Endovenous ablation of refluxing saphenous and perforating veins

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Summary: Since the end of the nineties endovenous thermal ablation and more recently non-thermal, non-tumescent techniques have been developed and improved. Until now, because of their favourable side effect profile in conjunction to sustained efficacy, in many countries they already replaced high ligation and stripping in the treatment of refluxing saphenous veins as well as for treatment of perforators and selected tributaries. Now, studies and comparative trials are available with long-term follow-ups for most of the techniques, providing valid data on occlusion and reflux rates, side effect profiles, and health related quality of life.

Keywords: Endovenous laser, radiofrequency ablation, thermal ablation, cyanoacrylate, saphenous vein, endovenous ablation

Introduction

Venous disease frequently affects patients' health-related quality of life (HRQoL) with substantial clinical symptoms like pain, heaviness, itching, cramps, and tired legs. These symptoms are usually already present in the early stage of venous disease. For standardized descriptions of venous complaints, clinical and haemodynamic abnormalities, the physician's Venous Clinical Severity Score and the CEAP-classification can be used [1]. The most commonly used disease-specific HRQoL tools for varicose veins and more advanced stages of CVD are the Aberdeen Varicose Vein Questionnaire (AVVQ) [2], the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ) [3], the specific quality of life and outcome response – venous (SQOR_V) [4] or the Venous Insufficiency Epidemiological and Economic Studies (VEINES) [5] questionnaire. Chronic stages of venous disease are the result of chronic venous congestion and at least partially irreversible once eczema, hyperpigmentation, lipodermatosclerosis or leg ulcers, as described by the CEAP classification [6], have occurred. Besides improvement of symptoms and prevention of chronic stages of venous disease, the treatment of varicose veins is aiming towards prevention of acute complications as well. Such complications are bleeding, superficial venous thrombosis, deep venous thrombosis (DVT), and pulmonary embolism.

Once patients' complaints or their cosmetically disturbing varicose veins brought them into the office of a phlebologist, duplex examination is often able to demonstrate reflux in the venous system which can be addressed by conservative, surgical or interventional treatment options.

While a conservative approach with medical elastic compression stockings has never gained much popularity amongst younger patients, surgical or interventional treatment of varicose veins belong to the most frequently performed operations in developed health care systems.

The need for less invasive, cosmetically superior treatment modalities has led to the introduction of minimally invasive, endovenous techniques around the year 2000. The main benefits to these techniques are the fact that there is no need of spinal or general anaesthesia, because they are performed with local tumescent anaesthesia, and that success rates as well as recurrence rates are at least similar if not more favourable compared to classic surgery [7]. These endovenous techniques are usually based on thermal action and they radically changed the treatment of varicose veins. Endovenous thermal ablation (EVTA) therapies based on radiofrequency (RFA), laser (EVLA) or steam (EVSA) have become the most frequently used type of therapy for saphenous varicose veins, particularly in countries where reimbursement of the procedure has been introduced. In the meantime, EVTA has been ranked superior to surgery and superior to foam sclerotherapy by scientific societies as well as by reimbursement directing government affiliated institutions, based on the evidence from multiple case-series and randomized controlled trials (RCTs) which show that EVTA leads to high success rates and very few treatment induced side-effects [8–10].

A recent large worldwide survey amongst experienced physicians evaluated how patient characteristics and duplex ultrasound (DUS) findings influence management decisions of physicians with specific expertise in the field of chronic venous disease. In this survey, physicians also

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Endovenous laser ablation

Frequently, endovenous laser ablation is performed as an outpatient procedure using tumescent anaesthesia. Venous access is usually obtained under DUS guidance by puncturing the vein with 16G or 18G needles at the distal point of reflux. Depending on the nature of the laser fibre tip, it may be necessary to place a full-length guide wire and sheath below the saphenofemoral junction (SFJ). The most important step in the EVLA procedure is positioning the tip of the laser fibre 1 to 2 cm distally from the SFJ, using DUS visualization. In case of treatment of a small saphenous vein (SSV), the fibre tip is usually propagated towards the popliteal vein as long as the SSV still remains at the immediate subfascial level. Depending on the length of the treated vein, about 250 to 500 mL of tumescent local anaesthesia (TLA) is injected perivenously under DUS guidance. TLA usually contains 1 mg epinephrine and 500–700 mg lidocaine or prilocaine per 1000 mL saline solution. A mechanical infusion pump is highly recommended. Tumescent local anaesthesia is warranted because it reduces pain, cools perivenous tissue, and decreases the venous diameter. Moreover it provides anaesthesia for several hours after the intervention. A precooled TLA may enhance the analgesic effect [29]. During the release of laser energy, the laser fibre is pulled back continuously with a speed of about 3–5 mm/s, however, the pullback can be performed gradually as well, when using lasers with pulsed energy. The velocity of the pullback depends on the laser power engaged and the vein diameter to deliver the intended amount of laser energy per cm vein length, resembling linear endovenous energy density (LEED). An endovenous fluence equivalent (EFE) of at least 25 J/cm² is recommended to achieve a sustained occlusion [21]. For example, an average vein with a diameter of about 8 mm demands a laser power of 15 W and a pullback speed of 2 mm/s which result in a LEED of 75 J/cm and an EFE of 29.9 J/cm². EFE is calculated by dividing LEED by the vein circumference in cm.

Parameters

Variables in endovenous laser treatment include laser wavelength, laser power, fibre pullback speed, and fibre type ().

Almost all studies that have been published on EVLA show very high success rates (>90%), independently of laser wavelength. The first case series suggesting that EVLA might be successful for treating large varicose veins were published in 2001 [30, 31]. Thereafter, multiple case series have been presented and systematic reviews have been published [32, 33]. In a prospective study, 93% of 499 GSVs were occluded two years after therapy. An Italian workgroup reported a success rate of 97% in 1,000 patients with a follow-up of three years, and another large study of more than 1,250 limbs showed a success rate of approximately 95% [34–36]. A four-year follow-up study of EVLA combined with ambulatory phlebectomies for the treatment of superficial venous incompetence showed re-

currence rates of 4.3% at four years, 3.6% at two years, and 5.9% at one year. [37] A meta-analysis showed that EVLA was significantly more effective than stripping, UGFS, and ClosurePlus-RFA [7]. The recently published randomized clinical trial of Rasmussen et al. showed that stripping, EVLA, and RSTA were equally effective [38]. Several other RCTs with long-term follow-up have proven the durable success of EVTA [39].

The first studies of EVLA report the use of 810 nm diode wavelength, targeting haemoglobin. Subsequently, other haemoglobin targeting wavelengths were introduced (940, 980, 1,064 nm) followed by higher wavelengths (1,320, 1,470, 1,500, 1,927, and 2,100 nm with water/vein wall as main target), however all the wavelengths are absorbed in varying degrees by blood constituents which can be either water or haemoglobin. All currently available wavelengths are successful in ablation of varicose veins. Success rates of EVLA are very high almost regardless of the amount of energy delivered as already described above. Unfortunately, studies that compare different levels of energy administered per centimetre, aiming to find the adequate dose needed for durable vein occlusion, are lacking. The first decade after the introduction of EVLA, most studies reported the use of a bare fibre tip combined with different laser wavelengths. Other fibre tip designs have been introduced since all of them aim to prevent direct contact of the fibre tip with the vein wall and thereby decrease the amount of vein wall perforations which may lead to pain and bruising. A radial fibre with radial emission of laser light has been combined with a wavelength of 1,470 nm showing good results [14, 40]. One study reported the results with a covered fibre tip, which has a metal tube-case and a glass weld at the distal tip, showing slightly lower occlusion rates than a bare tip [15]. One of the most recent inventions is the tulip tip that is designed to prevent perforations by centring the laser fibre within self-expandable blades [16, 41] and the 2-ring-radial fibre which proved to cause less pain during the first two weeks after EVLA compared to the 980 nm-bare-fibre combination [42].

Radiofrequency ablation

The procedure is very similar to EVLA. Access to the varicose vein is obtained with a micropuncture set and a 7F sheath under DUS guidance, typically at the distal point of reflux. The pioneering Closure Plus catheter (VNUS Medical Technologies, Inc., Sunnyvale, Calif), mainly in use between 1999 and 2007, is positioned 1 to 2 cm distally from the junction under longitudinal DUS visualization. However, due to its slow pullback speed it has been quickly replaced after the introduction of radiofrequency segmental thermal ablation (RSTA) [13]. It has a 7 cm therapeutic distal tip that heats up to 120 °C, [26] and the first case series of 252 treated GSVs showed an occlusion rate of 99.6% (Figure 1.) [13]. Follow-ups after five years

Endovenous steam ablation is another method of thermal vein ablation, which is relatively new and not very frequently used. It works by heating the vein wall and its contents with steam at a temperature of maximal 120 °C. The procedure of steam ablation is very similar to the other endovenous techniques. The vein is punctured with a 16-gauge needle or cannula under DUS guidance. The GSV is usually entered at the distal site of reflux and the SSV is usually punctured mid-calf, depending on vein diameter and extent of reflux. To prevent sural nerve injury, it is advisable to avoid puncturing the SSV in the lower third of the calf. The steam catheter (1.2mm diameter) is passed through the hollow needle into the vein and the echo-dense tip of the catheter is then carefully positioned at approximately 2-3cm from the junction under DUS guidance. About 250 to 500mL (depending on the length of the vein treated) of tumescent anaesthesia is administered around the vein within the fascia blades under DUS guidance. Because the steam is ejected perpendicular to the catheter with quite high pressure, it seems that more tumescent anaesthesia is needed compared to other EVTA treatments in order to avoid the sensation of heat or pain. After activation, the catheter releases small *puffs* of steam, and is gradually pulled back. At first activation, four puffs of steam should be administered, while gentle manual pressure is exerted on the junction. Depending on the diameter of the vein, two or three puffs of steam can be administered every following centimetre. It is advisable to continue applying manual compression on the junction during the first 4cm of the treated area, as the steam is ejected with pressure and can therefore reach several centimetres beyond the catheter tip.

The device suitable for steam ablation is Steam Vein Sclerosis® (SVS system; CERMA SA, France). This system consists of a generator and a connected hand piece. The catheter attached to the hand piece delivers the steam with a temperature of around 120 °C into the vein to be treated. The tip of the catheter has two holes with a diameter of 0.15 mm on the side of which the pulses of steam are released. Because the treatment is not frequently used and its costs are not reimbursed in many countries, there are very few publications on steam ablation [17, 51]. These studies show preliminary good occlusion rates. The first RCT on steam ablation versus laser ablation included more than 200 GSVs and it showed non-inferior occlusion rates, but slightly lower post-operative pain scores and shorter convalescence after steam ablation [52]. All EVTA treatments have in common that their effectiveness depends primarily on the amount of energy delivered to the vein wall [21, 53]. The first study on steam ablation showed that there were recanalizations which might be related to underdosing. An experimental study showed that administering one pulse per centimetre is not leading to a homogeneous temperature profile, where-

as three pulses per centimetre did [54]. The RCT also showed that the occlusion rates in patients treated with high-dose were better than in those treated with low-dose.

Indications of endovenous thermal ablation

The EVTA treatments all have in common that they can be performed in an outpatient setting using local tumescent anaesthesia. Patients are recommended to wear medical elastic compression stockings for one week after all treatments. Every treatment requires DUS experience, and in most cases, at least in Europe, DUS visualization during the procedure is performed by the physicians themselves. Because of the rigidity and size of the disposables, linear primary saphenous veins with a diameter of at least 3 mm are most suitable for EVLA. If thinner fibres are used, EVLA can be used for more tortuous veins such as parts of tributaries and perforator veins [55]. However, one should be careful with treating varicose veins that had a previous superficial thrombosis or were previously treated with foam sclerotherapy, as introducing the laser fibre may be difficult. The indications for RFA are comparable to EVLA. However, treating tortuous and relatively small varicose veins can be difficult and one should be careful to avoid vein wall perforations. Endovenous steam ablation can be used in saphenous varicose veins but also in tributaries, as the steam catheter is small, flexible, and the ejected steam can reach several centimetres. Of all EVTA techniques steam ablation may be the treatment of choice for recurrences after stripping, as these veins are usually tortuous and the steam catheter is very flexible. Also steam may find its way easier into side branches and loops. However, in our experience, ultrasound-guided foam sclerotherapy is usually the first treatment choice for tortuous recurrences after stripping.

Non-thermal, non-tumescent ablation of saphenous veins

While liquid and foam sclerotherapy for ablation of saphenous veins seem to be less successful and durable than endothermal techniques, and because the administration of tumescent local anaesthesia needs time and is associated with side effects like bruising, there has been a demand for non-tumescent, non-thermal techniques [56].

Mechano-chemical ablation (MOCA) is a catheter based system which should strip-off the endothelium of the vein using a rotating wire at its tip while liquid sclerosant is administered concomitantly. A system which does not need local anaesthesia apart from the local anaesthesia administered at the puncture site [19]. It is unknown whether this treatment results in durable vein occlusion, as long-term

results are not yet published. A disadvantage is that the system allows treatment of only one saphenous vein in a 24 hour period, because of dose limitations of sclerosing agents. Moreover, wearing medical elastic compression stockings for one week after treatment is still recommended. Nevertheless, when looking at pain scores during and along the first weeks after the intervention, MOCA outperforms RSTA [57]. Treating refluxing saphenous veins by cyanoacrylate ablation (CA) is the most recent development in non-tumescent, non-thermal ablation [58, 59] which overcomes even some of the limitations of MOCA. While both, MOCA and CA do not cause paraesthesia, in contrast to MOCA, CA is lacking a dose limit, allowing the simultaneous treatment of up to four saphenous veins in the same session. In addition, CA does not necessarily require medical compression stockings after the intervention and it has been reported to be at least equally effective as RSTA after three months follow-ups [60]. However, long-term follow-up data for CA as well are still lacking.

Treatment of refluxing perforator veins

Treatment of incompetent perforator veins is not recommended in patients with mild CVD. At present, there is no compelling level 1 evidence to provide a grade A recommendation that the treatment of incompetent perforator veins alone affects venous ulcer healing or recurrence. However, perforator treatment in combination with superficial vein ablation can be considered in patients with venous ulcers [61]. Endovenous treatment of perforator veins is more challenging than treatment of saphenous veins, because of the tortuosity, deep location, and short segment of the vein to be treated. Cannulation can also be more difficult, because perforating veins are often located in areas of sclerotic skin or ulcers. In addition, it is more difficult to apply the tumescent anaesthesia carefully around the perforator vein. Closure rates are reported to be lower than for saphenous veins, varying from 59 % to 90 % [62]. For RFA a special perforator stylet with a short heating element is available [63]. The treatment procedure of perforator veins with EVLA is similar to the procedure of saphenous veins, no other device is needed [64]. One study reports on ablation with CA of 33 incompetent perforator veins with 76 % occlusion rate, showing no serious complications [65].

Position endovenous thermal and non-thermal ablation therapies

The introduction of EVTA techniques almost 20 years ago has radically changed the approach to the treatment of varicose veins. Finally very effective treatments with a mild

side-effect profile are available. The occlusion rates of the current EVTA treatments is excellent (>90 %). Also, side-effects are mild, convalescence is very short and serious complications are rare. These favourable outcomes have led to a rapid increase in the use of EVTA and a significant decrease in the frequency of conventional ligation plus stripping. One should, however, try to address the remaining questions concerning the exact working mechanisms. Also, there is still a lack of knowledge on long-term effects of the different treatments, not only in terms of efficacy. The type and frequency of potential recurrences many years after EVTA will need attention and investigation. The long-term effect of carbonized products that remain inside the body after EVLA is not known either. Although there are some RCTs with five-year follow-ups, longer follow-up data would be interesting, in order to learn about the differences in durable efficacy of the different treatment options. Furthermore, dose-finding studies are needed to assess the optimal treatment parameters, especially for EVSA. But EVLA as well does not have a standardized protocol yet. Several advantages and disadvantages of the three different EVTA techniques can be summarized based on the available literature and on personal experience (Table I). We should also incorporate cost-effectiveness in our treatment strategy, as this is an increasingly important aspect in treatment choice, especially in countries where reimbursement of EVTA is lacking. Several publications support the hypothesis of the ascending etiology of varicose disease, starting from the distal superficial venous network [66]. The surgical approach focusing on the treatment of tributaries by phlebectomies and simultaneous preservation of the saphenous vein is enjoying renewed attention. Treating insufficient tributaries of the insufficient saphenous vein may lead to abolition of the saphenous reflux, so the saphenous vein could be saved. One prospective study with 100 patients with a refluxing GSV plus a refluxing tributary showed that one year after treatment of tributaries with only phlebectomies, the GSV was reflux-free in 50 % of patients [67]. This concept challenges the current opinion on the treatment of venous insufficiency, which is usually primarily aimed at treating the refluxing saphenous vein. A selected group of patients may be better off with a less invasive treatment with phlebectomies only. Another group of patients, probably with more advanced diseases (e.g., junctional reflux, large segment of GSV reflux, large GSV diameter etc.) may benefit more from a combined treatment. To select the right treatment strategy for the individual patients, the patient characteristics, which can predict a favourable outcome of phlebectomies, should be further investigated. The treatment of tributaries by phlebectomies and UGFS has been practiced for many years. The current EVTA therapies seem to be less useful in treating tributaries. EVLA and segmental RFA are usually not indicated because of tortuosity of the tributaries. EVSA, however, may be useful for treating tributaries because of the following reasons. First, the catheter is very flexible, second, steam reaches several centimetres and third, EVSA can be used for deeper veins that are not visible and palpable and con-

Table I. Advantages and disadvantages of the different endovenous thermal treatments.

Characteristics	EVLA	RFA	EVSA	MOCA	CA
Effective	+++	+++	++#	++#	++#
Major complications	+/-	+/-	+/-	+/-	+/-
Device-related complications	+	+	+/-	?	?
High patient satisfaction/preference	++	+++	+++	+++	+++
Standardized procedure	+	++	++	++	++
Costs					
Generator/laser	+	+	+	-	-
Disposables	+/-	++	+	++	+++
Treatment of perforator veins	++	+/-	++	-	+/-
Treatment of tributaries	+-	-	+	-	+/-

EVLA: endovenous laser ablation; RFA: radiofrequency ablation; EVSA: endovenous steam ablation; MOCA: mechano-chemical ablation; CA: cyanoacrylate ablation; #: no long-term evidence yet.

sequently are less suitable for phlebectomies. When after treatment of the tributaries saphenous insufficiency remains, the saphenous vein can be treated at a later stage, if the patient still has complaints.

Conclusions

Endothermal and non-tumescent ablation of pathological vein reflux have reached a sophisticated level today. These new technologies are able to replace traditional varicose vein surgery and further allow much less invasive treatment in delicate cases.

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