VARICOSE VEINS OF THE LOWER EXTREMITIES

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Overview
Varicose veins of the lower extremities are found in the superficial venous system which includes the great saphenous vein (GSV) and the small saphenous vein (SSV), and their tributaries. One-way valves are present in the superficial venous system. These valves prevent backward flow of blood within the vein (reflux) and keep the blood moving toward the heart. The condition of improperly functioning valves and the resultant valve reflux (incompetence) in the superficial venous system is known as chronic venous insufficiency. Varicose veins are the most frequent manifestation of chronic venous insufficiency. (Tassiopoulos et al., 2000; Nicolaides AN, 2000) Approximately 25% of the population has lower extremity varicose veins, and age is the only consistently identified risk factor. The incidence of varicose veins increases linearly with age. Varicose veins have long been considered a cosmetic problem however varicose veins are frequently the cause of disability, loss of limb and loss of life.

Classification of varicose veins
Heyerdale and Stalker proposed the first anatomic classification of varicose veins in 1941, and over the years various ways of classifying varicose veins have been used. None of these classifications achieved universal acceptance and widespread use. Because of this, there was no possibility for meaningful communication about chronic venous disease, and a basis for a more scientific analysis of management alternatives was missing. An international committee produced a consensus document for the

1 Over many years, lower limb venous anatomical terminology has been the subject of much controversy. An International Interdisciplinary Consensus Committee on Venous Anatomical Terminology met in Rome in 2001 to develop a universally accepted common anatomical terminology (Caggiati et al. 2002). The great saphenous vein is also known as the long saphenous vein, and the small saphenous vein is also known as the lesser or short saphenous vein. This has led to confusion because the acronym “LSV” can represent either the long saphenous vein or the lesser saphenous vein. This policy uses the nomenclature great saphenous vein and small saphenous vein, however it should be noted that current CPT nomenclature uses long and short saphenous vein.

2 The superficial venous system connects to the deep venous system at the following locations:
   • Saphenofemoral junction (SFJ): located proximally at the groin where the GSV meets the femoral vein.
   • Saphenopopliteal junction (SPJ): located behind the knee where the SSV meets the popliteal vein.
   • Perforator veins: these veins traverse the muscular fascia of the lower extremity to connect superficial veins with deep veins. A number of perforators are found in the leg.

3 Valvular reflux is defined as abnormal—and the valve incompetent—when retrograde flow through the valve lasts longer than 0.5 seconds by duplex criteria.

4 The GSV is the source of venous reflux in 60% of patients, the SSV is the source of reflux in 20% of patients, and the remaining 20% of patients have reflux in both the GSV and SSV (Labropoulos et al., 1997; Engelhorn et al., 2005).
classification and grading of chronic venous disease known as the CEAP classification in 1995. The most recent revision of the CEAP classification was published in 2004 (Eklof et al., 2004)

Currently, venous disease of the legs is classified according to the severity, cause, site and specific abnormality using the CEAP classification. Use of such a classification improves the accuracy of the diagnosis and improves communication between specialists. The elements of the CEAP classification are:

- Clinical severity – see table below
- Etiology
  - Ec: congenital
  - Ep: primary
  - Es: secondary (postthrombotic)
  - En: no venous cause identified
- Anatomy
  - As: superficial veins
  - Ap: perforator veins
  - Ad: deep veins
  - An: no venous location identified
- Pathophysiology
  - Pr: reflux
  - Po: obstruction
  - Pr,o: reflux and obstruction
  - Pn: no venous pathophysiology identifiable

CEAP is not a static classification; disease can be reclassified at any time. Classification starts with the patient’s initial visit, but can be better defined after further investigations. A final classification may not be complete until after surgery and histopathologic assessment. Eklof et al. therefore recommend that any CEAP classification be followed by the date, for example, C4bS, Ep, As, Pr (2003-08-21).

The grades of increasing clinical severity are:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C 0</td>
<td>No evidence of venous disease.</td>
</tr>
<tr>
<td>C 1</td>
<td>Telangiectasis or reticular veins less than 3 mm</td>
</tr>
<tr>
<td>C 2</td>
<td>Simple varicose veins (3 mm or larger)</td>
</tr>
<tr>
<td>C 3</td>
<td>Ankle edema of venous origin (not foot edema)</td>
</tr>
<tr>
<td>C 4a</td>
<td>Skin pigmentation or eczema</td>
</tr>
<tr>
<td>C 4b</td>
<td>Lipodermatosclerosis or atrophie blanche</td>
</tr>
<tr>
<td>C 5</td>
<td>Healed venous ulcer</td>
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<tr>
<td>C 6</td>
<td>Open venous ulcer</td>
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<tr>
<td>S</td>
<td>Symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction</td>
</tr>
<tr>
<td>A</td>
<td>Asymptomatic</td>
</tr>
</tbody>
</table>
Conservative treatment

Asymptomatic varicose veins that cause no symptoms require no treatment unless there is a desire to improve the aesthetic (cosmetic) appearance of the leg. Varicose veins that cause symptoms, which may include tingling, aching, burning, pain, muscle cramps, swelling, sensations of throbbing or heaviness, itching skin, restless legs, leg tiredness and fatigue, require treatment. The first-line treatment for symptomatic varicose veins is conservative treatment including leg elevation, daily exercise, weight reduction where appropriate, and compression therapy. The different forms of compression therapy include gradient compression stockings, paste gauze boots (UNNA boot), multilayer elastic wraps/bandages, and pneumatic compression devices. The rationale of compression therapy is to compensate for the increased venous hypertension.

A systematic review of compression stockings for uncomplicated varicose veins was published by Palfreyman and Michaels in 2009. They analyzed data from 11 prospective randomized controlled trials, 12 non-randomized trials, and 2 guidelines. Wearing compression improved symptom management in cases of uncomplicated varicose veins, however the studies did not provide evidence that wearing compression stockings slowed disease progression or prevented recurrence of varicose veins after treatment. The authors speculate that the results could have been confounded by the high number of noncompliant patients in these studies. (Palfreyman and Michaels, 2009). In a 2011 systematic review of compression stockings for the initial treatment of varicose veins, Shingler et al. found insufficient high quality evidence to determine whether or not compression stockings can effectively manage and treat varicose veins in the early stages. (Shingler et al., 2011). The evidence for the benefit of compression therapy is equivocal. Well designed randomized controlled trials are needed to assess the efficacy of this intervention.

The efficacy of conservative treatment versus surgical treatment for simple varicose veins (CEAP Clinical Classification C2) was evaluated by Michaels et al. (2006). The REACTIV Trial randomized 246 patients to conservative treatment or surgery. Conservative treatment included exercise, leg elevation, weight management, and compression stockings. Patients in the surgical arm also received the same lifestyle advice but underwent high ligation, stripping and phlebectomy. In the first 2 years after treatment, there was a significant quality of life benefit for surgery, and in a cost-effectiveness analysis, surgery produced an estimated discounted benefit of 0.054 quality-adjusted life years (QALYs). Economic modeling suggested that surgery produced a still greater benefit when considered with a 10-year time horizon. The Clinical Practice Guidelines for the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) recommend gradient compression stockings with an ankle pressure of 20 to 30 mm HG for patients with symptomatic varicose veins (CEAP Clinical Classification C2) who are not candidates for surgery. (Gloviczki et al., 2011)

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5 Simple elevation of the legs above heart level for 30 minutes three or four times per day can reduce swelling and improve circulation and may be the only treatment needed for people with mild venous insufficiency. (Abu-Own et al., 1994)

6 Gradient compression stockings are classified into four grades on the basis of pressure exerted at the ankle. Stockings are graded as 20-30 mm Hg, 30-40 mm Hg, 40-50 mm Hg, or greater than 50 mm Hg. (Weingarten MS, 2001)
Approximately 1% to 1.5% of people with varicose veins will develop secondary complications such as superficial venous thrombophlebitis (SVT) and venous stasis ulcers. (Nicolaides AN, 2000)

- SVT is the combination of thrombosis and inflammation in a superficial vein, and involves the GSV in 60% to 80% of cases. SVT should not to be confused with a deep vein thrombophlebitis (DVT), which is a blood clot in a deep vein, however SVT may be associated with acute DVT in 6% to 40% of cases (and with symptomatic pulmonary embolism in 2% to 13% of cases). Given the potential morbidity of untreated SVT, prompt recognition and understanding of the pathophysiology and sequelae are paramount for physicians treating this disease (Litzendorf and Satiani, 2011)

- Venous stasis ulcers are ulcers arising from chronic venous insufficiency. Venous stasis ulcers may persist for weeks to many years, and tend to recur. Larger ulcer size and longer duration of the ulcer usually signify a worse prognosis. Severe complications of venous ulcers include cellulitis, osteomyelitis, and malignant changes.

Compression therapy remains the standard of care for patients with advanced varicose veins and venous ulcers (CEAP Clinical Classification C3 through C6). In patients with venous stasis ulcers, gradient compression is effective as the primary treatment to aid healing of venous ulceration and as adjuvant therapy to prevent recurrences of venous ulcers. (Howard et al., 2008; O’Meara et al., 2009; Beavis and Earnshaw, 2011) The Effect of Surgery and Compression on Healing and Recurrence (ESCHAR) study randomized 500 patients with leg ulcers to compression treatment alone or compression combined with superficial vein ablation. Compression consisted of multilayer compression bandaging, followed by Class 2 (18-24 mm Hg,) below-knee stockings. Superficial venous surgery included saphenous vein ablation with high ligation and stripping (HL/S) as well as avulsion of varicose veins of the calf. General anesthesia could not be used in 25% of the patients, and in these, high saphenous vein ligation alone was performed. Compression treatment alone was as effective as compression with surgery to heal venous ulcers (65% versus 65%), but 12-month ulcer recurrence rates were reduced in the compression with surgery group versus those with compression alone (12% versus 28%). The difference in ulcer recurrence rates persisted between the two groups at 4 years. (Barwell et al., 2004; Gohel et al., 2007) The Clinical Practice Guidelines for the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) recommends compression therapy as the primary therapy to aid in healing of venous stasis ulcers and the adjuvant therapy to superficial vein ablation to prevent ulcer recurrence. (Gloviczki et al., 2011)

**Ligation and stripping**

Surgical treatment with high ligation and stripping is the gold standard against which new endovenous and surgical methods should be compared. High ligation and stripping is defined as ligation of the GSV at its confluence with the common femoral vein (SFJ), including ligation and division of all upper GSV tributaries. The primary goal is removal of refluxing vein(s) and improvement of symptoms.

Ligation and stripping is typically a three-step process:
1. Control of the most proximal point of reflux, most commonly at the SFJ, as identified by Doppler or duplex ultrasound. Ligation is the most common treatment for controlling reflux. Ligation refers to the surgical tying off of an incompetent (i.e., varicose) vein in the leg. The GSV is typically treated by high ligation at the SFJ followed by stripping to the knee. Most commonly the SSV is ligated at the saphenopopliteal junction (SPJ) only.\textsuperscript{7}

2. Removal of the incompetent vein from circulation.\textsuperscript{8} The most common strategy for this is vein stripping (more appropriately called saphenectomy). Stripping refers to the removal of the incompetent vein through incisions in the groin area and behind the knee (stripping is limited to between the groin and knee). An alternative to stripping is stab phlebectomy also known as stab avulsion or ambulatory stab phlebectomy.

3. Removal of varicose tributaries. Strategies for removal may include stab phlebectomy or sclerotherapy, either at the time of ligation or subsequent to.

Much has been written on the topic of recurrent of varicose veins following ligation and stripping (REVAS). Over the past several years, the concept of “neovascularization” has gained increasing popularity and attention. Neovascularization is defined as growth and development of new venous tributaries (angiogenesis) at the site of previously ligated or stripped varicosities. Neovascularization is particularly prevalent at the SFJ but may occur at any point of previous vascular surgery. Its exact prevalence and time of occurrence are difficult to establish because most patients are lost to follow-up. It can manifest itself as long as 10 years after the initial surgery and often leads to recurrence of symptoms and unsightly visible varicosities.

**Endovenous radiofrequency therapy and endovenous laser therapy**

Minimally invasive alternatives to surgical ligation and stripping have been developed in recent years for the treatment of chronic venous insufficiency of the GSV, notably, endovenous radiofrequency therapy (EVRT) and endovenous laser therapy (EVLT).\textsuperscript{9} Both of these procedures can be performed in an office or outpatient setting with local anesthesia and typically requiring no sedation. EVRT and EVLT are similarly designed to damage the endothelium of the vein resulting in fibrosis and ultimately occlusion of a segment of the vein, thus eliminating reflux or the backflow of blood. The vein therefore need not be ligated surgically and stripped out. Several endovenous ablation devices have received FDA approval.

Randomized controlled trials have compared EVRT and EVLT of the GSV to ligation and stripping. In a February 6, 2009 technology assessment, Winifred S. Hayes, Inc. found that “evidence from a number of randomized comparative trials and prospective

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\textsuperscript{7} It is now recognized that stripping of the GSV to the level of the knee is sufficient to obtain optimal results and avoids the troublesome complications of saphenous nerve injury associated with stripping to the calf.

\textsuperscript{8} Ligation of the GSV at the SFJ as a stand-alone procedure is unproven as a treatment for chronic venous insufficiency. Ligation of the GSV as a stand-alone procedure is associated with higher rates of neovascularization and recurrence of varicose veins compared to ligation and stripping. (Racek C, 2004; Winterborn et al., 2004; Dwerryhouse et al., 1999; Jones et al., 1996; Rutgers et al., 1994; Sarin et al., 1994)

\textsuperscript{9} EVRT and EVLT are unproven as a treatment of chronic venous insufficiency of the SSV. Randomized controlled trials are needed.
studies suggests that endovenous laser therapy (EVLT) effectively provides venous occlusion to treat symptomatic varicose veins due to great saphenous vein (GSV) reflux in adult patients. Several studies of moderate to good quality that evaluated the relative efficacy of EVLT compared with conventional surgical techniques reported comparable or superior clinical results of EVLT, with rates of recurrence generally less than 5%.” (Endovenous Laser Therapy for Varicose Veins Due to Great Saphenous Vein Reflux. © 2009 Winifred S. Hayes, Inc.)

Rass et al. (2011) recently published a study with 2 year follow-up, comparing EVLT to ligation and stripping in 400 randomly assigned patients. Clinically recurrent varicose veins after surgery were similarly observed in both groups: 16.2% (EVLT) versus 23.1% (ligation and stripping). However, duplex-detected saphenofemoral reflux occurred significantly more frequently after EVLT as compared to ligation and stripping (17.8% versus 1.3%). Rass et al. concluded that the matter of duplex-detected saphenofemoral reflux should be investigated further. (Rass et al., 2011)

Results of several randomized controlled studies question the continuing role of open surgery with high ligation and stripping as the gold standard treatment for varicose veins. The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) published clinical practice guidelines for the care of patients with varicose veins of the lower extremities. For the treatment of the incompetent GSV, the SVS/AVF Clinical Practice Guidelines now recommend endovenous thermal ablation (EVLT or EVRT) over high ligation and stripping because of reduced convalescence and decreased pain and morbidity. (Gloviczki et al., 2011)

It is important to note that patient selection for endovenous ablation is critical to the success of the procedure. Endovenous ablation is only a treatment option for sufficiently straight superficial vein segments that will allow passage of the device. (Khilnani et al., (2010) Ligation and stripping is indicated for patients with overly large or dilated and tortuous saphenous veins located immediately under the skin, those with a history of superficial thrombophlebitis resulting in a partially obstructed saphenous vein (because of previous thrombophlebitis of the GSV or SSV, percutaneous placement of the laser fiber or radiofrequency catheter may not be possible, and open techniques have to be used for removal of the vein), and those with varicose anterolateral thigh veins (if these originate at the SFJ, EVLT or EVRT will not be effective).

Subfascial endoscopic perforator surgery
Over the years, the role of incompetent perforator veins has been investigated in patients with advanced clinical sequelae of chronic venous insufficiency (i.e., venous ulcers). Perforator veins allow blood to pass from the superficial venous system to the deep venous system. An open surgical procedure known as the Linton procedure was developed in 1938 to treat incompetent perforator veins. The Linton procedure requires a long incision through compromised skin, frequently results in non-healing surgical incisions, infection, and recurrence of ulcers, and has largely been abandoned. In 1985 an endoscopic approach to the treatment of incompetent perforator veins known as subfascial endoscopic perforator surgery (SEPS) was introduced. A number of studies have shown that SEPS appears to be a safe procedure compared to the Linton procedure. However the controversy relates to questions regarding the role of
perforator incompetence in the treatment of chronic venous insufficiency. In general there is an incomplete understanding of how the hemodynamics of one venous system may affect the hemodynamics of the other. A variety of factors limit an evidence-based approach to assessment of SEPS:

1. There is inadequate evidence with which to make a determination of efficacy of SEPS compared to medical management, either in terms of healing of venous ulcers, or in preventing recurrent venous ulcers.
2. In many of the reported case studies and randomized controlled trials, patients have undergone both SEPS and other treatments of the superficial venous system making it difficult to assess the independent contribution of either component alone.
3. Patients with venous leg ulcers represent a heterogeneous group. Venous insufficiency may be either superficial, perforator or deep venous, or a combination. Results may be different in patients with primary venous insufficiency compared to those with post-thrombotic superficial venous insufficiency. In addition, the severity is variable in reported case series, ranging from those with active ulcers, healed ulcers, skin changes or simply the presence of varicose veins.

“The role of incompetent perforator vein ablation alone or with concomitant with GSV treatment awaits the results of properly conducted randomized controlled clinical trials. (O’Donnell, 2008) The Clinical Practice Guidelines for the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) has determined that current studies do not support treatment of perforator veins in patients with CEAP Class C2 disease. Patients with advanced chronic venous insufficiency (large >/= 3.5 mm, incompetent pathologic perforators with reflux >/= 500 ms located in the affected area of the limb with outward flow on duplex scan), CEAP Class C5 or C6, may benefit from the SEPS procedure. (Gloviczki et al., 2011)

With respect to the use of endovenous ablation for the treatment of incompetent perforator veins, at this time, “the scope and quality of the clinical studies are insufficient to conduct an evidence-based assessment of the safety and efficacy of EVLT for incompetent perforator veins. Hence, no recommendation regarding the adoption or use of this technology can be offered at this time.” (Winifred S. Hayes, Inc., Endovenous Laser Therapy for Incompetent Perforator Veins) The recommended treatment for varicose veins and venous stasis ulcers is saphenous vein ablation.

Sclerotherapy
Sclerotherapy is the injection of a chemical (sclerosing agent) into a visible vein to achieve endoluminal fibrosis and obstruction of the vein. Sclerosing agents are regulated by the FDA. Current FDA-approved sclerosing agents include osmotic agents, detergents, and alcohol agents. Liquid sclerotherapy is used primarily for obliteration of spider veins, reticular veins or telangiectasia (veins < 3 mm in diameter, CEAP Class C1). Liquid sclerotherapy is performed using small gauge needles. The procedure is started at the proximal end of the vein. Gauze pads are placed on the injection sites and the patient is instructed to wear gradient compression stockings for several days after treatment.

There is little evidence for the use of liquid sclerotherapy as the primary treatment of symptomatic varicose veins. Most clinicians consider liquid sclerotherapy an adjunctive
treatment to other procedures, i.e., ligation and stripping, EVLT or EVRT of the GSV. Liquid sclerotherapy as the sole treatment of symptomatic varicose tributaries of the GSV is not indicated in the presence of SFJ or SPJ reflux. Published studies indicate that such treatment, without definitive treatment of valvular incompetence of the saphenous veins without stripping and ligation or other surgical treatments provides little long-term benefit and leads to high recurrence rates. (Tisi et al., 2006)

The overwhelming majority of symptomatic varicose tributaries are related to valvular incompetence of the GSV or LSV. However, a small subset of patients may have symptomatic varicose veins in the absence of underlying junctional incompetence. Sclerotherapy as a sole therapy has been proposed for these patients. A literature search identified one controlled study of this group. In this placebo-controlled randomized study of 25 patients, those receiving sclerosant reported a high obliteration rate compared to those receiving normal saline at 12 weeks follow-up. Although this study valuated sclerotherapy efficacy in obliterating varicosities, it did not address its effectiveness at relieving pain. (Kahle and Leng, 2004)

Ultrasound-guided foam sclerotherapy is a modification of liquid sclerotherapy but instead of injecting liquid, the liquid is transformed into foam by forcibly mixing it with air or other type of gas such as oxygen or carbon dioxide. Ultrasound-guided foam sclerotherapy is increasingly used in clinical practice and it has become clear that foam sclerotherapy is more effective than liquid sclerotherapy. (Ouvry et al., 2008, Rabe et al., 2008; Yamaki et al., 2008)

Only a few high-quality randomized controlled studies have been published on the results of ultrasound-guided foam sclerotherapy for the treatment of varicose GSV, although the results are encouraging. (Wright et al., 2006; Figueiredo et al., 2009; Rasmussen et al., 2011; Liu et al., 2011) On the basis of the available data, the Clinical Practice Guidelines for the SVS/AVF recognizes that results of foam sclerotherapy have improved but concludes that they are not yet equivalent to those obtained for ligation or endovenous thermal ablation for the treatment of varicose GSV. The Committee recommended that there is an urgent need for well-designed, large randomized controlled studies comparing the results of ligation, EVLT and foam sclerotherapy. (Gloviczki et al., 2011)

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10 Sclerotherapy directed at the underlying reflux saphenous veins (as opposed to the visible varicosities of the tributary veins) requires ultrasound guidance. This procedure is referred to as ultrasound-guided foam sclerotherapy or echosclerotherapy. One protocol for sclerotherapy of valvular incompetence of the greater or lesser saphenous vein is the COMPASS procedure. COMPASS is an acronym for comprehensive objective mapping, precise image-guided injection, antireflux positioning, and sequential sclerotherapy. Comprehensive objective mapping describes the preoperative use of Duplex ultrasound to identify the point of origin of reflux and other contributing refluxing sources. Precise image-guided injection refers to the use of intraoperative Duplex ultrasound to guide the injection of the sclerosant into the greater saphenous vein. Antireflux positioning refers to the positioning of the patient with legs elevated to eliminate reflux and venous hypertension. Finally, sequential sclerotherapy refers to the use of 2 or 3 sessions of sclerotherapy until the varicosities resolve, with ongoing monitoring and repeat treatment, if needed, for up to 12 months.
The current evidence supports the current place of sclerotherapy (liquid or foam) in modern clinical practice, which is limited to the treatment of residual or recurrent varicose tributary veins following control of reflux in the GSV either by ligation or endovenous thermal ablation.\textsuperscript{11}

**Definitions**

**Chronic venous disorder** - The term chronic venous disorder includes the full spectrum of morphologic and functional abnormalities of the venous system, from telangiectasias to venous ulcers. Some of these, such as telangiectasias, are highly prevalent in the healthy adult population, and in many cases use of the term “disease” is not appropriate. The term chronic venous insufficiency implies a functional abnormality of the venous system, and is usually reserved for more advanced disease, including edema (C3), skin changes (C4), or venous ulcers (C5-6).

**Duplex ultrasound** - a type of vascular ultrasound procedure done to assess blood flow (reflux and patency) and the structure of the leg veins. The term "duplex" refers to the fact that two modes of ultrasound are used - Doppler and B-mode. The Doppler probe within the transducer evaluates the velocity and direction of blood flow in the vessel. The B-mode transducer (like a microphone) obtains an image of the vessel being studied.

**Lipodermatosclerosis** – is caused by an excessively high venous pressure in the subcutaneous veins in the lower leg in patients with long-standing venous insufficiency. Lipodermatosclerosis is a slow process that occurs over a number of years, and two-thirds of affected patients are obese. Lipodermatosclerosis affects the skin just above the ankle, usually on the inside surface. Over time the skin becomes brown, smooth, tight and often painful. The precise mechanism of lipodermatosclerosis is not fully understood. The most important part of management is compression therapy to correct venous stasis. Unless the underlying cause is treated, the patient is at high risk of developing venous leg ulcers. Once lipodermatosclerosis is established, the skin has been permanently and irreversibly damaged and treatment at that stage can only hope to prevent progression to an open leg ulcer.

**Saphenous veins** – The superficial veins of the foot and leg interconnect to form a complex network below the skin. These vessels drain into two major trunks: the small and great saphenous veins. The "small saphenous vein (SSV)" begins on the lateral portion of the foot and passes upward, rising along the back of the calf, enters the popliteal fossa (a depression in the bone behind the knee) to join the popliteal vein. The "great saphenous vein (GSV)," which is the longest vein in the body, begins on the medial side of the foot. It rises to extend up along the inner side of the leg and penetrates deep into the thigh just below the inguinal ligament in the lower abdomen, where it joins the femoral vein. Near its distant end, it receives vessels that drain the upper thigh, groin, and lower abdominal wall. The femoral and the great saphenous veins merge into the external iliac vein.

**Stab phlebectomy** – also known as ambulatory phlebectomy, a surgical treatment for varicose veins. This procedure involves the removal of varicose veins through small “stab” 1-2 mm incisions in the skin overlying the vein. The varicose vein is hooked and

\textsuperscript{11} Sclerotherapy is used for the treatment of reticular varicosities and telangiectasia (CEAP Class C\textsubscript{1}). Any treatment, including but not limited to sclerotherapy for reticular varicosities and telangiectasia is considered cosmetic and not medically necessary.
brought to the surface at each incision site to release it from the surrounding tissues and to sever any connections to other veins. This procedure is most effective when performed adjunct to surgical ligation of the incompetent vein (GSV).

**Stripping** – a surgical treatment for varicose veins. In this procedure, an incision is made in the groin, and the GSV is ligated. Then, a wire ‘stripper’ is threaded into the varicosed vein and the stripper and vein are then pulled (stripped) distally.

**Stasis dermatitis** – Stasis dermatitis is an inflammatory skin disease that occurs on the lower extremities in patients with chronic venous insufficiency with venous hypertension. The condition rarely occurs before the fifth decade of life, except in patients with acquired venous insufficiency due to surgery, trauma, or thrombosis. Stasis dermatitis is usually the earliest sequela of venous insufficiency, and it may be a precursor to more problematic conditions, such as lipodermatosclerosis and venous leg ulceration.

**Thrombophlebitis** – inflammation in a vein in an area where a blood clot has formed. (Often the term thrombophlebitis is shortened to "phlebitis.") There are two types of thrombophlebitis:

1. Superficial venous thrombophlebitis (SVT) occurs when a blood clot and inflammation develop in a small vein near the surface of the skin. SVT is usually self-limiting.
2. Deep vein thrombophlebitis (DVT) occurs when a blood clot and inflammation are deep inside a vein in a leg, the lower abdomen (pelvis), or, rarely, the arm. In deep vein phlebitis, a blood clot may break away and travel to the lungs, where it may block a blood vessel (a condition known as pulmonary embolus).

**Transilluminated powered phlebectomy (TIPP)** – In October 2003 the FDA approved the Trivex™ System (Smith & Nephew, Inc., Andover, MA) for the resection and ablation of varicose veins. This procedure involves the use of two devices: an illuminator and a resector. The illuminator is introduced via a groin incision underneath the varicose vein so that the vein becomes visible. The resector is then inserted beneath the illuminated vein. The tip of the resector is advanced slowly, ablating the varicose vein and aspirating the fragments. TIPP has been proposed as an alternative to stab phlebectomy. The scope and quality of the clinical studies of this treatment for varicose veins are insufficient to conduct an evidence-based assessment of safety and efficacy, therefore TIPP is considered experimental/investigational.

**Varicose veins** – Varicose veins of the lower limbs are dilated subcutaneous veins that are >/=3 mm in diameter measured in the upright position. Varicose veins, also called varicosities, are most common in the legs, although they can be found in other parts of the body. The term “varicose vein” does not apply to spider veins (telangiectasias) or reticular veins that are less than 3 mm in diameter (CEAP Class C).

12 The international CEAP consensus document (Eklof et al., 2004) for the classification and grading of chronic venous disease provides the following definitions of reticular veins and telangiectasias:

- Reticular veins are visible, dilated, bluish, subdermal, nonpalpable veins 1 to 3 mm in diameter. Reticular veins are often called “feeder veins” because they give rise to telangiectasias.
- Telangiectasias are very small (<1 mm) dilated blood vessels usually found in clusters near the surface of the skin. Telangiectasias are commonly called spider veins or thread veins.
Venous incompetence (reflux) – backward blood flow in a superficial vein due to a defective or damaged valve which results in high venous pressure. When there is sustained superficial venous hypertension, the vein eventually becomes varicose or distorted, distended and tortuous.

Policy
Prior authorization by FTC is required for the treatment of varicose veins of the lower extremities. Photographs of the affected limb(s) may be required at FTC’s discretion. FTC covers ligation and stripping, endovenous radiofrequency therapy (EVRT) or endovenous laser therapy (EVLT) of the great saphenous vein (GSV) or short saphenous vein (SSV) when documentation of all the following medical necessity criteria is submitted:

1. History and physical exam findings consistent with varicose veins caused by incompetence/reflux of the superficial venous system.
2. Reflux in the GSV/SSV has been demonstrated by duplex scan (performed no more than 12 months prior to the date of the requested procedure)
3. The vein to be treated is ≥ 3 millimeters in diameter (CEAP Class C2 through CEAP Class C6).
4. A trial of conservative therapy, which has included the use of properly fitted gradient compression (minimum 20 mmHg) stockings (unless medically contraindicated) has failed to relieve symptoms or complications directly attributable to varicose veins of the lower extremities (see number 5 below).
   a. For CEAP Class C2 - a minimum three (3) month trial of conservative therapy is required.

Reticular veins and spider veins (CEAP Class C1) are not associated with symptoms that significantly impair mobility or interfere with activities of daily living and their treatment is considered cosmetic.

13 Duplex scan is recommended as the first diagnostic test for all patients with suspected chronic venous insufficiency. Duplex scan is safe, noninvasive, cost-effective and reliable. It has much better diagnostic accuracy in the assessment of venous insufficiency that Doppler ultrasonography. Duplex scan should be performed with the patient upright. The supine position gives both false-positive and false-negative results of reflux. (Gloviczki et al., 2011)

14 Medical contraindications for the use of gradient compression stockings include severe peripheral arterial disease of the lower extremities (ABPI < 0.8), absence of palpable pedal pulses, or arterial compromise due to massive venous obstruction, or the physical inability to apply stockings daily, e.g. severe arthritis, arm paralysis, and unavailability of a caregiver to apply stockings daily. (Kahn et al. 2007)

15 Symptoms directly attributable to varicose veins include aching, throbbing, feeling of a heavy leg, fatigue, cramps, pruritus, restless leg, ankle swelling, and tenderness or pain along bulging varicose veins which significantly impairs mobility or interferes with activities of daily living, or one of the following complications of varicose veins exists:
   a. Recurrent (more than 2) episodes of superficial venous thrombophlebitis where an incompetent superficial vein is a significant contributing factor.
   b. Venous stasis ulceration where an incompetent superficial vein is a significant contributing factor.
   c. Severe stasis dermatitis or lipodermatosclerosis where an incompetent superficial vein is a significant contributing factor.
   d. Rupture and external hemorrhage of a varicose vein.
b. For CEAP Class C₃ through CEAP Class C₆ - a minimum two (2) week trial of conservative therapy is required.

FTC covers ligation and stripping or sclerotherapy of accessory saphenous veins, i.e., veins that ascend in parallel to the GSV, e.g., the anterior accessory saphenous vein (AASV), posterior accessory saphenous vein (PASV) and superficial accessory saphenous vein (SASV), when the GSV has been previously eliminated or is being eliminated during the same operative session, when documentation of all the following medical necessity criteria is submitted:
1. Reflux in the accessory saphenous vein has been demonstrated by duplex scan (performed no more than 12 months prior to the date of the requested procedure)
2. The vein to be treated is ≥ 3 millimeters in diameter (CEAP Class C₂ through CEAP Class C₆).

A maximum of 3 sessions of sclerotherapy (per leg) will be authorized (CPT codes 36470 or 36471) over a period of not more than 12 months following the primary procedure (i.e., GSV ligation and stripping, EVRT or EVLT).

FTC covers ligation and stripping (sclerotherapy is only covered as an adjunct procedure) of accessory saphenous veins with preservation of a competent GSV when documentation of all the following medical necessity criteria is submitted:
1. History and physical exam findings consistent with varicose veins caused by incompetence/reflux of the superficial venous system.
2. Reflux in the accessory saphenous vein has been demonstrated by duplex scan (performed no more than 12 months prior to the date of the requested procedure)
3. The vein to be treated is ≥ 3 millimeters in diameter (CEAP Class C₂ through CEAP Class C₆).
4. A trial of conservative therapy, which has included the use of properly fitted gradient compression (minimum 20 mmHg) stockings (unless medically contraindicated) has failed to relieve symptoms or complications directly attributable to varicose veins of the lower extremities (see number 5 below).

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16 Most patients (85%) have only GSV reflux and GSV stripping has been shown to restore SFJ competency at the 1 year follow-up. When SFJ incompetence is associated with reflux in more than one vein, all incompetent veins require stripping to restore SFJ competency. (The existing literature does not support EVLT or EVRT for veins other than the GSV.) Isolated AASV/SFJ reflux occurs in approximately 10% of patients. During surgery many surgeons strip the AASV and the competent GSV because of the possibility that stripping of the incompetent AASV may subsequently promote GSV reflux and recurrence of varicose veins. Although stripping of incompetent axial/trunkal veins is required to avoid recurrence, there is not evidence to support this for competent veins. (Theivacumar et al., 2009)

17 Duplex scan is recommended as the first diagnostic test for all patients with suspected chronic venous insufficiency. Duplex scan is safe, noninvasive, cost-effective and reliable. It has much better diagnostic accuracy in the assessment of venous insufficiency that Doppler ultrasonography. Duplex scan should be performed with the patient upright. The supine position gives both false-positive and false-negative results of reflux. (Gloviczki et al., 2011)

18 Medical contraindications for the use of gradient compression stockings include severe peripheral arterial disease of the lower extremities (ABPI < 0.8), absence of palpable pedal pulses, or arterial compromise due to massive venous obstruction, or the physical inability to apply stockings daily, e.g. severe arthritis, arm paralysis, and unavailability of a caregiver to apply stockings daily. (Kahn et al. 2007)
a. For CEAP Class C\textsubscript{2} - a minimum three (3) month trial of conservative therapy is required.
b. For CEAP Class C\textsubscript{3} through CEAP Class C\textsubscript{6} - a minimum two (2) week trial of conservative therapy is required.

FTC covers sclerotherapy (using foam or liquid sclerosant) or stab phlebectomy for symptomatic varicose tributaries of the GSV as an adjunct to ligation and stripping, EVRT or EVLT of the GSV by when documentation of all of the following medical necessity criteria is submitted:
1. Reflux in the tributary has been demonstrated by duplex scan (performed no more than 12 months prior to the date of the requested procedure).
2. The vein to be treated is $\geq 3$ millimeters in diameter (CEAP Class C\textsubscript{2} through CEAP Class C\textsubscript{6}).

A maximum of 3 sessions of sclerotherapy (per leg) will be authorized (CPT codes 36470 or 36471) over a period of not more than 12 months following the primary procedure (i.e., GSV ligation and stripping, EVRT or EVLT).

One session of stab phlebectomy (per leg) will be authorized (CPT codes 37765 or 37766), not more than 12 months following the primary procedure.

FTC covers ligation (SEPS procedure) for the treatment of large ($\geq 3.5$ mm), incompetent pathologic perforators (CEAP Class C\textsubscript{5} or C\textsubscript{6}) by when documentation of all of the following medical necessary criteria is submitted:
1. Duplex ultrasound has demonstrated perforator vein incompetence/reflux (reflux $\geq 500$ ms located in the affected area of the limb with outward flow).
2. Venous ulceration persists despite previous treatment for incompetence of the GSV and/or SSV and gradient compression therapy.

Exclusions
1. Surgical treatment of varicose veins is contraindicated in patients who cannot remain active enough to reduce the risk of post-operative deep vein thrombosis.
2. Surgical treatment of varicose veins is contraindicated during pregnancy because many varicose veins spontaneously regress after pregnancy.
3. Sclerotherapy for the treatment of valvular incompetence/reflux of the saphenofemoral junction or saphenopopliteal junction or for the treatment of varicose saphenous veins is considered experimental/investigational. Compressive

 Symptoms directly attributable to varicose veins include aching, throbbing, feeling of a heavy leg, fatigue, cramps, pruritus, restless leg, ankle swelling, and tenderness or pain along bulging varicose veins which significantly impairs mobility or interferes with activities of daily living, or one of the following complications of varicose veins exists:

1. Recurrent (more than 2) episodes of superficial venous thrombophlebitis where an incompetent superficial vein is a significant contributing factor.
2. Venous stasis ulceration where an incompetent superficial vein is a significant contributing factor.
3. Severe stasis dermatitis or lipodermatosclerosis where an incompetent superficial vein is a significant contributing factor.
4. Rupture and external hemorrhage of a varicose vein.
sclerotherapy for the treatment of incompetent perforator veins is considered experimental/investigational. Compressive sclerotherapy of varicose saphenous tributaries without concomitant or prior ligation of the greater or lesser saphenous veins is considered experimental/investigational.

4. Stab phlebectomy for the treatment of valvular incompetence/reflux of the saphenofemoral junction or saphenopopliteal junction or for the treatment of varicose saphenous veins is considered experimental/investigational. Stab phlebectomy for the treatment of incompetent perforator veins is considered experimental/investigational. Stab phlebectomy of varicose saphenous tributaries or perforators without concomitant or prior ligation of the greater or lesser saphenous veins is considered experimental/investigational.

5. Transilluminated powered phlebectomy (Trivex™ System, Smith & Nephew, Inc., Andover, MA) is considered experimental/investigational. The scope and quality of the clinical studies of this treatment for varicose veins are insufficient to conduct an evidence-based assessment of safety and efficacy. There is no specific CPT/HCPCS code for this procedure. The correct CPT code to report this procedure is unlisted procedure code 37799.

6. Open ligation of perforator veins (e.g., Linton procedure), CPT codes 37760, 37761, for any indication including chronic venous ulcers, is considered experimental/investigational.

7. Treatment for telangiectasias (spider veins) or reticular veins (CPT codes 36468 and 36469) is not covered.

Codes
Ultrasound guidance for endovenous ablation is considered incidental to the procedure.
Ultrasound guidance for needle placement (CPT 76942) is considered incidental to the injection procedure.

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td>36470</td>
<td>Injection of sclerosing solution; single vein</td>
</tr>
<tr>
<td></td>
<td>36471</td>
<td>Multiple veins, same leg</td>
</tr>
<tr>
<td></td>
<td>36475</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated</td>
</tr>
<tr>
<td></td>
<td>36476</td>
<td>Second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (Use 36476 in conjunction with 36475)</td>
</tr>
<tr>
<td></td>
<td>36478</td>
<td>Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated</td>
</tr>
<tr>
<td></td>
<td>36479</td>
<td>Second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (Use 36479 in conjunction with 36478)</td>
</tr>
<tr>
<td></td>
<td>37500*</td>
<td>Vascular endoscopy, surgical, with ligation of perforator veins, subfascial (SEPS)</td>
</tr>
</tbody>
</table>
### Codes

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>37700</td>
<td>Ligation and division of long saphenous vein at saphenofemoral junction, or distal interruptions</td>
</tr>
<tr>
<td>37718</td>
<td>Ligation, division, and stripping, short saphenous vein</td>
</tr>
<tr>
<td>37722</td>
<td>Ligation, division, and stripping, long (greater) saphenous veins from saphenofemoral junction to knee or below</td>
</tr>
<tr>
<td>37735</td>
<td>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</td>
</tr>
<tr>
<td>37760</td>
<td>Ligation of perforator veins, subfascial, radical (Linton type), including skin graft, when performed, open, 1 leg</td>
</tr>
<tr>
<td>37761</td>
<td>Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg</td>
</tr>
<tr>
<td>37765</td>
<td>Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions</td>
</tr>
<tr>
<td>37766</td>
<td>More than 20 incisions</td>
</tr>
<tr>
<td>37780</td>
<td>Ligation and division of short saphenous vein at saphenopopliteal junction (separate procedure)</td>
</tr>
<tr>
<td>37785</td>
<td>Ligation, division, and or excision of varicose vein cluster(s), one leg</td>
</tr>
</tbody>
</table>

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**References**


64. Wright D, Gobin JP, Bradbury AW, et al. Varisolve® Polidocanol Microfoam Compared with Surgery or Sclerotherapy in the Management of Varicose Veins in


