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34

Great Saphenous Vein Endovenous Treatment

Bernadette Aulivola

General Principles

Treatment methods for addressing great saphenous venous insufficiency have evolved over the past several decades. The standard treatment technique for saphenous insufficiency for many years involved surgical ligation at the saphenofemoral junction (SFJ) and stripping of the great saphenous vein (GSV). This approach was noted to be associated with prolonged recovery time and high recurrence rates of 25% at 5 years [1]. Endovenous ablation is now the primary mode of treatment for symptomatic insufficiency of the great saphenous vein; saphenous vein ligation and stripping are rarely performed.

Multiple modalities are available for saphenous ablation. Endovenous techniques have been available since the late 1990s and have undergone multiple improvements since that time. Earlier endovenous ablation techniques included endovenous laser ablation (EVLA) and radiofrequency ablation (RFA), both of which use thermal energy sources to cause venous fibrosis, sclerosis, and thrombosis of the treated vein. EVLA and RFA are equally effective and safe in treating GSV reflux. As compared with GSV stripping, thermal ablation is associated with reduced recovery time and less periprocedural pain, discomfort, and morbidity. Other techniques used for saphenous ablation that avoid the need for tumescent anesthesia are adhesive closure using n-butyl cyanoacrylate (VenaSealTM closure system, Medtronic, Minneapolis MN) and mechanicochemical ablation (ClariVein®, Merit Medical, South Jordan, UT). Such non-thermal ablation techniques accomplish venous ablation quickly with minimal patient discomfort and quick recovery time. All techniques have certain advantages and indications, with significant overlap in the roles that they play in treatment. Sclerotherapy alone has not been demonstrated to be as effi-

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cacious as endothermal ablation for GSV treatment and is not discussed further here.

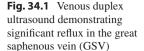
The method of venous ablation often depends on physician preference, as several techniques have been demonstrated to have acceptable outcomes with respect to technical success and incidence of complications such as deep venous thrombosis [2–4]. Patient-related and anatomic factors may play a role in the recommendation for one ablation technique over another, and insurance coverage is not uniform for all ablation techniques. The practicalities of decision-making on ablation technique should take into consideration many factors. Optimal management of GSV insufficiency requires a comprehensive understanding of the venous anatomy of the lower extremity, appropriate diagnostic evaluation, and proper patient selection.

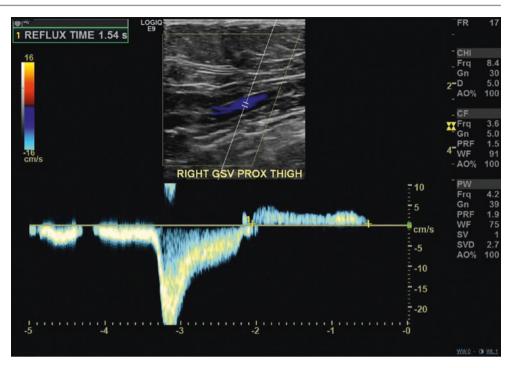
Evaluation of Venous Insufficiency

Duplex ultrasound of the lower extremities is essential in the evaluation and diagnosis of venous insufficiency and thrombosis. Standard venous reflux imaging protocols include assessment of the deep, superficial, perforating, and tributary venous systems for reflux or obstruction. In the evaluation of the superficial venous system, the presence or absence of reflux is identified in the great saphenous and small saphenous veins, as well as in tributary and accessory veins. Diagnostic criteria for the presence of significant reflux within the superficial venous system of the lower extremities includes reversal of flow for greater than 500 ms (Fig. 34.1). In the deep veins, reversal of flow for greater than 1000 ms is diagnostic of significant reflux. Treatment algorithms for venous insufficiency are tailored to the patient, taking into consideration clinical symptoms and the location of reflux. Typically, the approach involves addressing the most proximal extent of the superficial venous reflux, which often entails treatment of the great saphenous vein.

[©] Springer Science+Business Media, LLC, part of Springer Nature 2021 J. J. Hoballah, C. F. Bechara (eds.), *Vascular Reconstructions*, https://doi.org/10.1007/978-1-0716-1089-3_34

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Indications for Endovenous Treatment

It is essential to adopt a standard system for evaluation in the clinical assessment of venous insufficiency. Many use the CEAP classification (clinical, etiologic, anatomic, pathophysiologic). This chapter does not comprehensively cover the indications for saphenous ablation, but rather covers the techniques available to effect saphenous ablation. One should consider the risks and benefits of ablation of the saphenous vein. Known risks of saphenous ablation include deep venous thrombosis, pain and discomfort, saphenous and sural neuropathy, ecchymosis, and symptoms associated with superficial thrombophlebitis.

Relative contraindications to saphenous ablation include the presence of concomitant peripheral artery disease or coronary artery disease, given the destruction of a potential future autogenous vein conduit for bypass. However, it is also helpful to take into consideration in this patient population that tortuous, enlarged saphenous veins may not serve as a suitable conduit for autogenous vein use anyway. A discussion with the patient regarding the risk/benefit ratio is warranted prior to treatment planning. Deep venous reflux is not a contraindication to saphenous ablation, but deep vein obstruction is a relative contraindication.

There exists some controversy as to whether adjunctive treatments such as stab phlebectomy or reticular, spider, or varicose vein sclerotherapy should be performed at the same time as saphenous ablation or in a staged manner. In patients undergoing concomitant saphenous laser ablation and phlebectomy, 94% avoided additional ambulatory phlebectomy procedures [5]. In a study of patients undergoing saphenous

RFA first, 75% required additional treatment with ambulatory phlebectomy [6]. A systematic review of the literature on this topic identified three prospective randomized trials, two prospective trials, and three retrospective reviews. Based on these data, Quality of Life scores improved more quickly with a combined approach; 30% to 60% of patients who underwent ablation required subsequent treatment of varicosities. Few complications were seen with either sequential or staged procedures. This review concluded that combined treatment of saphenous reflux and symptomatic varicose veins results in better short-term results and better to equivalent long-term patient outcomes [7].

General Ablation Techniques

Patient Preparation

GSV ablation may be safely and comfortably performed in the office setting. Patient preparation should include assessment for the need for intravenous sedation or an oral anxiolytic medication such as diazepam prior to the procedure. Our practice rarely uses these; our patients tolerate the procedure quite well using local anesthetic only. The application of EMLA cream (lidocaine 2.5%, prilocaine 2.5%) to the skin along the course of the vein to be ablated may help to avoid some of the discomfort related to the injection of tumescent anesthesia required for thermal ablation procedures. If used, EMLA is applied to the anteromedial thigh and calf 1 hour prior to the intervention. The area is covered with an occlusive dressing to allow enough time for it to take effect.

Given the risk of deep venous thrombosis associated with saphenous ablation procedures, individualized thromboembolism prophylaxis is considered. We routinely administer a prophylactic dose of 5000 units of subcutaneous heparin prior to the ablation procedure in any patient with an elevated risk of venous thromboembolism, such as those with a known hypercoagulable state, obesity, recent cancer diagnosis, or history of venous thromboembolic event, if they are not already on therapeutic anticoagulation. It is unnecessary to discontinue antiplatelet agents or anticoagulants for saphenous ablation procedures.

Procedure Room Setup

Venous ablation procedures may be safely and comfortably performed in the clinic or procedure room setting. The typical table setup is shown in Fig. 34.2 for EVLA and Fig. 34.3 for adhesive ablation. Room setup typically includes the following:

- Tilt table.
- Sterile field and drapes.
- Ultrasound machine with sterile probe cover (Fig. 34.4).
- Local anesthetic (1% plain lidocaine) in 10 cc syringe.
- Injectable normal saline.
- Micropuncture access kit.
 - Echogenic-tipped 18-gauge needle, 0.018" guidewire, 4 or 5 French sheath.
- Long guidewire.
- Ablation sheath and catheter.
- · Ablation device.
- Tumescent pump for thermal ablation.
- Laser safety goggles for patient and staff (for laser ablation).
- Sclerosing agent (for mechanicochemical ablation).
- · Skin prep sticks.

Additional items that should be available:

- Torque device.
- Angled hydrophilic guidewire.



Fig. 34.2 Table setup for endovenous laser ablation (EVLA)

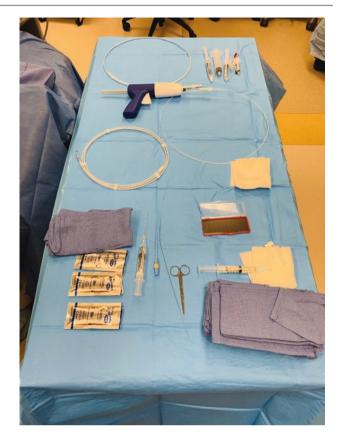


Fig. 34.3 Table setup for adhesive ablation (VenaSeal)



Fig. 34.4 Ultrasound machine setup

Patient Setup and Venous Access

Patients presenting for great saphenous vein ablation typically have undergone a full venous reflux imaging protocol, but real-time imaging from the SFJ distally is essential to clarify the anatomy. The ipsilateral lower extremity is prepped and draped using standard sterile technique. The groin should be included in the prepped area, as imaging of the SFJ at the groin crease is necessary. In patients with venous ulceration, care should be taken to keep wounds remote from the procedural field, assuming that vein access need not involve this area. Placement of a roll of towels under the bent knee and external rotation at the hip facilitates imaging of the great saphenous vein. Great saphenous vein puncture may be facilitated by placing the patient in the reverse Trendelenburg position to dilate the incompetent vein, if a tilt table is available. This is not necessary but is helpful, especially if the diameter of the vein is small. Use of an ultrasound technologist for intraprocedural imaging is an option but is not our routine.

Once the patient is positioned properly, ultrasound imaging is performed starting at the groin crease (Fig. 34.5). The common femoral vein and SFJ are identified first, following the great saphenous vein distally. The great saphenous vein is typically located within the saphenous sheath, but it may be located more superficially if it exits the sheath. Endothermal ablation may be performed even if the saphenous vein exits the sheath, as long as its depth after tumescent solution infiltration is more than 1.0 cm from the surface of the skin. When performing thermal ablation, the decision about access location should consider the risks of heat-induced nerve injury when the vein is treated below the knee. Typically, access of the great saphenous vein is achieved at or just below the knee for this reason when EVLA or RFA is being performed. When adhesive or mechanicochemical ablation is being used, the vein may be accessed at the ankle for treatment of the entire length, without concern about nerve injury.

Once the area to be punctured is identified, local anesthetic is infiltrated at the skin level. Typically 1% plain lidocaine is used. Local anesthetic containing epinephrine should be avoided, given its vasospastic effect. Venous puncture using an echogenic-tipped micropuncture needle is performed under ultrasound guidance. We prefer to perform the puncture with the ultrasound probe in transverse imaging orientation (Fig. 34.6). A micropuncture wire is then inserted and the needle is exchanged for a 4 Fr or 5 Fr micropuncture sheath. The sequence of events differs for thermal versus non-thermal ablation techniques, as described below.



Fig. 34.5 Patient positioning and ultrasound imaging of groin



Fig. 34.6 Ultrasound-guided micropuncture access of the great saphenous vein

Thermal Endovenous Ablation Techniques

Endovenous ablation techniques that utilize thermal energy are generally performed with the use of perivenous tumescent local anesthesia. The desired effects of the infiltration of tumescent solution include its anesthetic effects, protection of the skin and surrounding structures (such as nerves) from thermal injury, and induction of vasospasm and compression of the treated vein to facilitate contact with the thermal ablation device. The exact composition of the tumescent solution may vary, but it typically includes a crystalloid fluid, local anesthetic, and epinephrine, as well as bicarbonate to reduce its acidity and thus alleviate patient discomfort related to its injection:

- 450 mL normal saline
- 50 mL 1% lidocaine with 1:200,000 epinephrine
- 5 mL 8.4% sodium bicarbonate.

Endovenous Laser Ablation

It is essential that the patient and all members of the patient care team don laser safety goggles when a laser device is used. Figure 34.7 shows the VenaCure 1470 nm laser (AngioDynamics, Latham, NY). Many institutions require completion of a laser safety training course with annual recredentialing as a prerequisite to using this device. Once saphenous vein micropuncture access is performed, an 0.035" J-wire is advanced from the puncture site proximally towards the SFJ (Fig. 34.8). It is helpful to follow the tip of the wire throughout its course with ultrasound imaging. The tip of the wire should be advanced until it passes through the SFJ into the common femoral vein. Imaging is most easily performed with the ultrasound probe in the transverse orientation while following the wire as it is advanced proximally, transitioning to a longitudinal view at the SFJ (Fig. 34.9).

There are several situations in which challenges may be encountered in navigation of the guidewire from the punc-

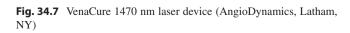




Fig. 34.8 Guidewire placement via micropuncture access



Fig. 34.9 Guidewire positioning across the saphenofemoral junction (SFJ). CFV—common femoral vein

ture site to the SFJ. If the vein is narrow in caliber, the J wire may not advance easily. In this case, the wire may be retracted to straighten the J-shaped tip, or it can be inserted from its back end, which has a straight, floppy tip. If the saphenous vein is tortuous or has large branches, it is helpful to have an angled 0.035" hydrophilic guidewire and torque device on hand to steer through the region using ultrasound guidance. External manual pressure may also aid in navigation through tortuous veins. More rarely, if the ablation is being performed after a prior failed ablation or in the setting of previous superficial thrombophlebitis and segments of the vein are occluded, it may be necessary to treat separate segments of the vein via multiple access sites.

Once guidewire access is achieved across the SFJ, the micropuncture sheath is exchanged for the long sheath, which is inserted to the common femoral vein (CFV). The sheath tip is much more easily visualized on ultrasound after the wire and dilator are removed. The tip of the sheath is then withdrawn to a location 2 cm distal to the distal aspect of the SFJ. The laser catheter is inserted into the sheath. A white plastic peel-away marker on the laser catheter prevents its inserted, the plastic peel-away marker is removed and the sheath is withdrawn to join it to the laser fiber, and the two are secured together. This step ensures that the laser catheter is positioned properly with its tip 2 cm away from the SFJ.

Infiltration of tumescent solution from the catheter insertion site to the SFJ is required for any thermal ablation procedure. Though manual injection using a large syringe is an option, the use of an injector pump facilitates this step of the procedure (Fig. 34.10). The echogenictipped 18-gauge needle is connected to a 500 cc bag of tumescent solution via the injector pump tubing. The tubing is threaded through the injector pump. Ultrasoundguided puncture of the saphenous sheath is performed at the laser insertion site. The pump is typically set with the dial at 5, but a slower injection rate can be used if the patient reports significant discomfort. Ultrasound imaging is performed, scanning in the cranial direction, to follow the most proximal extent of the tumescent solution infiltration. Tumescent solution is injected within the saphenous sheath but outside of the saphenous vein. One can observe external compression of the great saphenous vein, in addition to its increasing distance from the skin, as the tumescent solution is injected. When using the pump, typically three or four punctures are required to allow tumescent solution to track along the length of the vein. The pump is activated by a foot pedal. Depending upon the length of vein to be ablated, between 250 cc and 500 cc of solution



Fig. 34.10 Tumescent solution injection pump (AngioDynamics)

may be required. Tumescent solution infiltration can be imaged in the longitudinal or transverse orientation.

The 1470 nm wavelength diode laser targets water as a chromophore to absorb laser energy. Given that the vein contains water, laser energy is transmitted to the vein wall, causing sclerosis and fibrosis. The laser device is typically set at 5–10 watts; the maximum setting is 12 watts. Effective vein ablation occurs with the targeted energy of 30–50 joules per centimeter at a setting of 5–7 watts. The laser may be set at a higher wattage, which allows for increased speed of catheter withdrawal. A foot pedal is used to activate the laser, and then the laser catheter is withdrawn at a steady rate. At 8 watts, the catheter is withdrawn 1 cm every 5 seconds. The laser can be set to have a notification beep sound at 5-second intervals to help pace the catheter withdrawal.

Caution must be exercised in laser treatment of the great saphenous vein in the calf, given the proximity of the saphenous nerve, the small saphenous vein, and the sural nerve, as heat-induced nerve injury can occur.

Radiofrequency Ablation

Radiofrequency ablation (RFA) (VenefitTM procedure; ClosureFast catheter) requires a radiofrequency generator (Fig. 34.11). Once venous access is achieved as detailed above, a short 7 Fr sheath is inserted and the RFA catheter is advanced using ultrasound guidance to a location 2 cm distal to the SFJ. In most cases, the catheter can be advanced on its own to the region of the SFJ, but if the vein is tortuous, it can be advanced over an angled 0.025" hydrophilic guidewire. Tumescent solution is infiltrated around the vein as described above. The RFA catheter treats the saphenous vein in a segmental fashion, typically treating a 7 cm segment of the vein over a 20-second interval. Successful RFA ablation depends on vein wall contact with the catheter, so ultrasound-guided compression is performed over the segment being treated, to enhance contact between the catheter and the vein wall. Positioning the patient in Trendelenburg position is also helpful in decompressing the vein to facilitate its contact with the RFA catheter. The catheter delivers uniform heat to the vein, which denatures collagen and smooth muscle in the vein wall, causing fibrosis and thrombosis of the treated vein segment. The most proximal segment of the vein is treated twice before withdrawing the catheter 7 cm. Activation of the radiofrequency device is triggered by depressing a button on the catheter itself. After each segment is treated, the catheter is withdrawn 7 cm at a time, using markers on the catheter to guide the withdrawal distance. The RFA catheter is also available with a tip 3 cm long, for treatment of shorter refluxing vein segments.



Fig. 34.11 Radiofrequency ablation system (Covidien ClosureFastTM)

As with EVLA, caution should be exercised in treatment of the great saphenous vein at calf level or the small saphenous vein, given the risk of heat-induced nerve injury.

Mechanicochemical Ablation

Mechanicochemical ablation utilizes a 3 Fr infusion catheter with a rotating wire tip for dispersion of a physician-selected sclerosing agent to the targeted treatment area. This device is fully disposable. Given that this is a non-thermal ablation technique, there is no need for infiltration of tumescent solution around the targeted treatment vein. The device includes an infusion catheter with a motor drive unit that is operated by a low-voltage, self-contained power system. Multiple speed settings allow for rotation of the wire tip between 2000 and 3500 revolutions per minute. The device also includes a syringe and stopcock for delivery of the sclerosing agent (Fig. 34.12).

Micropuncture access is achieved as described above. The ClariVein catheter is advanced through the micropuncture sheath to the region of the SFJ. Its device tip is angled and allows for some steering of the device as it advances into the vein. Once the catheter is in place, its distal end is attached to the motor drive unit and clicked into place. When the catheter is clicked fully into the handle, the treatment wire protrudes from the end of the catheter. Confirmation of device positioning 2 cm distal to the SFJ is performed with ultrasound prior to starting treatment. The wire rotation is activated by squeezing the trigger with the index finger while injecting a sclerosing agent (such as sodium tetradecyl sulfate) with the thumb on the plunger of the attached syringe. The pullback rate is approximately 1.5 mm per second, or 1 cm per 6-7 seconds. A total of 20-30 cc of sclerosing agent is typically used for treatment of the thigh segment of the great saphenous vein, so the attached 5 cc syringe must be refilled several times during the treatment. There is a marker

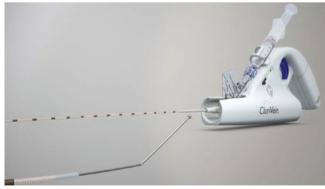


Fig. 34.12 Mechanicochemical ablation device (ClariVein®, Vascular Insights LLC)

on the distal aspect of the catheter past which an additional 2 cm may be withdrawn prior to ceasing treatment. The wire should be resheathed prior to removal. Compression of the vein is not required during treatment with the mechanico-chemical ablation device.

Adhesive Ablation

Adhesive ablation (VenaSealTM closure system, Medtronic) is a non-thermal form of ablation that may be used throughout the saphenous system without concern for thermal injury to surrounding structures. Tumescent solution is not required. This system is completely disposable and involves a catheterbased injection of a small volume of medical adhesive, cyanoacrylate. Once micropuncture access of the saphenous vein is achieved (Fig. 34.13), a 0.035" 180-cm J-wire is inserted though the sheath vein proximally to the SFJ (Fig. 34.14). The sheath is exchanged for the 7 Fr blue introducer/dilator. Once inserted to the SFJ, the wire and dilator are removed. The blue introducer is then flushed with normal saline and pulled back under ultrasound guidance so that its tip is positioned 5 cm distal to the SFJ (Fig. 34.15). The adhesive is drawn up using the 3 cc syringe, taking care to



Fig. 34.13 Micropuncture access for adhesive ablation



Fig. 34.14 J-wire insertion via micropuncture access for adhesive ablation

remove air bubbles from the syringe. The adhesive syringe is attached to the 5 Fr adhesive delivery catheter. The adhesive syringe is then inserted into the dispenser gun and rotated clockwise to lock it in place. The delivery catheter is primed by pulling the trigger to advance adhesive to the distal marker, located 3 cm from the catheter tip. The primed delivery catheter is then advanced into the blue introducer until the laser mark on the proximal aspect of the catheter reaches the hub of the blue introducer (Fig. 34.16). The blue introducer is then pulled back at the skin an additional 5 cm, and the adhesive catheter is inserted the remainder of the way, locking it in place. Prior to treatment, the tip of the adhesive delivery catheter should be confirmed at 5 cm distal to the SFJ.

Ultrasound imaging of the great saphenous vein is performed to identify the proximal tip of the catheter. The ultrasound probe should be oriented in transverse position and the great saphenous vein should be compressed just proximal to the catheter tip prior to injection. Adhesive injection is then performed by pulling the trigger on the dispenser gun. The catheter is pulled back by 1 cm, and a second injection is performed. The catheter is pulled back 3 cm, and the region distal to the ultrasound probe is manually compressed for





Fig. 34.16 Adhesive ablation delivery catheter insertion

Fig. 34.15 Adhesive ablation introducer

3 minutes (Fig. 34.17). Subsequently, treatment of the remainder of the vein is performed with the following sequence: Compress vein just proximal to catheter tip, inject, pull catheter back 3 cm, inject, pull catheter back 3 cm, then compress the 6 cm treated segment for 30 seconds. This sequence is repeated for the length of the treatment zone. Once the treatment is completed, the catheter should be pulled back into the introducer, then both are removed as a unit.

Adhesive ablation has been demonstrated to have a 95% closure rate at 5 years [4, 8].

Subsequent Care

On completion of ablation, ultrasound imaging at the SFJ should document a patent segment of the proximal great saphenous vein. This region should be compressible, with color-flow documented. It is quite rare to see extension of thrombus to the SFJ following ablation.

Regardless of the method of ablation, a single bandage at the catheter insertion site is placed on completion of the procedure (Fig. 34.18). Medical-grade compression stockings are advised following the procedure, with various protocols for compression therapy following the ablation. Patients undergoing thermal ablation procedures may expe-



Fig. 34.17 Manual and ultrasound compression after adhesive injection



Fig. 34.18 Bandage placement after saphenous ablation

rience inflammatory changes and discomfort following the ablation. These symptoms are generally mild and may be alleviated with nonsteroidal anti-inflammatory medication (such as ibuprofen 600 mg PO q 8 hours), which may be taken around the clock for 24 to 28 hours to minimize soreness.

Following ablation, patients are instructed to resume normal activity. We do not limit patient activity following the B. Aulivola

procedure. Patients return for duplex imaging of the ipsilateral lower extremity within 5–7 days in order to document successful ablation and to rule out deep venous thrombosis. The follow-up duplex imaging protocol does not assess for reflux.

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