Varicose vein ablation: navigating the treatment options - 2
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Chapter I
An update on operative treatments of primary superficial vein incompetence

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Abstract

For more than a century, open surgery and liquid sclerotherapy were the only options used for operatively treating primary varices. In the last 20 years, management of primary varices has dramatically changed due to ultrasound investigations and innovative techniques. Development of endovenous treatments, including thermal ablation and/or chemical ablation, has provided a patient-friendly option for an office-based procedure, improving both the postoperative course and convalescence duration. This book will describe the new procedures and their possible complications, provide an analysis of the outcomes after the new procedures for short-, mid-, and long-term follow-up, and discuss the indications and the international guideline recommendations for operative treatment of varicose veins. For the outcome analysis, all randomized controlled trials (RCTs) published since 1990 on operative treatments of varicose veins were collected and the references were gathered in tables according to either the procedure used or the patient’s clinical status. Case series and meta-analyses were taken into account in this review when RCTs were not available. For more details regarding clinical or instrumental outcomes of the studies described, please go to www.phlebolymphology.org.

Preface

The term operative treatment has been intentionally chosen instead of interventional treatment because interventional treatment means any kind of treatment that interferes with the natural history of the disease. For example, both compressive treatments and vеноactive drugs modify the natural evolution of primary varicose veins.

Introduction

For a century, ancillary open surgery had the highest recommendation, and subsequently, was the most frequently used procedure for operatively treating varicose veins. In the past decade, the development of minimally invasive endovenous techniques for primary superficial venous reflux has provided a patient-friendly means of treating this disorder as an office-based procedure with ablation of the saphenous veins and tributary varicosities by using radiofrequency ablation, endovenous laser ablation, or sclerotherapy. Sclerotherapy regained favor for two reasons: (i) ultrasound investigation, which provided security for the
procedure; and (ii) the use of foam, which enhances the efficacy of the sclerosing agent. More recently, new procedures have been used, including steam ablation, ClariVein®, laser-assisted foam sclerotherapy, and glue, and these procedures will be described in the present book.

Simultaneously, surgery, including the CHIVA procedure (Cure Hemodynamique de l’Insuffisance Veineuse en Ambulatoire [conservative ambulatory hemodynamic management of varicose veins]),¹ and more recently, the ASVAL procedure (ablation sélective des varices sous anesthésie locale [ambulatory selective vein ablation under local anesthesia]),² were developed to preserve the great saphenous vein.

Open surgery without conservation of saphenous trunks

Modern open surgery should be performed under local anesthesia and directed by preoperative ultrasound assessment and skin mapping. Treatment of the great saphenous vein involves flush ligation of the saphenofemoral junction, which is completed using saphenous invagination stripping. Stripping can also be done using a cryoprobe. Treatment of the incompetent small saphenous vein usually involves flush saphenopopliteal junction ligation and stripping by invagination. Nontruncal varicosities can be excised using stab avulsion–powered phlebectomy or they can be treated with sclerotherapy in the same session or later.

Stripping of both the great saphenous vein below the knee and the distal small saphenous vein may reduce varicose vein recurrence, but it is associated with an increased risk of nerve injury.³ The usefulness of flush ligation was recently called into question after a randomized controlled trial.⁴ Nontruncal varicosities can be excised either by stab avulsion–powered phlebectomy, or treated by sclerotherapy in the same session or later.

In addition, there is a consensus for recommending elastic compression stockings for no more than 1 week after the operation.⁵,⁶

Complications of surgery

The early complications of surgery include discomfort (common), bruising (common), hematoma (rare), bleeding (very rare), lymphatic damage (rare), femoral vein or artery injury (extremely rare),⁷ wound infections (2% to 6%), and injury of the saphenous or sural nerve (10%). Symptomatic and asymptomatic deep venous thrombosis and pulmonary embolism following open surgery vary from 0.4% to 5.3% and 0% to 0.5%, respectively.⁸,⁹ The risk of complications, such as venous thromboembolisms, increases with redo surgery and surgery of the small saphenous vein.⁸ Modern open surgery under local anesthesia has dramatically lowered the rate of thromboembolic complications. Late complications include permanent nerve damage (5%).¹⁰
Open surgery with preservation of the saphenous trunk

CHIVA

Due to the possible future use of the great saphenous vein as a vascular graft, it is necessary to preserve the vein. The principle of the CHIVA technique consists of redistributing refluxes from the superficial to the deep system using staged ligations on the great saphenous vein or tributaries. CHIVA is a complex procedure that requires careful mapping and understanding of the anatomy and function of the superficial system by well-trained and experienced physicians who are aware of the shunt classifications.

ASVAL

While CHIVA is based on a descending theory, the ASVAL method is based on an ascending or multifocal approach to the primary varicose veins. In order to improve or suppress the saphenous vein reflux, a stab phlebectomy of incompetent tributaries is performed to remove the distal venous reservoir. Compared with trunk varicose vein ablation, the major advantage of ASVAL is the preservation of the great saphenous vein. After the ASVAL procedure, most patients had less advanced stages of varicose veins.

Endovenous thermal ablation

The term “endovenous thermal ablation” includes radiofrequency ablation, endovenous laser ablation, endovenous steam ablation, and endovenous microwave ablation. In endovenous thermal ablation procedures, ablation of the treated vein is achieved using heat, which is delivered into the vein through a percutaneously placed catheter or probe. The heat causes a direct thermal injury to the vein wall, resulting in destruction of the endothelium, denaturation of collagen in the media, and subsequently, thrombotic and fibrotic occlusion of the vein. Endovenous thermal ablation is performed under local tumescent anesthesia (except for endovenous microwave ablation) to provide anesthesia; protect the perivenous tissue from the heat created by the catheter, probe, or wire when activated; and spasm the vein to obtain the best contact with the heating device. In addition, all endovenous thermal ablation procedures are performed using ultrasound guidance and conducted as an outpatient-based procedure.

For the great saphenous vein, echo-guided vascular access occurs just below the knee (except for endovenous microwave ablation); therefore, heating is done from the groin (2 cm below the saphenofemoral junction) down to the distal part of the vein, usually just below or above the knee. For the small saphenous vein, echo-guided access occurs at the lower one-third of the lower leg, and heating is done from the popliteal fossa (2 cm below the saphenopopliteal junction) down to just above (8 to 10 cm) the tibial malleolus.
Radiofrequency ablation

Introduced in 2007, the current ClosureFAST radiofrequency catheter (VNUS Medical Technologies/Covidien) (Figures 1 and 2) is easy to use. The entire pullback time takes 3 to 4 minutes, generating heat around 120°C. Celon RFITT, another radiofrequency ablation system for bipolar radiofrequency-induced closure, is now available (Olympus Medical Systems). This system generates heat at 60 to 85°C and operates with a continuous pullback speed of 1 to 1.4 cm/second.

![Figure 1. ClosureFAST catheter.](image1)
The first 7 cm (left) of the coated heating element and the thermocouple (right).

![Figure 2. ClosureFAST heater and thermocouple catheter.](image2)
The thermocouple (1) is mounted distally to the heating element (2).

Endovenous laser ablation

Fiber lasers can provide either low wavelength beams (810, 940, and 980 nm) or high wavelength beams (1319, 1320, 1470, and 1500 nm). Theoretically, light of lower wavelengths is less specifically absorbed by the chromophores (hemoglobin, water, proteins) compared with the light of higher wavelength lasers.12 Previously, the fibers were bare tipped, but the new radial fibers are more effective and include the Radial fiber R (Biolitec) (Figure 3), Never-Touch R (Angiodynamics), and Tulip fiber R (Tobric). A continuous withdrawal technique is the current rule and it is recommended to deliver 50 to 70 J/cm of energy.

![Figure 3. Fiber with radial emission.](image3)
Fiber with single radial emission (Panel A) and double radial emission (Panel B).
Radiofrequency ablation vs endovenous laser ablation

Endovenous laser ablation and radiofrequency ablation are similar techniques that treat similar patient profiles. After percutaneous access, the radiofrequency ablation catheter or laser fiber is pushed proximally until the tip is positioned 2 cm from the saphenofemoral junction or saphenopopliteal junction (Figure 4). After tumescent anesthesia, the vein is ablated in a retrograde fashion. The postablation procedures are similar for both techniques.

Endovenous steam ablation

In 2006, Milleret et al introduced steam as a cheaper alternative to laser and radiofrequency ablation. The principle consists of injecting pulses of water vapor at 120°C in the vein to be ablated, with each pulse delivering 60 J of energy into the lumen. Steam is injected under pressure, whereby the first pulse dislodges the blood and the subsequent ones heat the vein wall. A 5F gauge stainless steel catheter is used because it is flexible enough to navigate through the tortuosity without using a guide wire. Two lateral holes close to the tip eject the steam, avoiding the risk of heating deep veins when heating the junctions.
A comparative animal study by Thomis et al compared steam with either ClosureFAST radiofrequency or a 1470 nm TULIP fiber laser. The three methods generated comparable results regarding scores for low perivenous tissue destruction and high vein wall destruction.\textsuperscript{13}

In a pilot study by van den Bos et al, 11 out of the 19 veins treated were completely obliterated at 6 months, with a partial reopening in the other veins. However, the energy delivered was too low, 1 pulse/cm instead of the 2 to 4 pulses/cm that is advised by the manufacturers of the technique.\textsuperscript{14} In a series of 75 patients, the complications included a thrombus protrusion in the femoral vein, an ecchymosis at the entry site in 1 patient, and moderate pain lasting 8 days in 6 patients. Subsequently, a randomized controlled trial was designed and it is still ongoing.\textsuperscript{15}

**Endovenous microwave ablation**

After ligation of the saphenofemoral junction, the microwave treating wire is inserted into the great saphenous vein until the medial aspect of the ankle and is guided by the illuminated tip of the wire. The treating wire is withdrawn from distal to proximal at 2 to 4 mm/s, delivering 80 J/cm of energy. In 16.4% of patients, the treating wire could not be passed to the ankle; therefore, it was inserted in the great saphenous vein at a puncture in the ankle and the vein ablation was conducted from groin to ankle. In the same session, all superficial varicose veins and perforators are ablated using short-wire power (10 to 15 W) under ultrasound guidance.\textsuperscript{16}

**Complications of endovenous thermal ablation**

In a review analyzing randomized controlled trials conducted on open surgery (radiofrequency ablation [317 patients], endovenous laser ablation [1057 patients], and open surgery [975 patients]), the short-term complications included venous thromboembolism, wound infection, and paresthesia.\textsuperscript{17} There was a significantly higher rate of wound infection for open surgery (2.3%; 95% CI, 1.3%-3.1%) vs endovenous laser ablation (0.5%; 95% CI, 0.3%-1.3%; \( P < 0.006 \)), but not between open surgery and radiofrequency ablation (1.5%; 95% CI, 0.4%-3.0%; \( P = 0.094 \)). The paresthesia rate was significantly lower with endovenous laser ablation (3.8%; 95% CI, 2.4%-4.5%) compared with radiofrequency ablation (5.2%; 95% CI, 3.1%-7.9%; \( P = 0.001 \)) and open surgery (7.4%; 95% CI, 5.3%-8.3%; \( P < 0.001 \)). The rate of thrombophlebitis was significantly lower for open surgery (3.0%; 95% CI, 2.9%-4.0%) compared with both radiofrequency ablation (5.5%; 95% CI, 3.0%-7.8%; \( P = 0.003 \)) and endovenous laser ablation (5.6%; 95% CI, 4.2%-7.0%; \( P = 0.003 \)). Thermal skin burns occurred with equal frequency between radiofrequency ablation and endovenous laser ablation.\textsuperscript{17}

A review of radiofrequency ablation complications has been reported and this method has been compared with those of other operative procedures. Early complications include pain, phlebitis (7% to 9.6%), arteriovenous fistula (0.15%), endovenous heat-induced thrombosis (EHIT), deep vein thrombosis (<0.01%), lidocaine toxicity, wound problems (6% to 8%), and skin burns (0.5%). Late complications are mostly transient and may include skin pigmentation (6% to 19%) and nerve damage (4% to 20%).\textsuperscript{18,19} Complications from endovenous laser ablation have also been compiled and include phlebitis (1.87%), skin burns (0.46%),...
nerve injury (3.08%), arteriovenous fistula (0.15%), endovenous heat-induced thrombosis, and deep venous thrombosis (0.27%).

Only one multicenter trial has reported the outcomes of endovenous steam ablation (n=117). Postprocedural pain was lower in endovenous steam ablation compared with endovenous laser ablation. Other outcomes included thrombophlebitis (9.2%), nerve injury (0.9%), and hyperpigmentation (4.6%), but no deep vein thrombosis or skin burns were identified. Complications after endovenous microwave ablation have been reported in a single-center study, where endovenous microwave ablation was responsible for skin burns related to ablation of subcutaneous tributaries (10.2%).

Chemical ablation

Sclerotherapy

Sclerotherapy refers to the introduction of a foreign substance into the lumen of a venous vessel to damage the venous wall and occlude the vessel. Liquid sclerotherapy has been used primarily for obliteration of spider veins. However, interest in using sclerotherapy for telangiectasia and varicose veins significantly increased in 1995 when Cabrera et al reported that foam, prepared by mixing gas with the detergent polidocanol, was effective for obstruction of larger veins. The use of ultrasound-guided foam sclerotherapy has rapidly spread for the treatment of primary and recurrent varicose veins, including the great saphenous vein, small saphenous vein, saphenous tributaries, and perforating veins.

Sclerosing agents

The mechanism of action for sclerosing agents includes destruction of venous endothelial cells, exposure of subendothelial collagen fibers, and ultimately, the formation of a fibrotic obstruction. Delivery of the solution as a foam prolongs the contact time and amplifies the effect of the chemical substance. For producing endothelial injury, sclerosing solutions can be classified into three categories: detergent, osmotic, or chemical irritant.

In Europe, approved agents for sclerotherapy include sodium tetradecyl sulfate, polidocanol, morrhuate sodium, hypertonic saline, and glycerin.

- Sodium tetradecyl sulfate is a detergent that destroys the endothelium by denaturation of the cell surface proteins. The solution is safe and painless when injected. When the solution is injected at higher concentrations, extravasation may result in tissue necrosis. Hyperpigmentation, matting, and allergic reactions have been described, but rarely occurred. Generating foam with a sodium tetradecyl sulfate agent is easy.

- Polidocanol is another detergent that is safe and painless when injected and has a low risk of tissue necrosis when used at low concentrations. It may cause hyperpigmentation, but has a very low rate of allergic or anaphylactic reactions. There is a consensus that polidocanol has fewer overall complications compared with sodium tetradecyl sulfate.
Sodium morrhuate is a detergent that is used less frequently due to a relatively higher incidence of skin necrosis observed with extravasation and a higher risk of anaphylactic reactions within a few minutes after injection.

- Glycerin is a chemical irritant that destroys the cell surface proteins by affecting chemical bonds. Chromated glycerin is frequently used as a solution of glycerin, sterile water, and benzyl alcohol. Chromated glycerin is safe and rarely leads to tissue necrosis, hyperpigmentation, or allergies, but frequently there is local pain at the injection site. This treatment is particularly suitable for treating small veins or telangiectasia.

- Hypertonic saline, an osmotic agent, is a weak sclerosing agent that causes dehydration of endothelial cells through osmosis, which leads to endothelial cell death. Burning pain is frequent during injection. Extravasation may cause skin ulcers and tissue necrosis.

Liquid sclerotherapy

Liquid sclerotherapy is currently used for treating reticular veins and telangiectasia.

Foam sclerotherapy

Due to the enhanced sclerosing properties of foam, ultrasound-guided foam sclerotherapy has been shown to be more effective than liquid sclerotherapy, Tessari et al used a three-way stopcock connected to two syringes to produce foam and they developed the most popular technique used today. Other techniques for producing foam involve a two-way female-to-female connector.

Experts recommend a ratio of 1 part sodium tetradecyl sulfate or polidocanol to 4 or 5 parts air. Mixing the drug with air using two syringes and pushing the mixture from one syringe into the other 20 times results in an approximate bubble size of <100 μm. Coleridge Smith advises puncturing the veins in supine patients and then elevating the limb 30 degrees to inject the foam. Ultrasonography is used to monitor the movement of foam in the veins. The saphenous vein is injected first, followed by varicose and perforating veins, if indicated. A maximum of 10 mL of foam is injected during one session. The procedure is completed by placing a short-stretch bandage or a 30 to 40 mm Hg graduated compression stocking on the limb. Most experts recommend 1 to 2 weeks of compression.

Severe complications of ultrasound-guided foam sclerotherapy comprise anaphylaxis (extremely rare), large tissue necrosis (extremely rare), stroke and transient ischemic attack (extremely rare), distal deep venous thrombosis (very rare), pulmonary embolism (extremely rare), and motor nerve injury (extremely rare). Benign complications are visual disturbances (uncommon), headaches and migraines (uncommon), sensory nerve injury (rare), chest tightness (very rare), dry cough (very rare), superficial thrombophlebitis (unclear), skin reaction (very rare), matting (common), residual pigmentation (common), minimal skin necrosis (very rare), and embolia cutis medicamentosa (very rare).

The complications are listed in the European guidelines for sclerotherapy in chronic venous disorders, along with recommendations to avoid and manage these complications. Ultrasound-guided foam sclerotherapy of the saphenous vein is the least invasive of the endovenous ablation techniques. In 2008, the European
Consensus Meeting on Foam Sclerotherapy reported that foam was an effective, safe, and minimally invasive endovenous treatment for varicose veins with a low rate of complications. The most complete book on sclerotherapy was written by a team of editors in 2007.

**Cyanoacrylate glue ablation**

A new nonablative procedure that intravenously delivers a cyanoacrylate adhesive mixture has been developed to improve some of the limitations of radiofrequency ablation, endovenous laser ablation, and sclerotherapy ablation. Upon intravascular injection, the cyanoacrylate adhesive rapidly solidifies via a polymerization reaction and results in an inflammatory reaction in the vein wall.

The disposable Sapheon Closure System includes 4 mL of Sapheon Cyanoacrylate Adhesive (SCA) and a Sapheon delivery system (Figures 5 and 6). The Sapheon delivery system consists of a 7F-introducer sheath/dilator, a 5F-delivery catheter, a 3 mL syringe, and a dispenser gun. The hydrophobic 5F-delivery catheter has a novel configuration with air-filled microchannels to enhance sonographic visibility. The dispenser gun will deliver 0.08 to 0.16 mL of SCA with each trigger pull. Access to the great saphenous vein is achieved by applying the Seldinger technique, which uses a standard micropuncture kit under ultrasound localization. The Sapheon introducer sheath and dilator is advanced to the saphenofemoral junction over a 0.035 J guide wire. The cyanoacrylate adhesive is extracted from its glass vial and loaded into a syringe, which is then attached to the 5F delivery catheter. The combined syringe and catheter are connected to a dispenser gun. The catheter is then primed by advancing the glue with the dispenser gun to within 3 cm of the catheter tip. To prevent thrombus extension through the saphenofemoral junction, the hydrophobic delivery catheter is placed approximately 5 cm below the saphenofemoral junction. The saphenofemoral junction is manually compressed with the ultrasound transducer and the proprietary adhesive is delivered using the Sapheon delivery system using two injections at 1 cm intervals. Compression of the saphenofemoral junction and the delivery site is maintained for 3 minutes. The adhesive is delivered at 3 cm intervals through the remainder of the target vein using 30 seconds of compression for each subsequent delivery of adhesive (Figure 6). The last injection site is 2 to 4 cm from the entrance site to prevent the glue from migrating outside the vein. After venous closure is confirmed by ultrasound imaging, the catheter is removed and compression is applied to the catheter entry site until hemostasis is achieved. A single adhesive bandage is applied; neither compression stockings nor compression bandages are used. This protocol has been described in details in two articles. Postoperative complications were minimal.
Almeida et al reported a series of 38 patients treated for great saphenous vein incompetence. Postoperative side effects included a thread-like thrombus or glue extension across the saphenofemoral junction (21.1%), which resolved at 3 months, transient thrombophlebitis (16%), and hyperpigmentation (2.4%). In another series including 43 great saphenous veins and 22 small saphenous veins, thrombophlebitis of the great saphenous vein occurred 4 times. The primary potential advantage with this new technique is that it does not require tumescent anesthesia and patients do not need postoperative compression stockings.

Mechanochemical ablation

Recently, a new hybrid mechanochemical device (ClariVein®) has been developed. Mechanochemical endovenous ablation (MOCA) achieves venous occlusion by utilizing a wire within the lumen of the vein that rotates at 3500 rpm, which abrades the intima and causes venospasms, thereby increasing the efficacy of the sclerosant (Figures 7 and 8). A liquid sclerosant (sodium tetradecyl sulfate or polidocanol) is concomitantly infused through an opening close to the distal end of the catheter near the rotating wire. These two modalities—mechanical and chemical—achieve venous occlusion results equal to endothermal methods. The system includes an infusion catheter, motor drive, stopcock, and syringe. The dispersion wire extends through the catheter lumen and it is connected to an interface cartridge unit for connection to the 9V DC battery of the motorized handle unit on the proximal end, which controls wire rotation. The handle unit also provides a grip and syringe holder to facilitate physician-controlled infusion. The wire and the catheter sheath are inserted percutaneously into the vein under site anesthesia while the patient is in a reversed Trendelenburg position. The catheter sheath is retracted to expose the wire tip, which is positioned 2 cm from the saphenofemoral junction. The patient is then rotated into a flat position for the remainder of the procedure. The catheter motor is turned on and the catheter is pulled down the vein at a rate of approximately 1 to 2 mm/second, while the wire rotates and the sclerosing agent is infused. After removal of the catheter, occlusion of the great saphenous vein and patency of the common femoral vein is checked by duplex ultrasound.
The advantages of this hybrid system are claimed to be standard percutaneous access, endovenous treatment, local anesthesia only (without the need for tumescent anesthesia), and a short procedure time. Since the system does not use thermal energy, the potential for nerve damage is minimized. Compression is applied for 2 weeks without restricting the patient’s activity.29

In a small series of 25 patients presenting with great saphenous vein incompetence, minor postoperative complications were identified, including localized ecchymosis at the puncture site in 9 patients and transient thrombophlebitis of distal tributaries in 4 patients.30 In a series of 50 patients presenting with small saphenous vein incompetence, minor postoperative complications were identified, including localized ecchymosis induration around the puncture site (12%) and transient thrombophlebitis of the treated vein (14%).31

Pelvic and ovarian vein embolization

When varicose veins are fed by incompetent pelvic and ovarian veins through the pelvic floor, which may or may not be related to left renal or iliac vein compression, embolization of the refluxive veins by coils and sclerosing agents is a minimally invasive method. Nevertheless, when reflux is related to iliac vein compression iliac stenting, another noninvasive technique, is the first-line treatment.32,33

Outcomes after operative treatment

Randomized controlled trials (RCTs) are very good tools for comparing the results of the various operative treatments for varicose veins.34,35 Yet, before drawing definitive conclusions on any of these procedures, an accurate publication analysis is mandatory as RCTs often contain hard-to-identify bias. For example, the short-term results of a procedure greatly depend on the type of anesthesia performed during varicose vein ablation (local tumescent anesthesia or general anesthesia).36 In the absence of RCTs for evaluating a procedure, case series are considered even though they provide a weaker level of evidence. Well-designed meta-analyses can provide valuable information for clinicians. By combining RCTs, meta-analyses increase the sample size, and thus, the power to study the results of a given procedure. Study outcomes are usually divided into the following 3 categories: (i) postoperative outcomes (<1 month); (ii) short- to mid-term outcomes (1 month to 3 years); and (iii) long-term outcomes (>3 years for RCTs and >5 years for case series. Nevertheless, this review’s outcome analysis has been divided into two parts: (i) postoperative and mid-term outcomes and (ii) long-term outcomes.

Postoperative and mid-term outcomes

Open surgery

Classic open surgery has been compared with conservative treatment both in C2 and C5-C6 patients (Tables I.1 and I.2).37-48 In addition, classic open surgery has been compared with open surgery variants
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### Operative procedures

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Table I. Randomized controlled trials, case series, and meta-analyses comparing operative procedures for the treatment of primary superficial vein incompetence.

For more information on the trials, please go to www.phlebolymphology.org.

Abbreviations: CHIVA, Cure Hémodynamique de l’insuffisance Veineuse en Ambulatoire (Conservative ambulatory Hemodynamic management of Varicose veins); EMA, endovenous microwave ablation; EVLA, endovenous laser ablation; GSV, great saphenous vein; HL, high ligation; RFA, radiofrequency ablation; SEPS, subfascial endoscopic perforator surgery; SFJ, saphenofemoral junction; UGFS, ultrasound-guided foam sclerotherapy.
Varicose vein ablation: navigating the treatment options - 2

(Tables I.3 and I.4), such as cryostripping\textsuperscript{49,50} and tributary-powered phlebectomy\textsuperscript{51-55}—techniques that are only rarely used in current practice. Some RCTs (Table I.5)\textsuperscript{4,56-68} provide interesting information on how cryostripping influences nerve damage,\textsuperscript{56,63} the short- and long-term outcomes according to the procedure used,\textsuperscript{58,64,67} the results following saphenofemoral junction ablation and ligation\textsuperscript{4,50,69} or associated perforator ablation.\textsuperscript{61} The RCTs comparing classic open surgery with other ablative procedures are more interesting and are shown in Tables I.6 to I.15.\textsuperscript{70-119} Additionally, the CHIVA method is performed under local anesthesia when other open surgery techniques need spinal or general anesthesia, and as a result, CHIVA shortens the length of the hospital stay (Table I.6).\textsuperscript{70-71}

All RCTs that compared the short-term results of classic open surgery with radiofrequency ablation, endovenous laser ablation, endovenous steam ablation,\textsuperscript{115} endovenous microwave ablation, ultrasound-guided foam sclerotherapy (UGFS), and high ligation with tributary phlebectomy concluded that both endovenous procedures and high ligation with tributary phlebectomy are less painful than classic open surgery and these procedures shorten the time required before returning to normal activity. Sensory impairment and ecchymosis are less severe with endovenous microwave ablation than open surgery, even though endovenous microwave ablation causes skin burns, 10\% of which are related to slow probe withdrawal or using energy that is too high (Table I.14).\textsuperscript{16} However, when modern open surgery is performed under local anesthesia (unfortunately by very few teams), it is as effective postoperatively as any endovenous procedure.

Endovenous procedures

Endovenous procedures have been widely studied and compared with open surgery and other endovenous procedures.

Thermal ablation

Radiofrequency ablation. Radiofrequency ablation has been compared with open surgery, cryostripping, invagination stripping, endovenous laser ablation, and ultrasound-guided foam sclerotherapy (Tables I.7, I.12, I.16, and I.17).\textsuperscript{72-92,113,114,120-124} Studies of endovenous laser ablation using bare fibers vs radiofrequency ablation favored the latter since it is less painful and results in less ecchymosis. However, it is now acknowledged that radial fibers, which are currently used, provide better postoperative results than bare fibers.\textsuperscript{125} No differences in efficacy and undesirable effects were observed between radiofrequency ablation and ultrasound-guided foam sclerotherapy in a 4-arm study.\textsuperscript{113,114} At a 1-year follow-up, redo operations were less frequent after radiofrequency ablation compared with deleted or synchronized ambulatory incompetent tributary avulsion (Table I.18).\textsuperscript{126}

Endovenous laser ablation. Treating varicose veins with endovenous laser ablation is a safe procedure in patients with active ulcers. Ulcers healed faster after endovenous laser ablation than in patients undergoing compression therapy alone and no ulcer recurrence occurred during a 1-year period posttreament.\textsuperscript{48} Endovenous laser ablation has been compared with open surgery, cryostripping, invagination stripping, endovenous laser ablation, and ultrasound-guided foam sclerotherapy (Tables I.8, I.11, I.12, I.16,
Endovenous laser ablation and cryostripping (Table I.29) \(^{127-129}\) were similarly effective in patients with varicose veins,\(^ {127,128}\) and endovenous laser ablation had a similar, but slightly higher, cost.\(^ {129}\)

When comparing ultrasound-guided foam sclerotherapy and endovenous laser ablation (Tables I.11 and I.25),\(^ {110-112,130-132}\) no differences at 3 months\(^ {130,131}\) were observed for clinical results or vein obliteration, but ultrasound-guided foam sclerotherapy outperformed endovenous laser ablation in cost, treatment duration, postoperative pain reduction, and recovery. At 15 months,\(^ {132}\) there were no differences in clinical results, but vein occlusion was higher with endovenous laser ablation. At a 1-year follow-up, Biemans et al found no difference between the ultrasound-guided laser ablation and ultrasound-guided foam sclerotherapy in complications and clinical results, but ultrasound-guided foam sclerotherapy resulted in lower occlusion rates.\(^ {110}\) Brittenden et al showed similar clinical efficacy between ultrasound-guided foam sclerotherapy and endovenous laser ablation, but endovenous laser ablation had fewer complications and ultrasound-guided foam sclerotherapy had lower ablation rates at both 6 weeks and 6 months posttreatment.\(^ {111}\) Tassie et al showed that endovenous laser ablation has the highest probability of being cost-effective compared with classic open surgery and ultrasound-guided foam sclerotherapy.\(^ {112}\)

The 1-year treatment success of high-dose endovenous laser ablation was not inferior to that of endovenous steam ablation. Several secondary outcomes (eg, painful legs, patients’ satisfaction, duration of analgesia, and limitations in daily life) were in favor of endovenous steam ablation (\(P<0.001\)).\(^ {20}\)

Data from ten RCTs on endovenous laser ablation variants (Table I.20)\(^ {12,125,133-142}\) show that: (i) below-knee endovenous laser ablation was not associated with saphenous nerve injury;\(^ {136}\) (ii) lower postoperative pain and better Venous Clinical Severity Scores (VCSS) were obtained with radial fibers compared with bare fibers\(^ {125}\) or tulip fibers;\(^ {12}\) (iii) cold tumescent anesthesia had fewer side effects and a reduction in analgesic intake than warm tumescent anesthesia;\(^ {138,139}\) and (iv) symptom intensity was lower and quality of life better when compression was applied for 2 to 7 days posttreatment.\(^ {141}\)

**Chemical ablation**

**Sclerotherapy.** Postoperative, short-term, and mid-term results are difficult to compare because many different protocols and outcome criteria were used (Tables I.10 to I.12).\(^ {99-114}\) RCTs on variants of sclerotherapy provide some data on postoperative course and short- or mid-term outcomes.\(^ {143-157}\) Foam sclerotherapy provides better results than liquid sclerotherapy (Table I.22),\(^ {143-148,156,157}\) and occlusion rates are similar when using either a 1% or 3% polidocanol foam solution (Table I.23).\(^ {149-152}\) The use of postoperative compression does not influence the percentage of patients with side effects after ultrasound-guided foam sclerotherapy (Table I.25).\(^ {153-155}\)

**Glue.** No RCTs evaluating glue vs other procedures have been conducted, but a case series has reported good results at a 2-year follow-up—occlusion rates were 92% and a significant improvement in VCSS was observed.\(^ {27}\)
Mechanochemical ablation

There are no RCTs for ClariVein®, but case series are available.29–31 At a 6-month follow-up, the occlusion rate was 96% and the VCSS improved in a series of patient presenting with saphenous vein varices.29 In the case series by Boersma et al on patients who underwent short saphenous vein ablation, the occlusion rate at 1 year was 94% and the VCSS improved.31

Long-term outcomes

Clinical parameters

PREVAIT

The term PREsence of Varices After operative Treatment (PREVAIT) was adopted in the VEIN-TERM transatlantic interdisciplinary consensus document.158 PREVAIT is a frustrating problem for both the patients with varicose veins and the physicians who treat these varicose veins. Recurrent Varices After Surgery (REVAS) have been previously compared with classic open surgery.159

Severity scores

Three severity scores—VCSS, Venous Segmental Disease Score (VSDS), and Aberdeen Varicose Vein Questionnaire (AVVQ)—are used in the literature to assess treatment success rates. VCSS is a very good tool for evaluating the treatment of complicated varices, but it is less informative for uncomplicated C2 patients.160,161

Generic and specific health-related quality of life questionnaires

Many health-related quality of life questionnaires have been used, including AVVQ, the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ), and the Specific Quality of Life and Outcome Response-Venous (SQOR-V), and the results have been compared with anatomic, hemodynamic, and clinical outcomes before and after operative treatment.162 Patient-Reported Outcome Measures (PROMs) are new and very promising tools.163

Instrumental investigation measurements

These measurements rely on occlusion rates and hemodynamic function. It has been clearly identified that the correlation between clinical and investigational parameters is far from perfect.

Information provided by RCTs

Open surgery vs high ligation and tributary phlebectomy

These procedures were assessed in 3 RCTs with 4, 5, and 11 years of follow-up68,69,116–119 and there were no differences in clinical outcomes. More redo surgery was performed in the group with high ligation and tributary phlebectomy, but preoperative and postoperative investigations were outdated in both groups.
Open surgery vs CHIVA

CHIVA was compared with classic open surgery in 2 RCTs with 5 and 10 years of follow-up (Table I.6). Both RCTs favor CHIVA in terms of PREVAIT reduction, but bias was identified to weaken the authors’ conclusions.

Open surgery vs radiofrequency ablation

Only one RCT comparing long-term outcomes (3-year) of open surgery with radiofrequency ablation is available and there was no difference in clinical results between the two groups, but the Closure catheter used was older and less efficient than the ClosureFAST catheter.

Open surgery vs endovenous laser ablation

At a 5-year follow-up, a RCT comparing endovenous laser ablation with open surgery found no difference between the 2 groups in persistent reflux, PREVAIT, redo treatment, VCSS, and generic and specific health-related quality of life scores. In this trial, open surgery was minimally invasive and the endovenous laser ablation procedure used a bare fiber with a 980-nm diode laser and a stepwise laser withdrawal.

Sclerotherapy vs various open surgery procedures

Belcaro et al reported two series with long-term follow-up data, but no conclusive results were obtained. The RCT comparing ultrasound-guided foam sclerotherapy complemented by high ligation with open surgery at a 3- to 5-year follow-up was more informative, showing that the treatment was equally effective in both groups, which was demonstrated by improvements in the VCSS, VSDS, and the generic health-related quality of life scores. At 5 years posttreatment, the AVVQ was significantly better in the open surgery group.

Information provided by case series

Open surgery

The most documented outcomes are provided by classic open surgery, but most studies are retrospective. In a 34-year follow-up study, varicose veins were present in 77% of the lower limbs examined and most were symptomatic—58% were painful, 83% had a tired feeling, and 93% showed a reappearance of edema. In two prospective studies concerning classic open surgery are available with a 5-year follow-up. In both studies, patients were preoperatively investigated with duplex scanning and treated by high ligation, saphenous trunk stripping, and stab avulsion. In the Kostas et al series, 28 out of 100 patients had PREVAIT after 5 years, where the recurrent varices mainly resulted from neovascularization (8/28, 29%), new varicose veins as a consequence of disease progression (7/28, 25%), residual veins due to tactical errors (eg, failure to strip the great saphenous vein (3/28, 11%), and complex patterns (10/28, 36%).

In the van Rij series, 127 limbs (CEAP class C4-C6) were evaluated postoperatively by clinical examination, duplex scanning, and air plethysmography. At the clinical evaluation, recurrence of varicose veins was progressive from 3 months (13.7%) to 5 years (51.7%). In line with clinical changes, a progressive deterioration in venous function was measured by air plethysmography and reflux recurrence was assessed by duplex scanning. These two studies showed that recurrence of varicose veins after surgery is common,
even in highly skilled centers. Even if the clinical condition of most affected limbs after surgery improved compared with before surgery, progression of the disease and neovascularization are responsible for more than half of the recurrences. Rigorous evaluation of patients and assiduous surgical techniques might reduce the recurrence resulting from technical and tactical failures.

Other procedures

A 5-year follow-up of a large series of patients treated with radiofrequency ablation using a Closure plus catheter showed that vein occlusion and absence of reflux were present in 87.2% and 83.8% of patients, respectively. Symptoms, including pain, fatigue, and edema, significantly improved compared with preoperative status. The rate of PREVAIT progressed from 6 months (7.7%) to 5 years (27.4%).167 Currently, no long-term results are available for Glue and ClariVein®.

Information provided by meta-analyses

Since 2009, six meta-analyses on operative treatment of primary varicose veins by open surgery, radiofrequency ablation, endovenous laser ablation, and ultrasound-guided foam sclerotherapy were identified—all produced similar conclusions.168-173

Final remarks concerning outcomes after operative treatment

The immediate postoperative course, including side effects, recovery time, and convalescence, is better in all other procedures compared with classic open surgery, but this point is questioned if modern and minimally aggressive open surgery is used. No differences in recurrence between classic open surgery compared with radiofrequency ablation and endovenous laser ablation are present at the mid- or long-term follow-up. PREVAIT is more frequent after ultrasound-guided foam sclerotherapy compared with other mentioned procedures, but PREVAIT can be easily and effectively treated with redo ultrasound-guided foam sclerotherapy.

Operative treatment indications

According to CEAP class and instrumental investigations

In patients with primary superficial reflux who are classified as C2, indications for operative treatment rely on patient complaints, such as symptoms and cosmetics, and the extent and size of the varices. For patients in the C3 to C6 classes, operative treatment must be considered in all cases, except for the usual contraindications. However, in all clinical classes, nonvenous causes must be identified because venous symptoms are not pathognomonic and some signs, including edema and ulcers may be due to other etiologies. In the presence of axial deep primary reflux combined with primary varices, varicose veins must be treated first. However, we know that, in about 5% of patients, axial deep primary reflux is not corrected by varicose vein ablation and its persistence is responsible for varices recurrence.174,175

When incompetent perforators are associated with primary varices, do they need to be treated in the same session? As no RCTs have compared the outcomes after varicose vein ablation with perforator
ablation + varices ablation, no evidence-based information is available. Nevertheless, we know that, in half of these patients, incompetent perforators are no longer identified after varices ablation. To summarize, perforator ablation can be reserved for patients with persistent incompetent perforator vessels, abnormal hemodynamic parameters, or continued symptoms and/or signs (C4b-C6) after superficial ablative surgery. Nevertheless, one RCT favors treating perforators in C6 patients to prevent ulcer recurrence (Table I.28).

Operative treatment indication in PREVAIT patients

PREVAIT represents a particular situation in terms of indication. Managing patients with PREVAIT varies according to the clinical situation. Patients attending a routine follow-up, who are either asymptomatic or symptomatic, and possibly complaining of recurrences are managed differently than symptomatic patients who are complaining of cosmetic problems and presenting with complicated varices (C3-C6). A consensus document agrees that ultrasound-guided foam sclerotherapy is the first-line treatment in almost all cases, except in patients presenting with varicose veins of the lower limbs that are fed by pelvic refluxive veins. The European guidelines for sclerotherapy assigned a grade 1B to this procedure. In the absence of RCTs, this recommendation is based on case series.

Operative treatment choice

In practice, the choice of the procedure is frequently not made on evidence-based data, but on other factors, such as: (i) personal mastery of the different techniques—practitioners will favor the procedures they have mastered; (ii) coverage/reimbursement by the health services/health insurance, which varies from country to country; (iii) the patient’s choice, which is influenced by possible postoperative problems, recovery time, time off work, the procedure that provides the easiest control of recurrences, and information from friends, literature, or the internet.

Guidelines

Recommendations from five guidelines are summarized in Table II. The guidelines of the Society for Vascular Surgery/American Venous Forum (SVS/AVF) were published in 2011. Most recommendations remain valid, but are not fully applicable in Europe. The SVS/AVF guidelines were analyzed by a European team. In 2013, the European Guide for Sclerotherapy was available, giving much information on sclerotherapy, including practical information. In 2014, the European Venous Forum (EVF) and the International Union of Angiology (IUA) published a guidelines document on the management of chronic venous disorders. The International guidelines on endovenous thermal ablation were published in 2015. This consensus document also provides many technical details. The same year, the European Society for Vascular Surgery (ESVS) endorsed guidelines on the management of chronic venous disease.

Most of these guidelines used the Guyatt grading scheme, which classifies recommendations as strong (grade 1) or weak (grade 2), according to the balance among benefits, risks, burdens, cost, and the degree of confidence in the estimates of benefits, risks, and burdens. It classifies quality of evidence as high (grade A), moderate (grade B), or low (grade C) according to factors, such as study design, consistency of the results, and directness of the evidence. Only the ESVS guidelines used the European Society of Cardiology’s
<table>
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<tr>
<th>Operative procedures</th>
<th>SVS/AVF\textsuperscript{186}</th>
<th>EVF/IUA\textsuperscript{187}</th>
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<tr>
<td>Classic open surgery</td>
<td>GSV 2B*, SSV 1B*</td>
<td>2A*</td>
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<td>Modern surgery</td>
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<td>1B*</td>
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<td>CHIVA</td>
<td>2B*</td>
<td>NG</td>
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<tr>
<td>ASVAL</td>
<td>2C*</td>
<td>NG</td>
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<td>EVLA or RFA</td>
<td>1B*</td>
<td>1A*</td>
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<td>Glue</td>
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<td>UGFS</td>
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<td>Thermal ablation vs</td>
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<td>UGFS (GSV)</td>
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<td>NG</td>
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<td>Thermal ablation vs</td>
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<td>NG</td>
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<td>Surgery for PREVAIT</td>
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<tr>
<td>UGFS for PREVAIT</td>
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<tr>
<td>Endovenous thermal ablation for PREVAIT</td>
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Table II. Recommendations for operative procedures for the treatment of superficial refluxing veins from the recent guidelines.

\textsuperscript{*}Guyatt’s grading\textsuperscript{190}

\textsuperscript{**}Grading system of the European Society of Cardiology\textsuperscript{191}

Abbreviations: ASVAL, Ablation Sélective des Varices sous Anesthésie Locale (Ambulatory Selective Vein Ablation under Local anesthesia); AVF, American Venous Forum; CHIVA, Cure Hémodynamique de l’Insuffisance Veineuse en Ambulatoire (Conservative ambulatory Hemodynamic management of Varicose veins); EGS, European Guide for Sclerotherapy; EVLA, endovenous laser ablation; ESVS, European Society of Vascular Surgery; ETAV, Endovenous Thermal Ablation for Varicose Vein Disease; EVF, European Venous Forum; GSV, great saphenous vein; IUA, International Union of Angiology; IUP, International Union of Phlebology; NG, not graded; PREVAIT, PREsence of VArices after operatIve Treatment; SSV, small saphenous vein; SVS, Society of Vascular Surgery; UGFS, ultrasound-guided foam sclerotherapy.
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<table>
<thead>
<tr>
<th>ESVS (^{189})</th>
<th>ETAV/IUP (^{188})</th>
<th>EGS (^{24})</th>
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<td>I B**</td>
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grading system. For each recommendation, the letter A, B, or C marks the level of current evidence. Weighing the level of evidence and expert opinion, every recommendation is subsequently marked as either class I, IIa, IIb, or III. The lower the class number, the more proven the efficacy and safety of a certain procedure.191

In 2013, the National Institute for Health and Care Excellence (NICE) published a document on varicose veins of the leg,192 where the recommendations for people with confirmed varicose veins and truncal reflux were as follows:

- First, offer endothermal ablation (radiofrequency ablation for varicose veins [NICE interventional procedure guidance 8]193 and endovenous laser ablation for the long saphenous vein [NICE interventional procedure guidance 52]194).
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (see NICE interventional procedure guidance 440195).
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.
- If incompetent varicose tributaries are to be treated, consider treating them at the same time.192

Conclusions

Currently, there are a number of surgical options for treating varicose veins, but there is no definitive system for identifying which people will benefit the most from interventional treatment and no established framework for the diagnosis and management of varicose veins. Conversely, perioperative investigations are well stated and described. In a review of the randomized controlled trials on the treatment of varicose veins, the authors concluded that there are many treatment options available for the ablation of varicose veins, not solely thermal ablation.34,35 Operative treatment of primary varicose veins is currently performed using minimally invasive procedures, excluding spinal or general anesthesia. The problem is that the development of new procedures or devices is so rapid that when long-term outcomes are available, particularly for RCTs, the technique or material evaluated is frequently no longer used. Postoperative quality of life has improved, complications are far less frequent, and sick leave is shorter. The long-term frequency of PREVAIT is approximately the same for all techniques used, as long as the initial procedure has been correctly executed. To minimize the severity of PREVAIT, it is crucial to have regular patient follow-up and use ultrasound investigation to manage possible varices recurrence.
References


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Varicose vein ablation: navigating the treatment options

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