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Varicosities of the lower extremity, new approaches: cosmetic or therapeutic needs?

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Summary

Varicose veins of the lower extremity (VVLE) are a frequently encountered vascular disorder in the general population. The general view that VVLE are a non-serious disease with primarily aesthetic impact is a common misconception, as the disease can have a significant negative impact on generic and disease-specific quality of life. Further, VVLE may be associated with potentially threatening clinical conditions, such as chronic venous ulceration, venous thromboembolism and haemorrhage from ruptured varicose veins.

In the case of symptomatic varicose veins, in the presence of advanced lower limb skin changes or when venous complications occur, a referral for dedicated evaluation by the vascular medicine specialist is recommended. The initial diagnostic test of choice to detect the extent of the varicose disease and to plan treatment is duplex ultrasound.

Traditionally, compression therapy, surgical high ligation and stripping of the truncal veins have been considered standard of care for VVLE. Driven by the aim to reduce surgical trauma and improve the long-term effectiveness, minimally invasive treatment options have been developed in the last two decades, namely endovascular vein ablation techniques (EVA). Endovenous laser ablation and radiofrequency ablation have been established as first-line treatments for varicose veins associated with axial reflux on the basis of the most recent international guidelines. For practical purposes and depending on the concrete clinical situation, the various EVA and surgical techniques are often combined, leading to multimodal varicose vein therapy management. Knowledge of the different techniques is of utmost importance for the vascular medicine specialist.

The purpose of this article is to provide an overview of the new EVA techniques and to elucidate the different therapeutic strategies for VVLE.

Key words: *varicose veins; venous disease; endovascular vein ablation; endovenous thermal ablation*

Background

Varicose veins are a manifestation of chronic venous dysfunction [1]. In a consensus statement from the American Venous Forum, varicose veins are defined as subcutaneous, usually tortuous and dilated veins, 3 mm or larger in diameter as measured in the upright position. The disease may involve the saphenous veins, saphenous tributaries or nonsaphenous superficial leg veins [2]. Varicosities can develop as sequelae of deep vein thrombosis or obstruction, superficial thrombophlebitis, arteriovenous fistula or venous malformation. However, in the majority of patients varicose veins develop in the setting of primary venous disease [3].

Varicose veins of the lower extremity (VVLE) are a frequently encountered vascular disorder in the general population with a reported prevalence ranging from 14 to 64%. The prevalence of the more advanced stages of VVLE, including trophic skin changes, ranges from 3.3 to 9.6% [4–8]. VVLE are typically associated with a certain risk factor profile including higher age, positive family history, overweight, pregnancy and daily activities associated with orthostasis [4, 7, 9]. In the course of the disease the superficial leg veins change in morphology and become varicose. The consequence of disease progression is ambulatory venous hypertension in the setting of reflux due to incompetent vein valves.

If appropriate management is not initiated, a series of changes in the skin and subcutaneous tissue occur as a result of the venous hypertension. These changes can include tissue oedema, skin hyperpigmentation, lipodermatosclerosis (induration caused by fibrosis of the subcutaneous fat), eczematous dermatitis, atrophy blanche (white scar tissue) or venous ulceration [10]. Moreover, protracted venous hypertension can cause secondary lymphoedema. More threatening complications include haemorrhage from a ruptured varicose vein [11] as well as superficial varicophlebitis with the possible development of deep vein thrombosis with or without pulmonary embolism [12]. Associated symptoms in patients suffering from varicose veins are itching, feeling of heaviness, tightness, swelling and pain after standing or sitting, and muscle cramps [9, 13, 14]. These symptoms are nonspecific [15], but can be suggestive of chronic venous disease, especially if they are exacerbated by warm weather or if they worsen during the course of the day, and are improved by raising the legs [1, 16]. The symptoms associated with VVLE can have a considerable negative impact on mental and physical health, potentially even decreasing quality of life [17–19]. Further, VVLE can interfere with activities of daily life and work, especially when long lasting activities are part of the daily routine. Treatment of varicose veins with surgery or endovenous ablation techniques improves symptoms and general quality of life, and these treatment options for VVLE are associated with high patient satisfaction [20–23].

Treatment of varicose veins

The first step in all patients with varicose veins is adequate education about the significance of varicose veins, the likelihood of progression of the illness, the possible complications and the treatment options. Recommendations should be given to the patient with regard to weight control, light to moderate physical activity, if possible avoidance of known risk factors and when to seek vascular specialist expert help [24]. In the case of symptomatic varicose veins, in the presence of advanced lower limb skin changes or in the presence of threatening complications, such as venous leg ulcer, thrombophlebitis or bleeding from superficial varicose veins, a more aggressive therapeutic approach is recommended [24]. The initial diagnostic test of choice to determine the extent of the varicose disease and for treatment planning is duplex ultrasound [3, 25–27].

Traditionally, the mainstay of varicose veins treatment included long-term elastic compression stockings or bandages, as well as surgical approaches, namely high ligation, crossectomy and stripping of the truncal veins, combined with phlebectomies of the tributaries. However, for several years surgical approaches have increasingly been replaced by minimally invasive endovascular vein ablation techniques, particularly endothermal methods such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA). This shift from surgical to endovascular techniques is also reflected in the latest international guidelines, developed by the Society for Vascular Surgery, the American Venous Forum, the UK National Institute for Health and Care Excellence (NICE) and the European Society for Vascular Surgery. The endothermal methods (EVLA, RFA) are now recommended in preference to surgical therapy for the treatment of the truncal vein [3, 24, 28]. The reason for the preference of the endothermal methods over surgery is the reduced morbidity, decreased pain levels, quicker recovery and faster return to normal activities. The efficacy profile of endovascular versus surgical techniques is at least comparable [3, 24, 28].

New therapeutic methods

In recent decades, novel minimally invasive procedures for the treatment of varicose veins of the lower extremity have been developed and continually optimised. These new procedures can generally be performed on an outpatient basis. In contrast to surgery, where the treated vein is commonly removed or dissected, with these new techniques the treated vein is left *in situ* and closed from inside (endovenous ablation) with the aid of a catheter or a cannula placed into the vein under ultrasound guidance. Thus, there is only a single small incision with a reduced risk of bleeding and bruising. Table 1 gives an overview of the main differences between crossectomy/stripping as open surgical technique and the endovascular vein ablation (EVA) procedures. Once the catheter is placed within the vein, the vein can be closed with either thermic energy or alternatively with a chemical substance (fig. 1). It is important to emphasise that for a given pathological situation, different endovenous and surgical (for example, mini-phlebectomy) techniques can be combined to achieve the best clinical outcome. Essential prerequisites for successful VVLE management are a good knowledge of the venous anatomy and pathophysiology, an awareness of the different therapeutic possibilities for treating varicose veins and advanced technical ultrasound skills. The main endovenous ablation techniques will be discussed in the next sections. Table 2 gives an overview of the differences between the various EVA techniques.

Endovenous thermal ablation

Endovenous thermal ablation (ETA) is a minimally invasive procedure which applies, at the tip of an intraluminal placed catheter, intense local heat-based energy, thereby destroying the vein wall and obliterating the vein lumen [29]. Another common feature of this outpatient based technique is so-called tumescent anaesthesia, which is performed with ultrasound-guided application of a large volume of diluted local anaesthetic and epinephrine. Besides improving tolerability of the procedure, the goals of tumescent anaesthesia are also the protection of the surrounding tissue from thermal damage and the reduction of the vein lumen, thereby increasing the efficacy of thermal delivery to the vein wall. The different types of ETA relate to the nature of the heating-source, namely EVLA, RFA and steam vein sclerosis (SVS).

Endovenous laser ablation

The heating source of EVLA is laser energy that is absorbed by the target tissue and converted into heat [30]. After cannulation of the target vein, a laser fibre is placed through a sheath of 1 to 2 mm in diameter near to the saphenofemoral or saphenopopliteal junction. Ultrasound guidance is used for precise placement. Tumescence anaes-

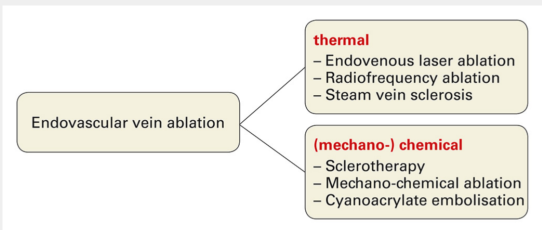

Figure 1

Overview of the different techniques of endovascular vein ablation.

thesia is applied and the laser treatment is conducted from proximally to distally. Histological studies have shown that the result of this acute thermic exposure is damage to the intima and the inner third of the media [31]. Three months after EVLA there is the endothelium is absent and an organised thrombus has formed in the lumen [32]. Laser systems have evolved significantly in the recent past. There has been a shift from bare fibres with shorter wavelength (810 to 1320 nm) to radial fibres with longer wavelength (1320 to 1550 nm). Radial fibres nowadays emit light at 360°, thus causing homogenous venous ablative changes. Another advantage of radial fibres compared with bare fibres is a lower incidence of skin bleeding and decreased pain, probably secondary to the fact that vein perforation is unlikely [33, 34]. The reported efficacy with the 1470 nm diode laser using radial fibres is high, with short-term (<1 year) ultrasonographically proven occlusion rates that vary between 91 and 100% [33–39], and mid-term ultrasound data after 1 year demonstrate that in the majority of cases the treated vein segment disappears completely [36]. The most common reported side effects are haematomas/ecchymoses and pain with or without induration in the region of the treated vein. These side effects are generally mild and self-limiting [40]. Phlebitis (<10%) and mostly transient par- and dysaesthesias (<10%) are less frequently reported [41]. Serious complications such as venous thromboembolism, skin burns and necrosis or wound infections are exceedingly rare [42].

Radiofrequency ablation

The heating source for RFA originates from a bipolar catheter, and temperatures of up to 100 °C (RFITT©) and 120 °C (ClosureFAST©) can be reached. The preparation and placement of the RFA catheter, the application of tumescence anaesthesia, and the ablation direction from proximal to distal are similar to EVLA. This endovenous ablation procedure is segmental, not continuous. The consequence is acute thermal damage to the endothelium, leading to obliteration of the treated vein. The efficacy of RFA is similar to that of EVLA with short-term (<1 year) occlusion rates that vary between 91 and 99.6% in the most recently published reports [43–50]. Long-term occlusion rates are as promising with 87.1% [51] and 91.9% [52], respectively,

Table 1: Overview of the differences between crossectomy/stripping and the endovascular vein ablation procedures. Note that some advantages and disadvantages are the authors' opinions with lack of clear evidence.

	Crossectomy/stripping	Endovenous vein ablation
Advantages	Vein removed Comparable efficacy to endovascular vein ablation Longstanding experience Very dilated veins can be treated	Vein obliteration Comparable efficacy to open surgery Outpatient setting Local or tumescence anaesthesia No femoral/popliteal incision Decreased post-procedural complications Reduced pain Quicker recovery (faster return to normal activities and work) Better quality of life during the recovery phase Ultrasound guided (direct visualisation of the treated vein) Anticoagulation and obesity are generally not a problem
Disadvantages	Usually inpatient setting (outpatient setting possible but challenging) Mostly spinal or general anaesthesia (local or tumescence anaesthesia possible in selected cases) Femoral/popliteal incision	Difficult to treat very dilated veins Inadequate for very tortuous veins (exception: sclerotherapy and steam vein sclerosis) Catheter costs

Table 2: Overview of advantages and disadvantages between the different types of endovascular vein ablation.

	Specific advantages	Specific disadvantages
EVLA/RFA	Best evidence High occlusion rates	Tumescence anaesthesia Possible thermal injury Catheter costs
SVS	Tortuous veins can be treated	Long term efficacy not well established Tumescence anaesthesia Possible thermal injury Catheter costs
Sclerotherapy	Reduced procedural costs Treatment of tortuous veins, reticular/spider veins and venous malformations possible No tumescence anesthesia No thermal injury	Less effective compared with ETA Often need of multiple treatment sessions Pigmentation Phlebitis reaction
MOCA	No tumescence anaesthesia No thermal injury (therapy of the distal GSV and SSV possible) Decreased postoperative pain	Long term efficacy not well established Catheter costs
Cyanoacrylate	No tumescence anaesthesia No thermal injury (therapy of the distal GSV and SSV possible) No compression therapy needed	Long term efficacy not well established Phlebitis reaction Catheter costs

Cyanoacrylate = cyanoacrylate embolisation; ETA = endovenous thermal ablation; EVLA = endovenous laser ablation; GSV = great saphenous vein; MOCA = mechanochemical ablation; RFA = radiofrequency ablation; SSV = small saphenous vein; SVS = Steam vein sclerosis after 5 years. Overall, RFA is a safe procedure and complication rates and types are comparable to EVLA [41].

Steam vein sclerosis

With the aid of a transcutaneous 60 cm long microcatheter with a diameter of 1.2 mm (VenoSteam™, cermaVEIN), micropulses of steaming water are injected into the accessed vein and the techniques is also combined with tumescence anaesthesia. Steam condensates back to water and the vein wall absorbs the resulting heat. In this way, the heat damages the vein wall and causes obliteration of the varicose vein. One of the advantages of SVS is the increased flexibility of the microcatheter, making it is easier to navigate through tortuous veins [53, 54]. A limited number of studies have been published up to now on the efficacy of SVS in the treatment of varicose veins. In 2013, Milleret reported the first more clinically relevant study in a series of 88 great saphenous vein treatments with an obliteration rate of 96% at 6 months. No major complications were reported. One relevant minor complication was protrusion of thrombus into the femoral vein due to positioning of the delivery catheter close to the saphenofemoral junction. Further minor complications included ecchymosis, pain, symptomatic venous inflammation, skin burn at the entry site and decreased sensitivity at the treatment site [54].

Chemical ablation

In chemical ablation procedures (sclerotherapy, mechanochemical ablation, cyanoacrylate glue), the obliteration of the target vein is secondary to application of a chemical substance. There is no need for thermal energy and for tumescence anesthaesia. Therefore, patient discomfort and possible ETA-related procedural complications due to heat application and to tumescence anaesthesia are minimised when performing chemical ablation.

Sclerotherapy

During the sclerotherapy procedure a liquid or foamed sclerosing drug (for example, polidocanol, Aethoxysklerol®) is injected into the lumen of the varicose vein, with the aim to damage the vessel wall and eventually lead to occlusion of the affected vasculature secondary to fibrotic vascular transformation. Because of their better efficacy in the treatment of varicose veins, the sclerosing substances are usually applied as foam (foam sclerotherapy) [55]. After contraindications are taken onto account, all forms of varicose veins (intradermal, subcutaneous or transfascial), as well as venous malformations, can be treated with sclerotherapy [56]. The reported occlusion rates at 1 year vary between 72% [57] and 84% [46] and are lower if compared with EVTA, RFA or surgery. However, in these studies all treatment groups showed a similar improvement in the clinical status and quality of life. Sclerotherapy is by far the most cost effective procedure of all invasive treatments of varicose veins. Frequently encountered (in the range 1–10%) complications are phlebitis, matting (new occurrence of fine telangiectasias in the area of the sclerosed vein) and residual pigmentation. Rare complications (<1%) include distal deep vein thrombosis, headache/migraine and temporary visual disturbances; exceedingly rare complications (<0.01%) include skin necrosis and proximal deep vein thrombosis [56].

Mechanochemical ablation

Mechanochemical ablation (MOCA, Clarivein®) combines the endomechanical destruction of the endothelium and media using a rotating wire placed at the tip of a catheter with the simultaneous injection of a liquid sclerosant over the rotating wire [58]. The combination of these two methods results in vein obliteration and fibrosis [59, 60]. The reported occlusion rates of the treated veins in prospective series after 6 months vary between 94 and 97%, and after 12 months vary between 88 and 94% [42]. The most commonly encountered complications are superficial thrombophlebitis (3–10%), haematoma/ecchymosis (10%) and induration along the course of the treated vein (12%) [61, 62]. Unlike the endothermal methods, there is no thermal injury risk to skin, nerves, muscles and blood vessels and there is no need for tumescent anaesthesia. A further advantage is the decreased pain and discomfort reported during the procedure [63].

Cyanoacrylate embolisation

With cyanoacrylate embolisation (VenaSeal™ Closure System), a modified medical glue (cyanoacrylate) is applied segmentally along the target vein with a Teflon catheter in conjunction with manual compression using sonographic guidance. There is no need for tumescent anaesthesia with this procedure. The adhesive polymerises into a solid material in the vessel via an anionic mechanism, leading to chronic occlusion of the treated vein. It has to be mentioned that this glue has longstanding use for a variety of conditions, such as for the treatment of intracranial arteriovenous malformations [64]. The long-term safety of the glue is well established. This procedure has a strong efficacy profile in the treatment of varicose veins. The most frequent reported side effect (side effect rates between 11 and 18.5%) is a predominantly a mild phlebitis reaction, which can be well controlled with nonsteroidal anti-inflammatory medications. The reported closure rates are 99% at 3 months and 92% at 12 months [65–67]. Compared with ETA techniques, cyanoacrylate embolisation has the advantage that no tumescence anaesthesia is needed, obviating the need for multiple needle sticks. Furthermore, the risk of thermal-associated complications such as damage of nerves and surrounding tissues is minimal. Finally, no post-procedural compression therapy is needed. The drawbacks of this procedure are the higher costs and lack of long-term data for VVLE treatment.

Discussion

The general view that VVLE is a non-serious disease with primarily aesthetic impact is a common misconception. This is supported by the fact that VVLE can have a considerable negative impact on generic and disease-specific quality of life [17–19]. The disease is associated with potential serious clinical conditions, such as chronic lower extremity tissue loss, venous thromboembolism and haemorrhage from ruptured varicose veins [10–12]. Hence, in cases of symptomatic varicose veins and in the presence of advanced lower limb skin changes or when venous complication occur, a referral to a vascular medicine specialist for individualised patient management is recommended [24].

Regarding the treatment of varicose veins, over recent decades several EVA techniques have been developed to treat truncal vein incompetence. Compared with the traditional surgical varicose vein approaches, the EVA techniques have a comparable efficacy profile and a reduced morbidity, decreased pain and a faster return to normal activities and, therefore, reflect an attractive option for VVLE treatment. However, the above-mentioned advantages of EVA could lead to an extension from strictly medically indicated treatment of VVLE to treatment for primarily aesthetic purposes. An indirect indicator of this possible shift is the clear growth of venous interventions during the last decade. A careful evaluation and justified indication is necessary for each affected individual in order to prevent unnecessary harm to the patient and to avoid increasing healthcare costs. The choice of a specific EVA technique from those discussed in this article for the treatment of varicose veins should be based on availability, local expertise, advantages and disadvantages, patients' preferences and the individual reimbursement situation of the corresponding country. In Switzerland, since January 1 2016 only EVAL and RFA are covered by health insurance even though other endovenous techniques for the treatment of varicose veins have been proven to be effective in abolishing reflux. Long-term clinical data for the newer endovenous techniques is warranted to further improve patient care when treating truncal varicose veins.

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Figures (large format)

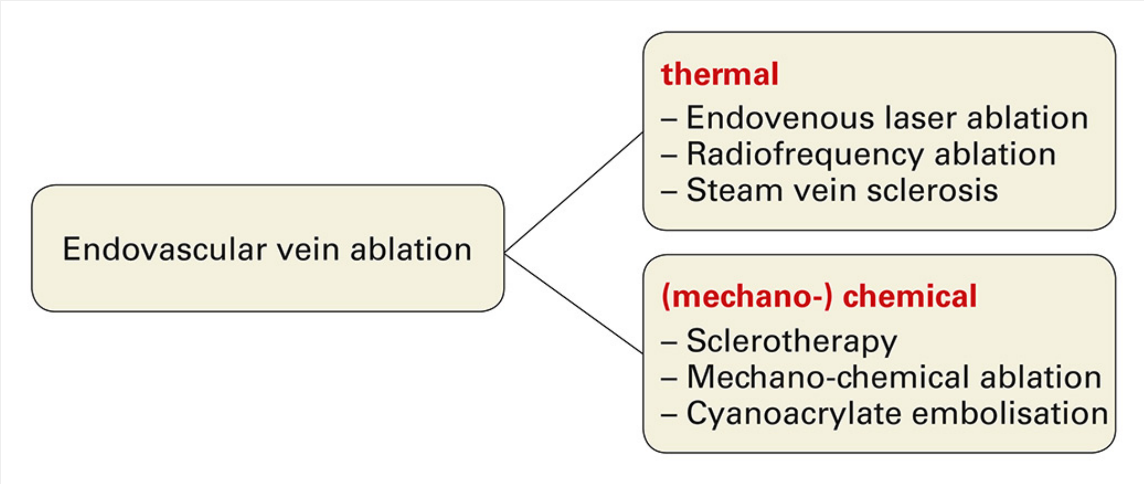

Figure 1

Overview of the different techniques of endovascular vein ablation.