

Current Modalities in the Treatment of Varicose Veins

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ABSTRACT

Varicose veins is a very common disease pathology. An understanding of the nature and management of venous disease is critical to address this imbalance and improve the quality of patient's lives. They may have a myriad of presentation and clinical evaluation along with duplex scan helps in establishing the diagnosis and the exact site. Various different treatment modalities are available for the treatment of varicose veins. However, no one particular modality is the gold standard for every patient. This review focuses on the various available treatment options for varicose veins along with newer modalities.

Keywords: Treatment, Varicose Veins.

INTRODUCTION

Varicose vein is a common disease entity and the management of venous disease is a major cause of healthcare expense worldwide.^{1,2} Up to 40% of the adult population in resource rich countries have diseases of the veins of leg, this extraordinary prevalence along with the associated impairment in health-related quality of life make it very important area of surgical practice.^{3,4} A widespread appreciation of the growing prevalence and importance of chronic venous disease has driven a wave of research and innovation in venous diagnostics and treatment modalities. Optimal patient management involves a detailed holistic patient assessment, evaluation of patient expectations and minimally invasive, multimodal therapy to address underlying hemodynamic abnormalities and reduce venous hypertension. Surgical intervention has been revolutionized by the development of endovenous techniques which is associated with very high clinical outcome and cost-effectiveness.^{5,6} The adult prevalence of visible varicose veins is between 30% and 50%.⁷

PATHOPHYSIOLOGY

The underlying cause of venous disease is chronic venous hypertension. Persistent high venous pressure causes pathophysiological changes leading to the clinical manifestations

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of chronic venous disease. A common cause is superficial venous reflux secondary to vein valve incompetence, but other factors contributing to chronic venous hypertension may include deep venous reflux, venous outflow obstruction (post-thrombotic, non-thrombotic or extrinsic compression), calf muscle pump failure (usually due to ankle stiffness or poor calf muscle bulk), dependency or patient obesity.⁸

CLINICAL PRESENTATION

The patients with symptomatic varicose veins commonly report heaviness, discomfort and extremity fatigue. The pain is characteristically dull, does not usually occur during recumbency or early in the morning, and is exacerbated in the afternoon, especially after prolonged standing. Cutaneous burning, termed venous neuropathy, can also occur in patients with advanced venous insufficiency. Patients may have pruritis due to hemosiderin deposition in distal calf region.⁹ The clinical signs include presence of dilated tortuous subcutaneous veins, confined to Great saphenous vein and Short saphenous vein in approximately 60% and 20% of cases respectively.¹⁰ Large dilated veins may present around SFJ, prominent on standing and disappear when recumbent.

Venous symptoms correlate with severity of venous reflux on duplex imaging. The CEAP classification, a useful and widely used tool to describe a patient using Clinical, Etiological, Anatomical and Pathophysiological criteria. The clinical component of the CEAP classification is often used in isolation. It should be noted that the CEAP classification is a descriptive tool and is not intended for monitoring progression of disease or response to treatment. Other recognized scoring systems include the venous clinical severity score (VCSS) and venous disability score (VDS). In recent years, there has also been a growing interest in patient reported outcomes and quality-of-life scores, which are likely to be most useful for evaluating success after venous interventions.

INVESTIGATION

Tourniquet test and use of hand held Doppler have now largely been abandoned. There is good evidence to support the policy of duplex scan which is highly reliable imaging technique, give direct visualization of veins, functional and anatomical information also. Duplex scan reflects presence of reflux in the deep and superficial venous system, exact distribution and extent of reflux, presence of obstruction in deep venous system, presence of thrombus in superficial veins, an indication of pelvic source of reflux or obstruction

TREATMENT MODALITIES

With dramatic recent advances in the treatment of venous disease, a wide range of modalities are now available and an individual management strategy should be considered for each patient. This may involve using multiple treatment modalities and/or more than one treatment episode. For patients with bilateral varicose veins, opinion varies regarding the optimal approach (one-stage or multistage intervention). Patient preference should be considered and the treatment strategy adapted accordingly.

A. CONSERVATIVE OPTIONS, MEDICATIONS AND COMPRESSION

Even in an era of minimally invasive interventions, conservative measures or compression may be the most appropriate therapy in some patients, particularly those unsuitable for or unwilling to undergo a procedure. Specific groups where conservative therapy or compression may be preferred include pregnant patients; elderly patients with significant comorbidity; patients with mild symptoms, or symptoms that may not be due to venous disease; patients unwilling to accept the risks of surgical or endovenous interventions.

Conservative measures such as weight loss, limb elevation and reduced periods of standing may improve symptoms, but may be difficult to achieve for patients in full-time employment or those with young families.

Several venoactive drugs have been studied in patients with chronic venous disease. Commonly studied medications include micronised purified flavonoid fraction and suledoxide, with some promising clinical results. Small studies have suggested potential benefits with horse chestnut seed extract, although their use is limited.

Compression therapy has been used for the treatment of venous disease for centuries and remains the mainstay of management

for patients with venous ulceration. For patients with healed venous ulceration (CEAP C5), the use of elastic compression stockings has been shown to reduce the risk of recurrent ulceration. For patients with CEAP C2–C4 disease, stockings are prescribed frequently, but the evidence for benefit is less clear. Compression therapy is the mainstay of treatment for patients with chronic venous ulcers and may reduce symptoms of varicose veins and improve the patient's quality of life; prevention or slowing of disease progression. Compression therapy includes many different devices made of various materials, including graduated compression stockings, bandages, boots, and intermittent pneumatic compression devices. Therapies are generally divided into elastic and inelastic techniques based upon the extensibility (or stretch) of the material with which the device is made.

B. TRADITIONAL SURGERY FOR VARICOSE VEINS

Trendelenburg described ligation of the proximal GSV in 1890 and modifications of this technique have remained the mainstay of treatment for varicose veins for over a century. With the increasing popularity of minimally invasive, endovenous modalities, the proportion of patients treated with surgical stripping has declined in recent years.

C. AMBULATORY CONSERVATIVE HEMODYNAMIC MANAGEMENT OF VARICOSE VEINS (CHIVA)

The French acronym CHIVA (Cure Conservatriceet Hemodynamique de l'Insuffisance Veineuse en Ambulatoire) describes a minimally invasive, saphenous-sparing strategy first described in 1988 by Franceschi and colleagues. Haemodynamic surgery is based upon the premise that varicose veins arise secondary to a dysfunction in the venous drainage hierarchy, which normally allows venous flow to drain from tributaries, to the truncal vein, to the deep venous system. The formation of pathological venovenous shunts allows reflux between the superficial and deep systems. The aim of CHIVA is to disrupt these shunts by interrupting the refluxing venous outlets without compromising the saphenous vein. The technique relies on precise preoperative anatomical and hemodynamic duplex mapping of the areas of reflux, allowing the operator to identify specific targets to ligate that will enable disconnection of the venovenous shunt and restoration of hierarchical venous drainage.¹¹

In experienced hands CHIVA is more effective than saphenous stripping, with reduced long-term recurrence. A retrospective comparison of CHIVA to EVLA reported significantly reduced pain scores, bruising and residual varicosities in the CHIVA group. There are currently no studies comparing CHIVA with RFA and it remains the preserve of specialist centers.

D. AMBULATORY SELECTIVE VARICES ABLATION UNDER LOCAL ANAESTHESIA (ASVAL)

ASVAL removes the venous reservoir by targeting superficial varicosities. Via this technique, multiple phlebectomies are performed on varices without intervening on the refluxing saphenous veins. Postoperative reduction in saphenous vein reflux, improvement in symptoms, with up to 88.5% of patients free from variceal recurrence on 4-year follow-up has been reported. 17 Isolated phlebectomies appear to improve venous

hemodynamics by reducing GSV reflux duration, peak velocity and diameter. Ten-year follow-up data of 360 limbs reveals absence of saphenous reflux in 64.4%, absence of clinical recurrence in 68.8%, absence of reintervention in 76.7% and functional improvement in 69.9% of cases.¹²

E. ULTRASOUND-GUIDED FOAM SCLEROTHERAPY (UGFS)

Sclerotherapy is a type of chemical ablation, where the sclerosant acts on the vein wall to induce fibrosis and closure of the lumen. Three broad categories of endovenous sclerosant are available: detergent (sodium tetradecylsulphate [STS], polidocanol), osmotic (hypertonic saline, used in Europe and the USA), chemical irritant (chromated glycerine).¹³ In the UK, STS and polidocanol are in popular use, although the latter is unlicensed. In general, larger veins require a stronger concentration of sclerosant. The conversion of liquid sclerosant into foam by mixing it with air or carbon dioxide (Tessari method) has gained popularity in recent years. This approach has the advantage of increasing the potency and volume of the sclerosant, as well as making it echogenic. For the treatment of truncal veins (such as GSV or SSV), foam sclerosant is superior to liquid sclerosant.

F. TRANSILLUMINATED POWERED PHLEBECTOMY SYSTEM

Powered phlebectomy has been offered as an option to the traditional stab phlebectomy for the treatment of branch varicosities. The TRIVEX System (Smith and Nephew, Inc, Endoscopy, Andover, MA, USA) is described as a powered phlebectomy system combined with a transilluminator and tumescent anesthesia infuser.¹⁴ The transilluminator cannula is first inserted through a small (2–3 mm) incision, and tumescent anesthesia is infused into the subcutaneous space adjacent to the target varicosities. The powered resector cannula is then inserted through a second small incision into the subcutaneous plane adjacent to the target vein but slightly more superficial than the transilluminator cannula. After resection of the varicosity, which is much like a directed liposuction, tumescent anesthesia is again infused to prevent hematoma formation. The reported complications of powered phlebectomy include ecchymosis, pain, hematoma, infection, swelling, paresthesia, and hyperesthesia.

G. ENDOVENOUS THERMAL ABLATION

Endovenous thermal ablation is a technique that uses a laser or high-frequency radio waves to create intense local heat in the varicose vein or incompetent vein, heat is directed through a catheter to close up the targeted vessel. This treatment closes off the problem veins but leaves them in place so there is minimal bleeding and bruising. Compared with ligation and stripping, many patients find that endovenous thermal ablation results in less pain and a faster return to normal activities, with similar cosmetic results.¹⁵

1. Radiofrequency Ablation (RFA):

RFA is a technique by which thermal energy (85–120 °C) is employed to seal the incompetent vein via heat damage. The vein is cannulated under ultrasound guidance using the Seldinger technique and the endovenous catheter is inserted to approximately 2 cm from the junction between the superficial and deep systems. Tumescent anaesthesia is instilled under

ultrasound guidance with the aim of surrounding the vein, separating it from the surrounding structures in order to avoid thermal injury and compressing it on the catheter to maximize energy transfer to the vein wall, reduce power requirements and providing pain relief. Once adequate coverage is obtained and the temperature at the probe tip is reduced (25 °C) the RFA system can be activated and treatment started. The patient should be placed in the Trendelenburg position and extrinsic compression can be used to ensure vein wall/ catheter apposition to maximize treatment efficacy. The catheter tip is active during treatment, heating the vein segment over 20 seconds at a temperature of 120°C. Depending on the system used, for a 7 cm catheter tip, the treatment rate is 0.35 cm/s, with visual and auditory feedback to notify when the treatment is complete. The catheter has an inbuilt feedback mechanism that enables delivery of consistently high temperatures and ongoing ablation by adjusting energy delivery. Usually two rounds of treatment are given in the segment closest to the junction to ensure an adequate seal. Subsequently, the catheter is pulled back after each treatment.

The early RFA systems required continuous pullback at a rate of 3 cm/min resulting in a treatment rate of 0.05 cm/s, making it a longer procedure with potentially less consistent ablation as the rate of continuous drawback could be difficult to gauge. The new generation catheters are superior with respect to reduced rates of DVT and obliteration of the GSV. A meta-analysis comparing open and endovascular treatment of varicose veins found that at 3 months there was no difference in recurrence rates between open surgery, EVLA or RFA, although endovenous ablation conferred a faster return to work.¹⁵ Prospective randomized studies revealed that RFA has comparable results to high-tie and stripping with regards to recurrence both in the short, mid and long-term.¹¹ RFA was better tolerated by patients and associated with a quicker recovery period and improved quality of life scores. RFA has been shown to be a minimally invasive, safe and effective procedure for the treatment of varicosities.

When consenting patients for this procedure, they must be warned of the risk of bleeding, infection, nerve damage (due to direct thermal injury to the saphenous/sural nerve) and DVT. Risks specific to RFA are difficulty with cannulation, guidewire passage and catheterization through tortuous segments, superficial burns, pigmentation and phlebitis. Bipolar radiofrequency induced thermotherapy is another type of endothermal ablation. The main differences are that the vein is heated to lower temperatures (85 °C) and the system requires a continuous pull-back technique. Its efficacy has been demonstrated in the incompetent saphenous veins, particularly when performed by a skilled operator.

2. Endovenous Laser Ablation (EVLA)

It uses laser (light amplification by stimulated emission of radiation) and fibre-optic catheter technology to generate thermal energy. It acts by heating the vein wall and blood, reaching temperatures of up to 800°C; this is not dependent on the laser wavelength itself but on the speed of pullback and on the power supplied. Unlike RFA, the catheter does not have a feedback mechanism to maintain a constant temperature. To prevent under- or over-treatment it is important to maintain constant pullback at a rate of 1 cm every 5 seconds (0.2 cm/s); using 14W power the energy delivery is 70 J/cm. The procedure for EVLA is the same as for RFA in terms of vein catheterization and use of tumescent anaesthesia.

EVLA is effective for saphenous vein surgery, with impressive clinical outcomes that are at least comparable to, if not better than open surgery.¹⁶ As with RFA, patients tend to prefer the endovenous option, with improved satisfaction, reduced postoperative pain and quicker return to work. Two-year follow-up has revealed durable results. EVLA short-term outcomes are equivalent to high-tie and ligation, with reduced postoperative pain and bruising. RFA and EVLA have similar outcomes, with >90% GSV occlusion rates.¹⁶ A recent meta-analysis reported similar outcomes in terms of safety, efficacy, quality of life and occlusion rates, although RFA may have a reduced risk of overall complications.¹⁷ EVLA can be used in the GSV and SSV, as well as for branch varicose veins. Complications include bruising, induration, numbness, thermal burns and superficial thrombophlebitis. It is more expensive than conventional surgery, requiring additional equipment in the form of eye goggles, fibre-optic catheters, micropuncture kit and a protected room. The catheters are very small (0.5-1 mm diameter) and can be difficult to navigate up a tortuous vein. The rate of post-operative DVT is 0.5%. Overall, RFA and EVLA have been demonstrated to be more cost effective than open surgical techniques for the treatment of varicose veins with similar improvement in quality of life. NICE, hence, recommends their use as first line treatment for truncal vein incompetence.

3. Steam Therapy (Steam Varicose System: TM)

In endovenous steam ablation (EVSA) a catheter delivering pulsated steam reaching temperatures of 120°C causes endothelial destruction and fibrosis. A pilot study revealed a 65% occlusion rate at 6 months, with the remaining 35% showing small-segment recanalization that was not clinically relevant. A subsequent study of 20 patients with GSV incompetence demonstrated occlusion rates of 96% at 6-month follow-up, with most patients returning to normal activity within 3 days. A 2014 randomized controlled trial comparing EVLA with EVSA in 227 limbs revealed non-inferiority of EVSA in terms of truncal occlusion (>90%) and quality of life measures at 1 year. Interestingly, EVSA patients reported reduced pain following the procedure and greater procedural satisfaction. Further studies comparing steam to other types of endothermal ablation are awaited.¹⁶

4. Endovenous Microfoam Sclerotherapy/Varithena

Foam sclerotherapy refers to administration of a liquid sclerosant that has been mixed with gas to produce a foam preparation. While foam can be manually compounded via the Tessari technique, Varithena is a pharmaceutical grade, low-density, injectable Polidocanol (POL) microfoam that is formulated via a proprietary canister system. In the proprietary Varithena formulation, POL, the sclerosant agent, is mixed with oxygen, carbon dioxide, and an ultra-low amount of nitrogen within a canister to produce a 1% POL microfoam solution. POL foam displaces blood instead of mixing with it, maximizing endothelial surface contact area and time. POL disrupts the osmotic barrier of the venous endothelium, leading to vessel wall damage and vasospasm. As a result, the interior surface of the vein becomes thrombogenic, leading to thrombosis and occlusion. The occluded vein is eventually replaced by fibrous connective tissue.¹⁷

5. Mechanochemical Ablation (MOCA)/ClariVein®

MOCA refers to a hybrid method of endovenous ablation utilizing both mechanical abrasion via a rotating wire tip and simultaneous

chemical ablation via injection of liquid sclerosant, either sodium tetradecyl sulfate (STS) or POL. The MOCA technique combines mechanical damage to the endothelium caused by the rotating wire with the chemical damage caused by the infused sclerosant agent. The mechanical damage promotes coagulation activation by damaging the endothelium; induces local vasospasm and decreases the diameter of the treated vein; promotes better distribution of the sclerosant within the vascular lumen; and increases the action of the sclerosant agent by mechanical damage to the endothelium.¹⁸ The liquid sclerosant further damages the lipid cell membrane of the endothelium, ultimately resulting in occlusion and fibrosis of the treated vein.

H. CYANOACRYLATE EMBOLIZATION/VenaSeal™ Saphen CLOSURE SYSTEM

Cyanoacrylates are liquid adhesives that have been safely used in numerous medical applications including brain arteriovenous malformation embolization, retinal repair, and wound and tissue closure.¹⁹ The VenaSeal™ Saphen Closure System utilizes a proprietary cyanoacrylate formulation that is delivered endovenously to treat varicose veins.

The proprietary VenaSeal adhesive is n-butyl-2-cyanoacrylate based and formulated to increase viscosity, decrease the rate of polymerization, and result in a flexible adhesive end product. Cyanoacrylate polymerizes in a cascade reaction upon contact with blood, creating an adhesive bond. The formed adhesive halts blood flow through the vein and the adhesive is eventually encapsulated in a fibrosis reaction to establish chronic occlusion.

In the VeClose trial comparing CAE and RF ablation, intraprocedural pain was self-rated by patients as mild and similar for both procedures. Less ecchymosis was present in the treated region at day 3 in the CAE group compared to the RF ablation group, presumably due to lack of tumescent anesthesia. Superficial thrombophlebitis was seen in 6% of the CAE group versus 3% of the RF ablation group.²⁰

TREATMENT OF RECURRENT VARICOSE VEINS

Up to a quarter of patients presenting with varicose veins have had previous superficial venous surgery. These patients present a unique management challenge as the patterns of venous reflux may be significantly more complex than for patients with primary venous disease. Patients should undergo detailed clinical assessment and comprehensive colour duplex imaging to map the pattern of superficial and deep venous disease. Attention should be paid to sites and reasons for recurrent superficial reflux (such as neovascularisation, incompetent perforating veins or pelvic sources of reflux). Redo groin surgery or popliteal fossa surgery is associated with an unacceptable risk of complications, including infection, seroma, DVT and nerve damage. Therefore, even for enthusiastic open vascular surgeons, endovenous interventions are widely considered the first line in the treatment of patients with recurrent varicose veins, particularly in the popliteal fossa.²¹

Endovenous interventions should be considered the first line for patients with recurrent varicose veins.

CONCLUSIONS

With a dramatic expansion in available treatment modalities, the management of patients with varicose veins has evolved rapidly in recent years. Endovenous thermal ablation procedures such as

endovenous laser and radiofrequency ablation are considered the gold standard and have largely replaced traditional surgery. Non-thermal endovenous procedures such as ultrasound-guided foam sclerotherapy, mechanochemical ablation and cyanoacrylate glue closure may also have a role. After a century of open surgery and vein stripping, the modern management of varicose veins involves the routine use of colour duplex imaging and delivery of a range of minimally invasive, effective and well-tolerated treatments, under local anaesthesia in an office-based setting.

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