J VASC ENDOVASC SURG 2010;17:217-23

Truncal vein ablation for laser: radial firing at high wavelength is the key?

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Endovenous laser ablation at wavelengths between 810 nm and 1 470 nm is effective at ablating pathologic saphenous veins. Serious complications, such as clot extension into deep veins and permanent nerve injury, are rare, occurring in less than 1% of patients. Side effects, such as postoperative pain and bruising, however, remain common, although usually mild in intensity. Several innovations have been proposed to decrease these side effects. Higher laser wavelength lasers target water preferentially to hemoglobin. Fiber tips can be designed to fire radially at 360 degrees instead of linearly. Although theoretically appealing, these ideas still need to be tested against currently used options such as 810-980 nm bare tip lasers or radiofrequency devices in randomized, controlled trials. Proper energy dosing and tumescent anesthesia are currently more important keys to success than laser wavelength or radial firing.

Key words: Varicose veins - Saphenous veins, diseases - Laser therapy.

Since its Food and Drug Administration (FDA) approval in 2002, endovenous laser has become the most common means of saphenous ablation in the US.[1] Endovenous laser ablation (EVLA) has remained popular despite other effective options, such as endovenous radiofrequency ablation (RFA),[2] endovenous chemical ablation,[3] improved traditional surgical techniques such as ultrasound-guided high ligation and stripping under local anesthesia,[4] and alternative surgical strategies avoiding saphenous ablation such as ultrasound-guided hemodynamically targeted surgical ligations (CHIVA) [5] and surgical removal of the varicose reservoir (ASVAL).[6]

Multiple types of veins have been treated successfully with EVLA, including great saphenous,[7-9] anterior accessory great saphenous,[10] small saphenous,[11-13] perforator,[14] saphenous tributary,[15, 16] and venous malformations.[17] It seems that any vein straight enough to cannulate can be closed with EVLA.

The results with current lasers are already quite good. Several studies have shown an improved quality of life after EVLA.[4, 12, 18, 19] Ablation rates out to three years based on postoperative ultrasound are around 94%.[20] Most failures in the current experience have occurred early, within the first year, and so the ablation appears durable.[7] Several studies have also shown cosmetic improvement of varicose veins after EVLA.[18, 19, 21]

There is some evidence that EVLA may have a lower risk of groin neovascularization compared to surgery for saphenous reflux. Groin neovascularization is the leading cause of recurrent varicose veins after surgery.[22] In a prospective cohort study, 18% (11/60) of surgical

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vs. 1% (1/69) of EVLA patients had ultrasound-detected groin neovascularization. Historical surgical neovascularization rates have ranged from 8-60%.[23] Low groin recurrence rates have also been reported with RFA.[2, 24]

EVLA complications are uncommon. The risk of major complications, such as thrombus extension into the deep veins, or nerve injury, is less than 1%. Other complications, such as phlebitis, dysesthesias, skin burns, and hyperpigmentation, are uncommon.[25] Pain and bruising are common, however, and reduction of these events has been a focus of research in this field.

Technique of EVLA of the great saphenous vein

The patient is placed supine and in 10-20 degrees of reverse Trendelenburg. This step helps increase vein diameter and make the vein an easier target. The course of the great saphenous vein (GSV) to be treated is marked using ultrasound. The patient is cleaned and prepped..

The GSV is accessed using a micropuncture system and ultrasound guidance.[26] After access, the patient can be placed in 10-20 degrees of Trendelenburg position to help reduce vein diameter, which helps insure apposition of the laser fiber to the vein wall as well as theoretically reduce the chance of thrombotic, rather than sclerotic occlusion. The guide wire is placed through the micropuncture catheter and advanced to the saphenofemoral junction, verified by ultrasound.

The catheter is advanced over guide wire, with the tip placed 2 cm from the saphenofemoral junction, verified by ultrasound. The laser fiber is advanced through the catheter, with the tip placed 2 cm from the saphenofemoral junction, verified by ultrasound. Placement at this spot allows good efficacy while minimizing risk of postoperative clot extension.

Tumescent anesthesia is placed around the target vein within the saphenous sheath with a 1 cm circumferential halo placed around the catheter and laser fiber, verfied by ultrasound, along the entire course of the segment of GSV treated. The GSV should also be pushed at least 1 cm below the skin surface using tumescent techniques to prevent skin burns. A total of 5-10 mL per cm of treated vein is typically needed. Tumescent anesthesia provides analgesia, compresses the vein, and acts as a heat sink protecting structures adjacent structures to the treated vein from thermal injury.

Laser safety goggles are applied to the patient and all health care providers. Laser fiber energy is delivered in continuous wave at 70-80 joules per centimeter of vein. A setting of 13 watts continuous wave with pullback speed of 6 seconds per centimeter is commonly used. The laser is turned to standby before removal of the catheter and laser fiber from the skin.

After completion, ultrasound is used to verify GSV ablation and lack of clot extension into the deep system during and immediately after the procedure, and again at 48 to 72 hours post procedure. A compression dressing is applied to the needle entry site. The patient is ambulated for a minimum of 20 minutes.

Mechanism of action

In EVLA, laser light is emitted into the vein wall lumen through a sheath with a flexible optical fiber. The laser provides single wavelength light amplified by mirrors which is converted into heat energy. The light consists of photons running parallel and in phase. Successful ablation seems to require circumferential and irreversible damage to the endothelium and vein wall tunica intima, resulting in fibrosis and vein obliteration.

In an attempt to clarify the mechanism of action, Bush collected saphenous vein samples shortly after, 4-6 weeks after, and 4 months after EVLA. Both 940 nm pulsed and 1319 continuous lasers were used and energy delivery was around 80 J/cm in both groups. Histologic results were quite similar. Shortly after EVLA, the endothelium and tunica intima were destroyed. There was fibrin deposition indicating early thrombosis. At 4-6 weeks, fibrocytes and chronic inflammatory cells were present. Neovascularization was seen in the thrombus. At 4 months, collagen deposition was prominent and inflammatory cells had dramatically decreased.[26]

Temperatures at the laser fiber tip have been reported to be above 1300 °C. Temperatures decrease markedly away from the tip, dropping to approximately 142 °C at 4 mm from the tip.[27] This is in marked contrast to RFA, where temperatures are maintained by feedback loops between 85 °C and 120 °C, depending on the catheter used. Viarengo *et al.* measured endovenous and perivenous (1 mm outside the vein) temperatures in a group of 27 saphenous veins during EVLA using a 980 nm pulsed laser and delivering about 90 J/cm with tumescent anesthesia. Mean endovenous temperature was 79.3 °C and range 61-96 °C. Mean perivenous temperature was 43 °C, with range 35-48 °C. As seen in Figure 3, endovenous temperatures peaked at the time the laser fiber tip passed the thermometer, while perivenous temperatures only increased a few degrees.[28] These findings are consistent with perivenous temperatures of 50 °C with EVLA of pig ears performed with tumescent anesthesia.[29]

Vein wall perforations have been noted after EVLA, in contrast to RFA, and some hypothesize that these perforations result in increased bruising and pain for patients undergoing EVLA compared to RFA.[27] Continuous laser firing has been adopted by many practioners, as pulsed laser firing is believed to be a possible cause of the perforations.[30]

It is still a matter of controversy exactly how heat energy damages the vein wall. There are four current hypotheses. First, steam bubbles generated at the laser fiber tip may deliver convection heat to the vein wall when they collapse.[26, 31, 32] Second, direct absorption of laser light may cause vein wall changes.[33, 34] Third, direct contact between the laser fiber tip and vein wall may provide the energy.[35] Fourth, heat diffusion from the fiber tip may provide the necessary heat.[36]

Energy dosing

Proper energy dosing is critical in effective saphenous ablation and reduction of side effects. The temperature and duration of heat application are important in producing irreversible and circumferential tunica intima damage leading to fibrosis, rather than thrombosis of the vein, which may result from inadequate energy delivery. Linear endovenous energy density (LEED) is defined as the amount of energy delivered per length of vein, in joules per centimeter. The practitioner can vary LEED by changing power (watts) or fiber pullback speed (mm/s). Low LEED doses decrease saphenous ablation rates.[37, 38] Lasers in the 810-980 nm range do well around 80 J/cm. Some authors recommend higher doses proximally and lower doses distally.[39]

High LEED may increase paresthesia rates. In one case series with average total dose 15,240 J (254 J/cm if we assume very long 60 cm veins were treated), and no tumescent anesthesia, 36.5 % of patients had at least temporary paresthesias.[40] In the initial 1470 nm case series, paresthesia rates were a high overall 15.5% at over 100 J/cm, but dropped to 2.3% with doses less than 100 J/cm.[41] Higher LEED has also been effective with minimal side effects with good tumescent anesthesia.[42]

Fluence, or LEED per vein diameter (J/cm^2), may be a more accurate parameter measuring energy dosing. This variable is very practical and useful in using surface lasers to treat telangiectasias. It is impractical for use in endovenous procedures, however, because the vein diameter varies along the course of the target vein. Vein pullback speed would need to be immediately corrected based on vein diameter to deliver a constant fluence dose during treatment. Additionally, veins tend to spasm and decrease in diameter after instrumentation and decrease further during delivery of tumescent anesthesia, making it difficult to determine the appropriate energy dose. Despite its difficulty in use, one retrospective review found EVLA was less effective in veins with larger diameters and lower LEED did not affect results.[43]

Tumescent anesthesia

Proper tumescent anesthesia (TA) is also critical to EVLA efficacy and safety. TA was first described by Klein for liposuction.[44] A 1 cm "halo" is commonly generated around the saphenous vein within the saphenous sheath by placing a needle into the saphenous sheath under ultrasound guidance. The tumescent fluid is easily visible on ultrasound.

In EVLA, a solution of dilute lidocaine, such as 0.1%, is often used. The lidocaine can be combined with dilute epinephrine to help ensure venospasm, and bicarbonate to decrease patient injection pain. The maximum volume used is often 500 mL, since 500 mg is the maximum dose of lidocaine with epinephrine officially recommended.[45] Higher lidocaine doses of 35 mg/kg [46] or even 55 mg/kg [47] were found safe in separate studies.

TA likely performs three important functions during EVLA. First, the fluid acts as a "heat sink" to prevent damage to non-target structures like nerves and skin. In a case series without TA, the authors found very high rates of 36.5% for paresthesias and 4.5% for skin burns.[40] In contrast, EVLA in the below-knee great saphenous vein has been found unlikely to cause injury to the saphenous nerve in contrast to surgery when proper TA is used.[48, 49] Higher wavelength lasers penetrate more deeply into tissue and may make careful energy dosing and enough tumescent anesthesia even more important than with lower wavelength lasers.

Second, TA reduces patient pain during the procedure. Even at high wavelength 1470 nm and low energy level 20-30 J/cm and low power 3-5 W, patients required TA to prevent significant procedural pain.[50] Interestingly, a small group of 12 patients did well with EVLA and saline tumescent anesthesia delivered at 4 °C.[51]

Third, TA is one way to compress the vein around the laser fiber tip, along with venous spasm response to instrumentation, Trendelenburg positioning, and delivery of epinephrine. Hand compression has also been advocated during EVLA,[52] but also criticized as contributing to venous perforations.[53] Mathematical modeling shows a reduced fluence need when the vein diameter is smaller.[33] Lack of TA results in lack of complete cirumferential vein wall injury, especially at high vein wall diameters.[54, 55]

Higher laser wavelengths

EVLA was initially described at a wavelength of 810 nm.[54] With hemoglobin was the initial target chromophore, higher wavelengths of 940, 980 and 1064 nm were tested to see if a higher specificity for hemoglobin would provide better results. In a randomized trial between 810 and 940 nm, with similar LEED, there were few significant differences. Interestingly, pain scores at the final 4 month follow up were better for 940 nm-treated extremitites, 1.50 *vs.* 1.21 out of 10, although possibly due to higher phlebitits rates among the 810 nm-treated group.[55, 56]

Next, even higher wavelength lasers were made to improve results by targeting water instead of hemoglobin as a chromophore. Lasers can be divided into the hemoglobin-specific laser wavelengths (HSLW), between 810 and 1064 nm, and the water-specific laser wavelengths (WSLW), currently between 1320 and 1470 nm. Some hypothesize that WSLW will produce less patient pain.

Two mechanisms have been proposed for how WSLW could produce less pain. First, targeting water in the vein wall instead of hemoglobin in the blood vessel may prevent perforations which are felt to be the source of bruising, which is believed to be the primary cause of pain following EVLA.[27] Second, because the vein wall is the main target, and WSLW have greater affinity for water than HSLW, lower LEED can be delivered and still achieve vein closure. Patients receiving lower LEED may have less postoperative pain.[51]

A case series of 24 limbs at WSWL 1320 nm describes good results. Treated at 5 W and with LEED 50 J/cm, all limbs were occluded at postoperative ultrasound and "no complications" such as pain, were reported.[57] In a nonrandomized trial comparing HSLW (940 nm) to WSLW (1320 nm), patients did have less pain, bruising, and analgesic use in patients treated at the two groups with similar LEED (around 60 J/cm). Efficacy was similar based on postoperative occlusion. Phlebitis and paresthesia/dysesthesia rates were not statistically significantly different. Still, only 18% (6/33 legs treated) were free of side effects. Pain occurred in 50% and ecchymosis in 61% at 1320 nm.[58] If bruising is caused by vein perforation, and not tumescent anesthesia or other causes, this ecchymosis rate is disappointing.

The initial clinical experience with 1470 nm, radial fiber laser has been reported. One year occlusion rates for saphenous veins was 100% (115/115). The procedure was well tolerated with the exception of a high paresthesia rate of 7.6% at one year. As discussed earlier, a high LEED seemed to be the critical factor. Patients treated at over 100 J/cm had a 15.5% risk, while those treated with less than 100 J/cm had a much lower rate of 2.3%.[41]

The 1470 nm, silicone-covered fiber was used at 30 J/cm and compared with historical controls with the 980 nm, titanium-covered fiber. Thirty-three patients and 41 veins were treated in the 1470 nm group. Postoperative "pain control" was necessary in 21% of patients and postoperative pain scores were 0 in all these cases. Ecchymosis was present in 68% of limbs.[50]

Radial, covered, and tulip laser fiber tips

The standard laser fiber tip is hottest at the laser fiber tip and heat radiates linearly from the tip. In contrast, the radial fiber tip emits light at 360 degrees to cause homogenous vein wall damage. In a nonrandomized observational cohort study, 312 extremities were treated at 1470 nm with either a radial or bare laser fiber. LEED was around 60 J/cm in the radial fiber group and 80 J/cm in the bare fiber group. Ablation rates were 100% in both groups. Ecchymosis rates (64% *vs.* 84%) and analgesic use (82 *vs.* 103 mg diclofenac) were better in the radial fiber group.[59] It is unclear whether the better results were due to the lower LEED or the radial fiber.

Another innovation is the covered fiber tip. Either a ceramic or metal cover is placed at the distal laser fiber tip. In the case of the ceramic cover, the goal is to prevent direct vein wall to fiber contact felt to be the cause of vein wall perforations. In addition to the buffer effect of the ceramic cover, the metallic tip also diverts the light, resulting in a similar LEED generated with less power. The goal is to reduce pain and bruising.[52]

Vuylstke *et al.* tested a tulip-shaped, self-expandable laser catheter in comparison to bare tip fiber in goat lateral saphenous veins using a 980 nm laser at around 60 J/cm. The goal was to prevent direct vein wall-fiber tip contact. They obtained histologic samples immediately after, 10 days after, and 3 weeks after the EVLA. They found the tulip tip minimzed wall perforation and ulceration while it maximized circumferential vein wall necrosis.[60]

Endovenous radiofrequency ablation

Higher laser wavelength lasers and radial fire tips are an attempt to improve EVLA results by combining perceptions that EVLA is more effective while RFA causes less pain and bruising. RFA uses bipolar electrodes to generate heat with feedback loop to maintain a constant temperature. The practitioner controls the duration of heat application. In a head-to-head randomized, patient-blinded, practitioner-unblinded trial sponsored by VNUS, the maker of the RFA device, RFA patients had less bruising and pain than EVLA patients. Pain scores were good for both groups, however, with RFA patients at 0.7 and EVLA patients 1.9 out of 10 at 48 hours.[61] Although earlier ultrasound-determined ablation rates may have been lower with RFA than EVLA,[20] initial results with the new segmental RFA catheter have been quite successful.[62] In a meta-analysis, EVLA initially proved more durable than RFA after one year, with EVLA having very few technical failures (saphenous recanalization).[20] It will be important to verify RFA results over longer periods of time. The initial RFA devices were also not considered effective at high saphenous vein diameters, and it is unclear whether later RFA catheters have overcome that limitation.

Conclusions

Laser wavelengths between 810 and 1470 nm are effective in ablating pathologic saphenous veins. Serious complications, such as clot extension into deep veins and paresthesias, are rare and comparable among different laser wavelengths. The key elements of success are appropriate energy dosing and proper tumescent anesthesia. Venous access skills and accurate fiber tip placement are also important.

Patient side effects, like pain and bruising, remain significant after EVLA. Higher laser wavelength, radial fiber tips, or covered fiber tips may decrease these side effects. The 1470 nm radial fiber laser is a promising technology with good initial results. A randomized, controlled trial looking at patient outcomes for this device against HSLW and RFA would be useful in the future to test this hypothesis. Further, as a new technology, it is important to prove durability of results over time.

The data shows a trend towards less bruising and pain at higher wavelengths. However, the histology was not much different between 940 and 1319 nm wavelengths post-operatively.[26] While pain may sometimes be caused by bruising, it is likely that other factors such as patient pain tolerance, induration, phlebitis, and paresthesias play a role. In one study looking at the 1470 nm laser, in fact, no patients reported pain and only 21% required pain management, but 68% had bruising.[50] Regarding bruising, tumescent anesthesia technique and anticoagulant use (*e.g.* warfarin, aspirin) likely play a role as well as vein wall perforations. Bruising rates with higher wavelength lasers remain high, even when they are lower than lower wavelength lasers.

Laser technology continues to develop, with lasers at wavelength 2000 nm apparently next. Innovations at the laser fiber tip, such as radial firing or covered distal ends, may prove important. Even now, EVLA is an excellent procedure, with high efficacy, low risk of complications, and usually mild perioperative and postoperative pain.

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