

IVIGRC White Paper

Intersociety Venous Insurance and Government Relations Committee (IVIGRC)

Treatment of Superficial Treatment of Venous Disease of the Lower Leg and Pelvis

Background

In the last 10 years the diagnosis and treatment of venous disease has advanced more than in the last 100 years. Ultrasound, endovenous ablation devices, foam sclerotherapy and tumescent anesthesia have greatly improved patient care and have moved treatment from the operating room to the office or radiology suite. This has created challenges for insurers. Medical necessity policy for the treatment of chronic venous disease (CVD) has become fragmented and inconsistent across the U.S. and among private insurers, and Medicare. As with any medical specialty, those who are most committed to that specialty generally provide the best care. Commitment includes some form of training, a practice focused in that area, and continuing education through attendance at meetings and other CME. The American College of Phlebology (ACP) the American Venous Forum (AVF), the Society of Interventional Radiology (SIR) and other organizations have been at the forefront of advancing education, research and appropriate treatment of venous disease. Dedicated venous physicians representing these organizations formed the Intersociety Venous Insurance and Government Relations Committee (IVIGRC).

In 2011, the Society for Vascular Surgery and the American Venous Forum¹ undertook a comprehensive summary of all the available venous research and graded it by relevance and quality of data. Their goal was to analyze all the available evidence-based medicine and create rational guidelines for treatment of venous disease of the lower limbs and pelvis. This 70 page review by Gloviczki et al was well received by the medical community across specialties treating venous disease.

The IVIGRC has accepted the challenge of taking this review and formatting it in a document that would be more suitable to the insurance industry. It reflects the evidence based recommendations in the Gloviczki paper and other studies. Recommendations are based on a consensus of a panel of experts where the evidence based research is sparse. It is focused on those interventions that have the most policy variation in the insurance industry or where policies substantially deviate from the evidence based research available.

We acknowledge that all carriers are free to determine coverage guidelines etc. based upon their own independent review of the literature and resources like Cochrane and others.

However, we suggest that evidence based medical necessity should not vary greatly based on geography or insurer. We would like to introduce the concept of “medically significant venous insufficiency” or “evidence-based medical significance“. This eliminates confusion around terms like “cosmetic” or not medically necessary“. The medical evidence should determine the definition of medically significant venous insufficiency using a combination of CEAP and VCSS (discussed below). We would propose that payers retain the evidence-based definition of medical significance, but choose at what level it becomes either a

“covered benefit” or a “non-covered benefit”. Insurers could establish different benefit levels for their various premium options. In this way the evidence-based medical criteria would still be consistent across the industry.

The IVIGRC understands the importance of delivering quality care in a cost effective manner and welcomes the opportunity to work with the insurance industry in whatever way possible to achieve those ends.

In the following pages are our medical necessity guidelines in a summary format. The recommendations of the IVIGRC (and the Gloviczki paper) have been determined by the method suggested by the Grading of Recommendations Assessment, Development, and Evaluation system (GRADE) working group. (www.gradeworkinggroup.org) For each guideline, the letter A, B, or C marks the quality of current evidence as high, medium or low quality. The grade of recommendation of a guideline can be strong (1) or weak (2), depending on the risk and burden of a particular diagnostic test or a therapeutic procedure to the patient vs. the expected benefit. The words “we recommend” are used for GRADE 1—strong recommendations—if the benefits clearly outweigh risks and burdens, or vice versa; the words “we suggest” are used for GRADE 2—weak recommendations—when the benefits are closely balanced with risks and burdens. Where current evidence is weak or lacking, the degree of consensus of the committee reflects the grade with the quality of the recommendation adjusted accordingly.

Following the summary are the common ICD9 and CPT codes for venous disease. This is followed by the accompanying appendix **Benchmark Evidence Based Policy for Treatment of Chronic Venous Disease and Varicose Veins** which provides the detailed review and references for these recommendations.

Summary of Guidelines for Treatment of Venous Disease

Indications for Treatment

Treatment of asymptomatic varicose veins is not medically necessary. **GRADE 1A**

Indications for treatment include pain (achiness, heaviness), edema, varix hemorrhage, recurrent superficial phlebitis, stasis dermatitis, or ulceration.

Patients should be evaluated using the CEAP classification and the Venous Clinical Severity Score (VCSS). We would define medically necessary as a CEAP classification of C2 or higher and a VCSS score of 5 or higher. **GRADE 1A**

We suggest the treatment of some CEAP C2 patients with isolated varices, by medical compression hose alone may an acceptable form of treatment. **GRADE 2C**

We recommend against compression therapy being considered the primary treatment of symptomatic varicose veins (class C2) in those patients who are candidates for saphenous vein ablation **GRADE 1B**.

In Addition

All patients being considered for treatment must have a duplex ultrasound. Great Saphenous Vein (GSV), Small Saphenous Vein (SSV, Anterior Accessory of the Great Saphenous Vein (AAGSV) and Posterior Accessory of the Great Saphenous Vein (PAGSV)) incompetence must have a reflux time > 500 msec. "Pathologic" perforating veins includes those with outward flow of ≥ 500 ms, with a diameter of ≥ 3.5 mm, located beneath a healed or open venous ulcer. **GRADE 1B**

We suggest all noninvasive vascular diagnostic studies be performed by a qualified physician or by a qualified technologist under the general supervision of a qualified physician. These individuals should have passed some form of credentialing examination and hold a certificate from a nationally recognized credentialing organization such as the American Registry of Diagnostic Medical Sonographers (ARDMS) or Cardiovascular Credentialing International (CCI) **GRADE 2C**

We suggest a follow up ultrasound examination CPT code 93971 after endovenous thermal ablation or ultrasound guided chemical ablation to confirm non compressibility and absence of reflux in the treated area. **GRADE 2C**

Treatment of Great or Small Saphenous Veins

We recommend endovenous thermal ablation (laser and radiofrequency) is the preferred treatment for saphenous and accessory saphenous (GSV, SSV, AAGSV, PAGSV) vein incompetence. **GRADE 1B**

We recommend open surgery is appropriate in veins not amenable to endovenous procedures but otherwise is not recommended because of increased pain, convalescent time, and morbidity. **GRADE 1B**

When open surgery of the great saphenous vein is performed we suggest it should include high ligation and invagination stripping to the level of the knee. **GRADE 2B**

When open surgery of the small saphenous vein is performed we recommend it include high ligation at the knee crease and selective invagination of the proximal portion. **GRADE 1B**

Treatment of Circumflex Veins and Other Non Truncal Veins

The treatment of other non-truncal, tributary varicose vein reflux (circumflex veins (anterior and posterior thigh) and intersaphenous vein) is more complex. The medical record should reflect that these veins are incompetent, and note their size, presence or absence of tortuosity, and depth relationship to the skin, i.e. accessible or not accessible by phlebectomy.

We recommend varicose (visible) tributary veins can be treated by stab phlebectomy, liquid sclerotherapy or foam chemical ablation. **GRADE 1B**

We suggest (non visible) tributary veins be treated by ultrasound guided liquid sclerotherapy or foam chemical ablation. **GRADE 2B**

Treatment of Perforator Veins

We recommend against selective treatment of incompetent perforating veins in patients with simple varicose veins (CEAP class 2). **GRADE 1B**

We suggest treatment of “pathologic” perforating veins located beneath a healed or open venous ulcer (CEAP class 5-6). **GRADE 2B**

For treatment of “pathologic” perforating veins we suggest the SEPS procedure, ultrasound-guided chemical ablation or thermal ablations. **GRADE 2C**

Coding Reference

CPT/HCPCS Codes	
36011	SELECTIVE CATHETER PLACEMENT, VENOUS SYSTEM, FIRST ORDER BRANCH
36468	SINGLE OR MULTIPLE INJECTIONS OF SCLEROSING SOLUTIONS, SPIDER VEINS (TELANGIECTASIA); LIMB OR TRUNK
36470	INJECTION OF SCLEROSING SOLUTION; SINGLE VEIN
36471	INJECTION OF SCLEROSING SOLUTION; MULTIPLE VEINS, SAME LEG
36475	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, RADIOFREQUENCY; FIRST VEIN TREATED
36476	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, RADIOFREQUENCY; SECOND AND SUBSEQUENT VEINS TREATED IN A SINGLE EXTREMITY, EACH THROUGH SEPARATE ACCESS SITES (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
36478	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, LASER; FIRST VEIN TREATED
36479	ENDOVENOUS ABLATION THERAPY OF INCOMPETENT VEIN, EXTREMITY, INCLUSIVE OF ALL IMAGING GUIDANCE AND MONITORING, PERCUTANEOUS, LASER; SECOND AND SUBSEQUENT VEINS TREATED IN A SINGLE EXTREMITY, EACH THROUGH SEPARATE ACCESS SITES (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
37204	TRANSCATHETER OCCLUSION OR EMBOLIZATION, PERCUTANEOUS, ANY METHOD, NON-CENTRAL NERVOUS SYSTEM, NON-HEAD OR NECK
37500	ENDOSCOPY, SURGICAL, WITH LIGATION OF PERFORATOR VEINS, SUBFASCIAL (SEPS)
37700	LIGATION AND DIVISION OF LONG SAPHENOUS VEIN AT SAPHENOFEMORAL JUNCTION, OR DISTAL INTERRUPTIONS
37718	LIGATION, DIVISION, AND STRIPPING, SHORT SAPHENOUS VEIN
37722	LIGATION, DIVISION, AND STRIPPING, LONG (GREATER) SAPHENOUS VEINS FROM SAPHENOFEMORAL JUNCTION TO KNEE OR BELOW
37735	LIGATION AND DIVISION AND COMPLETE STRIPPING OF LONG OR SHORT SAPHENOUS VEINS WITH RADICAL EXCISION OF ULCER AND SKIN GRAFT AND/OR INTERRUPTION OF COMMUNICATING VEINS OF LOWER LEG, WITH EXCISION OF DEEP FASCIA
37760	LIGATION OF PERFORATOR VEINS, SUBFASCIAL, RADICAL (LINTON TYPE), WITH OR WITHOUT SKIN GRAFT, OPEN
37765	STAB PHLEBECTOMY OF VARICOSE VEINS, ONE EXTREMITY; 10-20 STAB INCISIONS
37766	STAB PHLEBECTOMY OF VARICOSE VEINS, ONE EXTREMITY; MORE THAN 20 INCISIONS
37780	LIGATION AND DIVISION OF SHORT SAPHENOUS VEIN AT SAPHENOPOPLITEAL JUNCTION (SEPARATE PROCEDURE)
37785	LIGATION, DIVISION, AND/OR EXCISION OF VARICOSE VEIN CLUSTER(S), ONE LEG. FOR BOTH LEGS, REPORT WITH A MODIFIER 50.
37799	UNLISTED PROCEDURE, VASCULAR SURGERY
75894	TRANSCATHETER THERAPY, EMBOLIZATION, ANY METHOD RADIOLOGICAL SUPERVISION AND INTERPRETATION
76942	ULTRASONIC GUIDANCE FOR NEEDLE PLACEMENT (EG, BIOPSY, ASPIRATION,

	INJECTION, LOCALIZATION DEVICE), IMAGING SUPERVISION AND INTERPRETATION
93770	DETERMINATION OF VENOUS PRESSURE
93965	NONINVASIVE PHYSIOLOGIC STUDIES OF EXTREMITY VEINS, COMPLETE BILATERAL STUDY (EG, DOPPLER WAVEFORM ANALYSIS WITH RESPONSES TO COMPRESSION AND OTHER MANEUVERS, PHLEBORHEOGRAPHY, IMPEDANCE PLETHYSMOGRAPHY)
93970	LOWER EXTREMITY VENOUS DUPLEX ULTRASOUND - BILATERAL
93971	DUPLEX SCAN OF EXTREMITY VEINS INCLUDING RESPONSES TO COMPRESSION AND OTHER MANEUVERS; UNILATERAL OR LIMITED STUDY

ICD-9 Codes	
448.1	NEVUS, NON-NEOPLASTIC (SPIDER VEINS)
448.9	TELANGIECTASIA, TELANGIECTASIS
451.0	PHLEBITIS AND THROMBOPHLEBITIS OF SUPERFICIAL VESSELS OF LOWER EXTREMITIES
451.2	PHLEBITIS AND THROMBOPHLEBITIS OF LOWER EXTREMITIES UNSPECIFIED
454.0	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER
454.1	VARICOSE VEINS OF LOWER EXTREMITIES WITH INFLAMMATION
454.2	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER AND INFLAMMATION
454.8	VARICOSE VEINS OF LOWER EXTREMITIES WITH OTHER COMPLICATIONS
456.6	VULVAR VARICOSITIES OF PIRENIUM (SPECIFICALLY)
459.10	POSTPHLEBETIC SYNDROME WITHOUT COMPLICATIONS
459.11	POSTPHLEBETIC SYNDROME WITH ULCER
459.12	POSTPHLEBETIC SYNDROME WITH INFLAMMATION
459.13	POSTPHLEBETIC SYNDROME WITH ULCER AND INFLAMMATION
459.19	POSTPHLEBETIC SYNDROME WITH OTHER COMPLICATION
459.31	CHRONIC VENOUS HYPERTENSION WITH ULCER
459.32	CHRONIC VENOUS HYPERTENSION WITH INFLAMMATION
459.33	CHRONIC VENOUS HYPERTENSION WITH ULCER AND INFLAMMATION
459.81	VENOUS(PERIPHERAL) INSUFFICIENCY, NSPECIFIED
459.89	OTHER SPECIFIED DISORDERS OF CIRCULATORY SYSTEM (PHLEBOSCLEROSIS, VENOFIBROSIS, COLLATERAL CIRCULATION[VENOUS], ANY SITE)

Appendix

Benchmark Evidence Based Policy for Treatment of Chronic Venous Disease and Varicose Veins

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I. Introduction:

The purpose of this policy document is to update providers and third party payors with the most current evidence-based guidelines for care of chronic venous disease and varicose veins.

Evidence-based medicine involves utilizing the best available scientific information to make decisions about patient care.¹⁴ It has been used successfully in recent years to guide indications for therapy, validate new techniques for efficacy and cost control, and to develop reliable outcome assessment methods in many areas of clinical practice. Chronic venous disease and varicose veins have seen recent advances in minimally invasive therapies and clinical research that are leading more patients to seek treatment. This in turn has led to more procedures performed by physicians from a variety of specialties, and advances in industry resulting in new technology. Academic interest in venous disease has focused on the analysis of data for validity and scientific interest, as well as analysis of treatment outcomes.

In the US and Europe, varicose veins are found in more than 20% of the population, with approximately 5% of patients exhibiting signs of chronic venous disease, including edema and skin changes. Around 1% of patients have active or healed venous ulcers.⁵⁷ In the US alone, according to the San Diego epidemiologic study, in excess of 33 men and women between 40 and 80 years old have varicose veins, with more than 2 million suffering from advanced chronic venous disease with skin changes or ulcers.¹ Each year in the US alone, more than 20,000 patients are newly diagnosed with venous ulcers.³

The Bonn Vein Study,⁵⁹ a large European population based study, enrolled 3072 adults aged 18 to 79. In this group, uncomplicated varicose veins were identified in 14.3%, with symptoms of more advanced chronic venous disease including edema or skin changes found in 49.1% of men and 62.1% of women.

Many cases of varicose veins are due to primary venous disease, caused in some cases by an intrinsic vein wall abnormality, although the etiology can be multifactorial. Labropoulos⁵⁴ wrote that primary varicose veins can arise from local or multifocal weakness of the vein wall that occurs with or without saphenous valvular incompetence. Varicosities can result from secondary causes, including deep vein thrombosis (DVT) or obstruction, superficial thrombophlebitis, or arteriovenous fistula. Varicose veins may also be congenital and manifest as a venous malformation³⁷⁶. It has been shown that primary varicose veins can progress to chronic venous disease with severe symptoms, including venous ulcers. In 1948 Bauer⁶³ reported that 58% of his patients with symptoms of severe CVD had primary venous disease without a history of deep vein thrombosis (DVT). The North American subfascial endoscopic perforator surgery (SEPS) registry includes more patients with advanced CVD resulting from primary venous disease than post-thrombotic syndrome (70% vs 30%).⁶²

Varicose veins and the complications of chronic venous disease are associated with a high direct cost to the patient and society as a whole. Chronic pain, refractory swelling and the open sores of

venous ulcers are associated with disability, loss of working days and lower quality of life (QOL), loss of working days. In the United States, the direct medical cost of CVD has been estimated to be between \$150 million and \$1 billion annually.^{3,4} In the United Kingdom, 2% of the annual national health care budget is spent on treating venous ulcers.¹

Varicose veins and chronic venous disease are prevalent in the adult population of the US. Advances in scientific technology have resulted in new minimally invasive endovascular surgical techniques, changing the way physicians care for patients with venous disease. Patient acceptance of office-based, outpatient procedures has been very strong, and clinical outcomes from these procedures are positive. More interventions for chronic venous disease are being performed every year, and interest in these procedures has grown among patients, physicians, device manufacturers, and third party payors.³⁷⁶

II. Methodology of guidelines

Guidelines for the care of patients with varicose veins, as recommended here, are based on scientific evidence. The need for adopting evidence-based guidelines and reporting standards for venous diseases has been recognized by leaders in the field for some time.^{15,16,17, 18, 19, 20} The current guidelines have been formulated by a Venous Guideline Committee, who reviewed the literature, including consensus documents and guidelines already in existence,^{21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31} as well as meta-analyses,^{6, 7, 8, 9, 10, 11, 12, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42} reports^{13, 43, 44, 45, 46} and recommendations from the American Venous Forum.⁴⁷

The guidelines offered here are based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system, as it was described by Guyatt et al (Table I).⁴⁸ For each guideline, the letter A, B, or C marks the level of current evidence. The grade of recommendation of a guideline can be strong (1) or weak (2), depending on the risk and burden of a particular diagnostic test or a therapeutic procedure to the patient vs the expected benefit. The words “we recommend” are used for GRADE 1—strong recommendations—if the benefits clearly outweigh risks and burdens, or vice versa; the words “we suggest” are used for GRADE 2—weak recommendations—when the benefits are closely balanced with risks and burdens³⁷⁶.

III. Definitions

Currently accepted terminology for the superficial, perforating, and deep veins of the leg and pelvis are used.^{49, 50} Definitions of varicose and spider veins as well as other manifestations of CVD follow recommendations of the CEAP classification and the recent update on venous terminology of the International Committee of the AVF.^{51, 52}

Varicose veins of the lower limbs are dilated subcutaneous veins that are ≥ 3 mm in diameter measured in the upright position.⁵³ Synonyms include varix, varices, and varicosities. Varicosity can involve the main axial superficial veins—the great saphenous vein (GSV) or the small saphenous vein (SSV)—or any other superficial vein tributaries of the lower limbs.

Varicosities are manifestations of chronic venous disease (CVD).^{51,52} CVD includes medical conditions of long duration, involving morphologic and functional abnormalities of the venous system manifested by symptoms and/or signs, indicating the need for investigation and care. The term chronic venous disorder is reserved for the full spectrum of venous abnormalities and includes dilated intradermal veins and venules between 1 and 3 mm in diameter (spider veins, reticular veins, telangiectasia; CEAP class C1).

Varicose veins can progress to a more advanced form of chronic venous dysfunction such as chronic venous insufficiency (CVI).^{55,56} In CVI, increased ambulatory venous hypertension initiates a series of changes in the subcutaneous tissue and the skin: activation of the endothelial cells, extravasation of macromolecules and red blood cells, diapedesis of leukocytes, tissue edema, and chronic inflammatory changes most frequently noted at and above the ankles.^{41,53} Limb swelling, pigmentation, lipodermatosclerosis, eczema, or venous ulcerations can develop in these patients.

IV. The scope of the problem

In the US and Europe, varicose veins are found in more than 20% of the population, with approximately 5% of patients exhibiting signs of chronic venous disease, including edema and skin changes. Around 1% of patients have active or healed venous ulcers.⁵⁷ In the US alone, according to the San Diego epidemiologic study, in excess of 33 men and women between 40 and 80 years old have varicose veins, with more than 2 million suffering from advanced chronic venous disease with skin changes or ulcers.¹ Each year in the US alone, more than 20,000 patients are newly diagnosed with venous ulcers.³

The Bonn Vein Study,⁵⁹ a large European population based study, enrolled 3072 adults aged 18 to 79. In this group, uncomplicated varicose veins were identified in 14.3%, with symptoms of more advanced chronic venous disease including edema or skin changes found in 49.1% of men and 62.1% of women.

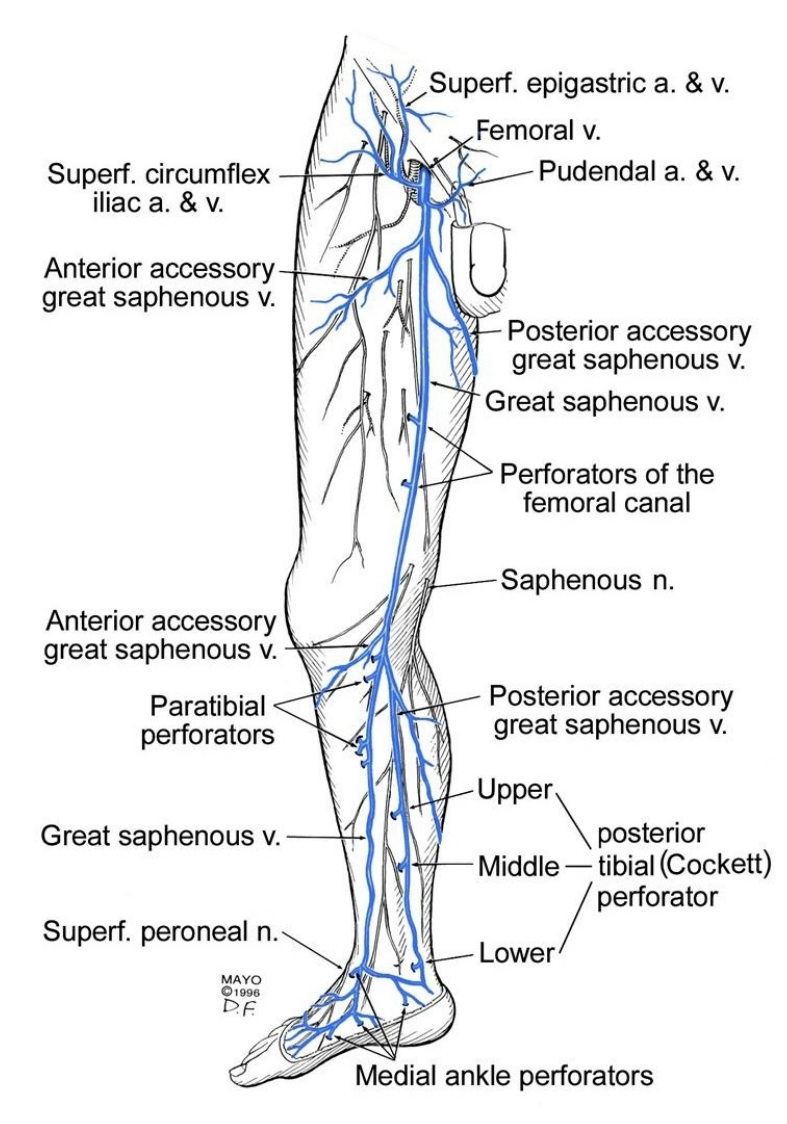
Varicose veins and the complications of chronic venous disease are associated with a high direct cost to the patient and society as a whole. Chronic pain, refractory swelling and the open sores of venous ulcers are associated with disability, loss of working days and lower quality of life (QOL), loss of working days. In the United States, the direct medical cost of CVD has been estimated to be between \$150 million and \$1 billion annually.^{3,4} In the United Kingdom, 2% of the annual national health care budget is spent on treating venous ulcers.¹

V. Anatomy

New venous terminology has recently been developed and is in use by vascular societies around the world.^{47,49,61} The success of assigning uniform names to common veins was accompanied by new information on anatomy obtained with duplex ultrasonography, three-dimensional computed tomography (CT), and magnetic resonance (MR) imaging; all these resulted in better understanding of the anatomy of veins and the pathology of CVD.^{33,62}

Superficial veins

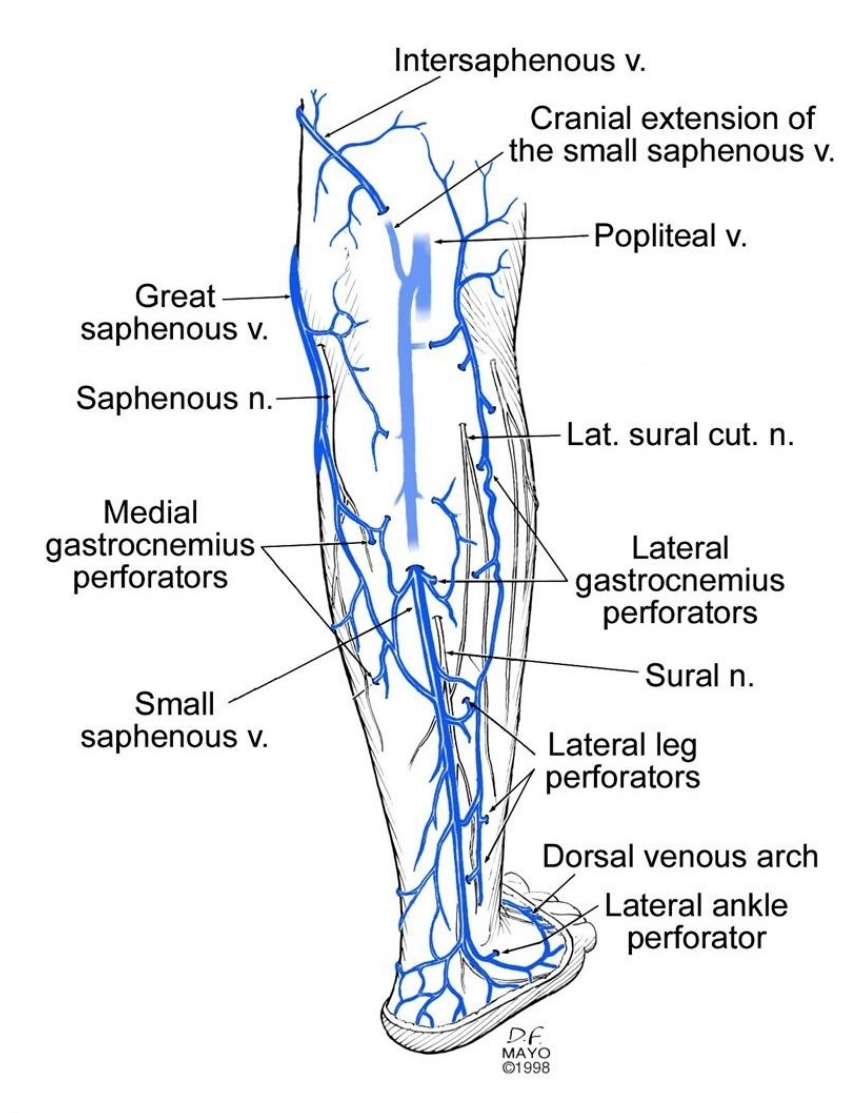
Superficial veins of the lower limbs are those located between the deep fascia, covering the muscles of the limb, and the skin. The main superficial veins are the great saphenous vein (GSV) and the small saphenous vein (SSV). The GSV originates from the medial superficial veins of the dorsum of the foot and ascends in front of the medial malleolus along the medial border of the tibia, next to the saphenous nerve (Fig 1). There are posterior and anterior accessory saphenous veins in the calf and the thigh. The saphenofemoral junction (SFJ) is the confluence of superficial inguinal veins, comprising the GSV and the superficial circumflex iliac, superficial epigastric, and external pudendal veins. The GSV in the thigh lies in the saphenous subcompartment of the superficial compartment, between the saphenous fascia and the deep fascia.



(Used with permission of Mayo Foundation for Medical Education and Research.)

- Fig 1. Medial superficial and perforating veins of the lower limb.

The SSV is the most important posterior superficial vein of the leg (Fig 2). It originates from the lateral side of the foot and drains blood into the popliteal vein, joining it usually just proximal to the knee crease. The intersaphenous vein (vein of Giacomini), which runs in the posterior thigh, connects the SSV with the GSV.⁶⁵



(Used with permission of Mayo Foundation for Medical Education and Research.)

- Fig 2. Posterior superficial and perforating veins of the leg.

Deep veins

Deep veins accompany the main arteries of the limb and pelvis. The deep veins of the calf (anterior, posterior tibial, and peroneal veins) are paired structures, and the popliteal and femoral veins may also be paired. The gastrocnemius and soleal veins are important deep tributaries. The

old term *superficial femoral vein* has been replaced by the new term *femoral vein*.⁵² The femoral vein connects the popliteal to the common femoral vein.

The pelvic veins include the external, internal, and common iliac veins, which drain into the inferior vena cava (IVC). Large gonadal veins drain into the IVC on the right and the left renal vein on the left.

Perforating veins

Perforating veins connect the superficial to the deep venous system (Fig 1). They pass through the deep fascia that separates the superficial compartment from the deep. Communicating veins connect veins within the same system. The most important leg perforating veins are the medial calf perforators.⁶⁶ The posterior tibial perforating veins (formerly called Cockett perforators) connect the posterior accessory GSV of the calf (formerly called the posterior arch vein) with the posterior tibial veins and form the lower, middle, and upper groups. They are located just behind the medial malleolus (lower), at 7 to 9 cm (middle) and at 10 to 12 cm (upper) from the lower edge of the malleolus. The distance between these perforators and the medial edge of the tibia is 2 to 4 cm.⁶⁶ (Fig 1). Paratibial perforators connect the main GSV trunk with the posterior tibial veins. In the distal thigh, perforators of the femoral canal usually connect directly the GSV to the femoral vein.

VI. Diagnostic Evaluation

A. Clinical Examination

Patients with varicose veins may present with no symptoms at all; the varices are then of cosmetic concern only, with an underlying psychologic impact. Psychologic concerns related to the cosmetic appearance of varicose veins will, however, reduce a patient's QOL in many cases.

Symptoms related to varicose veins or more advanced CVD include tingling, aching, burning, pain, muscle cramps, swelling, sensations of throbbing or heaviness, itching skin, restless legs, leg tiredness, and fatigue.⁷⁰ Although not pathognomonic, these symptoms suggest CVD, particularly if they are exacerbated by heat or dependency noted during the course of the day and relieved by resting or elevating the legs or by wearing elastic stockings or bandages.⁵¹

Pain during and after exercise that is relieved with rest and leg elevation (venous claudication) can also be caused by venous outflow obstruction caused by previous DVT or by narrowing or obstruction of the common iliac veins (May-Thurner syndrome).^{69, 70, 71} Diffuse pain is more frequently associated with axial venous reflux, whereas poor venous circulation in bulging varicose veins usually causes local pain³⁷⁶.

B. Duplex scanning

Duplex Doppler scanning is recommended as the first diagnostic test for all patients with suspected CVD.^{5,79} The test is safe, noninvasive, cost-effective, and reliable. It is excellent for the evaluation of infrainguinal venous obstruction and valvular incompetence.⁸¹ It also differentiates between acute venous thrombosis and chronic venous changes.^{82,83}

Technique of the examination

Evaluation of reflux in the deep and superficial veins with duplex scanning should be performed with the patient upright, with the leg rotated outward, heel on the ground, and weight taken on the opposite limb.⁵ The supine position gives both false-positive and false-negative results of reflux.⁸⁴

The examination is started below the inguinal ligament, and the veins are examined in 3- to 5-cm intervals. For a complete examination, all deep veins of the leg are examined, including the common femoral, femoral, deep femoral, popliteal, peroneal, soleal, gastrocnemial, anterior, and posterior tibial veins. The superficial veins are then evaluated, including the GSV, the SSV, the accessory saphenous veins, and the perforating veins.

The four components that should be included in a complete duplex scanning examination for CVD are (1) visibility, (2) compressibility, (3) venous flow, including measurement of the duration of reflux, and (4) augmentation. Asymmetry in flow velocity, lack of respiratory variations in venous flow, and waveform patterns at rest and during flow augmentation in the common femoral veins indicate proximal obstruction. Reflux can be elicited in two ways: increased intra-abdominal pressure using a Valsalva maneuver for the common femoral vein or the SFJ, or by manual compression and release of the limb distal to the point of examination. The first is more appropriate for evaluation of reflux in the common femoral vein and at the SFJ, whereas compression and release is the preferred technique more distally on the limb.⁸⁴

The cutoff value for abnormally reversed venous flow (reflux) in the saphenous, tibial, and deep femoral veins has been 500 ms.⁸¹ International consensus documents previously recommended 0.5 seconds as a cutoff value for all veins to use for lower limb venous incompetence.^{5, 22, 86} This value is, however, longer, 1 second, for the femoral and popliteal veins.⁸¹ The Committee recommends 500 ms as the cutoff value for saphenous, tibial, deep femoral, and perforating vein incompetence, and 1 second for femoral and popliteal vein incompetence.

Perforating veins should be evaluated in patients with advanced disease, usually in those with healed or active venous ulcers (CEAP class C5-C6) or in those with recurrent varicose veins after previous interventions. The SVS/AVF Guideline Committee definition of clinically relevant perforating veins includes those with outward flow of ≥ 500 ms, with a diameter of ≥ 3.5 mm, located beneath a healed or open venous ulcer (CEAP class C5-C6).^{5, 81, 88, 89}

VII. Classification of CVD - Clinical CEAP

Venous disease of the legs can be classified according to the severity, cause, site and specific abnormality using the CEAP classification. Use of such a classification increases the accuracy of diagnosis and improves communication between providers.

The elements of the CEAP classification are: Clinical severity, Etiology or cause, Anatomy, Pathophysiology.

The CEAP grading table:

Grade	Description
C ₀	No visible or palpable signs of venous disease
C ₁	Telangiectases or reticular veins
C ₂	Varicose veins
C ₃	Edema
C _{4a}	Pigmentation and/or eczema
C _{4b}	Lipodermatosclerosis and/or atrophie blanche
C ₅	Healed venous ulcer
C ₆	Active venous ulcer
C _S	Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
C _A	Asymptomatic

VIII. Venous Severity Scoring and Outcome Measurement: VCSS

The Venous Clinical Severity Score is an evaluative instrument in the treatment of chronic venous insufficiency. This scoring system is beneficial in the specificity of each element of vein disease. It can also be used to compare treatment modalities. It was recently revised to improve ambiguities in descriptors.

1. Pain or other discomfort (i.e., aching, heaviness, fatigue, soreness, burning)

Choose, separately for each leg, the category that best describes the pain or discomfort the patient experiences.

Absent	0: None
Mild	1: Occasional pain or discomfort that does not restrict regular daily activity
Moderate	2: Daily pain or discomfort that interferes with, but does not prevent regular daily activities
Severe	3: Daily pain or discomfort that limits most regular daily activities

2. Varicose Veins

Choose, separately for each leg, the category that best describes the patient's superficial veins.

Veins must be >3 mm diameter to qualify as "varicose veins"

Absent	0: None
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- | | |
|----------|---|
| Mild | 1: Few, scattered, varicosities that are confined to branch veins or clusters. Includes corona phlebectatica (ankle flare), defined as greater than 5 blue telangiectases at the inner or sometimes the outer edge of the foot. |
| Moderate | 2: Multiple varicosities that are confined to the calf or the thigh |
| Severe | 3: Multiple varicosities that involve both the calf and the thigh |

3. Venous Edema

Choose, separately for each leg, the category that best describes the patient's pattern of leg edema. The clinician's examination may be supplemented by asking the patient about the extent of leg edema that is experienced.

- | | |
|----------|--|
| Absent | 0: None |
| Mild | 1: Edema that is limited to the foot and ankle |
| Moderate | 2: Edema that extends above the ankle but below the knee |
| Severe | 3: Edema that extends to the knee or above |

4. Skin Pigmentation

Choose, separately for each leg, the category that best describes the patient's skin pigmentation. Pigmentation refers to color changes of venous origin and not secondary to other chronic diseases (i.e. vasculitis purpura).

- | | |
|----------|---|
| Absent | 0: None, or focal pigmentation that is confined to the skin over varicose veins |
| Mild | 1: Pigmentation that is limited to the perimalleolar area |
| Moderate | 2: Diffuse pigmentation that involves the lower third of the calf |
| Severe | 3: Diffuse pigmentation that involves more than the lower third of the calf |

5. Inflammation

Choose, separately for each leg, the category that best describes the patient's skin inflammation. Inflammation refers to erythema, cellulitis, venous eczema, or dermatitis, rather than just recent pigmentation.

- | | |
|----------|---|
| Absent | 0: None |
| Mild | 1: Inflammation that is limited to the perimalleolar area |
| Moderate | 2: Inflammation that involves the lower third of the calf |
| Severe | 3: Inflammation that involves more than the lower third of the calf |

6. Induration

Choose, separately for each leg, the category that best describes the patient's skin induration. Induration refers to skin and subcutaneous changes such as chronic edema with fibrosis, hypodermatitis, white atrophy and lipodermatosclerosis.

Absent	0: None
Mild	1: Induration that is limited to the perimalleolar area
Moderate	2: Induration that involves the lower third of the calf
Severe	3: Induration that involves more than the lower third of the calf

7. Number of Active Ulcers

Choose, separately for each leg, the category that best describes the number of active ulcers.

Absent	0: None
Mild	1: One ulcer
Moderate	2: Two ulcers
Severe	3: Three or more ulcers

8. Active Ulceration, Duration

If there is at least one active ulcer, choose, separately for each leg, the category that best describes the duration of the longest unhealed ulcer.

Absent	0: No active ulcers
Mild	1: Ulceration present for less than 3 months
Moderate	2: Ulceration present for 3 to 12 months
Severe	3: Ulceration present for more than 12 months

9. Active Ulceration, Size

If there is at least one active ulcer, choose, separately for each leg, the category that best describes the size of the largest active ulcer.

Absent	0: No active ulcer
Mild	1: Ulcer of less than 2cm diameter
Moderate	2: Ulcer of 2 to 6cm diameter
Severe	3: Ulcer of greater than 6cm diameter

10. Use of Compressive Therapy

Choose, separately for each leg, the category that best describes patient compliance with the use of medical compression stockings.

Absent	0: Not used
Mild	1: Intermittent use of stockings
Moderate	2: Wears stockings most days
Severe	3: Full compliance with stockings

IX. Treatment

Indications for treatment:

Many patients seeking treatment for varicose veins have symptoms of aching, throbbing, leg heaviness, fatigue, cramps, pruritus, restless leg, ankle swelling, and tenderness or pain along bulging varicose veins. Some have a history of thrombophlebitis or bleeding from superficial varicose veins or signs of more advanced CVD, including edema and skin changes, which may include lipodermatosclerosis, eczema, pigmentation, atrophie blanche, corona phlebectatica, and healed or active ulceration³⁷⁶.

Treatment Options:

A. Compression treatment

Compression therapy is the basic and most frequently used treatment of varicose veins, venous edema, skin changes, and ulcerations. Compression is recommended to decrease ambulatory venous hypertension for patients with CVD in addition to lifestyle modifications that include weight loss, exercise, and elevation of the legs whenever possible.

The different forms of ambulatory compression techniques and devices include elastic compression stockings, paste gauze boots (Unna boot), multilayer elastic wraps, dressings, elastic and nonelastic bandages, and nonelastic garments. Pneumatic compression devices, applied primarily at night, are also used in patients with refractory edema and venous ulcers.¹³⁸

The rationale of compression treatment is to compensate for increased ambulatory venous hypertension. Pressures to compress the superficial veins in supine patients range from 20 to 25 mm Hg. When upright, pressures of 35 to 40 mm Hg have been shown to narrow the superficial veins, and pressures >60 mm Hg are needed to occlude them.¹³⁹

Varicose veins (CEAP class C2)

Reported case series of patients treated with elastic stockings frequently included the whole spectrum of patients with CVD (CEAP class C0-C6). A large systematic review of compression hosiery for uncomplicated simple varicose veins was recently published by Palfreyman and Michaels.³⁴ Although compression improved symptoms, the study concluded that evidence is lacking to support compression garments to decrease progression or to prevent recurrence of varicose veins after treatment.

The level of compression for patients with class C2 disease is also disputed. A meta-analysis by Amsler and Blattler¹⁴¹ found that in healthy patients with C1 to C3 disease, as well as after varicose vein surgery, medium compression stockings (>20 mm Hg) may add no benefit over stockings with a compression of 10-15 mm Hg.

Until further data on appropriate tension of elastic garments is available, for patients with simple varicose veins (class C2), the SVS/AVF Guideline Committee suggests graded prescription

stockings with an ankle pressure of 20 to 30 mm Hg (GRADE 2C). The most common length recommended is knee-high stockings, although thigh-high stockings and pantyhose are also available and may be appropriate for many patients. Skin breakdown and frank necrosis after incorrectly measured or applied garments have been reported.¹⁴² The Committee recommends that only those with the necessary skills and training prescribe stockings for patients with venous disease.

The need for a period of compression treatment before intervention for simple varicose veins has been controversial. Although third-party payors often require a trial of compression stockings, there is no scientific evidence to support such a policy. Saphenous ablation to treat superficial reflux is both efficacious and cost-effective, a fact supported by data of the REACTIV trial¹⁴³. In addition, some patients, such as the obese or the elderly, may have difficulties applying elastic stockings.¹³⁸ On the basis of the available evidence, the Guideline Committee recommends against compression therapy being considered the primary treatment of symptomatic varicose veins (class C2) in those patients who are candidates for saphenous vein ablation (GRADE 1B).

CVI (CEAP classes C3-C6)

On the basis of high-quality clinical evidence, the Guideline Committee recommends compression therapy for patients with CVI (class C3-C6), including those with leg ulcers. Compression therapy is now considered the primary therapy to aid in healing venous ulcers (GRADE 1B) and the adjuvant therapy to superficial vein ablation to prevent ulcer recurrence (GRADE 1A).

B. Open venous surgery

Open surgical treatment of varicose veins with ligation and stripping of the GSV or SSV, combined with excision of large varicose veins, has been the standard of care of varicose vein treatment for more than a century. During the past decade, endovenous thermal ablation has largely replaced the classic ligation and stripping operation, and open surgery for saphenous incompetence is performed much less frequently in the United States. Indications for ligation and stripping have been restricted to patients with large dilated and tortuous saphenous vein located immediately under the skin or to those with aneurysmal enlargement at the SFJ. Because of previous thrombophlebitis of the GSV or SSV, percutaneous placement of the laser fiber or radiofrequency (RF) catheter may not be possible, and open techniques have to be used for removal of the vein.

1. High ligation, division, and stripping of the GSV

This implies ligation and division of the GSV at its confluence with the common femoral vein, including ligation and division of all upper GSV tributaries. Partial or complete preservation of the upper GSV tributaries, when the GSV is ligated, stripped, or ablated, must therefore be

clearly stated. The term stripping means removal of a long vein segment, usually of the saphenous vein, by means of a device.⁵¹

2. High ligation, division, and stripping of the SSV

Complete stripping of the SSV is rarely performed because of possible injury to the sural nerve, but ligation of the SSV through a small transverse incision in the popliteal crease can be performed together with a limited invagination stripping of the vein to the mid calf, using the same technique described for GSV stripping.

3. Ambulatory phlebectomy

Ambulatory phlebectomy (stab or hook phlebectomy or miniphlebectomy) includes removal or avulsion of varicose veins through small stab wounds. Avulsion of the varicose veins is performed with hooks or forceps.^{172, 173}

4. Powered phlebectomy

Transilluminated powered phlebectomy (TIPP), an alternative technique for the removal of varicose veins, is especially useful for the removal of larger clusters of varicosities.^{184, 185} The potential advantages include a decrease in the number of incisions and much faster removal of a large amount of varicose vein tissue. Just as for ambulatory phlebectomy, TIPP is often combined with saphenous vein ablation procedures or stripping and ligation to eliminate the source of the reflux underlying a varicose venous cluster formation.

C. Endovenous Thermal Ablation Saphenous Vein

Endovenous thermal ablation of the saphenous veins has been the emerging standard of care for the last decade.²³² This treatment requires local tumescent anesthesia and is an outpatient procedure that can be performed in an office setting. The procedure is done under ultrasonographic guidance using percutaneous catheter placement. Patients report less pain and discomfort and return to work earlier than after open surgical procedures. Sources for endovenous thermal ablation include laser (EVLA) and radiofrequency (RFA). Both are effective as minimally invasive endovascular approaches to treating underlying superficial venous reflux.

D. Liquid sclerotherapy

Injection of a chemical into the vein to achieve endoluminal fibrosis and obstruction of the vein has been used for almost a century.²⁸⁸ Liquid sclerotherapy is performed using small tuberculin syringes and a 30- or 32-gauge needle. Treatment is usually started with larger varicose veins and ends with reticular veins and telangiectasia.

E. Ultrasound guided chemical ablation of the saphenous vein with foam

Although liquid sclerotherapy has been used for treatment of veins ≤ 3 mm in diameter, interest in the use of sclerotherapy greatly increased when Cabrera et al³⁰⁰ reported in 1995 that foam prepared by mixing a “physiologic gas” with the detergent polidocanol was effective for fibrosis of larger veins. Ultrasonographically guided foam chemical ablation has rapidly spread for treatment of primary and recurrent varicose veins, including the GSV and SSV, perforating veins, and venous malformations.^{301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311} Chemical ablation with foam of the saphenous vein is the least invasive of the endovenous ablation techniques, but requires a similar level of technical expertise. The European Consensus Meetings on Foam Sclerotherapy^{308, 309} and in the U.S. Rathbun et al³⁷⁷ reported that foam was an effective, safe, and minimally invasive endovenous treatment for varicose veins with a low rate of complications. Ultrasonography is used to monitor and guide the movement of foam in the veins. The saphenous trunk is usually injected first, followed by varicose and perforating veins if indicated.

X. Perforating veins

An association between incompetent perforating veins and venous ulcers was established more than a century ago. However, the emergence of ultrasonographically guided thermal ablations and sclerotherapy in recent years has transformed the techniques of perforator ablation.^{351, 352, 353, 354, 355, 356} Advantages of these techniques include the low risk of a minimally invasive procedure that is easily repeatable and can be performed under local anesthesia in an office setting.³⁵⁷ Current data do not support adding perforator ablation to ablation of the superficial system in patients with simple varicose veins,^{361, 362} and the Committee recommends against treatment of perforators in patients with CEAP class C2 disease (GRADE 1B). In patients with advanced CVI, current data provide moderate evidence that large (≥ 3.5 mm), high-volume, incompetent “pathologic” perforators (reflux ≥ 500 ms), located in the affected area of the limb with outward flow on duplex scanning in patients with class C5 or C6 disease, can be treated by experienced interventionists, unless the deep veins are obstructed (GRADE 2B).^{22, 56, 87} Clinical data on the efficacy of perforator ablations were obtained primarily by using the SEPS procedure, but ultrasonographically guided sclerotherapy or thermal ablations, when performed with similar low complication rates, can be suggested as alternative therapy for perforator treatment (GRADE 2C).

1. Subfascial Endoscopic Perforator Surgery - SEPS is performed under general or epidural anesthesia. Most surgeons use balloon dissection and carbon dioxide insufflation with a pressure of 30 mm Hg and a pneumatic thigh tourniquet inflated to 300 mm Hg to avoid any bleeding in the surgical field.³⁵⁸ Division of the fascia of the deep posterior compartment with a paratibial fasciotomy is required to identify all important medial perforating veins. Occlusion of the perforators can be done with endoscopic clips, although most surgeons use an ultrasonic harmonic scalpel for division and transection of the perforators. The operation is an outpatient procedure, and patients are encouraged to ambulate 3 hours after the operation.

2. Endovenous Thermal Ablation Perforating Veins- performed under local anesthesia with ultrasound guidance, with direct needle puncture of the perforating vein. This can be performed with a radiofrequency or laser device. It can be done as an office based outpatient procedure with the same early ambulation protocol as ablation of the saphenous vein.

3. Ultrasound Guided Chemical Ablation of Perforating veins with Foam– chemical ablation of perforating veins with foam is gaining acceptance because perforating veins can be accessed easily with a small needle without much patient discomfort. Chemical ablation using polidocanol or sotradecol foam is most common, with use of small needles and careful technique to avoid injection of the agent into the accompanying artery. Masuda et al³⁵¹ reported clinical results with ultrasonographically guided sclerotherapy in 80 limbs with predominantly perforator incompetence alone. The authors noticed a significant improvement in VCSS, and ulcers rapidly healed in 86.5%, with a mean time to heal of 36 days.

XI. Conclusions

The evolution of endovascular technology has changed the evaluation and treatment of venous disease during the past decade. To keep up with the rapidly changing technology, evidence-based guidelines for the management of varicose veins and chronic venous disease are essential. These guidelines play an important role in determining the best care for patients. The scientific evidence presented in these guidelines should be combined with the physician's clinical experience and the patient's preference to select the best treatment option for each individual patient.

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