

Medical Policy Manual

Topic: Varicose Vein Treatment

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Section: Surgery

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NOTE: This policy has been revised. The revised policy will be effective November 1, 2014. To view the revised policy, [click here](#).

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The venous system of the lower extremities consists of the superficial system (e.g., long and short saphenous veins and accessory or tributary veins that travel in parallel with the greater and lesser saphenous veins) and the deep system (e.g., popliteal and femoral veins). These two parallel systems are interconnected via perforator veins and at the saphenofemoral and the saphenopopliteal junctions.

Note: The long and short saphenous veins are also known as the great or greater and the small or lesser saphenous veins, respectively. This policy uses the nomenclature long saphenous vein and short saphenous vein as these terms are consistent with current CPT nomenclature.

One-way valves are present within all veins to direct the return of blood up the lower limb. Larger varicose veins, many protruding above the surface of the skin, typically are related to valve incompetence. As the venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence leads to increased hydrostatic pressure transmitted to the unsupported superficial vein system. Backflow (venous reflux) with pooling of blood ultimately results in varicosities. In addition, clusters of varicosities may appear related to incompetent perforating veins, such as Hunter and Dodd, located in the mid- and distal thigh, respectively and/or associated with incompetence at the saphenofemoral junction. In some instances, the valvular incompetence may be isolated to a perforator vein, such as the Boyd perforating vein located in the anteromedial calf. These varicosities are often not associated with saphenous vein incompetence since the perforating veins in the lower part of the leg do not communicate directly with the saphenous vein.

Although many varicose veins are asymptomatic, when present, symptoms include itching, heaviness, and pain. In addition, chronic venous insufficiency secondary to venous reflux can lead to peripheral edema, hemorrhage,

thrombophlebitis, venous ulceration, and chronic skin changes. In an effort to improve the consistency in diagnosing chronic venous disorders, particularly for patient selection in clinical trials, an international consensus committee developed CEAP classification.^[1] In this system, classification is based on clinical manifestations (C), etiology (E), anatomical distribution (A), and underlying pathophysiology (P). (See Appendix 1)

Note: The term "varicose veins" does not apply to the telangiectatic dermal veins, which may be described as "spider veins" or "broken blood vessels." While abnormal in appearance, these veins typically are not associated with any symptoms, such as pain or heaviness, and their treatment is considered cosmetic in nature.

Conservative Therapy

Treatment of venous reflux/venous insufficiency is aimed at reducing abnormal pressure transmission from the deep to the superficial veins. Varicose veins can usually be treated with non-surgical measures. Symptoms often decrease when the legs are elevated periodically, when prolonged standing is avoided, and when elastic compression stockings are worn.

Operative Therapy

If conservative treatment measures fail, additional treatment options typically focus first on identifying and correcting the site of reflux, and second on redirecting venous flow through veins with intact valves. Thus conventional surgical treatment of varicosities is based on the following three principles:

- Control of the most proximal point of reflux, typically at the saphenofemoral junction, as identified by preoperative Doppler ultrasonography. Surgical ligation and division of the saphenofemoral or saphenopopliteal junction is performed to treat the valvular incompetence.
- Removal or occlusion by ablation of the refluxing long and/or short saphenous vein from the circulation. The classic strategy for isolation is vein stripping in conjunction with vein ligation and division.
- Removal or occlusion of the refluxing varicose tributaries. Strategies for removal include phlebectomy (i.e., ligation/division/stripping, powered phlebectomy, or stab avulsion) or occlusion by injection sclerotherapy; either at the time of the initial treatment, or subsequently.
- Over the years various different minimally invasive alternatives to ligation and stripping have been investigated, including sclerotherapy and thermal ablation using radiofrequency energy (high frequency radiowaves), laser energy, or cryoablation (also called cryotherapy).

Endovenous Ablation

Thermal Ablation

The objective of endovenous ablation techniques is to cause injury to the vessel, causing retraction and subsequent fibrotic occlusion of the vein. Three endovenous thermal ablation techniques have been investigated as minimally invasive alternatives to vein ligation and stripping.

- Radiofrequency (RF) ablation is performed by means of a specially designed catheter inserted through a small incision in the distal medial thigh to within 1-2 cm of the saphenofemoral junction. High frequency radio waves (200-300 kHz) are delivered through the catheter electrode and cause direct heating of the vessel wall, causing the vein to collapse. The catheter is slowly withdrawn, closing the vein.
- Laser ablation is performed similarly; a laser fiber is introduced into the saphenous vein under ultrasound guidance; the laser is activated and slowly removed along the course of the saphenous vein.

- Cryoablation uses extreme cold to cause injury to the vessel. Technical developments since thermal ablation procedures were initially introduced include the use of perivenous tumescent anesthesia which allows treatment of veins larger than 12 mm in diameter and helps to protect adjacent tissue from thermal damage during treatment of the lesser saphenous vein.

Mechanochemical Ablation

Endovenous mechanochemical ablation utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates at 3500 rpm within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulphate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, without the need for the tumescent anesthesia used in thermal ablation.

Sclerotherapy

The objective of sclerotherapy is to destroy the endothelium of the target vessel by injecting an irritant solution (either a detergent, osmotic solution, or a chemical irritant), ultimately resulting in the complete obliteration of the vessel. The success of the treatment depends on accurate injection of the vessel, an adequate injectant volume and concentration of sclerosant, and post-procedure compression. Compression theoretically results in direct apposition of the treated vein walls to provide more effective fibrosis and may decrease the extent of the thrombosis formation.

Sclerotherapy is an accepted and effective treatment of telangiectatic vessels. Historically, larger veins and very tortuous veins were not considered to be good candidates for sclerotherapy. Technical improvements in sclerotherapy, including the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam sclerosant in place of liquid sclerosant, have improved its effectiveness in these veins. Other concerns have arisen with these expanded uses of sclerotherapy. For example, use of sclerotherapy in the treatment of varicose tributaries without prior ligation, with or without vein stripping creates issues regarding its effectiveness in the absence of the control of the point of reflux and isolation of the refluxing saphenous vein. Sclerotherapy of the long saphenous vein raises issues regarding appropriate volume and concentration of the sclerosant and the ability to provide adequate post-procedure compression. Moreover, the use of sclerotherapy, as opposed to the physical removal of the vein with stripping, raises the issue of recurrence due to recanalization.

Treatment of Perforator Veins

Perforator veins cross through the fascia and connect the deep and superficial venous systems. Incompetent perforating veins were originally addressed with an open surgical procedure, called the Linton procedure, which involved a long medial calf incision to expose all posterior, medial, and paramedial perforators. While this procedure was associated with healing of ulcers, it was largely abandoned due to a high incidence of wound complications. The Linton procedure was subsequently modified by using a series of perpendicular skin flaps instead of a longitudinal skin flap to provide access to incompetent perforator veins in the lower part of the leg. The modified Linton procedure may be occasionally utilized for the closure of incompetent perforator veins that cannot be reached by less invasive procedures. Subfascial endoscopic perforator surgery (SEPS) is a less-invasive surgical procedure for treatment of incompetent perforators and has been reported since the mid-1980s. Guided by Duplex ultrasound scanning, small incisions are made in the skin and the perforating veins are clipped or divided by endoscopic scissors. The operation can be performed as an outpatient procedure. Endovenous ablation of incompetent perforator veins with sclerotherapy and radiofrequency has also been reported.

Other

Deep vein valve repair or reconstruction and replacement are being investigated

Regulatory Status

The following devices have received specific U.S. Food and Drug Administration (FDA) marketing clearance for the endovenous treatment of superficial vein reflux:

- In 1999, the VNUS ® Closure™ system (a radiofrequency device) received FDA clearance through the 510(k) process for "endovascular coagulation of blood vessels in patients with superficial vein reflux." The VNUS RFS and RFS*Flex* devices received FDA clearance in 2005 for "use in vessel and tissue coagulation including: treatment of incompetent (i.e., refluxing) perforator and tributary veins. The modified VNUS® ClosureFAST™ Intravascular Catheter received FDA clearance through the 510(k) process in 2008.
- In 2002, the Diomed 810 nm surgical laser and EVLT™ (endovenous laser therapy) procedure kit received FDA clearance through the 510(k) process, "... for use in the endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux."
- A modified Erbe Erbokryo® cryosurgical unit (Erbe USA) received FDA clearance for marketing in 2005. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs.
- The Trivex system is a device for transilluminated powered phlebectomy that received FDA clearance through the 510(k) process in October 2003. According to the label, the intended use is for "ambulatory phlebectomy procedures for the resection and ablation of varicose veins."
- Varisolve® (BTG PLC, London) is a sclerosant microfoam made with a proprietary gas mix. A phase II safety study for the FDA has been completed. In late October 2009, the sponsor submitted a request to the FDA for a protocol assessment to agree on the design, endpoints and statistical analyses for the phase III trial.
- The ClariVein® Infusion Catheter received marketing clearance through the 510(k) process in 2008 (K071468). It is used for mechanochemical ablation. Predicate devices were listed as the Trellis® Infusion System (K013635) and the Slip-Cath® Infusion Catheter (K882796). The system includes an infusion catheter, motor drive, stopcock and syringe and is intended for the infusion of physician-specified agents in the peripheral vasculature.

MEDICAL POLICY CRITERIA

Note: This policy addresses only treatments involving the veins of the lower extremities. For varicose veins of the upper extremities apply the medical necessity criteria in medical policy Surgery No. 12, [Cosmetic and Reconstructive Surgery](#). For embolization of the ovarian or internal iliac vein for treatment of pelvic congestion syndrome, apply criteria in medical policy Surgery No. 147, [Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome](#).

- I. All of the following **general criteria** must be met for varicose vein treatment to be considered for coverage:
 - A. At least one of the following indications must be present:
 1. Functional impairment, attributed to varicose veins, which limits performance of instrumental activities of daily living (ADLs). Instrumental ADLs are defined as feeding, bathing, dressing, grooming, meal preparation, household chores, and occupational tasks that are required as a daily part of job functioning

Clinical records must specifically document the following:

- a. The specific instrumental ADL(s) that is impaired
 - b. A description of how performance of the instrumental ADL is limited
2. Significant recurrent attacks of superficial phlebitis
 3. Hemorrhage from ruptured varix
 4. Ulceration from venous stasis where incompetent varices are a significant contributing factor
- B. There is clinical documentation that ongoing medically supervised conservative therapy, including use of compression (minimum 20 mmHg) stockings, has been utilized for a minimum of three months, is currently being utilized, and did not successfully treat the patient's symptoms.

Clinical documentation must include the following:

1. History of present illness, physical examination, and conservative therapy treatment plan
Note: There are a number of different classification scales for compression stockings; for consistency, this policy requires that units of compression be documented in mmHg.
2. Progress notes from at least 1 office visit documenting patient compliance with and response to at least 3 months of conservative therapy.

For example, compression stockings should be worn daily while the patient is out of bed.

- C. Any incompetence in the superficial system veins (e.g., long and short saphenous veins and saphenous tributaries) must be documented by venous studies.
- D. Photographs are required on any affected areas of the leg, e.g., protruding varicose veins, and must be consistent with the submitted clinical description.

II. If the general criteria in I.A-D are not met, varicose vein treatment is considered **not medically necessary**.

III. Treatment sessions

- A. Plan will consider requests for coverage of initial sessions as follows: a bilateral session, or one initial operative session for each leg.
- B. After the clinical outcome of prior treatment(s) has been established and documented, Plan will consider requests for additional operative sessions one session at a time using the criteria detailed above.
- C. Each treatment session should address as much abnormality as is appropriate and reasonable, and may include more than one modality.

IV. Imaging

- A. A Doppler ultrasound or duplex study may be **medically necessary** prior to the treatment session(s) to map the anatomy of the venous system and evaluate for deep and superficial venous incompetence, when the criteria in I.A are met.

B. Intraoperative ultrasound guidance

1. Ultrasound guidance for sclerotherapy (echosclerotherapy) of the following superficial system veins, the short saphenous vein and saphenous tributaries including accessory saphenous veins, may be considered **medically necessary**.
2. Ultrasound guidance for sclerotherapy of varicose veins is considered **not medically necessary**, since ultrasound guidance has not been shown to increase the effectiveness or safety of sclerotherapy for varicose veins.

C. Follow-up venous studies performed within six months following the most recent ipsilateral treatment, in the absence of complications, are considered **not medically necessary**, including but not limited to routine confirmation studies following endovenous ablation.

D. Follow-up venous studies performed six months or longer following the most recent ipsilateral treatment may be **medically necessary** when the criteria in I.A. are met.

V. Ligation/stripping and phlebectomy (i.e., stab, hook, transilluminated powered)

Ligation/stripping and phlebectomy of incompetent superficial system veins (including the long and short saphenous veins and saphenous tributaries including accessory saphenous veins), and varicose veins 4 mm or greater in diameter may be considered **medically necessary** when both of the following criteria are met:

- A. Related incompetent superficial veins proximal to the incompetent vein to be treated either have been or are being treated concurrently
- B. All of the general criteria in I.A-D above are met.

VI. Endovenous ablation

A. Endovenous radiofrequency or laser ablation of incompetent long or short saphenous veins may be considered **medically necessary** when the all of the general criteria in I.A-D above are met.

B. Endovenous ablation is considered **investigational** for all of the following:

1. Cryoablation of any vein
2. Radiofrequency or laser ablation of veins other than the long or short saphenous veins, including but not limited to the following:
 - a. accessory saphenous veins
 - b. branch tributaries
 - c. varicose veins
 - d. perforator veins
3. Ablation of saphenous or other veins for treatment of all of the following:
 - a. pelvic congestion syndrome
 - b. vulvar varices
 - c. scrotal varices (varicocele)

4. Mechanochemical ablation of any vein

- C. Endovenous ablation of the entire incompetent saphenous vein usually can be accomplished in a single treatment session. Multiple separate sessions for ablation of segments of a continuous vein are considered **not medically necessary**. Although additional procedures, including ligation or sclerotherapy, performed in the same treatment session on the same ablated saphenous vein are considered included components of the ablation procedure, procedures on other saphenous venous systems may be distinct procedural services.

VII. Sclerotherapy

- A. Sclerotherapy of the following superficial system veins, short saphenous vein and saphenous tributaries including accessory saphenous veins, and varicose veins 4 mm or greater in diameter may be considered **medically necessary** when both of the following criteria are met:
1. Related incompetent superficial system veins proximal to the incompetent vein to be treated either have been or are being treated concurrently
 2. All of the general criteria in I.A-D above are met.
- B. Sclerotherapy of the following veins is considered **investigational**:
1. The long saphenous vein
 2. Perforator veins
- C. Sclerotherapy of small (less than 4 mm in diameter) superficial reticular veins and/or telangiectasias (spider veins) is considered **cosmetic**.

SCIENTIFIC EVIDENCE^[2]

Outcomes of interest for venous interventions include symptom control, healing and recurrence, recannulation of the vein, and neovascularization. Recannulation (recanalization) is the restoration of the lumen of a vein after it has been occluded; this occurs more frequently following treatment with endovenous techniques.

Neovascularization is the proliferation of new blood vessels in tissue, and occurs more frequently following vein stripping. Direct comparisons of durability for endovenous and surgical procedures are complicated by these different mechanisms of recurrence. Relevant safety outcomes include the incidence of paresthesia, thermal skin injury, thrombus formation, thrombophlebitis, wound infection, and transient neurologic effects.

Endovenous Ablation

Pelvic Congestion Syndrome and Genital Varices

No studies were found for ablation of the saphenous veins or other lower extremity veins for the treatment of pelvic congestion syndrome, or varices of the external male or female genitalia.

Radiofrequency Ablation of Varicose Veins

Endovenous radiofrequency ablation (RFA) of varicose veins has been proposed as an alternative to ligation and stripping, or to stripping alone. Outcomes of interest include short and long term recurrence rates, related either to recannulization of the saphenous vein or neovascularization. In terms of safety, relevant outcomes include the incidence of paresthesias, thermal skin injuries, thrombus formation, thrombophlebitis, and wound

infection.

Systematic Reviews and Meta-analyses

In 2012, a systematic review of randomized controlled trials (RCTs) and meta-analysis was conducted to compare the clinical outcomes of endovenous laser ablation (EVLA), radiofrequency ablation (RFA), ultrasound-guided foam sclerotherapy (UGFS), and surgical treatment of varicose veins.^[3] The review included 28 RCTs and reported no significant difference in primary failure and clinical recurrence with EVLA and RFA compared with surgery. The advantages of the endovenous ablation techniques over surgery were a lower rate of wound infections and hematoma, and a shorter recovery period.

Randomized Controlled Trials

A small trial randomized 28 patients to undergo either radiofrequency ablation or conventional ligation and stripping.^[4] Mean follow up was 50 days. A total of 7 minor postoperative complications were seen in each group, none of which required specific treatment. In all cases, radiofrequency ablation was considered successful based on the absence of Duplex detected flow in the treated segments of the long saphenous veins. Postoperative average pain was significantly less severe in the radiofrequency ablation group. Patients in the radiofrequency group also recovered faster, based on sick leave times and physical function. While this study suggests that radiofrequency ablation is associated with a faster postoperative recovery, long term recurrence rates were not addressed in this trial.

Lurie and colleagues reported the results of a larger trial that randomized 85 patients (86 limbs) to undergo either radiofrequency ablation or stripping and ligation.^[5] By ultrasonic evaluation after four months of follow-up, reflux was eliminated in all patients undergoing stripping and ligation, compared to 97% in the radiofrequency group. Time to return to normal activity and return to work were significantly improved in the radiofrequency group. In 2005, Lurie reported on the two year follow-up of the above trial.^[6] A total of 36 limbs of the original 46 undergoing radiofrequency ablation were assessed and 36 of the 40 undergoing ligation and stripping were assessed. Cumulative rates of recurrent varicose veins at combined one and two years follow-up were 14% for radiofrequency ablation and 21% for ligation and stripping. The authors concluded that radiofrequency ablation was associated with similar long term outcomes compared to ligation and stripping.

Nonrandomized Trials

Several case series have reported on endoluminal radiofrequency ablation.^[7-10] The largest was reported by Merchant and colleagues, who analyzed the data collected in the ongoing Closure Study Group registry focusing on the treatment of reflux of the long saphenous vein.^[7] Data were available on 890 patients and 1,078 limbs treated at 32 centers. Clinical and duplex ultrasound follow-up was performed at one week, six months, and yearly for four years. The vein occlusion rates were 91% at one week and 88.8% at four years, although only 98 limbs had been followed up to the four year mark. These results suggest that radiofrequency ablation results in durable occlusion. Radiofrequency ablation has typically been limited to vessels less than 12 mm in diameter. The rationale behind this patient selection criterion is that the electrodes must remain in direct contact with the vein wall during treatment and the largest diameter of the deployed radiofrequency electrodes is 12 mm. The authors noted that exsanguinations, perivenous tumescent infiltration, and external compression may promote electrode and vessel wall contact such that larger veins can be treated. However, in this large case series, there were only 58 limbs with vein sizes larger than 12 mm, and only 29 available for follow-up at six months or one year. While the occlusion rate was similar to that seen in smaller vessels, long-term data are inadequate to determine if this effect is durable.

Merchant and Pichot also reported the 5-year Closure Study Group registry data.^[11] There were 1222 limbs in 1006 patients treated at 34 centers with radiofrequency ablation of various levels of the long saphenous vein, the short saphenous vein, and the accessory saphenous vein. At 5 year follow-up using duplex ultrasound

examination, 185 limbs were considered failures due to nonocclusion (12.4%), recanalization of a previously occluded vein (69.7%), or groin reflux of a vein with occluded trunk (17.8%). In the latter group, the groin reflux often involved an accessory vein. Logistic regression analysis of risk factors of gender, age, body mass index [BMI], vein diameter, and catheter pullback speed showed that each unit increase in BMI over 25 was associated with increasing risk of long-term failure. In addition, a catheter pull-back speed over the standard speed of 3 cm/min was associated with failure to occlude or recanalization. The authors pointed out that this anatomical failure did not necessarily result in clinical failure; most patients experienced initial symptom relief that was maintained over 5 years.

Laser Ablation of Varicose Veins

Systematic Reviews

A systematic review of endovenous laser ablation (EVLA) versus surgery was published in 2009.^[12] Fifty-nine studies were included, with 7 studies that directly compared EVLA and surgery. Randomized and nonrandomized studies directly comparing outcomes for EVLA or surgery were included for the assessment of safety or effectiveness, while case series with a minimum patient population of 100 were included for the assessment of safety alone. For all studies, it was calculated that 5,759 patients (6,702 limbs) were treated with EVLA and 6,395 patients (7,727 limbs) underwent surgery. Few differences were apparent between treatments with respect to clinical effectiveness outcomes, although long-term follow-up was lacking. Nonclinical effectiveness outcomes generally favored EVLA over surgery in the first 2 months after treatment. The authors concluded that while EVLA offers short-term benefits and appears to be as clinically effective as surgery up to 12 months after treatment, clinical trials with a minimum of 3 years of follow-up are required to establish the enduring effectiveness of EVLA.

Randomized Controlled Trials

Three randomized trials from Europe (combined total of 316 patients) compared endovenous laser ablation to ligation and stripping of the great saphenous vein.^[13-17] No differences in reflux from the saphenofemoral junction or in quality of life at up to twelve months' follow-up were observed between the two treatment groups. Return to work following ligation and stripping took an average of 7 to 14 days. Days to return to work following laser ablation were found to be less than (17; 2 days), similar to (18; 7 days), or greater than (19; 20 days) surgical treatment. Differences in use of ligation and stab avulsion/mini-phlebectomy in conjunction with endovenous laser ablation may underlie these discrepancies. In contrast, another trial compared EVLA with ligation and stripping in 200 limbs (100 in each group).^[18] At 1-year follow-up, 98% of the limbs were reported to be free of symptoms. At 2-year follow-up, the EVLA group had 2 veins completely reopened and 5 partially reopened, which was significantly greater than in the ligation and stripping group. Continued follow-up is needed to assess whether adjunct treatment of tributaries alters long-term efficacy of endovenous laser ablation for varicose veins.

In 2009 Theivacumar et al. reported 2-year follow-up from 118 consecutive patients treated with either EVLA (69 limbs) or ligation and stripping (n=60 limbs).^[16] Sixty-eight of the patients agreed to be randomized to treatment; the remainder declined randomization but received one of the two treatments and agreed to follow-up. The rationale for the selection of treatment in the nonrandomized population was not described. Rates of clinical recurrence (7%) were similar in the two treatment groups at 2 years. Recanalization of the residual greater saphenous vein, reflux in the accessory greater saphenous vein, and reflux in incompetent perforator veins accounted for the majority of cases of clinical recurrence (6%) in both groups. Neovascularization was observed in only 1% of limbs treated with endoluminal ablation and 18% of limbs treated with ligation and stripping (2% were clinically significant at 2 years). Early neovascularization has been associated with clinical recurrence at 5 years.

Nonrandomized Trials

The bulk of the clinical trials on laser ablation of varicose veins are case series^[19-23] and registry data^[11]. Using historical controls for comparison is difficult since treatment outcomes are variably reported. There are no consistent definitions of success vs. failure, either based on patient or clinical assessment. In general, recurrence rates after ligation and stripping are estimated at around 20%. Doppler or Duplex ultrasound are perhaps the most objective form of assessment of recurrence, but many of the reports of the long term outcomes of ligation and stripping did not use ultrasound studies for postoperative assessment. Only two studies have reported objective results of ligation and stripping at 12 and 24 months. Jones and colleagues reported on the results of a study that randomized 100 patients with varicose veins to undergo either ligation alone or ligation in conjunction with stripping.^[24] The results of the ligation and stripping group are relevant to this discussion. At one year, reflux was detected in 9% of patients, rising to 26% at two years. Rutgers and Kitslaar reported on the results of a trial that randomized 181 limbs to undergo either ligation and stripping or ligation combined with sclerotherapy.^[25] The results of the ligation and stripping group are reviewed here. At two years, Doppler ultrasound demonstrated reflux in approximately 10% of patients, increasing to 15% at three years. Therefore, based on this crude assessment, the reflux rate of 13% for radiofrequency ablation at one year^[4] and 6% for laser ablation at two years^[19] is roughly comparable to the reflux rate of 9-10% reported by Jones et al and Rutgers and Kitslaar.

Practice Guidelines and Position Statements for Endovenous Radiofrequency or Laser Ablation

- In 2011, the Society for Vascular Surgery and the American Venous Forum (SVS/AVF) published clinical practice guidelines which included recommendations for endovenous thermal ablation (radiofrequency or laser) for the treatment of incompetent long saphenous veins.^[26] A Grade 1B recommendation was made in favor of endovenous thermal ablation over foam sclerotherapy and high ligation and stripping due to the reduced convalescence, pain, and morbidity. A Grade 1B recommendation was defined as a strong recommendation based on moderate quality evidence.
- In 2009 the American College of Radiology (ACR) published appropriateness criteria for the treatment of lower-extremity venous insufficiency considered endovenous ablation at least as effective as surgery.^[27]
- In 2003, the Society of Interventional Radiography (SIR) published a position statement^[28] that considered endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, an effective treatment of extremity venous reflux and varicose veins under the following conditions:
 - I. The endovenous treatment of varicose veins may be medically necessary when one of the following indications (A–E) is present:
 - A. Persistent symptoms interfering with activities of daily living in spite of conservative/nonsurgical management. Symptoms include aching, cramping, burning, itching, and/or swelling during activity or after prolonged standing.
 - B. Significant recurrent attacks of superficial phlebitis
 - C. Hemorrhage from a ruptured varix
 - D. Ulceration from venous stasis where incompetent varices are a contributing factor
 - E. Symptomatic incompetence of the great or small saphenous veins (symptoms as in A above)
 - II. A trial of conservative, nonoperative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.
 - III. The patient's anatomy is amenable to endovenous ablation.
- In a joint statement published in 2007, the American Venous Forum and SIR recommended reporting standards for endovenous ablation for the treatment of venous insufficiency.^[29] The document recommended that reporting in clinical studies should include the symptoms of venous disease, history of

disease and prior treatment, the presence of major comorbidities, and any exclusion criteria. It was noted that potential candidates for endovenous ablation may include patients with reflux in an incompetent greater saphenous vein or smaller saphenous vein or in a major tributary branch of the greater or smaller saphenous veins such as the anterior thigh circumflex vein, posterior thigh circumflex vein, or anterior accessory greater saphenous vein. The presence of reflux in these veins is important to document using duplex ultrasound imaging, and the ultrasound criteria used to define reflux should be indicated. It was also stated that in current practice, most vascular laboratories consider the presence of venous flow reversal for greater than 0.5 to 1.0 second with proximal compression, Valsalva maneuver, or distal compression and release to represent pathologic reflux.

Cryoablation

Klem and colleagues reported a randomized trial in 2009 that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins.^[30] The percentage of patients with greater saphenous vein remaining was 44% in the endovenous cryoablation group and 15% in the conventional stripping group. The Aberdeen Varicose Vein Questionnaire also showed better results for conventional stripping (score of 11.7) in comparison with cryoablation (score of 8.0). There were no differences between the groups in SF-36 subscores, and neural damage was the same (12%) in both groups.

Disselhoff and colleagues reported 2- and 5-year outcomes from a randomized trial that compared cryostripping with EVLA.^[31,32] Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP C2) with saphenofemoral incompetence and greater saphenous vein reflux. At 10 days after treatment, EVLA had better results than cryostripping with respect to pain score over the first 10 days (2.9 vs. 4.4), resumption of normal activity (75% vs. 45%) and induration (15% vs. 52%). At 2 year follow-up, freedom from recurrent incompetence was observed in 77% of patients after EVLA and 66% of patients after cryostripping (not significantly different). At 5 years, 36.7% of patients were lost to follow-up; freedom from incompetence and neovascularization was found in 62% of patients treated with EVLA and 51% of patients treated with cryostripping (not significantly different). Neovascularization was more common after cryostripping, but incompetent tributaries were more common after EVLA. There was no significant difference between groups in the Venous Clinical Severity Score or Aberdeen Varicose Vein Severity Score at either 2 or 5 years.

Mechanochemical Ablation

Current evidence of mechanochemical ablation of varicose veins is limited to a single preliminary case series. In 2012, Elias and Raines reported an industry-sponsored safety and efficacy study of the ClariVein® system.^[33] Thirty greater saphenous veins in 29 patients were treated with this device. Greater saphenous veins with diameters greater than 12 mm were excluded. In this series 77% of veins were CEAP Class 2 with 7% in Class 3 (varicose veins and edema) and 16% in class 4a (varicose veins with skin changes). At 6-month follow-up one vein had recanalized, for a primary closure rate of 96.7%. No adverse events or pain during the procedure were reported. Controlled studies with longer follow-up are needed.

Sclerotherapy

No studies have directly compared sclerotherapy of the saphenous vein as an alternative to ligation and stripping. In general, reported outcomes of uncontrolled studies have varied, as have the periods of follow-up. In many studies the outcomes are reported in terms of cure rates, but the criteria for cure or failure are poorly defined. Studies also report subjective patient-assessed outcomes or physician assessment, both of which may be poorly defined. More recent studies include results of Doppler or duplex ultrasonography. However, the relationship between finding ultrasonographic evidence of recurrent reflux and clinical symptoms is uncertain. Finally, it should be noted that sclerotherapy of the long saphenous vein is a fundamentally different approach than stripping. With stripping, recurrences are likely related to an incomplete surgical procedure or to

revascularization. With sclerotherapy, recurrences may be additionally related to recanalization of an incompletely fibrosed saphenous vein.

Below is a summary of articles that are representative of currently available published evidence. The results of these studies have established ligation and stripping as the gold standard treatments for saphenofemoral incompetence. Sclerotherapy is used primarily as an adjunct to treat varicose tributaries. The superiority of ligation and stripping is primarily related to improved long-term recurrence rates.

Systematic Reviews and Meta-analyses

An updated Cochrane Review, based primarily on randomized controlled trials from the 1980's, concluded that, "The evidence supports the current place of sclerotherapy in modern clinical practice, which is usually limited to treatment of recurrent varicose veins following surgery and thread veins."^[34] Other uses of sclerotherapy in the management of varicose veins could not be determined from the available literature. A comprehensive systematic review commissioned and funded by the United Kingdom's National Institute for Health and Clinical Excellence (NICE) concluded that, "there is insufficient evidence to allow a meaningful comparison of the effectiveness of this treatment with that of other minimally invasive therapies or surgery."^[35]

A systematic review from 2008 found that foam sclerotherapy of varicose veins is associated with a higher recurrence rate in patients with saphenofemoral incompetence compared to the rates of endovenous laser therapy or radiofrequency obliteration, while a 2009 systematic review suggested that outcomes from sclerotherapy are worse than those of surgery (ligation and stripping) for saphenous vein reflux.^[36,37] In a review of the literature on sclerotherapy of the long saphenous vein, much of which is reported in the international literature, Kanter reported a recanalization rate between 19% and 48% over follow-up of 1 to 3 years.^[38] More recent randomized trials using ultrasound-guided foam sclerotherapy of the greater saphenous vein (with or without ligation) showed high variability in success rates between centers (ranging from 25% to 100%) and a decline in success rates from 85% at 3-week follow-up to 53% at 2 years.^[39,40] Other studies indicate efficacy rates ranging from 12% to 76% for liquid sclerosant and from 57% to 84% for foam sclerosant.^[41]

Randomized Controlled Trials

Several controlled trials comparing sclerotherapy of varicose tributaries or the saphenous vein, with and without associated ligation and stripping have reported that the absence of ligation and stripping are associated with an increased frequency of recurrence. These trials are difficult to interpret because frequently it is not clear which vein – either the varicose tributaries or the saphenous vein itself – have undergone sclerotherapy. Nonetheless, these trials established the importance of control of the site of reflux (ligation) and isolation of the refluxing portion of the saphenous vein (stripping). For example, in a frequently cited article, Hobbs reported on the results of a trial that randomized 500 patients with varicose veins to undergo either sclerotherapy alone or ligation and stripping of the saphenous vein, followed by avulsion of the varicose tributaries.^[42] The injection site for sclerotherapy was the point where the incompetent perforating veins joined the superficial veins. Therefore, this trial essentially tested the concept that varicose veins could be treated without addressing the source of reflux. The author reported that after one year 82% of patients were adequately treated with sclerotherapy. However, after 6 years the cure rate was only 7%. Specifically, the sclerotherapy soon failed when there was incompetence of the saphenofemoral junction.

In another frequently cited article, Einarrson and colleagues reported on the results of a trial of 164 patients with varicose veins who were randomized to receive either sclerotherapy alone or ligation and stripping.^[43] Although not described in detail, it appears that the sclerotherapy was injected into the superficial tributaries. After 5 years, the failure rate of sclerotherapy was approximately 74% compared to 10% in the operative group.

Blaise et al. reported 3-year follow-up from a multicenter double-blind randomized trial (143 patients) that

compared treatment of the greater saphenous vein with either 1% or 3% polidocanol foam.^[44] Additional treatment with foam sclerotherapy was carried out at 6 weeks, 3 and 6 months if required to abolish persistent venous reflux. There were 49 additional injections in the 1% polidocanol group and 29 additional injections in the 3% group. At 3-year follow-up, venous reflux was observed in 21% of patients in the 1% group and 22% of patients in the 3% polidocanol group.

Neglen and colleagues reported on a “partially randomized” trial that compared the outcomes of three different treatment strategies: 1) sclerotherapy alone; 2) ligation and stripping, or 3) ligation combined with sclerotherapy.^[45] It was difficult to determine the target of the sclerotherapy. As described in the article, sclerosant was injected into all points of control (presumably at the junction of the perforator veins) and, “if possible, into the main stem of the long saphenous vein.” Thus, it seems that the intent of the sclerotherapy was not the obliteration of the long saphenous vein as an alternative to stripping, but as a treatment of the varicose tributaries. Therefore, among those patients who underwent ligation plus sclerotherapy, this trial tested whether or not stripping could be eliminated from the overall approach. In the group who received sclerotherapy alone, almost 70% of patients self-reported a cure immediately postoperatively, which declined to about 30% after 5 years. This gradual recurrence rate for sclerotherapy alone is similar to that reported in the above studies. For the ligation and sclerotherapy group, 70% reported a cure immediately postoperatively, dropping to 50% after 5 years. The best long-term results were reported for the ligation and stripping group, which reported an 80% immediate cure rate, dropping to 70% after five years. The physician assessment of treatment outcome showed greater differences among the three groups. For example, based on physician assessment (observation and foot volumetric measurements), only 5% of the sclerotherapy group were considered cured after 5 years, compared to 10% in the ligation and sclerotherapy group and 60% in the ligation and stripping group. Rutgers and colleagues reported on a trial that randomized 156 patients with varicose veins and saphenofemoral incompetence to undergo either ligation and stripping or ligation and sclerotherapy.^[25] The site of sclerotherapy was not described. At 3 years, the cosmetic results were better in those limbs that had undergone stripping. Additionally, the clinical and Doppler ultrasound evidence of reflux was significantly less in those undergoing stripping.

Nonrandomized Trials

More recently, there has been interest in injecting sclerosant into the saphenous vein either in conjunction with ligation as an alternative to stripping, as a stand-alone procedure, or as an alternative to both ligation and stripping. Kanter and Thibault reported on a case series of 172 patients with 202 limbs with varicose veins with associated saphenofemoral incompetence.^[46] Using ultrasound guidance, sclerosant was injected into the long saphenous vein 3-4 cm distal to the saphenofemoral junction. Injections were given at 30- to 90-second intervals, proceeding distally as previously injected segments were observed to spasm. Immediately after therapy, a thigh compression stocking was applied. Two weeks after the initial procedure, patients were reevaluated with Duplex ultrasound and were re-treated if found to have persistent reflux. There was a clinical recurrence rate of 22.8% at 1 year.

Myers and colleagues reported three-year follow-up from a prospective observational study of sclerotherapy in 489 patients with refluxing saphenous veins and related tributaries.^[47] Out of 807 veins treated, 56% were associated with the great saphenous vein and 22% with the small saphenous vein; 22% were tributaries alone. Ultrasound at three to five days after each treatment showed successful occlusion in an average of 1.5 sessions for the group as a whole (65% in one session and 26% in two sessions). Kaplan-Meier analysis showed three-year survival rates of 83% for tributaries, 53% for great saphenous veins, and 36% for small saphenous veins. These results do not support the use of sclerotherapy for refluxing saphenous veins.

Adverse Effects

Although long-term sequelae have not been reported, transient adverse effects have been found in up to 8% of patients, including cerebrovascular accidents, transient ischemic attacks, speech and/or visual disturbance,

migraine, shortness of breath, dizziness, and numbness.^[48,49] Bubbles appear in the right heart between 9 and 59 seconds after injection and emboli have been detected in the middle cerebral artery following sclerotherapy of saphenous trunks and varices. Deep venous occlusion after ultrasound-guided sclerotherapy has also been reported; risk was found to be greater when treating veins ≥ 5 mm in diameter (odds ratio of 3.7) and injecting 10 mL or more of foamed sclerosant (odds ratio of 3.6).^[50] A systematic review of visual disturbance following sclerotherapy found this adverse effect to be rare and transient; further research was recommended to clarify the mechanism of action of sclerosants.^[51]

Clinical Practice Guidelines and Position Statements

- The 2011 SVS/AVF practice guidelines^[26] included the following recommendations concerning sclerotherapy in varicose vein treatment:
 - Grade 1B (strong recommendation based on moderate quality evidence) recommendation for the use of sclerotherapy to treat varicose tributaries
 - Grade 1B recommendation against selective treatment of perforating vein incompetence in patients with simple varicose veins
 - Grade 2B (weak recommendation based on moderate quality evidence) for sclerotherapy to treat pathologic perforating veins (i.e., outward flow of ≥ 500 ms duration and a diameter of ≥ 3.5 mm) located under healed or active ulcers (CEAP class C5-C6)
- The 2009 ACR appropriateness criteria noted that liquid or foam sclerotherapy has not been shown to have long-term effectiveness for large veins, such as the long saphenous vein.^[27]

Summary

The current evidence is sufficient to determine that treatment of certain symptomatic varicose veins using ligation, phlebectomy, endovenous treatment with radiofrequency or laser ablation, and sclerotherapy may improve short-term clinical outcomes (e.g., pain and return to work). Therefore, these procedures may be considered medically necessary in select patients when criteria are met.

The evidence for endovenous ablation or sclerotherapy of the investigational indications discussed above is not sufficient to permit conclusions concerning efficacy and safety. Studies for these indications are limited and often suffer from methodologic limitations which impact the reliability of the reported results. These limitations include lack of randomized treatment allocation, lack of an appropriate control group for comparison, small study population, and short-term follow-up.

The current evidence of mechanochemical ablation of varicose veins, which is limited to a single small, short-term case series, is not sufficient to permit conclusions concerning efficacy and safety. Therefore, the use of mechanochemical ablation of any vein is considered investigational.

Appendix 1: CEAP Classification

Clinical classification (C)	C0: no visible or palpable signs of venous disease C1: telangiectasias or reticular veins C2: varicose veins (≥ 3 mm diameter) C3: edema C4: skin and subcutaneous tissue changes C4a: pigmentation or eczema C4b: lipodermatosclerosis or atrophie blanche C5: healed venous ulcer C6: active venous ulcer
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Each clinical class is further characterized by a subscript for symptomatic (S) or asymptomatic (A), for example, C2A or C5S.	
Etiologic classification (E)	Ec: congenital Ep: primary Es: secondary (postthrombotic) En: no venous cause identified
Anatomic classification (A)	As: superficial veins Ap: perforator veins Ad: deep veins An: no venous location identified
Pathophysiologic classification	
Basic CEAP	Pr: reflux Po: obstruction Pr,o: reflux and obstruction Pn: no venous pathophysiology identifiable
Advanced CEAP includes the addition of any of following 18 venous segments as locators:	
Superficial veins	Telangiectasias or reticular veins Great saphenous vein above knee Great saphenous vein below knee Small saphenous vein Nonsaphenous veins
Deep veins	Inferior vena cava Common iliac vein Internal iliac vein External iliac vein Pelvic: gonadal, broad ligament veins, other Common femoral vein Deep femoral vein Femoral vein Popliteal vein Crural: anterior tibial, posterior tibial, peroneal veins (all paired) Muscular: gastrocnemial, soleal veins, other
Perforating veins	Thigh Calf

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[Cosmetic and Reconstructive Surgery](#), Surgery, Policy No. 12

[Ovarian and Internal Iliac Vein Embolization as a Treatment of Pelvic Congestion Syndrome](#), Surgery, Policy No. 147

CODES	NUMBER	DESCRIPTION
CPT	36468	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); limb or trunk
	36469	Single or multiple injections of sclerosing solutions, spider veins (telangiectasia); face
	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)

CODES	NUMBER	DESCRIPTION
	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)
	37700	Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions
	37718	Ligation, division, and stripping, short saphenous vein (for bilateral procedure, use modifier 50)
	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 perforators veins, subfascial, radical (Linton type) including skin graft, when performed, open, 1 leg
	37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
	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
	37799	Unlisted procedure, vascular surgery
	93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
	93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited studies
HCPCS	S2202	Echosclerotherapy