Twenty Years' Experience with Endovenous Laser Ablation for Varicose Veins: A Critical Appraisal of the Original Procedure

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ABSTRACT

Objective: A critical appraisal of the original procedure of endovenous laser ablation (EVLA) for varicose veins.

Method: Evaluation of all practical aspects of the procedure.

Results: EVLA procedures are performed in a strictly ambulatory setting with tumescent local anesthesia (TLA). Technical improvements have resulted in the need for fewer incisions and re-punctures, less ecchymosis, and fewer technical failures. Administration of an appropriate amount of TLA via an infusion pump has reduced the risk of nerve injury, administration time, and pain during the procedure. Use of a 1470-nm diode laser and a radial fiber have significantly improved patient satisfaction and reduced the occurrence of complications such as pain, tightness, ecchymosis, and the need for additional procedures. Lastly, there are only a few indications left for high ligation and stripping.

Conclusion: Over the past 20 years, EVLA has evolved into an effective, cost-efficient, and safe procedure that provides high patient satisfaction.

INTRODUCTION

Endovenous laser ablation (EVLA) has become our procedure of choice for patients with symptomatic great[1] and small[2] saphenous (GSV/SSV) varicose veins. In 1999, we performed the first EVLA procedure in the Netherlands and have since published several peer-reviewed randomized controlled trials. This article reviews 20 years' experience with EVLA and the treatment of more than 20,000 patients. Here, we describe how improvements in technical aspects and skills have increased patient satisfaction and reduced complications.

METHOD

We evaluated the practical aspects of the procedure and possible improvements.

Duplex ultrasound technology and vein mapping

More powerful computer processors, increased frame rates, and improved software have reduced imaging artefacts. In combination with high-frequency imaging transducers, which provide better resolution, these advances have led to better images. Originally, we used a 10-5 MHz or 12-5 MHz linear array for imaging deep and superficial veins and for

duplex measurements, but nowadays we prefer an 18-10 MHz linear array probe, which is optimal for imaging superficial veins and for EVLA. Duplex scanning and measurements are performed while the patient is standing, using the transverse view for patency and diameter measurements, and the longitudinal view for spectral analysis. While the duplex examination was originally performed by a vascular technologist, this is now done by a duplex-experienced vascular specialist. This enables the specialist to link duplex findings with the patient's symptoms and decide on appropriate therapy, avoiding overtreatment and "image treatment". Moreover, complete venous mapping is no longer performed for uncomplicated varicose veins. Instead, we focus on refluxing GSV, SSV and anterior accessory saphenous vein (AASV), diameter measurements, tortuosity, venous dilatation, incompetent perforating veins (ICPV), closed or not-closed double-loop GSVs, thigh extension of the small saphenous vein, and the vein of Giacomini. We closely monitor the AASV, which is involved in about 10% of patients with varicose veins.[3] In these patients, the AASV is the only source of reflux if the GSV is competent, or there may be reflux in both the GSV and AASV. Since it has been shown that groin recurrence due to untreated refluxing AASV at baseline is seen in 14% of patients at 5-year follow-up after EVLA,[4] we treat refluxing AASV and GSV duplication from an incompetent SFJ at the same time as GSV ablation, thereby reducing the recurrence rate. A "wait and see' policy is justified for a non-refluxing AASV and a superficial tributary of a double-loop GSV.[5]

Operating room facilities

When the procedure was first introduced, we performed it on a day-care basis in the operating room with general anesthesia, two specialists, two assistants, and a vascular technologist. According to our clinic protocol, all patients received low-molecular-weight heparin as thrombosis prophylaxis on the day of treatment in the operating room. After the procedure, pain was relieved with diclofenac (100 mg b.i.d. for up to 1 week). Nowadays, we perform all procedures in an ambulatory setting in a simple treatment room (Fig. 1) with tumescent local anesthesia (TLA), one specialist, and one assistant (who works under non-sterile conditions to take care of the patient and service the laser device). There is no vascular technologist and only patients with risk factors for thrombosis such as a history of DVT or known thrombophilia[1] receive at least 1 week of prophylaxis with low-molecular-weight heparin starting directly after the procedure. These changes are cost-effective and reduce the treatment time.

Vein puncture, introduction guide wire, sheath, and laser fiber

Initially, it was difficult to gain venous access with a 19-G hypodermic needle under duplex imaging and we have since tested various puncture sets. At present, we use a 17-G cannula to access the GSV at or below the knee under transverse ultrasound monitoring. This results in less venous spasm, fewer re-punctures, less perivenous trauma, and a lower risk of nerve injury, and obviates the need for incisions. A 0.035-inch metal J-tip guide wire is then passed through the vein, followed by a 45-cm, 5-F introducer sheath and internal dilatator, after which the guide wire and dilatator are removed. The intraluminal position of the sheath is confirmed by visualization of venous blood. A 600-nm radial-emitting laser fiber with a red aiming bean connected to a 1470-nm diode laser is inserted into the sheath, advanced to the groin, and positioned, under ultrasound guidance, 2-2.5 cm below the saphenofemoral junction (SFJ) and epigastric vein and at femoral vein level for large (>15 mm)-diameter veins (Fig. 2).

This reduces the risk of endovenous heat-induced thrombosis (EHIT) without reducing occlusion rates. It can be difficult to advance the laser fiber if the vein is very tortuous or has large side branches and/or large incompetent perforating veins. Excellent technical skills are needed to reduce the risk of perforation, deep vein position of the laser fiber, and technical failures. If the GSV is tortuous, we advise stretching the GSV by placing the hand under the thigh and lifting it slightly.

Tumescent local anesthesia (TLA)

In the early years of EVLA, we administered a total of 200–250 mL of tumescent local anesthetic (200 mL physiological saline, 40 mL of 1% lidocaine with adrenaline (1:100,000) neutralized with 10 mL of 8.4% sodium bicarbonate) at room temperature in boluses of 5 mL every 3–5 cm, using a 20-mL syringe and a 19-G needle, to achieve analgesia, protect perivenous tissue, and facilitate closer contact of the laser tip with the vein wall by reducing the intraluminal blood volume and vein diameter. TLA is injected under duplex guidance into the saphenous compartment, visualized as a white needle tip and a black expanding area on duplex images. Since TLA delivered outside the saphenous compartment would diffuse away, it was sometimes necessary to inject additional anesthetic. Initially, we had problems delivering TLA into the saphenous compartment, so that patients experienced pain during injection and, in particular, laser coagulation. Since then, we have changed the protocol with a

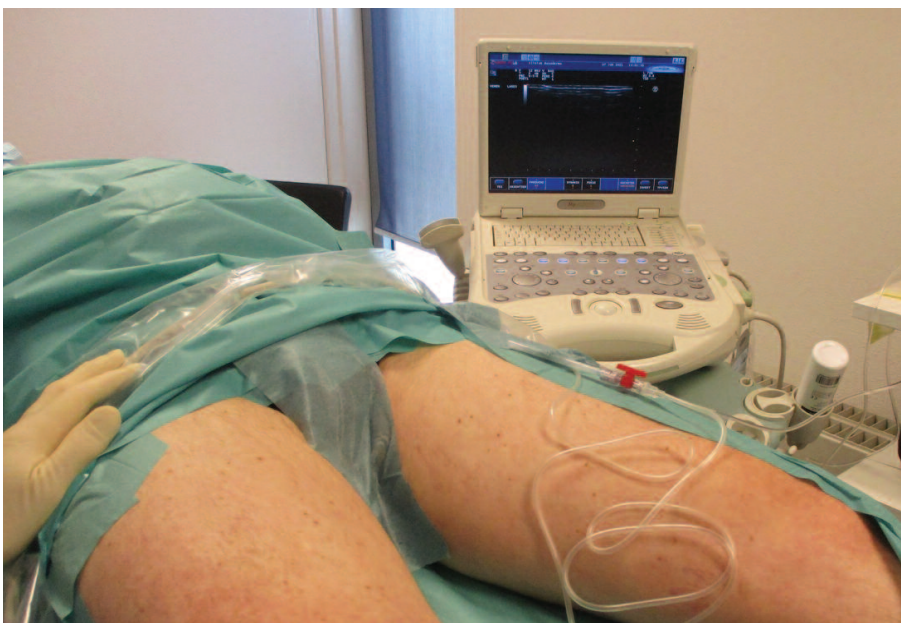

Figure 1. Preoperative setting for a bilateral EVLA procedure.

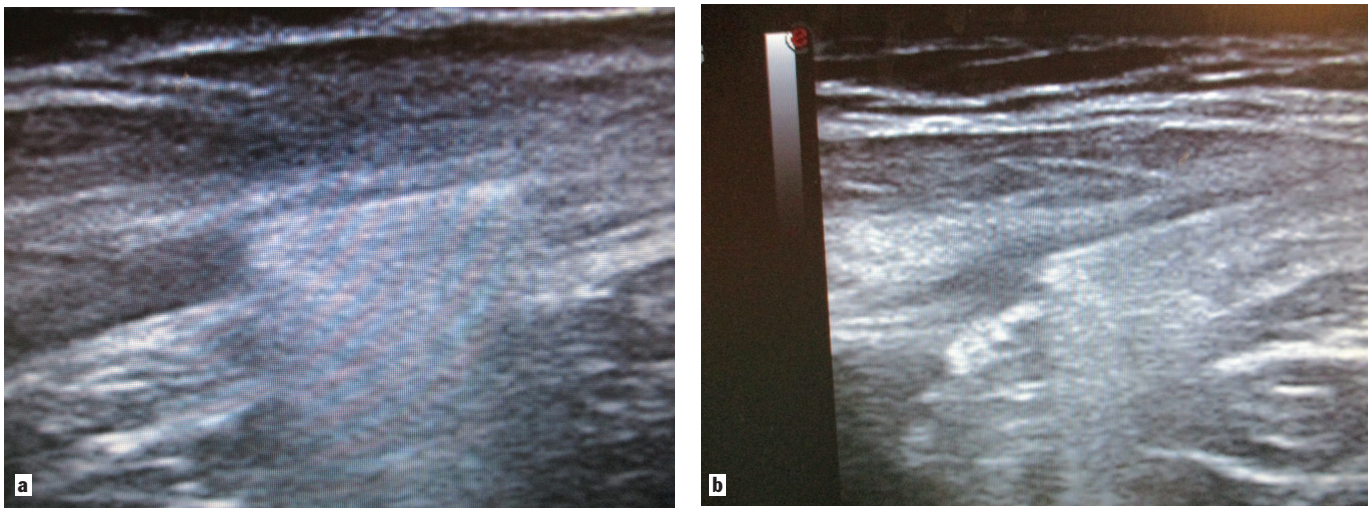

Figure 2a, b. Standard position of the tip of the laser fiber and position of the laser fiber at the femoral junction for large-diameter veins.

view to reducing the complication rate, treating large veins, and performing bilateral procedures. At present, we administer a diluted lidocaine solution (1000 mL physiological saline, 25 mL of 2% xylocaine, no adrenaline, and pH neutralized with 20 mL of 8.4% sodium bicarbonate) at room temperature using an infusion pump, tubing set, and sterile extension line for repeated use, and a long 23 G x 3 1/8 needle, delivering about 50 mL /10 cm vein. This results in a shorter administration time, fewer injections (every 10-12 cm), and less procedural pain. When planning bilateral procedures, it is important that the amount of anesthetic administered does not exceed the maximum dose allowed per kg body weight. There is some debate about the temperature of TLA administered with regard to procedural pain and complications, but it appears that proper delivery in adequate amounts is more important for a successful procedure.[6] A meticulous ultrasound technique is essential for appropriate perivenous TLA administration, to prevent intravenous administration, and we advise starting at the puncture site and moving up gradually. For ablation in thin patients, the superficial accessory saphenous vein and below-knee GSV,[7] it is essential to create a 2-cm gap between deep veins, nerves, and skin, by injecting a large volume of TLA, to protect against thermal damage (pain, tender cord, ecchymosis, and paresthesia) and to reduce the need for additional phlebectomies (Fig. 3).

Diode laser equipment

Since the introduction of endovenous laser treatment, there have been enormous advances in our understanding of how it works and the equipment needed, especially regarding which wavelength and laser fiber tip to use. The first-generation diode lasers used a wavelength of 810 nm, which resulted in the absorption of monochromatic light by hemoglobin. In the early protocols, laser energy was applied in a pulsed manner, with the laser fiber retracted slightly before each pulse. This approach was soon replaced by the use of a continuous laser beam and a more uniform retraction of the laser fiber, which reduced the treatment time and improved energy delivery. However, we often noticed carbonized blood on the tip of the laser fiber. In in vitro experiments, very high temperatures were recorded at the tip of the laser fiber, with a sharp decrease in temperature outside the vessel.[8] We subsequently changed the laser wavelength from 810 to 1470 nm, at which wavelength intracellular water from the vein wall and the water content of blood is affected. Moreover, the temperature at

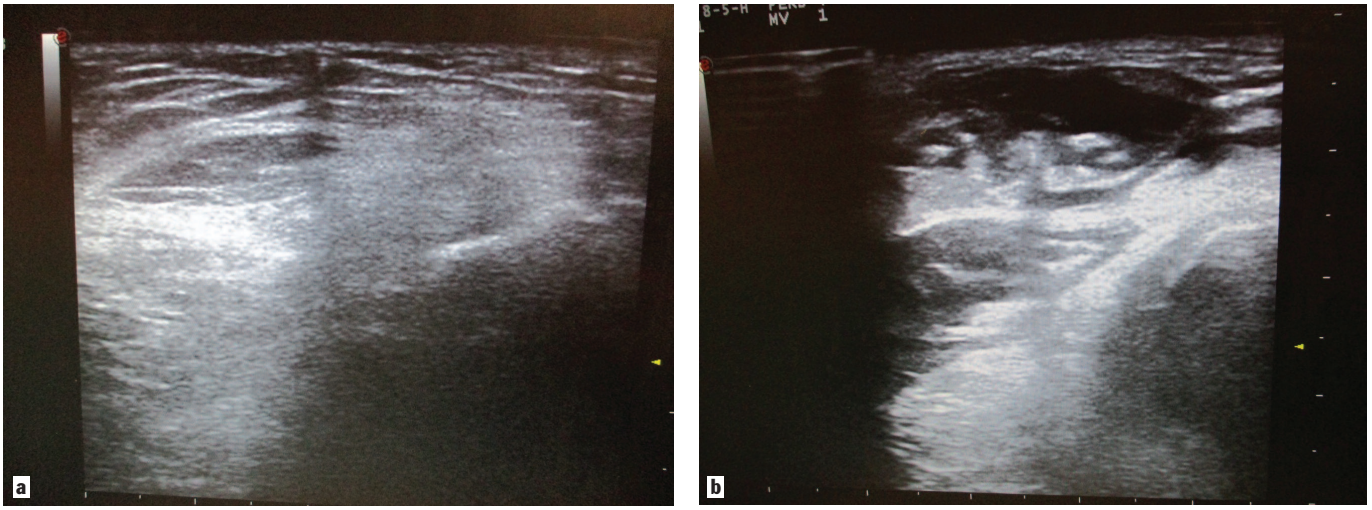

Figure 3a, b. Injection of a large volume of tumescent local anesthesia to prevent thermal damage to the skin.

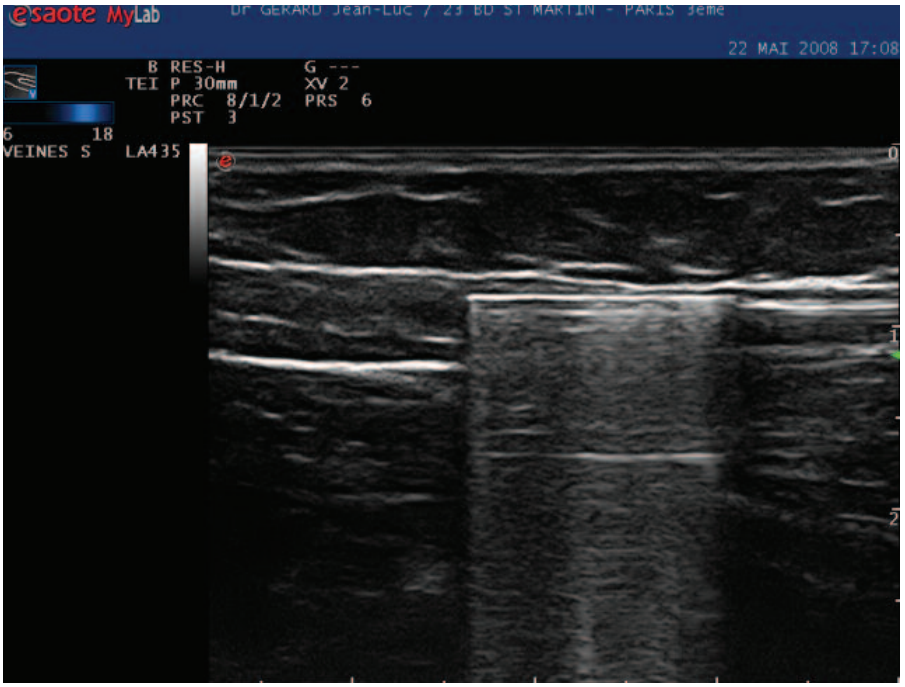

Figure 4. Excellent duplex ultrasound visualization of the ELVeS® Radial® 2ring radial fiber (biolitec® biomedical technology, Jena, Germany).

the tip of the laser fiber no longer continuously exceeds the boiling point of water. This results in fewer expanding steam bubbles arising at the tip of the laser fiber. An ideal procedure ensures sufficient heating of the vessel wall, which not only damages the endothelium but also denatures proteins in the vessel wall, preventing recanalization, with a minimal increase in temperature outside the vessel wall. Lower power and higher wavelengths generate lower (peak) temperatures. The effectiveness of the procedure, in terms of occlusion rates, did not appear to be significantly altered by any of these changes. Indeed, occlusion percentages have remained high, between 90% and 100%, regardless of the wavelength and wattage used, or the shape of the laser tip.[9] Use of a 1470 nm laser has led to substantially less pain, tightness, and ecchymosis after treatment, probably because perforation of the vessel wall occurs less often and better positioning of the laser tip on the vessel wall means that surrounding tissue is not exposed to high temperatures. Another change we made was to switch from a bare tip fiber to a radial fiber. EVLA was initially developed by the British company Diomed Ltd. using bare tip fibers in combination with a laser wavelength of 810 nm. Various companies have modified the fiber, such as the Gold Tip Nevertouch® system by AngioDynamics (Latham, NY), the CORONA radial by neoLaser (Caesarea, Israel), the ELVES® Radial® by biolitec® (Jena, Germany) and Tulip® by Tobrix (Waalre, The Netherlands). These new variants of the fiber tip may reduce the chance of perforation during the procedure. However, simultaneously with these developments at the fiber tip, the wavelength of the laser light used changed significantly from 810 to 1470 nm. The longer wavelength is combined with lower power to achieve the same effect. Lower power is thought to be the decisive development that reduces the chance of vein perforations, post-procedural pain and bruising. To our knowledge, there is no published evidence that either of these new fibers gives a superior duplex-defined occlusion rate over bare fibers at the same wavelength. With a radial fiber, laser light hits the vessel wall at a perpendicular angle; however, the scattering of laser light by steam bubbles at the laser tip is not essentially different from that seen with a bare tip fiber. A bare tip fiber has the advantage that the laser fiber can be introduced through a smaller cannula than is needed for a radial fiber; 17 versus 19 G. A smaller needle makes it possible to puncture even the smallest lumen vein. While the radial fiber has a blunt tip, which potentially decreases the risk of vein perforation, the increased diameter of the fiber makes it less flexible, which makes it more difficult to advance in tortuous veins. Although we have not found that radial fibers are better than bare tip fibers in practice, we prefer the radial fiber (higher ultrasound visibility, less risk of vein perforations and more direct delivery of laser energy to the vein wall) for EVLA starting at a femoral vein level ("laser GSV ligation") for large-diameter GSV/SFJ (reducing the need for additional SFJ ligation), and for refluxing AASV (Fig. 4). Currently, there is no consensus regarding how EVLA is best performed, or optimal laser settings. However, on the basis of 20 years of experience, we favor the following combination of settings: 1470 nm, radial fiber, 8-Watt, and a pullback rate of 7-8 seconds per cm, which results in an energy dose of approximately 70 J / cm. Use of a 1470-nm wavelength laser and a radial fiber has substantially improved postoperative recovery and patient satisfaction.[9] Even with the first-generation diode laser and a bare fiber, no lymphatic complications were described.[10]

POSTOPERATIVE CARE

A long-leg graduated compression stocking (20–30 mmHg) still has to be worn for 1 week (day and night for the first 2 days) and patients are instructed to walk immediately and to resume their normal daily activities and work. They leave the clinic after the procedure. All patients receive an aftercare form, and post-procedural pain medication is prescribed only for selected cases. As follow-up, patients are monitored by clinical evaluation and duplex imaging 3 months and 12 months after the procedure. Longer follow-up is recommended for patients with severe venous disease and for suspected recurrence.

PATIENT SATISFACTION

In the early days, patients, in particular those with rheumatoid arthritis and fibromyalgia, who were treated with an 810-nm wavelength diode laser and a bare forward-emitting laser fiber often experienced pain, tightness, ecchymosis, and paresthesia.[11] This was due to the absorption of emitted energy by hemoglobin, resulting in a very high fiber tip temperatures and damage to surrounding tissues.[8] In 2006, 1470-nm wavelength lasers were introduced, and radially-emitting laser fibers were introduced in 2008. At these wavelengths, the emitted energy is absorbed by water in

the vein wall, reducing laser tip temperatures, and the radial fiber distributes energy more homogenously in the vein wall.[9] With these refinements, patients no longer experience the nasty taste of carbonized blood and have significantly less pain, bruising, tightness, tender cord, and paresthesia after the procedure. Patient satisfaction has improved substantially as a result of better technical skills and fewer incisions, re-punctures, phlebectomies, SFJ ligations, and technical failures. The fact that all EVLA procedures, including bilateral procedures and multiple EVLA procedures in one leg, are performed in an ambulatory setting, in a simple treatment room with TLA and no restrictions after the procedure, has further increased patient satisfaction. Moreover, these technical improvements have made EVLA available to all patients–there are virtually no contraindications, which means that EVLA is suitable for even very thin patients, overweight patients (BMI > 40 kg/m^2), elderly patients (> 80 years), and patients on medication including anticoagulation. Lastly, patients greatly appreciate the principles of "one-stop shopping" and "one patient, one duplex-experienced specialist".

CONCLUSION

Advances in duplex ultrasound devices have improved the specificity of duplex findings. Patient selection is better if the examination is performed by a duplex-experienced vascular specialist in a "one-stop shopping" visit. All EVLA procedures are performed in an ambulatory setting with TLA–this is substantially less expensive and reduces treatment time. Improved vein puncture skills result in less venous spasm, fewer re-punctures, less perivenous trauma, a decreased risk of nerve injury, and less of a need for incisions. Excellent technical skills reduce the risk of EHIT, vein perforation, deep vein placement of the laser fiber and technical failure. Administration of dilute, buffered TLA via an infusion pump reduces TLA administration time, decreases the number of injections needed, and reduces the pain experienced during the procedure. In thin patients and patients undergoing superficial ASV and below-knee GSV ablation, it is essential to create a 2-cm gap to reduce the risk of tissue damage and the need for additional phlebectomies. Experience-guided changes in laser wavelength, power, and fiber type have significantly reduced pain during and after the procedure and ecchymosis. The radial fiber is ideally suited to perform EVLA, starting at a femoral vein level, for large-diameter GSV/SFJ (reducing the need for additional SFJ ligation) and for refluxing superficial ASV. Use of a 1470-nm wavelength laser and a radial fiber have significantly improved patient satisfaction, reduced the need for additional procedures, and made the procedure available to most patients. Lastly, EVLA obviates the need for surgical ligation and stripping. If EVLA is technically not feasible, we preform ambulatory phlebectomy with TLA and/or ultrasound-guided sclerotherapy. **STI**

AUTHORS' DISCLOSURES

The authors declare that there are no conflicts of interest.

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Surg Technol Int. 2021, June 27;39. pii: sti39/1453