory venous pressure is a function of the calf muscle pump ejecting capacity, the magnitude of reflux and the outflow resistance. If venous reflux is present the AVP is high and the refill time is quick.

Arm–foot pressure differential technique

This technique, developed by Raju,[146] is considered to be an excellent method of quantifying outflow obstruction.[126] The technique consists of recording the venous pressure in the veins of the foot and hand simultaneously after venous cannulation.

Treatment

The general indications for treatment of varicose veins are to prevent complications related to venous disease (especially venous ulcer), to relieve symptoms, and to improve the appearance of the leg.[59]

However, there is no national consensus as to which varicose veins should be treated based on site of incompetence, severity, etc. and as to which types of treatment to be offered.

There is an uncertain relationship between the location(s) of venous incompetence and the severity of the signs and symptoms of varicose veins. Since the natural history of varicose veins is largely undocumented, it is not clear whether varicose veins involving only the superficial venous system, and not accompanied by skin changes or great discomfort, should be treated for reasons other than cosmetic considerations, i.e. whether surgery has a prophylactic role in preventing severe venous disease. There is an argument that prompt surgery of patients with asymptomatic or mild varicose veins is likely to result in the maintenance of healthy skin, since the capillaries are undamaged. Once skin changes have occurred, surgery will improve the macrocirculation but will have no effect on the already damaged microcirculation.[147] There is scant evidence showing how many patients with asymptomatic or mild varicose veins progress on to more severe forms of venous insufficiency, and so it is extremely difficult to either support or refute the argument of prophylactic surgery. Whilst research is needed, current evidence would suggest that operating on only mildly symptomatic or asymptomatic varicose veins would be largely for cosmetic reasons and hence might not be deemed a priority for the NHS.

Conversely, there is general agreement that skin changes (CVI) and ulceration represent an indication for treatment. Symptoms of discomfort reported by the patient are variably interpreted as indications for treatment. Moderate and severe (clearly symptomatic) varicose veins are generally thought to be worthy of surgical treatment, with an improvement in venous return likely to be achieved at least in the short term. In some cases surgery is not warranted,[148] and a thorough assessment is therefore needed prior to surgery to define whether surgery is likely to be effective and at what sites to intervene to maximise long-term outcome and reduce recurrence rates.

Unless there are severe complications such as haemorrhage, treatment for varicose veins remains elective. There is evidence that other disorders (e.g. inguinal hernia and benign prostatic hyperplasia) which are generally treated electively can reach a stage where surgery is urgently required and patients can be admitted on an emergency basis. For varicose veins this is unlikely to happen (only 154 out of 55 512 episodes in 1998–99 were emergency admissions [HES data]), and there is thus little prospect of circumventing the long waiting lists for specialist treatment.

Treatment options

Conservative management

Pharmacotherapy

A variety of medications have been suggested to be effective for the relief of various individual symptoms of venous disease, such as heaviness, discomfort, itching, cramps, pain and aching, and swelling[27] (*see* Table 16). These are principally represented by the venoactive drugs, which may improve venous tone and the lymphatic and microcirculatory disturbances that result from increased venous pressure.

Compression therapy

Upon self-referral to a general practitioner, conservative treatment in the form of compression therapy may be offered. This may also be the preferred form of treatment if surgical intervention is not sufficiently indicated, or if the patient is seen as unfit for general anaesthesia. In addition, when varicose veins are severely complicated by deep vein incompetence, the only form of treatment offered may be compression therapy. Compression therapy can also be used as a therapeutic test – if symptoms improve with stockings it is likely that they are due to varicose veins and so surgery may be of value.

Table 16: Medications suggested to be effective for relief of the symptoms of venous disease.

Symptoms	Suggested medication
Heaviness	Diosmin coumarine rutine Dihydroergocristine Calcium dobesilate
Swelling	Rutosides Combination of ruscus, favonoids and proteolytic enzymes
Global symptoms	Diosmin Ruscus asculeatus Calcium dobesilate Hydroxyrutosides
Venous tone	Diosmin
Oedema	Rutosides Diosmin Calcium dobesilate Coumarine rutine Horse-chestnut extract
Active ulceration	Oral micronized diosmin Pentoxifylline

Source: Kurz *et al.*[27]

Compression relieves the symptoms of varicose veins, helps to heal and prevent the recurrence of ulcers and helps to prevent the deterioration of skin changes. It is the mainstay of venous ulcer treatment, acting to reduce vein calibre, capillary filtration and venous reflux and improving venous pumping.[27,149] These effects increase venous return, improve lymphatic drainage and decrease oedema. Materials used for compression include elastic and inelastic bandages, and elastic stockings. There are many ways of applying compression, such as single layers of bandaging, multiple layers of bandaging, compression stockings or a combination of bandages and stockings which are usually used to treat the more severe end of the spectrum (*see* Table 17). Intermittent pneumatic compression, a mechanical method of delivering compression to swollen limbs, is an alternative method.

It is now recommended that the external compression be graduated, with the amount of external pressure being greatest at the ankle and lower at the knee. This has been shown to increase blood velocity within the deep venous system.[150] The recommended gradients are that the calf pressure should be not

Table 17: Combination compression systems used in the treatment of venous ulcers.

Type	System
Short stretch/inelastic	Orthopaedic wool plus 1–3 rolls of short stretch bandage
Inelastic paste system	Paste bandage plus support bandage
Unna's boot	Non-compliant paste bandage
Three-layer elastic multi-layer	Orthopaedic wool plus class 3c bandage plus shaped tubular bandage
Four-layer elastic multi-layer	Orthopaedic wool plus support bandage (crepe) plus class 3a bandage plus cohesive bandage

more than 75% of the pressure exerted at the ankle and the thigh pressure not more than 50%.[3] The most suitable amount of pressure to apply to the leg is still disputed,[151] but it is generally accepted that this will depend on the severity of the condition.[152] It is important to note that before undertaking compression therapy the ankle brachial pressure index (ABPI) should be assessed. This is because patients with peripheral arterial disease with poor arterial circulation can develop ischaemia if compression is too high. The precise ABPI below which compression is contraindicated is often quoted as 0.8.[153]

Stockings are divided into three classes according to the British Standard (BS7505: 1995). The support offered and indications for their use are presented in Table 18. Bandages are categorised as retention, support or compression. The latter are further subdivided according to the level of compression they apply to the limb (*see* Table 19).

Table 18: Classes of compression stockings according to the British Standard (BS7505: 1995).

Class	Compression	Indications
I	Light support, 14–17 mmHg at the ankle	Mild varicose veins, venous hypertension in pregnancy
II	Medium support, 18–24 mmHg at the ankle	Mild oedema, moderate to severe varicose veins, prevention of ulcer recurrence in small, light people
III	Strong support, 25–35 mmHg at the ankle	Treatment of severe varicose veins and prevention of venous ulcers, large heavy legs

Table 19: Bandages.

Class	Compression
1	Retention bandages (used to retain dressings)
2	Support bandages (used to support strains and sprains, and for mild to moderate compression when particular application techniques are used and the bandages are reapplied frequently
3a	Light compression, 14–17 mmHg at the ankle
3b	Moderate compression, 18–24 mmHg at the ankle
3c	High compression, 22–35 mmHg
3d	Extra high compression, up to 60 mmHg

Source: Cullum *et al.*[279]

A patient requiring compression hosiery will need a detailed assessment, measurement to ensure the hosiery fits properly and advice on application and care. Two to three pairs of compression hosiery are recommended per patient to allow for washing, and if worn continuously they should be replaced every six months as frequent washing and wearing cause a loss of elasticity. Where daily removal is not possible Class I hosiery is recommended as this can be worn continuously and changed once a week by a carer.[152] In the presence of ulceration, it is recommended that stockings should be worn continuously, as long as there is no concomitant arterial disease, in order to improve the hypertensive microangiopathy.[147]

Elastic stockings are more difficult to manage in the elderly, obese or arthritic who may have problems reaching their feet and pulling on a tight stocking.[125,154] For this reason, elastic or impregnated bandages

might be preferred, although this generally needs the assistance of someone else. In addition, there are special aids to assist someone putting on compression stockings. They consist of slippery plastic; the aid is put inside the stocking and the foot 'walks' the stocking on by pushing against a special pad placed on the floor.[155] Patient compliance is essential but is generally problematic, particularly when compression therapy has been prescribed for long-term use.

Once healing has occurred, hosiery is recommended lifelong to prevent ulcer recurrence, especially when no surgery has been performed on superficial varicose veins. The cost of compression hosiery varies depending on class and design. Most compression hosiery and bandages are available as a prescription item. There are some products though where unless the patient is willing to pay, choice is limited by the restrictions imposed by the Drug Tariff (FP10).

Sclerotherapy

Sclerotherapy is the injection of an irritant solution into an empty vein, resulting in an endothelial reaction, fibrosis and complete venous destruction. The aim of sclerotherapy is to eliminate reflux in the superficial venous system and thereby eliminate visible varicose veins.[59] Injection sclerotherapy has a long history. In 1855 Chassaignac tried to obliterate veins by injecting a solution of ferric chloride.[156] Since then three names have been linked with the development of modern sclerotherapy techniques: Tournay (the French technique), Sigg (the Swiss technique) and Fegan (the Irish technique). The sclerotherapy process works such that a sclerosant causes damage to the endothelial and sub-endothelial layers, resulting in an inflammatory reaction of the venous wall which evolves to fibrosis over a period ranging from 6 months to several years. The aim of sclerotherapy is fibrotic obliteration and not thrombosis of the varicose vein.[59] Different sclerosants have been experimented with. Sodium tetradecyl sulphate is a popular choice, along with iodine, polidocanol and sodium salicylate.

A consensus statement on sclerotherapy of varicose veins[59] reached the following conclusions.

- Sclerotherapy can treat varicose veins but it cannot cure the underlying venous disease and will therefore not halt the formation of new varices.
- General indications for sclerotherapy are to prevent complications related to venous disease, to relieve symptoms and to improve the appearance of the leg.
- Sclerotherapy must be practised by a physician who is trained in phlebology and has specific experience in sclerotherapy.
- Sclerotherapy of secondary varicose veins, i.e. those with reflux and/or obstruction of the deep venous system, can be considered only after careful functional assessment.
- Sclerotherapy is the preferred treatment in patients presenting with telangiectases and reticular veins without reflux, i.e. cosmetic surgery.
- Sclerotherapy is an adequate treatment for large non-saphenous varicose veins:
  - there is no agreement as to whether sclerotherapy is suitable for treating large or small perforating veins, or whether thigh or calf perforators are amenable to sclerotherapy. The choice between surgery and sclerotherapy will depend on the experience of the clinician and the characteristics of the varicose vein.
- Sclerotherapy may be considered for the treatment of saphenous varicose veins:
  - there is no consensus regarding the role of sclerotherapy in the treatment of long saphenous veins but if it is used it should be performed by an experienced physician
  - short saphenous varicose veins may be treated by either surgery or sclerotherapy.
- Contraindications for sclerotherapy are:
  - a known allergy to the sclerosing agent
  - severe systemic disease

  - recent DVT
  - local or general infection
  - inability to ambulate
  - severe arterial disease, especially critical limb ischaemia.
- Sclerotherapy must be performed with caution in pregnant or breastfeeding women and when the following conditions are present:
  - allergic diathesis
  - hypercoagulability
  - recurrent DVT.
- Risks such as thromboembolism and intra-arterial injection, as well as cosmetic deterioration, must be weighed against the benefits of the treatment.

The evidence for the above statements is presented in Section 6.

Compression usually accompanies sclerotherapy, especially for larger varicose veins. Its importance in the sclerotherapy process, the strength of compression and the length of time it is applied vary and depend on the technique used. Compression is thought to aid the occlusion of the lumen by making opposing surfaces stick together without any intervening thrombus. The vein is theoretically converted into a thin fibrosed cord, not a vein full of red thrombus which can recanalise.[157] The effectiveness of sclerotherapy is open to debate and the amount and length of time of compression have been questioned.[158–161]

As a mode of treatment, sclerotherapy has been variably popular in Europe and the USA.[162–164] In France, sclerotherapy is used to obliterate even the sapheno-femoral junction, while in the UK this would more likely be treated by surgical ligation. Compression sclerotherapy is regarded as ideal for solitary varicose tributaries in the absence of main saphenous incompetence, and is used to varying extents for the treatment of incompetent lower leg communicating veins.[157] Sclerotherapy is advised for patients who are too old or unfit or who refuse operation, and constitutes the better mode of treatment for telangiectases.[163,165–167] Sclerotherapy can be combined with surgery either during or after operation.[59]

Complications of sclerotherapy include vasovagal attacks, allergic or anaphylactic reactions,[168] toxic reactions, skin necrosis and ulceration, recanalisation,[163] venous thrombosis,[169] pulmonary embolism (0.1%),[170] intra-arterial injection, injection of a nerve and skin discoloration.[171] This latter complication is a common side-effect of sclerotherapy. Brown pigmentation develops over the thrombosed vein and can (but not always) fade after one to two years.

In a survey of members of the Vascular Surgical Society,[120] 62% of respondents performed sclerotherapy for varicose veins privately, and 68% on the NHS. For thread veins the figures were 27% on the NHS and 49% privately. The main indicators for sclerotherapy were considered to be for missed varicose veins following surgery (60%), for isolated small varicose veins (73%) and for thread veins (50%). Only 18% of respondents ran a sclerotherapy clinic and injections were performed predominantly by consultants (65%) and surgical trainees (63%). An earlier survey of the Vascular Surgical Society of Great Britain and Ireland to determine the current practice and attitude towards venous sclerotherapy found that sclerotherapy is being used less frequently for varicose veins than in previous years and that most surgeons use it for residual varicose veins after operation and for those without proximal incompetence.[172]

In conclusion, sclerotherapy has a role to play in cosmetic surgery and in isolated varicose veins, especially those missed by surgery. It therefore has a small role in any NHS venous disease service as a complement to varicose vein surgery and compression. It should only be performed by trained surgeons.

Echosclerotherapy

Echosclerotherapy is a relatively new technique which involves injection of a sclerosing agent into a vein under ultrasound guidance. This allows accurate localisation of junctions. There are two main techniques, one using a catheter and the other using a needle connected to the syringe.[59]

Surgical management

Surgery is both the established treatment and the treatment of choice for sapheno-femoral vein incompetence and long saphenous vein varicosity.

The types of operation are listed below:

1 flush ligation of the sapheno-femoral junction, also called high saphenous ligation
2 stripping of the long saphenous vein[173]
3 sapheno-popliteal junction ligation, also called short saphenous ligation
4 stripping of the short saphenous vein (although avoided by most surgeons for fear of damaging the sural nerve)[127]
5 ligation of the medial lower leg communicating veins[174,175]
6 ligation of other communicating veins (i.e. gastrocnemius, lateral calf, Hunterian and miscellaneous veins)
7 phlebectomies (avulsions) of varicosities, ligation of tributaries and local excision of tributaries[176–180]
8 operations on recurrent varicose veins.[181]

There is growing interest in surgery for cases with isolated superficial vein incompetence and venous ulcer. If there is no deep vein incompetence, surgery may successfully hasten healing and reduce recurrence, though high-grade evidence is still lacking on this issue.

Post-operatively, compression is used to reduce the incidence of haematoma formation, and may reduce the incidence of deep vein thrombosis (heparin may be given during the admission for the same reason).[182] A survey in 1995 of members of the Vascular Surgical Society of Great Britain and Ireland ($n = 363$) found that surgeons use a variety of bandages and stockings after varicose vein operations, but crepe bandages were the most usual (52%) at the end of surgery and anti-embolism socks were the most common support recommended in the days that followed (55%).[183] As soon as anaesthesia wears off, patients are encouraged to mobilise as much as possible. Length of stay in hospital varies with the extent of the surgery, but day surgery is possible using both local and general anaesthesia.[184–187] This will depend on patient age and general fitness. Patients may be reviewed after three months when the wounds have healed and bruising disappeared (many patients who have had mild or moderate varicose veins do not get reviewed post-operatively). Residual varicose veins can be obliterated by injection sclerotherapy[188] or by local excision. The initial use of the long saphenous vein in coronary artery bypass grafting (CABG) encouraged a conservative approach to stripping,[186,189–192] but nowadays the long saphenous vein has been replaced by the internal mammary artery as the replacement graft of choice for CABG.

Contraindications to surgery include general ill-health affecting fitness for anaesthesia, arterial ischaemia of the lower limb, pregnancy, severe coexistent skin infection, lymphoedema and bleeding diatheses.[80] It is generally thought that there is an association between varicose veins and DVT, especially if there are other risk factors for DVT such as a past or family history,[193,194] although many surgeons with specialist interest in the venous system are sceptical of this association in patients with primary varicose veins.[183]

A survey of members of the Vascular Surgical Society found that the commonest indications for surgery were symptomatic (97%) and complicated (98%) varicose veins, although 55% of surgeons also

performed surgery for cosmesis.[120] It also found that surgery is the preferred option for primary treatment of varicose veins associated with long or short saphenous reflux.

Surgical treatment, typically consisting of inpatient admission for high ligation, stripping and phlebectomy under general anaesthesia, is not in the main regarded with much enthusiasm by surgical staff for reasons of technical interest, operating position, and length of time of surgery (40–60 minutes for the completion of the three stages in one leg; double the time for the 50% of patients with bilateral veins).[18] This surgery has in the past often been performed by junior members of a surgical team,[5] but this may be associated with higher recurrence rates due to inadequate primary surgery.[195,196] There is an increasing recognition of the need for consultant-led supervision of juniors.

Types of surgery performed for different conditions

A survey of members of the Vascular Surgical Society asked respondents what method of surgery they used for a range of types of varicose veins.[120] The results were as follows.

- For the treatment of primary long saphenous varicose veins, 90% of surgeons performed saphenofemoral disconnection, 82% stripped the long saphenous vein to the knee (20% stripped to the ankle), and 95% performed multiple phlebectomies, and 1% performed specific perforator ligation.
- For recurrent varicose veins associated with reflux in the groin, 94% performed groin re-exploration, 75% stripping of a residual long saphenous vein and 94% multiple avulsions.
- For recurrent varicose veins associated with reflux in the popliteal fossa, 91% performed re-exploration of the popliteal fossa, 27% stripping of a residual short saphenous vein and 90% multiple phlebectomies.

However, it is important to understand that the choice of method for recurrences depends on the investigation carried out beforehand on each patient.

Post-operative morbidity of varicose vein surgery

The morbidity after surgical treatment is poorly documented in the literature.[197,198] However, post-operative mortality is extremely low and post-operative complications are mainly associated with damage to the superficial nerves when veins are stripped to the ankle (range of 23–50% incidence of damage to the saphenous or sural nerve – because of this, most surgeons now strip veins to just below the knee),[199–202] deep vein damage, arterial damage, wound necrosis, haemorrhage, haematoma formation, lymphoedema and lymphocele, unsightly or keloid scars, persisting eczema,[203] recurrent ulceration and recurrence of varicose veins.[204] Operator experience has a significant effect on the outcome of surgery.[205,206]

In a study of 997 consecutive patients undergoing treatment in a district general hospital, complications occurred in 7 inpatients and a further 16 patients developed complications requiring readmission to hospital.[198] The complication rate appeared to be operator-dependent with an increased complication rate occurring after surgery by junior surgeons. Major complications included femoral vein injury, post-operative DVT, pulmonary embolism and groin lymphatic fistula requiring re-operation. In a retrospective review[197] of 599 patients (973 limbs) who had undergone varicose vein surgery between 1985 and 1993, wound complications occurred in 2.8% of limbs and minor neurological disturbance in 2.8%. Leakage of lymph from the groin occurred in 5 patients and major complications included three cases of DVT, one pulmonary embolism, one injury to the common femoral vein and one drop-foot. The overall incidence of major complications was 0.8% and minor complications occurred in 17% of patients.

Recurrent varicose veins

A major problem with varicose vein surgery is the high risk of recurrence, which is a common, complex and costly problem. The frequency of recurrent veins is stated to be between 20 and 80%,[48] depending on the definition, method of assessment, duration of follow-up, initial case-mix and quality of surgery. A consensus meeting on recurrent varicose veins in 1998 decided to adopt the definition 'the presence of varicose veins in a lower limb previously operated on for varices'.[48] Whilst some recurrence is inevitable due to the development of new varicose veins, some may be due to inadequate assessment and initial surgery. This is more likely if trainees operate, particularly when they are unsupervised.[195,196] Up to 20% of varicose vein surgery is for recurrence. One solution is much closer supervision and training of surgical trainees by consultants. Methods for the treatment of recurrent varicose veins include compression, drugs, sclerotherapy and redo surgery, although there is no general consensus in favour of sclerotherapy, surgery or both.[48]

New treatments for varicose veins

There are a number of new treatments for varicose veins[207,208] that claim advantages over conventional surgery by reducing operative trauma and bruising and speeding up post-operative recovery. The methods all close off the long saphenous vein under duplex ultrasound control. They are:

- radiofrequency ablation, where a radiofrequency probe obliterates the vein by controlled thermal energy[209,210]
- the use of a laser probe to obliterate the long saphenous vein[211,212]
- a novel application of sclerotherapy where a sclerosant is mixed forcibly with air to produce a foam that spreads rapidly and widely through the veins after injection.[213]

The procedures can be performed under local anaesthetic, but general anaesthetic is necessary if there are extensive varicosities. All the methods require a duplex ultrasound machine with a skilled operator.

Surgery in venous ulcer disease

The surgical management of venous ulcer can be considered once venous hypertension is established as the cause of the ulcer and the possible venous abnormalities have been demonstrated. In the 50% of venous ulcers that have superficial reflux as the main component, appropriate ligation can heal the ulcer. The role of perforator ligation is thought to be limited except in a group of patients with primary deep incompetence, in whom ulceration persists in spite of saphenous ligation.[214]

Skin grafts for venous ulcers

Skin grafts are used by some clinicians in order to stimulate healing of venous ulcers.[215] The skin grafts may be taken from the patient's own uninjured skin (e.g. thigh), grown from the patient's skin cells into a dressing (autografts), or applied as a sheet of bioengineered skin grown from donor cells (allograft). Preserved skin from other animals, e.g. pigs, has also been used and these are known as xenografts. They can provide immediate relief for patients with very painful ulcers, but they often fail after a period of time.

Other treatments

Laser treatment[216] has been investigated as a replacement for invasive sclerosing procedures for thread veins. Continuous-wave laser systems, such as carbon dioxide lasers and argon lasers, have been tested for

their effects on leg veins but there were a number of adverse sequelae. Pulsed-dye lasers have also given poor results. There are six laser systems that are currently advocated for the treatment of leg veins. It is suggested that these show promise as alternative or complementary therapies for thread veins.[217] Whilst compression therapy is the main venous ulcer therapy, various other interventions, including electrical stimulation, laser therapy and ultrasound, have been used in addition to or in replacement of compression where the latter is contraindicated.[218]

Configuration of services

Day surgery

Day-case surgery for varicose veins has been shown to be economic, safe and effective and to reduce waiting time for surgery.[184,219–221] It is now accepted as the most appropriate way to treat many patients who need common surgical procedures, and there has been a national drive to increase the percentage of varicose veins dealt with as day cases.[222] Some reported advantages of day-case varicose vein surgery are listed in Box 2. Despite this, day-case surgery is disliked by a proportion of patients and in the private sector varicose vein surgery is almost never carried out as a day case.[127]

Levels of day surgery have risen significantly since the early 1990s (*see* Health Episode Statistics later). A survey of members of the Vascular Surgical Society found that the percentage of operations performed as day cases was 50% (range 0–96%), the most common conditions operated on as day cases being unilateral primary long saphenous varicose veins and unilateral primary short saphenous varicose veins.[120] The Royal College of Surgeons guidelines on day-case surgery state that patients for general anaesthesia should be under 70 years old, of physical status ASA group I or II and that the procedure duration must be less than 60 minutes.[223] Patients for whom day surgery may be unsuitable include those with extensive varicosities, those needing open calf perforator surgery (rare), those requiring post-operative bed rest for venous ulcers, and those with pre-existing medical conditions.

The decision to perform day-case surgery can also be related to the anticipated duration of the procedure. Varicose vein operations often take a long time to perform, especially when carried out by a single surgeon. Two or more surgeons reduce the time taken to operate and decrease the risk of a DVT.[183] This level of resources is therefore recommended for NHS varicose vein operations.[7]

Box 2: Reported advantages of day-case varicose vein surgery. *Source*: Lane and Bourantas.[224]

- Efficient organisation with planned patient care
- Minimal disruption to the patient's working or domestic life
- Less risk of cancelled operation
- More experienced surgeons and anaesthetists
- Lower infection rate than for inpatients
- No 'hotel' charges
- Staff recruitment for normal working hours is easy
- Reduced cost

Waiting lists/effects of delaying surgery

Increasing pressure on surgical resources in terms of inpatient beds and operating-theatre availability has led to increasing waiting lists for chronic low-risk disorders such as varicose veins.[225] In an attempt to rate waiting lists by the expected level of benefit to patients, varicose vein surgery ranked low when considering benefits per resource requirement (hours of operating time, benefits per day-bed occupied).[226] A number of waiting-list initiatives have demonstrated that varicose vein waiting lists can be significantly reduced by careful assessment, an efficient system to minimise hospital stay and maximise bed utilisation, and the increased provision of day-case facilities.[225,227] A study looking at the deterioration in the condition of lower limbs in a group of 36 patients considered to be at low risk of worsening of their varicosities who were waiting for a median of 20 months for varicose surgery concluded that there was a significant deterioration in the clinical condition of patients and considerable morbidity for the patients while they waited.[228]

Management of venous ulcers

There is wide variation in the management of venous leg ulcers, with types of care including hospital inpatient care, hospital outpatient clinics, primary care clinics and home visits. There is some debate about whether every patient with a venous ulcer needs to see a vascular surgeon for thorough assessment and overseeing of preventive strategies. The initial assessment is to exclude non-venous ulcers and decide whether any varicose vein surgery is indicated. This suggests a multi-disciplinary team led by a vascular surgeon to assess all ulcers.

The care of ulcers associated with varicose veins is a burden which is normally carried by the primary health team, in particular the community nursing service (87% of patients with ulcers are managed by the primary care team). Chronic ulceration can of course become a considerable problem, a source of anguish and pain to the patient, and a cost to the community of an estimated £1200 to £2500 per unhealed ulcer per year in dressings and medical time.

Community ulcer clinics

A community leg ulcer service allows structured patient assessment and appropriate research-based treatment as well as providing a focus for nurse training in leg ulcer management.[229] The service normally consists of a multi-disciplinary team led by a clinical nurse specialist, often with the support of the consultant vascular surgeon and senior medical physicist from the local hospital. Dermatologists have been involved in and have set up services for venous ulcers in many places.[7] The leg ulcer team functions alongside the district nursing service under the overall direction and supervision of the clinical nursing lead. There are a number of requirements for a community leg ulcer clinic, including:

1. *good location* – the clinic needs to allow easy access for the majority of patients
2. *accurate wound assessment* – a simple hand-held Doppler is essential and will determine which patients may benefit from referral for more detailed evaluation.

The introduction of community ulcer clinics has been shown to significantly improve leg ulcer healing and reduce costs by about £150 000 per 250 000 population per annum.[230]

Patient preference

A questionnaire-based study investigating the preferences of patients with varicose veins for injection treatment or surgery, based on a series of explicit facts about each method, found that 25% expressed an overall preference for injections and 63% preferred surgery.[231] The majority of patients with bilateral varicose veins preferred a single bilateral inpatient procedure compared to two unilateral day-case operations.

Current practice and service provision

The assessment and treatment of varicose veins by members of the Vascular Surgical Society of Great Britain and Ireland has been investigated by a postal questionnaire.[120] The study identified current practice of vascular surgeons in the treatment of varicose veins and provided an overview of what is considered by surgeons within this field to be the appropriate management of varicose veins.

Sixty-five per cent of those sent a questionnaire responded, of whom the majority (77%) were general surgeons with a vascular interest, 21% were vascular surgeons only and 2% were non-vascular surgeons. The results of this survey have been presented throughout this section, but general findings were as follows.

- Of the respondents, 73% saw varicose vein patients in a vascular and/or dedicated venous clinic.
- Approximately five new patients (range 0–78) with varicose veins were seen per surgeon per week in clinics.
- The median waiting time to be seen in a clinic was 12 weeks (range 1–150 weeks).
- A median of three varicose vein operations per surgeon per week was undertaken.
- In total, 10–15% of surgery was performed for recurrent disease.

Health services utilisation data

The following data on current service provision are based on hospital episode data from NHS hospitals in England (HES data) from 1990–91 to 2000–01.[45] The data have been analysed on the basis of admissions rather than finished consultant episodes (FCEs), and were extracted on the basis of procedure codes (OPCS Fourth Revision Operations Codes L83, L85, L86 and L87; *see* Appendix 1). The procedure rates and any trends in service provision in the NHS need to be considered in the light of private health care provision over the same time period (*see* below).

There are several problems in making use of routine NHS health services utilisation data.

- The operation codes and diagnostic codes for varicose veins of lower extremities (*see* Appendix 1) allow little discrimination between medically complicated and uncomplicated varicose veins, and do not provide information on the site of incompetence, the extent of the varices, whether they affect one or both limbs, and whether they are recurrent or whether they are performed primarily for cosmetic or symptomatic reasons.
- NHS routine data exclude activity in private-sector hospitals.
- HES data exclude outpatient activity. In the absence of data on outpatient procedures, it is impossible, for example, to derive rates of injection sclerotherapy in the population. Data relating to episodes of injection sclerotherapy performed during an inpatient admission are available but they are unrepresentative of the total level of activity. Data relating to the level of injection sclerotherapy carried out in general practice are also unavailable.
- There are no data on venous ulcer disease, as this is largely undertaken by district nurses in the community.

- There are problems related to the quality and comparability over time of these data.

Volume of surgery

There were 107 020 operations for varicose veins in NHS hospitals in England in 2000–01, with 45 216 of these being main operations. Around two-thirds of operations were performed on women. Considering main operation rates only, the rates of surgical treatment for varicose veins showed an increase from 96 per 100 000 in 1990–91 to 121 per 100 000 in 1995–96. Since then the rates have generally shown a downward trend; with the exception of an increase in 1998–99, the overall rate was 92 per 100 000 in 2000–01 (*see* Figure 3).

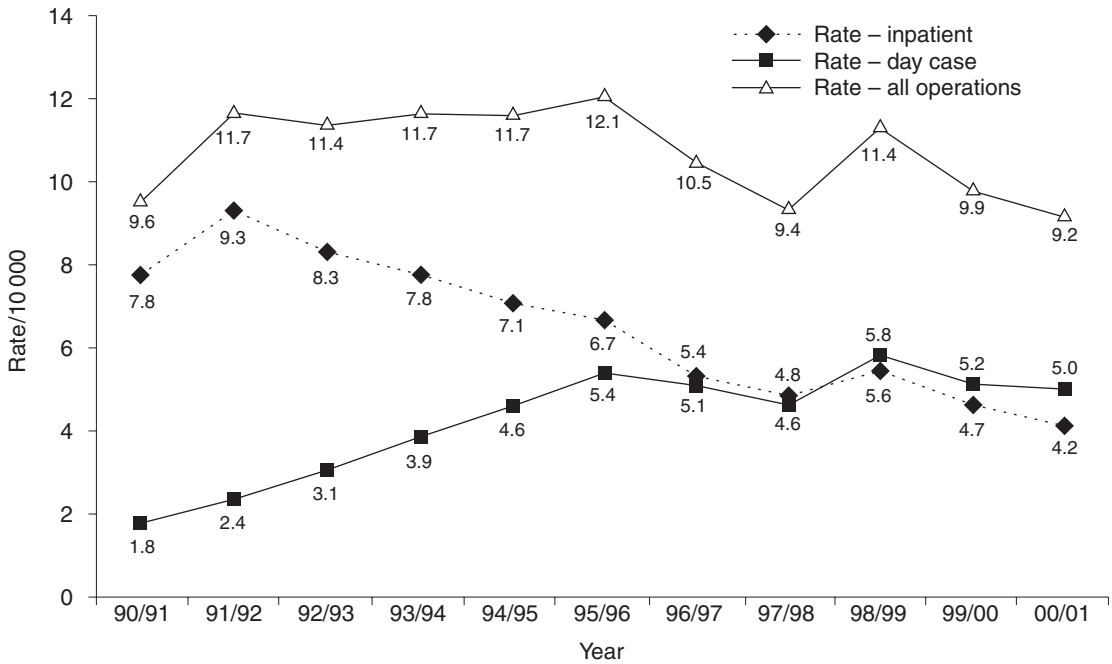

Figure 3: Rate of varicose vein operations (L83, L85, L86, L87) per 10 000, by admission type, England (1990–91 to 2000–01).

The type of operation most commonly performed is ligation (L85), followed by 'other operations on varicose veins of the leg', e.g. stripping of long and short saphenous veins and avulsion of varicose veins (L87). This is for both day surgery and patients who are admitted as inpatients. L85 is more likely to be performed on patients who are admitted as inpatients, whereas L86 (injection into varicose vein of the leg) is more likely to be performed as day surgery.

The rates for treatment for varicose veins are highest amongst females between 35 and 64 years of age (*see* Figure 4). In 1998–99, the highest rate of operations was for day-case admissions in females in the 35–44-year-old age group, with a rate of 17.1 per 10 000, whilst the highest rates in males were in the 55–64-year-old age group for ordinary admissions, with a rate of 10.3 per 10 000. When comparing the rates of operations that are performed on women compared to men, the difference is very apparent in the age groups up to 64 years. In particular, in the 35–44 years age group, women are almost three times

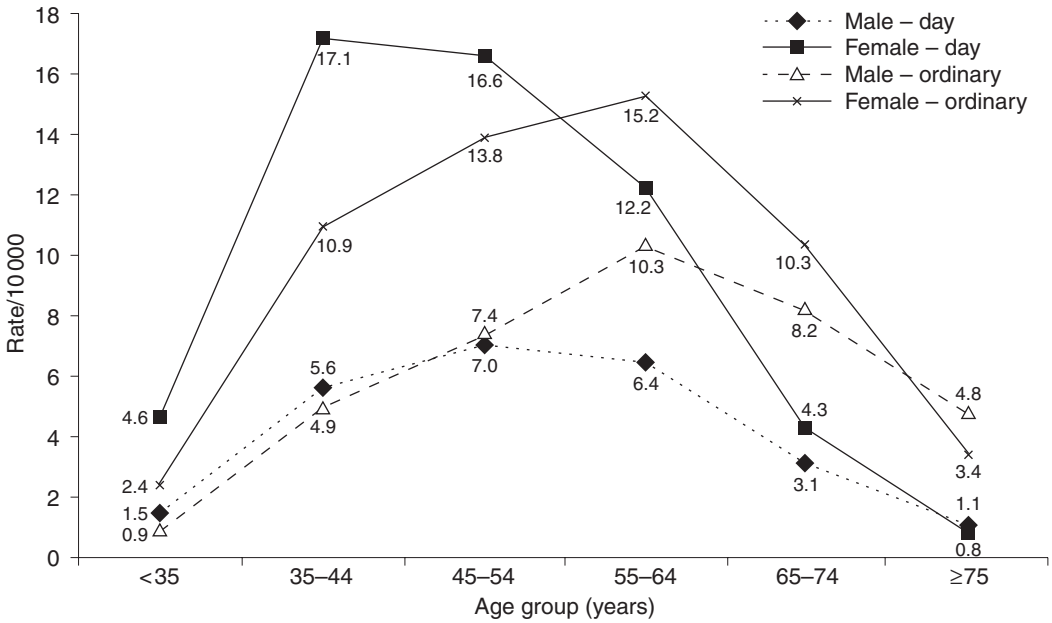

Figure 4: Rate of operations (L83, L85, L86, L87) per 10 000, by age, sex and admission type (1998–99, HES data).

more likely to have an operation than men. The median ages at start of episode for all admission types are 56 (L83), 48 (L85), 47 (L86) and 47 (L87) years.

The most notable trend over the eight years reviewed is that the proportion of operations for varicose veins carried out as day surgery has increased considerably, from 19% of operations in 1990–91 to 55% of operations in 2000–01(*see* Figure 3). The age and sex profile of patients undergoing day surgery is such that there are more females than males admitted for day surgery (as is the case for all operations for varicose veins), but the ratio of females to males having day surgery is higher than the ratio of females to males who are admitted as inpatients (2.5:1 compared to 1.8:1). Females are more likely to be admitted for day surgery rather than as inpatients up to the age of 55; for males it is up to the age of 45. The age groups where the rate of day-case surgery is highest are 45–54 for males and 35–44 for females (*see* Figure 4). These data suggest there may be unmet need in older age groups who have higher rates of varicose veins. However, older people may be less concerned with the cosmetic appearance and, as they are less active, may have less limiting symptoms, although these hypotheses require testing.

Waiting times and length of stay

Other important trends are the increase in waiting times for varicose vein operations despite the growth of day surgery, and the noticeable decrease in length of stay for those patients admitted as inpatients. Trends over the years 1990–91 to 1998–9 show that the median waiting time for patients admitted for inpatient surgery has steadily increased, particularly for the most frequently carried out operations, since 1996–97 (*see* Figure 5). In 1998–99 the median waiting time for L85 was 237 days and for L87 was 238 days. This is compared to a median wait of 145 days and 122 days, respectively, in 1990–91. Median waiting times for patients admitted for day-case surgery have also increased but not as dramatically. Median waiting times for L85 and L87 operations in 1998–99 are 213 days and 185 days. This is compared to 107 and 94 days in 1990–91.

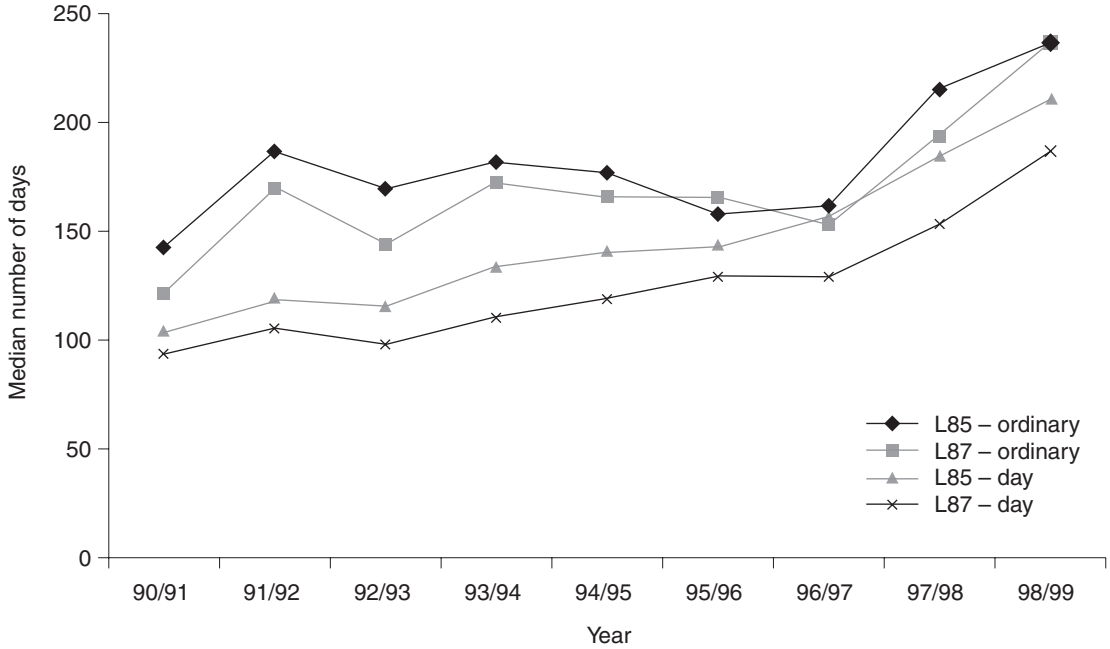

Figure 5: Median duration of wait for operation types L85 and L87 by admission type (1990–91 to 1998–99).

The increases in waiting times are despite a reduction in the median length of stay for surgery for all procedures. The median duration of stay for ordinary-admission operations coded as L85 and L87 has been one day since 1994–95, compared to two days previous to this year. The median length of stay for operations coded as L83 has decreased from 6 days to 2 days. The median length of stay for operations coded as L86 (injection into varicose vein of the leg) was 1 day in 1990–91 but since then has been 0 days (i.e. day cases).

Emergency surgery

There was a marked reduction in the percentage of patients undergoing varicose vein operations who were admitted as an emergency in 1989–90 compared to earlier years. This trend has continued. In 1989–90, 1% of patients having a varicose vein operation were admitted as an emergency, compared to only 0.4% in 2000–01. Some of these episodes may be miscoded HES data.

Rate of operations by health authority

The mean crude rate of operations for all health authorities (now PCTs) per 10 000 of the population was 10.8 in 1996–97, 9.7 in 1997–98 and 11.6 in 1998–99 (Department of Health, Hospital Episode Statistics, 1996–97 to 1998–99). However, there are variations in rates between health authorities, with the crude rate ranging from 2.6 per 10 000 to 38.7 per 10 000 in 1996–97, 1.8 per 10 000 to 31.6 per 10 000 in 1997–98, and 5.1 per 10 000 to 40 per 10 000 in 1998–99 (*see* Figure 6). Such variation is likely to be due to a combination of factors, including chance, age/gender population differences, the quality of local HES coding, and true differences in the prevalence of varicose veins and in the referral and treatment pathways and provision.

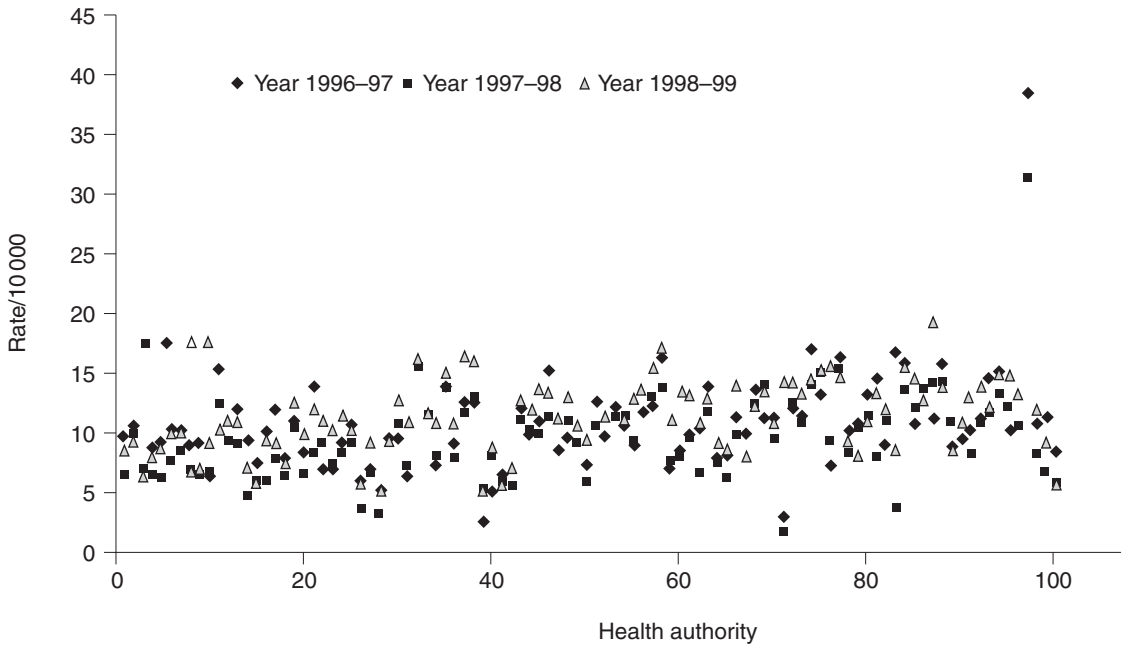

Figure 6: Rate of operations per 10 000 per year (1996–97 to 1998–99) for health authorities in England.

Number of bed-days required for varicose vein operations

Utilising the information on the median duration of stay and the number of operations performed in NHS hospitals it is possible to estimate the total number of bed-days required for elective varicose vein surgery in NHS hospitals in England. In 1998–99 this equated to an estimated 27 880 bed-days (*see* Table 20).

Independent-sector activity

There are no routinely collected data on elective hospital treatment carried out in England and Wales by the independent sector. Williams *et al.* found that in 1981 the proportion of elective treatments purchased privately in England and Wales was 13.2% and in 1986 it was 14.8%.[232] A similar survey comparing the volume and nature of elective hospital care funded publicly and privately was carried out in 1997–98.[5] This found that 14.5% of elective treatments were privately funded. More specifically, surgery performed in independent hospitals accounted for 24% of the ligation or stripping operations for varicose veins in England and Wales in 1997–98, and the number of operations privately funded accounted for 21%[5] (*see* Table 21).

Costs associated with the treatment of varicose veins

The National Schedule of Reference Costs, updated in January 2000 and based on costed activity for 1998–99, gives the average national reference costs for varicose vein procedures (HRG code Q11; *see* Appendix 1) as £747 for elective surgery, £921 for non-elective surgery and £495 for day-case surgery.[233]

Table 20: Total number of bed-days for varicose vein surgery (all operation codes) in 1998–99.

	L83	L85	L86	L87
Ordinary admission				
Number of operations	161	21,104	36	5,877
Median length of stay	2	1	0	1
Number of bed-days	322	21,104	0	5,877
Emergency admission				
Number of operations	5	110	7	32
Median length of stay	4	2	3	2
Number of bed-days	20	220	21	64
Admission – all other values				
Number of operations	0	90	1	72
Median length of stay	–	2	–	1
Number of bed-days	0	180	0	72
Total number of bed-days	342	21,504	21	6,013
Grand total	27,880			

Table 21: Number of operations for varicose veins (ligation or stripping) according to source of funding for residents of England and Wales, 1997–98.

Funding	Independent hospitals			NHS hospitals			Percentage privately funded
	Private	NHS	Total	Private	NHS	Total	
Ligation or stripping	12,782	733	21,186	505	48,340	48,845	20.8

Source: Williams *et al.*[5]

Table 22: Summary of services available.

Sub-category	Assessment methods	Treatment options
Mild discretionary	Clinical examination Continuous-wave Doppler ultrasound Duplex scanning	Do nothing Pharmacotherapy Compression therapy Sclerotherapy
Severe non-discretionary	Clinical examination Continuous-wave Doppler ultrasound Duplex scanning Other investigation, e.g. venography, phlethysmography	Pharmacotherapy Compression therapy Sclerotherapy Surgery
Venous ulcer	Clinical examination Continuous-wave Doppler ultrasound Duplex scanning Other investigation, e.g. venography, phlethysmography	Compression therapy Pharmacotherapy Surgery

6 Effectiveness

The effectiveness of the different forms of management for varicose veins can be assessed by the amount of reduction in the presenting symptoms and signs, and in the long term, by the volume of need for further treatment, particularly venous ulcer care. The goal of interventional procedures has been said to be to normalise venous physiology.[11]

Recurrence is frequently used as a measure of effectiveness, although it is extremely difficult to measure and classify, as there is always difference of opinion between observers on what constitutes a recurrence. Campbell *et al.*, on following up a small cohort for 10 years, have concluded that the rate of recurrence depends entirely on the question that is asked.[299] Almost every published long-term study lacks validity and credibility because of the large proportion of patients who cannot be followed up (partly due to the necessity of evaluating outcome after five and ten years),[234] and the absence of a clearly defined anatomical and physiological assessment by an independent observer.

When using recurrence as a measure of effectiveness it is important to distinguish between residual veins, recurrent veins and recanalised veins.[235,236] Residual veins are veins that were not treated at the original operation because they were not detected pre-operatively, were not found during the operation, were deliberately left untreated or were incompletely treated.[237] A failure to remove the full length of a tortuous vein is the most common cause of residual varicosities, but short saphenous vein incompetence may only become obvious when long saphenous vein incompetence has been treated, especially if it has not been carefully excluded before the first operation.

Recurrent varicose veins are veins which have become varicose after the original treatment, having been 'normal' at the time of that treatment. This often occurs when all the visible varicosities were treated but the underlying physiological abnormalities were not corrected; the remaining 'normal' veins therefore continue to be subjected to abnormal pressures and subsequently dilate. The role of incompetent thigh perforating veins has become recognised as a common cause of recurrence (39% of patients with recurrent varicose veins have incompetent thigh perforating veins demonstrated by venography),[238,239] as has failure to strip the LSV in the thigh and the involvement of the deep venous system.

The effectiveness of different types of treatment still remains unclear. A Task Force on Chronic Venous Disorders of the Leg was established in September 1993 with the purpose of comprehensively evaluating this area of medicine.[26] One of its mandates was to critically review existing scientific evidence on the diagnosis and treatment of the condition. A paper published in 1999 summarised their main findings. MEDLINE was searched from 1983 to 1996, the reference lists of review articles, theses and unpublished reports on the subject were screened, and a manual search was done of 30 scientific journals (including 15 not indexed by MEDLINE) for randomised controlled trials (RCTs) of drug treatment for venous disease. The titles and abstracts of articles located were then subjected to a number of tiers of screening by members of the Task Force. The main findings of the Task Force form the basis of this section on effectiveness. Where more current effectiveness data have been identified, this information has been included.

Effectiveness of assessment methods

In assessing data on the reliability and validity of diagnostic tests the Task Force only considered studies that had moderate to strong scientific evidence. Also, for assessment of validity, only studies providing quantitative information on specificity, sensitivity and/or predictive accuracy were considered.

Clinical examination

A study which assessed the validity of vein palpation by an experienced vascular surgeon for the prediction of long saphenous vein reflux, as verified by colour Doppler, reported a sensitivity of 0.43, and a very high specificity and positive predictive value of 1.0 each, and a negative predictive value of 0.58.[240] None of the studies retained by the Task Force allowed formal assessment of the validity of the Trendelburg test for diagnosing venous valvular incompetence, although there is some evidence to suggest it may help predict functional improvement after vein-stripping surgery.[241,242] Browse *et al.* consider that in conjunction with clinical examination, tourniquet tests provide sufficient understanding of the venous abnormality for management decisions in 80–90% of patients,[243] but other investigators dispute this.[125,141] Clinical examination may accurately diagnose valvular incompetence where there is gross long saphenous incompetence, but it will often miss short saphenous reflux and is poor for detecting reflux in the deep veins.[141]

Doppler

A hand-held Doppler provides clear answers regarding the presence or absence of reflux at the sapheno-femoral and/or sapheno-popliteal junctions in 90% of patients when used by an experienced practitioner.[126] A limitation of continuous-wave Doppler ultrasound is that it cannot detect the exact site of reflux.[244] It is also not accurate in localising incompetent perforating veins[245] and it is unreliable in the assessment of veins in the popliteal fossa.[141] The VEINES Task Force considered only validity data on the Doppler examination when Doppler was compared to duplex, phlebography or venous pressure measurements. Only two studies met the methodological criteria of the Task Force. Doppler had high sensitivity but low specificity for detecting incompetent sapheno-femoral junctions – this is confirmed by a study carried out in 1998.[56] The Task Force concluded that Doppler examination would be best used as a screening test rather than for diagnosis.

Duplex scanning

Studies assessing the validity of duplex scanning in detecting the site and severity of reflux compared to descending phlebography and venous pressure measurement found that sensitivity for deep vein reflux was 0.79–1.0, but specificity was only 0.63–0.88.[246–249] Popliteal incompetence as demonstrated by duplex was shown to be a good predictor of post-operative leg ulcer recurrence in patients undergoing perforator ligation for chronic ulceration (high sensitivity and specificity).[250]

Plethysmography

In the VEINES review, among the various phlethysmographic techniques, the Task Force found that photoplethysmography (PPG) was the only one for which validity data[240,251–254] were available once criteria for study selection were applied. PPG consistently demonstrated low sensitivity and specificity and poor predictive accuracy for the detection of venous reflux, and in some studies gave uninterpretable results in nearly a quarter of limbs.[252] Strain-gauge plethysmography, foot volumetry and air plethysmography may be useful for assessing venous function but their validity has not been formally tested.

Phlebography

Descending phlebography had high sensitivity but low specificity for the detection of deep reflux when compared to venous pressure measurement.[251]

Treatment of venous disease

In assessing the efficacy of treatment of varicose veins and venous disorders the outcomes evaluated by the VEINES Task Force were, where possible, treatment success, effect on symptoms, effect on signs, adverse effects, patient satisfaction and acceptability, patient compliance, effect on laboratory parameters and effect on quality of life (QoL).[24,26] The Task Force's results are summarised in Table 24 (*see* p. 60). More recent effectiveness evidence is discussed below.

Pharmacotherapy

- A placebo-controlled trial of 30 mg/day oral naftazone found that naftazone was more effective than placebo in providing clinical improvement in women with primary uncomplicated symptomatic varicose veins.[255] (Level of evidence: B I-2.)
- A systematic review assessing the evidence for or against horse-chestnut seed extract (HCSE) as a symptomatic treatment of venous insufficiency found that HCSE is superior to placebo and as effective as reference medications in alleviating the objective signs (lower leg volume and a reduction in leg circumference at the calf and ankle) and subjective symptoms (leg pain, fatigue, etc.) of CVI.[256] (Level of evidence: B I-1.)

Surgery

- A systematic review on the use of tourniquet in surgery for varicose veins is available on the Cochrane Library.[257] There were significant quality issues with available evidence, but the use of tourniquet would appear to reduce blood loss during surgery.
- A randomised controlled trial that investigated the possible long-term clinical advantages of stripping the long saphenous vein during routine primary varicose vein surgery vs. sapheno-femoral ligation alone found that stripping reduced the risk of re-operation by two-thirds after 5 years.[258] (Level of evidence: B I-2.)
- A prospective randomised trial has examined the efficacy of perforate invagination (PIN) stripping of the long saphenous vein in comparison to conventional stripping in the surgical management of primary varicose veins. There were no statistically significant differences between the two techniques in terms of time taken to strip the vein, percentage of vein stripped or the area of bruising at one week. However, the size of the exit site was significantly smaller with the PIN device, resulting in better cosmesis.[259] (Level of evidence: C I-2.)
- A prospective randomised trial comparing sequential avulsion with stripping of the long saphenous vein found that sequential avulsion is less painful, reduces bruising and avoids a significant scar below the knee.[260] (Level of evidence: B I-2.)
- A prospective, randomised controlled study with patients serving as their own controls compared the post-operative discomfort and long-term outcome following standard stripping and long saphenous vein-saving surgery. It concluded that the long-term results of long saphenous vein-saving surgery are as good as standard stripping provided the incompetent perforators are thoroughly mapped

pre-operatively and ligated at surgery. It also concluded that long saphenous vein-saving surgery causes less subjective post-operative discomfort than standard stripping.[261] (Level of evidence: C I-2.)

- A randomised study comparing the 5-year recurrence frequency and 3-year frequency of neural complications after partial and total stripping of the long saphenous vein showed that stripping the long saphenous vein below the knee increases the permanent nerve damage sixfold without reducing long-term recurrence.[262] (Level of evidence: E I-2.)
- A prospective study of 102 consecutive patients who underwent varicose vein surgery that included stripping of the LSV to the knee concluded that LSV surgery leads to a significant improvement in disease-specific health-related QoL for as much as two years.[263] (Level of evidence: B II-2.)
- Evidence for the newer treatments for varicose veins (radiofrequency ablation, endovenous laser treatment and sclerosing foam) is limited to case series and registry data, largely in private practice settings.[207] (Level of evidence: C III.)
- Sclerosant delivered into a vein as a microfoam preparation has shown promising results and is currently being compared with surgery in an RCT.[127]

Sclerotherapy

- A consensus statement on sclerotherapy published in 1997, considering literature classified in the *Index Medicus* from 1966 to 1994,[59] states that the published literature reports conflicting data on the efficacy of sclerotherapy and is greatly limited from a scientific and statistical point of view. This is compounded by doubts about the most appropriate outcome measures to use for assessing the results. Six randomised controlled studies comparing sclerotherapy with surgery were identified. The results of these are poor with regard to the rate of recurrence (*see* Table 23). However, the consensus participants were prevented from formulating a definitive statement regarding the results of sclerotherapy because of shortcomings in the studies. (Level of evidence: D I-1.)
- A systematic review on injection sclerotherapy for varicose veins is available on the Cochrane Library.[270] The main aims of the review were to determine whether injection sclerotherapy for treatment of varicose veins is effective in terms of symptomatic improvement and cosmetic appearance, to determine whether sclerotherapy has an acceptable complication rate and to define the rate of symptomatic or cosmetic recurrence following sclerotherapy. It compares the following:

1 sclerotherapy vs. other treatment options:
   - sclerotherapy vs. graduated compression stockings for varicose veins with superficial venous incompetence
   - sclerotherapy vs. graduated compression stockings or observation for varicose veins in the absence of superficial venous incompetence
   - sclerotherapy vs. laser treatment or no treatment (i.e. simple follow-up) in patients with thread veins
2 different sclerosants and sclerosant dose
3 injection techniques, bandaging and compression techniques and repeat treatment intervals.

The conclusions of the review are that evidence from RCTs suggests that type of sclerosant, local pressure dressing, degree and length of compression have no significant effect on the efficacy of schlerotherapy for varicose veins. This supports the place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins.

- In a study in the USA, the efficacy and adverse sequelae of two sclerosants were investigated. Both polidocanol and sodium tetradecyl sulphate were found to be safe and effective sclerosing agents for varicose and thread veins.[271]

Table 23: Randomised controlled trials comparing sclerotherapy with surgery.

Study	Chant *et al.*[264]	Beresford *et al.*[265]*	Hobbs[266]	Hobbs[267]†	Jacobsen[268]	Einarsson *et al.*[269]
Year	1972	1978	1974	1984	1979	1993
Number of patients	115	115	250	250	157	84
Sclerosing technique	Fegan	Fegan	Fegan	Fegan	Sigg	Fegan
Follow-up	3 years	5 years	6 years	10 years	3 years	1, 3, 5 years
Failure criteria	Patient did not come for treatment; retreatment	Patient did not come for treatment; retreatment	Objective evaluation of the limb	Objective evaluation of the limb	Subjective and objective evaluation	Subjective and objective evaluation
Rate of failure	22% at 3 years	40% at 5 years	66% at 6 years	90% at 10 years	Subjective: 30% at 3 years; objective: 64% at 3 years	Subjective: 50% at 5 years; objective: 74% at 5 years

* Beresford *et al.* report the 5-year follow-up of the same sample of patients as in the Chant *et al.* study.
† The second Hobbs study reports the 10-year follow-up of the same sample of patients as in the first Hobbs study.

Echosclerotherapy

The consensus statement on sclerotherapy reported that as echosclerotherapy is a recent technique only short-term studies are available.[59] The three studies identified reported failure rates of 18.7% at end of treatment, 13.3% at end of treatment and 21.5% at second session of echosclerotherapy (maximum of 18 months).[272,273] A study that retrospectively investigated major and minor complications associated with 1009 ultrasound-guided injections in two series of consecutive patients found that most complications were minor and localised and that the incidence of major complications was 0.1%.[274]

Venous ulcers

A review by Nelson *et al.*[275] conducted in 1999 came to the following conclusions on the effectiveness of treatments for venous ulcers.

- A systematic review of RCTS has found that compression heals venous leg ulcers more effectively than no compression (*see* 'Compression therapy' below). (Level of evidence: A I-1.)
- Limited evidence suggests that recurrence rates are lower with higher compression pressures but higher pressures are less well tolerated by patients. (Level of evidence: B II-1.)
- The effects of occlusive and non-occlusive compared with simple dressings such as gauze have not yet been adequately evaluated in RCTs.

- Limited evidence suggests that human skin equivalent or granulocyte–macrophage colony-stimulating factor may accelerate healing. (Level of evidence: C II-1.)
- Oral pentoxifylline increases the proportion of ulcers that heal completely. (Level of evidence: B.)
- Two RCTs suggest that flavonoids may accelerate healing, but there is no evidence that either stanozolol or rutoside decrease recurrence rates. (Level of evidence: C I-2.)
- There is no good evidence on the effects of intermittent pneumatic compression, ultrasound and vein surgery.

A review by Peters[276] on the factors influencing non-recurrence of venous leg ulcers concluded that there is some evidence that the use of compression hosiery is effective in reducing the incidence of venous leg ulcer recurrence. However, other strategies cited for ulcer prevention are not supported by documented evidence. (Level of evidence: C III.)

Pharmacotherapy

- A systematic review assessing the effects of pentoxifylline ('Trental 400') for treating venous ulcers, when compared with placebo or in comparison with other therapies, in the presence or absence of compression therapy, has been published on the Cochrane Library.[277] Nine trials involving 572 adults were included. Pentoxifylline appeared to be an effective adjunct to compression bandaging for treating venous ulcers. In the absence of compression it may be effective for treating venous ulcers, but the evidence should be interpreted cautiously. (Level of evidence: B I-1.)
- An RCT to assess the cost-effectiveness of using cadexomer–iodine vs. hydrocolloid dressing or paraffin gauze dressing in the treatment of patients with non-infected, venous leg ulcers concluded that cadexomer–iodine paste is an efficient, cost-effective and safe alternative.[278] (Level of evidence: B I-2.)

Compression therapy

- A Cochrane Review to assess the effectiveness and cost-effectiveness of compression bandaging and stockings in the treatment of venous ulcers concluded that compression (applied as bandages or stockings) increases ulcer healing rates compared with no compression.[279] It also concluded that multi-layered systems are more effective than single-layered systems and that high compression is more effective than low compression, but there are no clear differences in the effectiveness of different types of high compression. Rather than advocating one particular compression system, the authors concluded that it is more sensible to promote the increased use of any correctly applied compression therapy. (Level of evidence: A I-1.)

The Cochrane Review mentions two ongoing studies that will add to the current knowledge base. One is a study at St Thomas' Hospital in London comparing three- and four-layer compression bandaging. The other is the VenUS Bandage Trial, an RCT comparing short-stretch and four-layer bandaging, involving 400 patients, 4 clinical centres and the University of York. In addition, a randomised controlled trial involving 400 patients to compare the four-layer bandage and the short-stretch bandage systems has been commissioned by the HTA programme.

- A further Cochrane Review considered the effects of compression hosiery or bandages in preventing the recurrence of venous ulcers.[280] No trials were identified that compared compression with no compression for prevention of ulcer recurrence, but not wearing compression was associated with recurrence in two studies identified in the review. The authors concluded that recurrence rates may be

lower in high-compression hosiery than in medium-compression hosiery and therefore patients should be offered the strongest compression with which they can comply. (Level of evidence: B I-1.)

- A Cochrane Review to determine whether intermittent pneumatic compression (IPC) increases the healing of venous leg ulcers and the effects of IPC on health-related quality of life of patients identified four RCTs and concluded that further trials are required to determine whether IPC increases the healing of venous leg ulcers.[281] (Level of evidence: C I-1.)

Laser therapy

- A Cochrane Review to assess the effectiveness of low-level laser therapy in the treatment of venous leg ulcers concluded that there is no evidence of any benefit associated with this therapy on venous leg ulcer healing. One small study was identified which suggests that a combination of laser and infra-red light may promote the healing of venous ulcers but it was concluded that more research is needed.[282] (Level of evidence: D I-1.)

Electrical stimulation

- A systematic review assessing the effectiveness of electromagnetic therapy for treating venous leg ulcers has been published on the Cochrane Library.[283] A total of three eligible RCTs were identified and the reviewers concluded that there is currently no reliable evidence of benefit of electromagnetic therapy in the healing of venous leg ulcers. (Level of evidence: D I-1.)

Therapeutic ultrasound

- The potential role of ultrasound in the treatment of venous leg ulcers has been assessed in a Cochrane Review.[284] The authors identified seven eligible RCTs. None of the trials found a difference in healing rates between any of the therapies, but the direction of treatment effect was consistently in favour of ultrasound. (Level of evidence: D I-1.)

Skin grafting for venous ulcers

- A Cochrane Review assessing the effectiveness of skin grafts in the treatment of venous leg ulcers found that there is limited evidence that artificial skin used in conjunction with compression bandaging increases the chance of healing a venous ulcer compared to compression alone. Further research was recommended to assess whether other forms of skin grafts increase ulcer healing.[215] (Level of evidence: C I-1.)

Community leg ulcer clinics

- A randomised controlled trial study to establish the relative cost-effectiveness of community leg ulcer clinics that use four-layer compression bandaging vs. usual care provided by district nurses concluded that the former are more effective.[285] (Level of evidence: A I-2.)
- A study comparing two health authorities' approaches to care for leg ulcers found that the introduction of community clinics and four-layer compression bandaging in one health authority (Stockport) improved care and resulted in lower costs than the traditional approach employed by the other health authority (Trafford).[230] (Level of evidence: A II-1.)

There is debate about whether a venous ulcer service should include a vascular surgery-led clinic for the initial assessment to exclude arterial ulcer and to determine the role of surgery for superficial varicose veins in the absence of deep vein incompetence.

Table 24: Summary of the effectiveness of treatments based on an evidence-based report of the VEINES Task Force.

Sub-category	Pharmacotherapy	Compression therapy	Sclerotherapy	Surgery
Mild – discretionary	• Heaviness relieved by diosmin coumarine rutine, dihydroergocristine and calcium dobesilate • Swelling improved by rutosides and a combination of ruscus, flavonoids and proteolytic enzymes • Venous tone improved by diosmin • Reported adverse effects with drug therapies included nausea, headaches, gastric pain and insomnia • There is no scientific evidence for the efficacy of medications to treat telangiectases, spider veins or reticular veins	• Evidence for the use of compression in patients with symptoms alone is limited • There is no scientific evidence for the efficacy of compression to treat telangiectases, spider veins or reticular veins, but symptoms associated with these can be relieved by gradual compression stockings	• Properly controlled studies examining the efficacy, cost and long-term benefits of sclerotherapy for telangiectases, spider veins and reticular veins are lacking • Complication rates are thought to be related to the type and concentration of the sclerosing agent and to the operator's experience • 80% of patients in one study reported being satisfied or very satisfied with the outcome	• Telangiectases *per se* should not be treated by surgery
Severe – non-discretionary	• Rutosides, diosmin, calcium dobesilate, coumarine rutine and horse-chestnut extract improve objective indices of oedema • The available scientific evidence does not support the use of medications for skin changes	• Symptoms associated with varicose veins can be relieved by gradual compression stockings • Graduated compression stockings in excess of 35 mmHg and fixed or stretched bandages have been shown to be effective in improving objective indices of oedema • There is some evidence that graduated compression stockings in excess of 35 mmHg are effective for skin changes	• The reported treatment success when sclerotherapy is used to treat non-saphenous varicose veins (including residual and recurrent varicose veins after surgical treatment), and local varicose veins and varicose tributaries of the saphenous trunk without saphenous insufficiency, is approximately 70–80% at one year • Adverse effects include superficial phlebitis, subcutaneous clot retraction, pain, blistering, pruritis, swelling and pigmentation	• Randomised studies comparing sclerotherapy and surgery in the treatment of long saphenous varicose veins showed a significantly higher recurrence rate at long-term follow-up after sclerotherapy • There is no evidence to determine whether surgery or sclerotherapy is the best treatment for short saphenous varicose veins • In patients with symptoms caused by primary varicose veins who have evidence of sapheno-femoral

Sub-category	Pharmacotherapy	Compression therapy	Sclerotherapy	Surgery
			• Patient satisfaction is reported to be 80% at one year or less, dropping to 40% by 5 years • It is unlikely to improve skin changes secondary to venous insufficiency	junction or sapheno-popliteal junction reflux, there is clear evidence to support the use of surgical treatment • Surgery is indicated in patients without evidence of reflux in the large veins but with large tributaries feeding varicose veins[27] • Complications of surgery include saphenous vein and saphenous nerve injury in up to 39% of patients after total long saphenous vein stripping, a 2–15% risk of infection, up to 7% risk of haematoma and 3% risk of phlebitis • Reported patient satisfaction ranged from 75% to 90%
Venous ulcers	• No evidence available of the effectiveness of medications in preventing ulcer recurrence • Evidence of the efficacy of systemic medications, including antibiotics, and local topical therapies, including topical antibiotics, on venous ulcer healing is limited • A multi-centre clinical trial found that oral micronised diosmin in addition to compression might be more effective than compression alone in achieving complete ulcer healing for ulcers less than 10 cm in diameter	• There is some evidence that graduated compression stockings in excess of 35 mmHg are effective at preventing ulcer recurrence. • Bandages, both fixed and stretched, have been shown to be effective in the treatment of venous ulcers. They must be properly applied to produce significant benefits. Compression stockings in excess of 35 mmHg may also be used • Patient acceptability and compliance with compression therapy have both been reported to be about 70%, with few adverse effects	• No evidence showing that sclerotherapy prevents venous ulcer recurrence • It is unlikely to be effective in patients with venous ulceration unless there is superficial venous insufficiency, in which case it may have a role which is as yet unproven	• Patients with active venous ulceration and sapheno-femoral or sapheno-popliteal junction incompetence benefit from surgical treatment

Source: Adapted from Kurz *et al.*[27]

Cost-effectiveness

To determine the cost-effectiveness of treatment for the various severities of venous disease, costs must be considered in association with outcomes. There are no studies on the relative cost-effectiveness of treatment for varicose veins compared with other elective surgical procedures. A randomised controlled trial study by Piachaud and Weddell in the UK in the early 1970s found that outpatient treatment by injection/compression sclerotherapy was less costly than routine surgical removal, but the data are based on price, volume and outcome information related to 1972.[286,287]

Costs and benefits are likely to differ depending on both the severity of the varicose veins and the characteristics of the patient. The data currently available are not helpful in distinguishing those patients for whom treatment for varicose veins is most cost-effective, nor are they able to give any indication of the ideal levels of treatment. In the present climate of the NHS, in which some PCTs have explicitly decided not to treat some or all patients presenting with varicose veins on the basis of cutting costs, it seems that there is an urgent need to obtain better cost-effectiveness data for this condition to establish those categories of patients that should be treated. Without such data there is no real indication where the treatment of varicose veins should be on the list of NHS priorities.

An assessment of the cost-effectiveness of the treatment of varicose veins is being carried out as part of the HTA programme and is due for publication in 2005. The project will assess the cost-effectiveness of the commonly used treatments for varicose veins by the Markov process decision model. The model will allow an assessment of the incremental cost-effectiveness of each treatment modality in subgroups of patients based upon their symptomatic, investigative and demographic features. The review will also assess patient and societal priorities for treatment using a 'willingness-to-pay' technique.

Venous ulcers

A multi-centre randomised controlled trial to assess the cost-effectiveness of using clinic-based weekly treatment of leg ulcers with 4-layer bandaging vs. the usual home-based care by district nurses for the treatment of venous leg ulcers[285] was carried out between September 1994 and May 1995. Using 1995 prices, community-based leg ulcer clinics with specially trained nurses and single 4-layer bandaging were more effective than traditional home-based treatment. The benefit was achieved at a small additional cost which could be reduced further if certain service configurations were used.

7 Models of care/recommendations

Determining population need

This is difficult because of the uncertainty about what types of venous disease would benefit from NHS intervention. Local need would be increased substantially if cosmetic and mild symptomatic varicose veins were thought to warrant NHS treatment. The need represented by more serious venous disease is smaller, but quantifying it is hindered by the lack of good population-based prevalence data, especially in the elderly – need will be driven by policy for the management of venous disease in the elderly. The best estimate from the Edinburgh study would be 1% venous ulcer and 7–8% considered for surgery for CVI or symptoms. The future need is likely to rise as the population ages and the epidemic of obesity continues unabated.

Who to treat?

For commissioners the key question is to which groups of patients they should offer varicose vein surgery. Consensus is that the NHS should provide venous ulcer care, with a key element being the use of compression bandages overseen by trained nurses in accessible community clinics. However, there is debate about whether there should be a specialist vascular clinic overseen by a vascular surgeon, which would undertake the initial assessment to exclude arterial ulcers and to decide whether surgery of any superficial varicose veins should be performed – this approach being dependent on evidence that such surgery will aid healing and prevent ulcer recurrence.

Minor varicose veins with cosmetic effect should not be treated on the NHS. There is a growing private market in the care of such patients which needs regulation.

The difficult question is the identification of patients with significant symptoms due to varicose veins who would benefit from surgery and also the group at high risk of progressing to venous ulcer who might benefit from prophylactic surgery. Clearly, operating on 30% of the adult population to prevent ulcers in 1% is not feasible.

Organisation of a venous disease service

Key features of a venous disease service appear to be as follows:

1 appropriate referral of patients in whom varicosities are presented or suspected (*see* NICE referral advice)[122]
2 availability of appropriate diagnostic assessment tests and staff trained in their use – this includes not only Doppler but also ideally duplex ultrasound
3 trained junior surgical staff and supervision of inexperienced surgical trainees by consultants
4 maximal use of day surgery – wherever possible varicose vein treatment should be provided in a day-care setting
5 consideration of the opening of elective treatment centres following the model established in South Wales evaluated by Harvey *et al.*[288] Such centres reduced waiting times and increased the volume of varicose vein surgery. Direct-access assessment, whereby GPs can refer direct to the surgeon for operation, bypassing outpatients, did not however lead to substantially increased referral, probably because of the strong onus on GPs to undertake detailed assessment[289]
6 community venous ulcer clinics with appropriately trained nurses and an optimal flow of patients.

Prevention

The scope for prevention of varicose veins seems limited. Population strategies to halt the rising tide of obesity have not been effective. DVT prophylaxis, e.g. in hospitalised medical and surgical patients, may help reduce the consequences of DVT in terms of subsequent chronic venous disease. Compression stockings post-acute DVT may prevent the post-thrombotic limb.

8 Outcomes measures and audit methods

The most commonly evaluated outcome of medical and surgical treatment is the rate of recurrence. However, the definition, timing and method of assessment as well as case-mix should be stated. Other outcomes that need to be evaluated should be related to the reasons for treatment (symptomatic or not, presence of ulceration, etc). These may include prevention of complications and an improvement in appearance and symptoms. Other outcomes may include patient satisfaction, side-effects and costs.

Objective outcome measures could include any of the assessment methods, although the less invasive and easiest/most cost-effective to use (continuous-wave Doppler) would be preferable.

Quality of life

The Aberdeen Varicose Vein Questionnaire is a disease-specific questionnaire that measures health-related quality of life for patients with varicose veins.[290] The questionnaire consists of 13 questions relating to all aspects of the problem of varicose veins. The questionnaire has been assessed for reliability, validity, responsiveness and practicality, and was deemed a valid measure of quality of life for patients with varicose veins.[41] The Short Form 36 (SF-36) Health Assessment Questionnaire has also been used to assess patient outcomes following varicose vein surgery.[291] The Nottingham Health Profile and the SF-36 are the most popular generic tools used in the study of leg ulceration.

9 Information and research

There has been an expansion of interest in venous disease research. There is a need for more information on the following:

- epidemiology of venous disease in the elderly and in ethnic minorities
- the link between varicose veins and venous ulcer and prediction of risk of venous ulceration
- surgical vs. medical therapy for CVI
- the efficacy of varicose vein surgery in improving ulcer healing rates and in preventing recurrence
- the relationship between the location of venous incompetence and the severity of venous insufficiency
- the relationship between DVT and varicose veins.

There are protocols for systematic reviews of RCTs of the use of phlebotonics for CVI, community clinics vs. home management for venous leg ulcer treatment, oral antibiotics for treating venous leg ulcers and dressings for venous leg ulcers registered on the Cochrane Library.

The Cochrane Review on sclerotherapy recommended a comparison of surgery vs. sclerotherapy.[270] A consensus statement on sclerotherapy concluded that there is a need for proper randomised controlled trials to assess the effectiveness of sclerotherapy, and listed the essential characteristics that any new study considering the effectiveness of sclerotherapy should have[59] (*see* Box 3). These characteristics can also be applied to any study of the effectiveness of surgery.

Box 3: The characteristics of an ideal study on sclerotherapy. *Source*: Baccaglini *et al.*[59]

1 The study should be prospective, randomised and controlled.
2 The patient sample should be as homogeneous as possible, particularly with respect to the type of varicose veins to be treated. For this reason a careful pre-treatment assessment would be necessary.
3 The sclerotherapy technique should be standardised and clearly described.
4 All complications and side-effects of the treatment should be recorded.
5 An independent assessor should evaluate the results, and objective criteria should be used in evaluating the symptoms, the appearance of the leg and the instrumental examinations.
6 Follow-up should last for at least 5 years and subsequent treatments should be recorded.

Better information is required on the reasons for varicose vein treatment rate variation, using HES data. For much of venous disease (e.g. outpatients, private sector), information is lacking which would be useful for commissioning services. Locally, one needs to be able to determine local treatment rates that can be compared with national results. The proportion of varicose veins having day-case surgery and the size of the known venous ulcer disease population would also be valuable local figures. Recurrence rates are more difficult to determine and interpret – in terms of definitions, assessment and duration of follow-up.

A conference on venous disease held in Edinburgh, Scotland in 1999 highlighted the many gaps in the research and information base for varicose veins and venous disease in general. A book summarising the conference proceedings has been drawn upon in the writing of this chapter.[298]

Appendix 1: Selection of codes for analysis

OPCS Operation Codes

Table A1: OPCS Operation Codes, Fourth Revision (April 1988 onwards).

Code	Operation
L83	Operations for venous insufficiency
L85	Ligation of varicose vein of leg
L86	Injection into varicose vein of leg
L87	Other operations on varicose vein of leg (stripping of long and short saphenous veins, and avulsion of varicose veins)

Diagnostic codes

Table A2: Relevant ICD-9 codes.

Code	Operation
	Varicose veins of lower extremities
454.0	With ulcer
454.1	With inflammation
454.2	With ulcer and inflammation
454.9	Without mention of ulcer and inflammation (includes phlebectasia, varicose veins and varix of any part of lower extremity or of unspecified site) (456 includes varicose veins of five other sites but when the site is not specified, code 454.9 is used, apart from retinal varices, which are 362.1)

Table A3: Relevant ICD-10 codes (introduced in 1995–96).

Code	Operation
	Varicose veins of lower extremities:
183.0	With ulcer (any condition in 183.9 with ulcer or specified as ulcerated). Varicose ulcer (lower extremity, any part)
183.1	With inflammation (any condition in 183.9 with inflammation or specified as inflamed. Statis dermatitis NOS)
183.2	With ulcer and inflammation (any condition in 183.9 with both ulcer and inflammation)
183.9	Without mention of ulcer and inflammation (includes phlebectasia, varicose veins and varix of any part of lower extremity or of unspecified site) (186 includes varicose veins of other sites – sublingual, scrotal, pelvic, vulval, gastric – and varicose ulcer of nasal septum, but when the site is not specified, code 183.9 is used, apart from retinal varices which are H35)

Health care resource groups (HRG codes)

Health care resource groups are used to identify groups of patients expected to consume similar amounts of health care resources. They were adapted to suit the requirements of the UK health system from diagnosis-related groups (DRGs), which were developed in the USA.

Following modification, version 3 has been in use since 1998. HRGs are now being used to compare clinical efficiency between different hospitals nationally. The version 3 HRG code for varicose veins is Q11.

Appendix 2: CEAP classifications

All limbs diagnosed as having chronic vascular disease are assessed for clinical signs, aetiological problems, anatomical distribution of the process and pathophysiological nature of the dysfunction.

Clinical classification

There are seven categories based on objective signs of CVD.

Table A4: Categories of clinical classification.

0	No visible or palpable signs of venous disease
1	Telangiectases or reticular veins
2	Varicose veins
3	Oedema
4	Skin changes ascribed to venous disease (e.g. pigmentation, venous eczema, lipodermatosclerosis)
5	Skin changes (as defined above) in conjunction with healed ulceration
6	Skin changes (as defined above) in conjunction with active ulceration

Each numbered category is further characterised by a subscript for the presence or absence of symptoms, such as pain, aching or heaviness:

- S: symptomatic
- A: asymptomatic.

Aetiological classification

The roles of congenital, primary and secondary causes in venous dysfunction are recognised in the aetiological classification.

Table A5: Categories of aetiological classification.

Congenital	E_c	Apparent at birth or recognised later, e.g. Klippel–Trenaunay syndrome
Primary	E_P	Undetermined cause
Secondary	E_s	Known cause – post-thrombotic, post-traumatic, other

Anatomical classification

This has been presented in a simplified and expanded form. In the simplified version, the vasculature involved is classified as superficial (A_s), deep (A_d) or perforating (A_P). When more detail is required, the site and extent of involvement of the superficial, deep and perforating veins may be categorised using the anatomical segments listed below.

Table A6: Categories of anatomical classification.

Segment	
	Superficial veins ($\mathbf{A_s}$)
1	Telangiectases/reticular veins
2	Greater (long) saphenous veins, above the knee
3	Greater (long) saphenous veins, below the knee
4	Lesser (short) saphenous veins
5	Non-saphenous veins
	Deep veins ($\mathbf{A_d}$)
6	Inferior vena cava
7	Iliac, common
8	Iliac, internal
9	Iliac, external
10	Pelvic, gonadal, broad ligament, other
11	Femoral, common
12	Femoral, deep
13	Femoral, superficial
14	Popliteal
15	Crural, anterior tibial, posterior tibial, peroneal (all paired)
16	Muscular, gastrocnemial, soleal, other
	Perforating veins ($\mathbf{A_P}$)
17	Thigh
18	Calf

Pathophysiological classification

The physiological cause of venous dysfunction can be categorised as reflux (P_R) or obstruction (P_O), or both ($P_{R,O}$).

Appendix 3: A review of the published evidence concerning the population distribution of varicose veins

The diagnosis of varicose veins in the clinical setting obviously differs from the diagnosis of varicose veins that can be made in the field setting of a population study of prevalence. The use of criteria such as raised and elongated tortuous veins visible on the lower limbs is a subjective and crude ascertainment mechanism. For the examination of large numbers of individuals such a screen should be understood as a measure of the prevalence of palpable/visible varicosities, rather than a measure of the prevalence of venous abnormalities with varying potential for relief by surgical intervention. In this sense, estimates of the population prevalence of visible varicose veins in the population are of little relevance to the question of requirements for varicose vein treatment.

Studies which have attempted to estimate the prevalence of skin changes and different types of venous incompetence in series of clinic patients with varicose veins are limited in their comparability by selection bias, inclusion criteria and methods of investigation. The patient profiles revealed in these studies are unlikely to be representative of the general population of people with varicose veins. These studies do, however, point to a means of assessing the severity of the venous conditions which present in clinics, with an indication of the appropriateness of the different treatment options.

Table A7 lists the published studies of the prevalence of varicose veins in the UK, Europe and worldwide.

Table A7: Studies of the prevalence of varicose veins in different countries.

Study	Assessment methods/ design	Country	Year	Population/setting	Total number	Prevalence of varicose veins		
						Female	Male	Total
Preziosi *et al.*[84]	Yearly systematic clinical examination. Monthly follow-up by a telematic network and a non-specific questionnaire	France	1994–98	Participants of the SUVIMAX cohort. Women: 35–60; men: 45–60 (representative of the French population for the age range under consideration)	3,065 in total; 1,747 women; 1,318 men	18.1% medically diagnosed; 12.4% self-reported	10.8% medically diagnosed; 7.4% self-reported	
Bradbury *et al.*[64]	Cross-sectional population study. Self-administered questionnaire on the presence of lower limb symptoms and a physical examination to determine presence and severity of varicose veins	Scotland	1994–96	Men and women aged 18–64 resident in Edinburgh	867 women; 699 men	Trunk:174; 2 or 3. 30; Hyphenweb: 707; 2 or 3. 60	Trunk:191; 2 or 3. 32; Hyphenweb: 519; 2 or 3. 36	
Krijnen *et al.*[36]	Questionnaire about the presence of subjective complaints of the legs. Medical history followed by clinical examination. Doppler ultrasound investigation and light reflection rheography (LRR) of the lower legs performed and the volume of the lower legs measured twice daily	The Netherlands		Male European workers with a standing position at work (five companies in the meat industry, four shoe factories, two flower-packing departments, a foam-rubber industry, a small factory and a printing office)	387 men		58% (any size of varicosity); 38% (excluding intracutaneous veins	
Komsuoglu *et al.*[103]	Medical history and examination by a physician	Turkey	1994	Elderly people over 60 (mean age 73.3 ± 9) in a city in NE Turkey	850	38.3%; (saphenous type: 7.1%; segment type: 17.7%; reticular type: 3.7%; web type: 2.0%)	34.5% 6.4% 14.8% 6.1% 2.9%	36.7% 5.6% 16.5% 4.7% 2.3%

Table A7: Continued

Study	Assessment methods/ design	Country	Year	Population/setting	Total number	Prevalence of varicose veins		
						Female	Male	Total
Cesarone *et al.* [82]	Clinical history, clinical examination visually and duplex scanner used for ultrasound evaluation	Italy	1994	A sample of male and female residents of San Valentino, a village in Central Italy, aged 8 to 94 years (mean 46.3 ± 7)	746 in total; 379 women; 367 men			8%
Canonico *et al.* [85]	Interviews and a clinical assessment (always done in vertical posture where possible)	Italy	1991–92	Males and females aged 66–96 (mean 74.2). A random sample drawn by means of a stratified multi-stage sampling design using electoral rolls	1,319 in total; 560 men; 759 women	35.2%	17.0%	362 (27.4%)
Hirai *et al.* [96]*	Interview and examination by palpation of lower extremities and colour photographs	Japan	1990	Japanese women aged 15–90 (mean 43 ± 23). Patients without vascular disease, hospital staff and residents in homes for the elderly. Japanese men aged 19–90 (mean 45 ± 15)	646 in total; 541 women; 105 men	45% (saphenous type: 22%; segment type: 35%; reticular type: 28%; web type: 16%)	34%	
Franks *et al.* [65]*	Self-administered questionnaire. Randomly selected from age–sex register	England	1989	Patients from general practices in West London aged 35–70	1,338	31.5%	17.5%	25%
Leipnitz *et al.* [86]*	Interview. Physical examination	Germany	1989	Randomly selected from population. Male and female, aged 45–65	2,821	29%	14.5%	20.2%

Stvrtinova *et al.*[69]	Examination of the lower limb and questionnaire. Continuous-wave Doppler measurement made to assess patency and valvular function of the lower limb venous system	Czechoslovakia	1987–89	Workers in a large department store in Bratislava. Data on women only analysed	696 women	60.5% (hyphenwebs: 30.7%; reticular: 15.4%; trunk: 14.4%)		
Rudofsky[87]*		Germany	1988	Community sample. Males and females over 15 years of age	14,000			15%
Henry and Corless[88]	Questionnaire (interview) attached to the quarterly Economic Consumer Survey in Ireland	Ireland	1986	Random sample of households	4,900			622 (12.7%)
Maffei *et al.*[97]*	A questionnaire completed by a social worker and data from a physical examination of the lower limbs carried out by a general physician	Brazil	1986	Patients attending a university health centre in a country town. Men and women over 15 years of age. Mostly farm workers, railway workers or housewives of low socio-economic class	1,755	50.9%	37.9%	47.6%; 21.2% (severe or moderate)
Fischer[89]*	Interview. Colour slide examination	Germany	1980	Random sample of males and females aged 17–70. City	4,530			59%
Sisto *et al.*[72]	Cross-sectional study with self-administered questionnaires and examination. Prevalence of varicose veins diagnosed by a physician	Finland	1978–81	Adults over 30 years of age. A national health examination survey	7,217	25%	7%	

Table A7: Continued

Study	Assessment methods/ design	Country	Year	Population/setting	Total number	Prevalence of varicose veins		
						Female	Male	Total
Novo *et al.*[90]	Clinical examination	Western Sicily, Italy	1977–79	A sample of the population of the village of Trabia, which mainly comprises farmers and fishermen and a few craftsmen and traders	1,122	46.2%	19.3%	35.2%
Richardson and Dixon[76]*	Examination	Tanzania	1977	Tanzanians in a provincial town, aged 18 and over, attending outpatient clinics with various mild illnesses	1,000	5%	6.1%	5.5%
Beaglehole *et al.*[77]	Examination whilst standing	Cook Island (Pukapuka)	1975	Males and non-pregnant females aged 15–64	377	4.0	2.1	
Beaglehole *et al.*[77]	Examination whilst standing	Cook Island (Rarotonga)	1975	Males and non-pregnant females aged 15–64	417	14.9	15.6	
Beaglehole *et al.*[77]	Examination whilst standing	New Zealand (Maori)	1975	Males and non-pregnant females aged 15–64	721	43.7	33.4	
Beaglehole *et al.*[77]	Examination whilst standing	New Zealand Pakehas (European)	1975	Males and non-pregnant females aged 15–64	356	37.8	19.6	
Beaglehole *et al.*[77]	Examination whilst standing	New Zealand (Tokelau Island)	1975	Males and non-pregnant females aged 15–64	786	0.8	2.9	
Daynes & Beighton[104]	Examination	South Africa	1973	Rural community in South Africa. Women aged 18 and over	297	7.7%		
Stanhope[75]*	Examination whilst standing	New Guinea	1972	Residents of home villages or Madang town aged 20 years or over	1,457 in total; 729 females; 728 males	0.1%	5.1%	

Malhotra[105]*	Survey carried out by one observer	India (North)	1972	Railway sweepers working in Amjer. The work involves standing for long hours sweeping roads	354 males		6.8%
Malhotra[105]*	Visual inspection and palpation from the groin to the toes and survey carried out by one observer	India (South)	1972	Railway sweepers working in Madras. The work involves standing for long hours sweeping roads	323		25.1%
Widmer[292]*	Phlebologic examination consisting of an interview and an examination including inspection, palpation and documentation with colour photography	Switzerland, (Basle Study III)	1971–73	'Healthy' employees and workers of the Basle chemical companies	4,529	55%	56%
Prior *et al.*[74]*	Medical interview and examination	New Zealand (European)	1970	A cluster sample of European adults aged 20 and over from the North Island town of Carterton	432	42%; Mild: 29%; Moderate: 10%; Gross: 2.5%	25%; Mild: 16%; Moderate: 4%; Gross: 5%
Guberan *et al.*[73]*	Interviews and colour slides analysed by three observers	Switzerland	1970	Women working full-time in five department stores and in one department of a watch factory. Mean age 37.6 years	610	29.0%	
Abramson *et al.*[95]*	An interview and examination by a physician using standardised questions, procedures and criteria	Western Jerusalem, Israel	1969 –71	Residents aged 15 and over in a Jewish neighbourhood of Western Jerusalem mainly populated by immigrants from central and eastern Europe, North Africa and Middle Eastern countries and their offspring	4,802	29%	10%

Table A7: Continued

Study	Assessment methods/ design	Country	Year	Population/setting	Total number	Prevalence of varicose veins		
						Female	Male	Total
Mekky *et al.* [101]*	Questionnaire and examination by one researcher	Egypt	1969	Women cotton workers from five mills in and around the Nile Delta. Aged 15–74	467	6%		
Mekky *et al.* [101]*	Questionnaire and examination by one researcher	England	1969	Women cotton workers from two mills, one in Rochdale and one in Carlisle. Aged 15–74	504	32%		
Weddell[67]*	Questionnaire and examination (standing up) carried out by one observer	Wales	1966	Randomly selected from the electoral roll. Males and females aged 15 and over	289	53%; Type 2: 36%; Type 3: 17%	37%; Type 2: 31%; Type 3: 6%	
Bobek *et al.* [293]*		Bohemia	1966	Community sample over 15 years of age	15,060	14.1%	6.6%	11%
Da Silva *et al.* [98]	Colour slides	Switzerland (Basle Study II)	1965–67	Employees and workers of the Basle chemical companies. Average age 47 ± 11 (men) and 43 ± 10 (women)	4,376	68%; (n = 778)	57%; (n = 3,598)	62%
Recoules-Arche[294]*		France	1965	Community sample aged 16–54	5,424			14%
Berge and Feldthusen[295]*		Sweden	1963	Community sample, aged 50 and aged 20	1,354			Aged 50: 50%; aged 20: 20%

Coon *et al.*[91]*	A longitudinal study of a total community. Physical examination in the standing position	USA	1959–60 and 1962–65	Residents of Tecumseh, a city in SE Michigan, aged 10 years and over	6,389	25.9% (moderate to severe: 16.7%)	12.9% (moderate to severe: 7.4%)	
Arnoldi[92]*		Denmark	1958	Clinic attenders over 25 years old	1,981	38%	18.4%	28%
Lake *et al.*[71]*	Complete physical examination of the lower extremities	USA	1942	Males and females over 40 years of age representing four different types of occupational activity: sitting, standing, walking, climbing	536	73.2%	40.7%	

* Identified by Callam in his review on the epidemiology of varicose veins in 1994.[78]

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