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Endovenous Laser Ablation of Incompetent Perforating Veins with 1470 nm, 400 μm Radial Fiber

Mert Dumantepe, M.D., Arif Tarhan, M.D., Ilhan Yurdakul, M.D., and Azmi Özler, M.D.

Abstract

Objective: To evaluate the efficacy of endovenous laser ablation (EVLA) of incompetent perforating veins (IPVs) with 1470 nm laser with 400 μm radial fiber. ***Background data:*** EVLA for perforating veins can be performed with insignificant postprocedural morbidity. This allows treatment to be offered to elderly patients with co-morbidities that would preclude anesthesia for surgical treatment or subfascial endoscopic perforator surgery (SEPS). ***Methods:*** A total of 24 perforating veins in 16 limbs of 13 patients were treated between July 2010 and December 2011 in our clinic. Follow-up duplex scans were performed at 1 week and 1, 3, 6, and 12 months after the procedure, to determine the treatment outcome. ***Results:*** Of the 23 treated IPVs, 20 (86.9%) were occluded on the duplex examination at 12 months. The average energy administrated per perforating vein treated was 174 J (range 105–236 J). Four of five ulcers had healed after 8 weeks in clinical-etiology-anatomy-pathophysiology (CEAP) C6 group. Two patients reported localized paresthesia, which subsided spontaneously, but no deep venous thrombosis or skin burn was observed. All components of the Venous Clinical Severity Score (VCSS) demonstrated significant improvements at each postprocedural visit ($p < 0.001$ for all), except for pigmentation and compression, which exhibited variation throughout the follow-up period. ***Conclusions:*** Especially in the case of liposclerotic or ulcerated skin in the affected region, EVLA of IPVs with 1470 nm diode laser is highly effective and safe, and appears to be feasible. Additionally, repeat treatment can easily be performed should recurrence of IPVs arise.

Introduction

Incompetent perforator veins (IPVs) are typically observed in patients with chronic venous insufficiency (CVI), but their impact on hemodynamics has been controversial.[1]

Despite still being controversial, substantial evidence points to a potential role for IPVs in the pathogenesis of advanced CVI. Older, respected studies by Linton[2] and Cockett[3] highlight the contribution of IPVs to CVI. It is also clear that deteriorating clinical-etiology-anatomy-pathophysiology (CEAP) grade of CVI is associated with an increase in the number and diameter of calf IPVs.[4]

Treatment of IPVs in severe CVI to reduce superficial venous hypertension has been suggested as one of the possible therapeutic options,[5] and this treatment has been shown to result in more rapid healing of ulcers and lower recurrence rates.[6,7] The numerous possible options used for the treatment of IPVs of the leg include open surgical ligation,[8] subfascial endoscopic perforator surgery (SEPS),[9] and sclerotherapy.[10]

IPV closure by endovenous ablation is a relatively new, minimally invasive technique, which closes off potential sources of reflux.[11] As long as the incompetent perforating vein can be visualized, it can be cannulated and ablated.

These developments led us to believe that percutaneous endovenous thermal ablation of perforating veins (PAP) could also benefit certain patients by not requiring any incisions in the limb, using only local anesthesia, causing less pain, and leading to shorter hospital stays. We were interested in whether the main objective of this method of treatment, that is, stopping reflux by occlusion of the perforator vein, could be obtained by endovenous laser ablation (EVLA). Further, this study was designed to examine the safety and efficacy of endovenous ablation of IPVs with 1470 nm diode laser using a 400 μm radial fiber.

Methods

Study design

Consecutive symptomatic patients, who were referred to our clinic with objectively documented perforating vein

Department of Cardiovascular Surgery, Memorial Atasehir Hospital Istanbul, Turkey.

insuffiency following a duplex ultrasonography (DUS) examination, were considered for entry into this study. After an interview and a physical examination, all patients underwent preoperative duplex venous mapping in our vascular surgery clinic, performed by an experienced phlebologist. For this purpose, a Toshiba Xario SSA-660A series (Toshiba Medical system corporation Nasu-Tokyo Japan) color Doppler US system was used with a 4.8–11 MHz (Toshiba PLT 704 AT) linear transducer. Scanning was performed with the patients sitting on a high examining couch, with their feet resting on a low stool and their knees partially flexed. Reflux times were measured on the release of manual compression of the foot, calf, or thigh, always distal to the evaluated venous segment. A perforator was considered to be incompetent when outward flow >0.5 sec in duration was documented immediately after the release of manual compression. Legs with one or more incompetent perforating veins in the affected area of the leg were treated by EVLA. In addition, all incompetent saphenous trunks in the limb were also treated simultaneously. Informed consent for participation in the study was obtained according to the guidelines of the institutional review boards, and the local ethics committee approved the study protocol.

Technique

The patient was positioned on the operating table in a reverse Trendelenburg position to enhance venous fill and dilate veins. IPVs were identified by transverse scanning, starting from the medial malleolus to the knee. When the target vein was localized, the probe was slowly rotated to achieve the image, including the entire perforator length from its most superficial to the deepest end below the muscle fascia. The IPVs were marked on the skin where they penetrated the fascia (Fig. 1A). We used a 21-gauge Seldinger needle to puncture and access the IPVs. After puncturing, a guide wire was inserted in to the vein (Fig. 1B). A 5 Fr dilator of a micropuncture introducer set was placed over the guide wire into the vein (Fig. 1C). Then the 400-μm diameter, radial emitting laser fiber was inserted through the 5 Fr dilator (Fig. 1D).

Perivascular local tumescent anesthesia, (500 mL saline 0.9%, 10 mL hidroclorure, 0.5%, 1 mL epinenephrine 1:1000, 10 mEq $NaHCO_3$) was given under US control, which also had the advantage of compressing the vessel wall around the laser fiber. A 1470 nm diode laser (Ceralas E, biolitec) was used at a power of 10 W in the continuous pullback mode. Laser energy was administrated over the straight section of the vessel, by pulling back slowly under US control. Additional EVLA of all incompetent truncal saphenous veins was then performed in the same session when necessary.

After treatment, DUS is used to confirm occlusion of the treated vein segment and patency of the deep veins. If there is residual flow in the IPV, repeat treatment is performed at that time. All patients had folded 4×4 gauze applied over treated perforators and elastic bandage wrapped around the leg from the ankle to the knee, with moderate pressure in a multilayer fashion. After treatment, all patients wore 20–30 mm Hg compression stockings for 1 week. Patients were advised to walk regularly (at least three times daily for 20 min) and instructed to ambulate for a minimum of 30 min daily and to refrain from prolonged sitting or standing for 3–5 days.

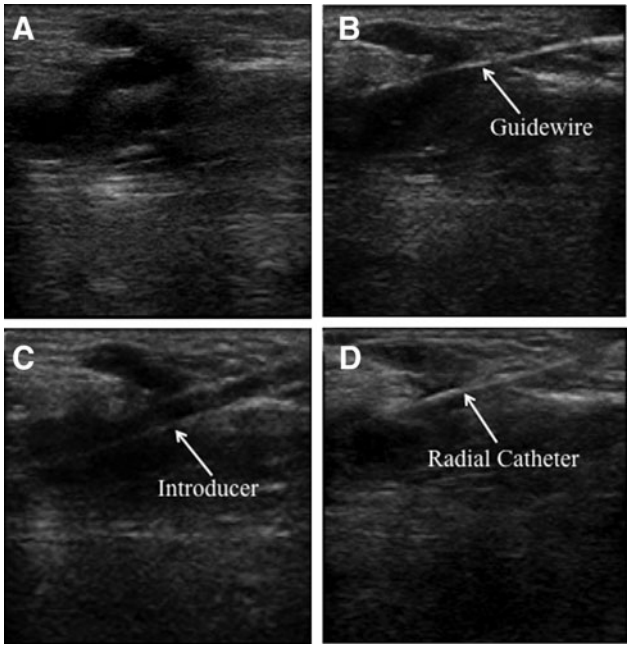

FIG. 1. **(A)** Doppler image of incompetent calf perforating vein. Intraoperative Doppler image of the **(B)** guide wire, **(C)** introducer, and **(D)** radial catheter of treating the target perforator.

Follow-up

Patients were then routinely followed up with a DUS evaluation at 48 h to assess for IPV ablation and deep system patency. Furthermore, follow-up duplex scans were performed at 1 week and 1, 3, 6, and 12 months after the procedure, to determine the treatment outcome. Venous Clinical Severity Score (VCSS),[12] patient satisfaction, recurrence rates, postoperative pain, duration of pain, duration of requirement for analgesia, return to daily activities, ecchymosis, skin burn, skin necrosis, induration, and paresthesia over treated parts of legs were recorded in a written form by the patients during the follow-up visits.

Results

Two vascular surgeons performed all procedures during a 14 month period. Twenty-three perforating veins of 16 legs with clinical signs and symptoms consistent with CVI were included in the study. There were seven females and six males with a mean age of 47 ± 18 years (range, 28–76 years). The clinical severity of the examined limbs, stratified according to the CEAP clinical stage, were C4 (43.7%), C5 (25%), and C6 (31.2%), respectively. The demographic and clinical characteristics of the patients are presented in Table 1. The average energy delivered per perforating vein treated was 174 J (range, 105–236 J). Mean tumescent anesthesia volume/limb was 25 mL (range, 20–35 mL). Operative data are shown in Table 2. Simultaneous treatment of truncal incompetence with EVLA was performed in eight patients (61.5%).

Of the 23 treated IPVs, 20 (86.9%) were occluded on the duplex examination at 12 months. The patient with patent IPV, which was treated by EVLA, was the first patient of the study group. Because this patient's IPVs were close to his deep veins, we decided to treat him with 5 W of energy,

Table 1. Patient and Limb Characteristics and Presenting Complaint

Patient characteristics		*Range*
Number of patients	13	
Number of limbs	15	
Male/female	6/7	
Age (median years)	47	28–76
Time to follow-up (median months)	14	11–18
Presenting complaint	n	%
Skin changes	9	69.2
Active/healed ulcer	6	46.1
Phlebitis	3	23
Cosmesis	4	30
Limb characteristics	n	%
Recurrent varicose veins	7	53.8
Prior EVLA to truncal vein	5	38.4
Concomitant procedures	8	61.5

EVLA, endovenous laser ablation.

delivered as a single pulse. We treated the same patient at the 7th month with 10 W continuous pullback mode, but IPVs were still occluded. Furthermore, simultaneously treated truncal veins were all occluded. In the C6 group of patients, four of five ulcers had healed 8 weeks after treatment (Fig. 2). Two of these limbs were treated by perforator ablation alone.

Minor complications consisted of pain in three patients, one of whom had not been prescribed postoperative analgesia. Two patients complained of paresthesia, which subsided spontaneously and, in another two cases, ecchymosis was observed. Skin burn was not recorded. Mean duration of pain was 2.3 ± 1.1 days and duration of analgesia need was 1.9 ± 0.8 days. No deep venous thrombosis or pulmonary emboli was seen in any patient at this assessment. Table 3 summarizes the side effects and other assessments of the outcome of this study.

Patients were followed up after the procedure on the 7th day and at 1, 3, and 6 months, with the VCSS administered at each visit. The overall mean VCSS for all 10 components decreased from 15.1 ± 3.2 to 7.8 ± 2.6 at the first follow-up visit. During the follow-up period, all VCSS components continued to improve, reaching a significant mean of 4.2 ± 1.3 at the third month visit ($p < 0.001$). The ulcer components of the VCSS proved useful in tracking the number, size, and duration of stasis ulcers after PAP, with 80% of ulcers healing at the 2nd month.

Table 2. Operative Data

Parameters	
Laser power (W)	10
Mean LEED (J/cm)	69 ± 11
Mean total energy/limb (J)	174 ± 75
Mean TLA volume/limb (mL)	35 ± 17
Mean procedure duration/limb (min)	$17 \pm 4{,}8$
Number of phlebectomies/limb	3.4 ± 1.5
Immediate postoperative closure rate (%)	100

LEED, linear endovenous energy density; TLA, tumescent local anesthesia.

Discussion

Stripping of the great saphenous vein (GSV) is a procedure being performed less frequently since the advent of endovenous ablation. These techniques offer patients less invasive alternatives, reducing pain, relief of symptoms, and improving quality of life.[13] Some patients, however, present with venous insufficiency involving not only the GSV but also the perforating veins. Most popular treatment for IPV is surgical subfascial ligation or SEPS.[14] SEPS, and other techniques such as that of Linton or its modifications, leave noticeable surgical scars and lead to high complication rates such as wound site infection, nerve injury, and postoperative pain, especially in patients with CVI-induced skin changes.[15]

Although SEPS is currently the most popular way to treat IPVs, ultrasound-guided endovenous ablation may demonstrate several potential advantages. Unlike SEPS, this technique is not limited to perforating vein location, and the IPVs that cannot be accessed by SEPS can easily be accessed at various locations, including those that are more proximal, such as Boyd's, Dodd's, the mid-thigh Hunterian, laterally located perforators, and perimalleolar vessels. EVLA also allows the flexibility of repeat treatment of persistent or newly developed IPVs, an option that is virtually unavailable with SEPS because of the disturbed tissue planes. As long as IPVs can be visualized by Doppler US, they can be ablated with a laser. Theoretical disadvantages of EVLA of perforator veins can be summarized as missed IPVs; skin, nerve, and deep vessel injuries; and recanalization of ablated IPVs.[11]

Cannulation of these vessels can be more technically challenging because of the small size of the target vessel. We believe that the difficulty will decrease considerably as the experience of the operator increases. Technical difficulties accessing the perforator vein may be solved by use of another technique developed by Uchino.[16] He reported successful obliteration of one perforator vein by laser ablation of a tributary vein (runoff vein) starting proximal to the IPV and ending distal to it. He reported also that this technique might not be useful in the treatment of all perforator veins because many perforator veins are directly related to varicose veins. Recent advances in endovenous interventions have resulted in the development of different types of US-guided percutaneous ablation of perforating veins.

Liquid sclerosants and, more recently, foam sclerosants have been used in the treatment of IPV for >30 years, with or without US guidance. US-guided sclerotherapy (UGST) with liquid or foam sclerosants can provide direct treatment of IPVs, while using a relatively small needle to gain access to the IPV or its tributary. Masuda et al. treated 80 limbs in 68 patients by UGST with liquid sodium morrhuate with a mean of three IPVs/limb.[17] Although initially, 90% of IPVs were occluded, this figure dropped to 70% at a mean follow-up of 20.1 months and new or recurrent IPVs occurred in 35 lesions. There were no reported instances of deep vein thrombosis (DVT), but one limb developed skin necrosis, when one of the small accompanying arteries was injected.

To avoid DVT in the posterior tibial veins, Coleridge-Smith[18] recommended liquid sclerosant for the lower calf IPVs

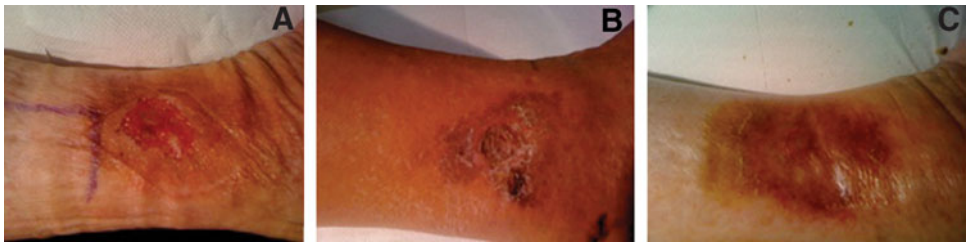

FIG. 2. (A) Preoperative view of clinical-etiology-anatomy-pathophysiology (CEAP) C5 clinical stage venous ulcer. **(B)** Ulcer healing at postoperative 2nd week and **(C)** postoperative 8th week healed venous ulcer.

while reserving foam sclerotherapy for the higher IPVs. He also reported that the tributary of the IPV can be cannulated and the sclerosant can be infused into the IPV by this route.

Bergan and colleagues have reported that PAP of IPV can be performed with a small incision or puncture site in the calf, but this entry site was recommended in the compromised skin directly over the IPV.[13] PAP violates the fundamental principle of a minimally invasive technique for IPVs, avoiding access through the damaged dermal and subcutaneous tissue associated with advanced CVI. Elias and colleagues have reported that a microneedle and a small laser fiber may be less traumatic to the skin and the subcutaneous tissue than a larger probe used in radiofrequency ablation (RFA). Additionally, they have appropriately stated that both techniques may experience significant difficulty when dealing with severely calcified or fibrotic tissue found in the lipodermatosclerotic medial calf.[11]

Clinical studies using RFA reported high initial success rates of 90–100%, but 1 year occlusion rates dropped down to 46–79%. The Van den Bos[19] study reported a procedural success rate of 100% in all treated IPVs, using RFA. At 3 month follow-up, only 9 of 14 treated IPVs were occluded (64%) and the other 5 IPVs showed recurrent reflux on US examination. Fortunately, no DVT was noted. Only two patients reported localized paresthesia in the lower leg.

Klem et al. described use of a cryoprobe, with an advantage that intraluminal access to the perforating vein is not mandatory and reported a 20-week success rate of 43% of treated veins.[20]

Scientific data on the technique, feasibility, safety, and outcomes of EVLA of IPVs are scarce. Proebstle[21] and colleagues reported laser ablation of 67 IPVs combined with phlebectomy or ablation of the great or small saphenous vein in 60 patients. They used laser wavelengths of both 940 and 1320 nm, with laser powers set to values between 5 and 30 W. The legs treated were classified predominantly as CEAP C2. They noted occlusion rates of 99% on perforating veins only 1 day after treatment. At the 3 month DUS assessment, the vein diameters remained the same, but occlusion rates at that time point were not mentioned. In our study, we have observed that of the 23 treated IPVs, 20 (86.9%) remained occluded on DUS examination at 12 months.

Table 3. Postoperative Data

Parameters	
Pain duration (day)	2.3 ± 1.1
Duration of analgesia need (day)	1.9 ± 0.8
Induration (number of limbs)	1
Ecchymosis (number of limbs)	2
Skin necrosis (number of limbs)	0
Skin burn (number of limbs)	0
Paraesthesia (number of limbs)	2
Deep vein thrombosis	0
Pulmonary Embolus	0
12th month closure rate (%)	86.9%

Patients were followed up with duplex Doppler after the procedure at the 7th day, and at 1, 3, and 6 months, with the VCSS administered at each visit. All components of the VCSS demonstrated significant improvements at each post-procedural follow-up time point ($p < 0.001$ for all), except for the pigmentation and compression components, which varied throughout the follow-up periods. At the initial post-procedure visit, the greatest improvement was noted in the pain, varicosity, edema, and inflammation components (Fig. 3).

Corcos and colleagues[22] reported on treating 534 IPVs of 303 limbs with EVLA. EVLA was performed using a 808 nm laser diode with a 0.6 mm fiber, delivered at continuous power of 4–10 W, and with energies of 10–20 J/cm. Follow up at a mean of 27.5 months (range, 3 months to 6 years) of 467 limbs demonstrated with high rates of occlusion and varying individual differences for patent perforating veins, mainly with diameters >6 mm. Minor complications were reported in 11% of patients.

Hissink et al. [23] reported on 28 patients with 58 IPVs treated percutaneously. During their study, an 810 nm diode laser was used at a power of 14 W in the continuous mode. Depending upon the available straight length of the perforator vein, total mean energy delivered was 187 J (range 87–325 J). However, in our study, a 1470 nm diode laser was used at a power of 10 W in the continuous pullback mode, and average energy administerd per perforating vein treated was 174 J (range 105–236 J). An occlusion rate of 78% achieved at 3 months in the Hissink study is comparable to our results; however. our complication rates, duration of pain, and need for analgesia were less than those for the studies mentioned previously.

There is no scientific evidence that laser wavelength has any effect on long-term outcomes, although short-term differences have been reported in the scientific literature.[24] Clinical trials using laser have reported extremely low rates of DVT and paresthesia, low risk of skin burns, and no documented cases of pulmonary embolism. Paresthesia and skin burns have been attributed to 1064 nm laser treatment. Most common complications seen with all laser wavelengths are bruising, localized pain, induration and discomfort along the treated vein, and superficial phlebitis.[25]

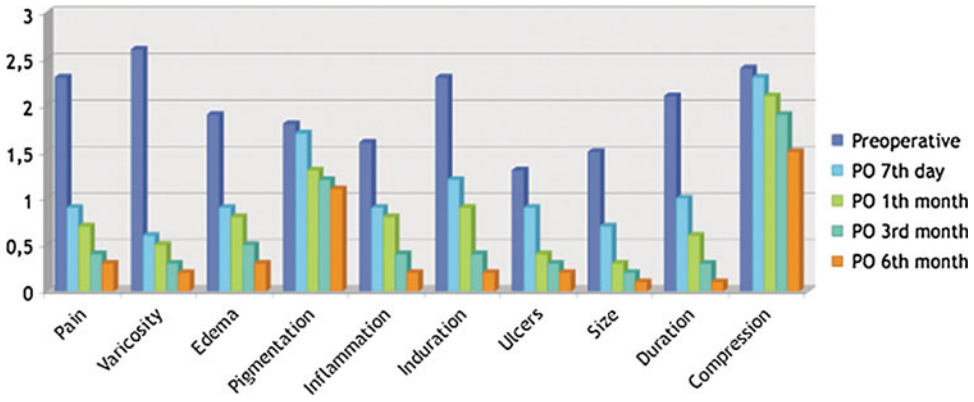

FIG. 3. Scores for each Venous Clinical Severity Scoring component showed significant improvement at each time interval, except for the pigmentation and compression component, over the course of follow-up.

Results after EVLA using 1320 nm laser light showed good occlusion rates and caused less bruising and less pain. Longer wavelengths led to greater water absorption, but less overall absorption by blood compared with shorter wavelength, hinting at certain advantages for EVLA.[26, 27] The 1470 nm laser has been in use since 2006 and operates at a relatively new wavelength for this treatment. The first successful results using this particular wavelength were published by Pannier et al.[28] However, no published data thus far have compared this laser wavelength with other commonly used wavelengths.

Conclusions

EVLA of IPVs can be undertaken with few postprocedural complications and little morbidity. This technique allows the treatment to be offered to elderly patients with comorbidities that would preclude anesthesia for surgical treatment or SEPS. In the case of liposclerotic or ulcerated skin in the affected region where the perforator treatment needs to take place, a percutaneous approach by EVLA seems safe, effective, and technically feasible. Another benefit is that repeat treatment can easily be performed in case of recurrence, and can be performed with laser ablation of the saphenous veins during the same session.

Author Disclosure Statement

The authors declare no conflict of interest or financial interests exist.

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Address correspondence to:
Mert Dumantepe
Merit Life Göl Konakları Sitesi, A-5 Blok
7 Daire: 20
Serifali/Umraniye 34660
İstanbul
Turkey

E-mail: mdumantepe@gmail.com