

ENDOVENOUS LASER ABLATION TREATMENT WITH 980 NM DIODE LASER FOR SAPHENOUS VEIN INSUFFICIENCY: 6 MONTHS FOLLOW UP RESULTS

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Objective: Superficial venous insufficiency is a common problem associated with varicose veins which, if untreated, may progress to venous ulceration. Endovenous laser ablation (EVLA) is a new, minimally invasive method for management of superficial venous insufficiency and varicose veins. The aim of this study was to demonstrate the effectiveness of 980 nm EVLA for treatment of symptomatic saphenous venous insufficiency and to present its early outcomes.

Methods: Thirty-eight great saphenous veins and 5 small saphenous veins in 40 patients with saphenofemoral reflux were treated with 980 nm diode endovenous laser equipment. The diameter and length of the vein treated, total laser energy and energy density (Joules/cm) delivered were recorded. To determine the severity of the venous disease Venous Clinical Severity Score (VCSS) and Visual Analogue Scale (VAS) were used. Patients were followed up for 6 months after the procedure. Complications were recorded prospectively.

Results: Forty-three saphenous veins in 40 patients were treated. The mean age of the patients was 39.9 (range 21-72) years. The mean diameter and length of the veins were 4.9 mm (range, 3.5 to 8.5 mm) and 30.2 cm (range, 16 to 50 cm), respectively. At 6 months follow-up, total occlusion rate was 95.4% (41/43), and recanalization rate was 4.6%. Significant decrease was observed for VCSS and VAS scores after the procedure. No major complication was detected.

Conclusion: EVLA treatment for superficial venous insufficiency is safe and can be carried out under local anaesthesia in an outpatient setting with good patient satisfaction and low complication rates.

Key-words: Lasers – Veins, extremities.

Venous disease which is observed in 40%-55% of the population is a common clinical problem which disrupts the quality of life. The most common cause of chronic venous insufficiency and varicose veins is saphenous vein insufficiency. The general symptoms include leg pain, edema, cramp, skin pigmentation and pruritus. In some advanced cases, eczema and ulcers may be observed (1, 2).

Treatment options for varicose veins include conservative methods, minimal invasive procedures and surgery. Conservative treatment alleviate the symptoms partially and slows down the progression, but does not provide complete cure. In surgical treatment, the most common operation is ligation and stripping (L&S). However, disadvantages include requirement of general anesthesia, postoperative pain and cut scar. In addition, recurrence is observed in approximately half of the patients in the first 5 years after treatment (3). As being a minimally invasive procedure, endovenous laser ablation (EVLA) is an alternative to conventional methods in treatment of superficial venous insufficiency and has replaced surgical treatment with a great extent.

The aim of this study was to evaluate the efficiency of 980 nm EVLA treatment in saphenous vein insufficiency and demonstrate short-term outcomes.

Patients and methods

Forty patients (18 male, 22 female) aged between 21 and 71 years (mean age; 39.9 ± 12.3 years) who were diagnosed with symptomatic saphenous vein insufficiency between April 2010 and August 2011 were included in this prospective study. The study was performed after obtaining ethics committee approval. Informed consent was obtained from all patients included in the study.

The patients were assessed clinically and by colored Doppler ultrasonography (US) in terms of skin changes, presence of edema and venous ulcer, extension and distribution of varicose veins. On colored Doppler US examination, the large saphenous vein (LSV) and small saphenous vein (SSV) were pursued along their traces. Presence of venous reflux was checked at 3 different levels including the saphenofemoral junction (SFJ), saphenopopliteal junction (SPJ) and along the saphenous vein traces. Reverse flow of

0.5 sec and above with Valsalva and distal compression maneuvers was recorded as pathological reflux. The diameters of the saphenous veins were measured approximately 3 cm caudal to the SFJ and SPJ level. If there was perforator venous insufficiency in the femoral and crural regions, they were recorded with their levels. In addition, the examined lower extremity was assessed using gray scale and colored Doppler US in terms of venous thrombosis, thrombophlebitis and severe arterial insufficiency.

The patients were classified clinically, etiologically, anatomically and pathophysiologically according to the CEAP classification.

Values of venous clinical severity score (VCSS) based on pre-treatment clinical complaints and findings were recorded. In addition, visual analogue scale (VAS) was used to determine the severity of the individuals (Table I).

The numerical value marked on the visual analogue scale was recorded as the severity of complaints generally experienced by the patients.

Patients who had deep vein thrombosis, marked deep venous insufficiency and severe arterial insufficiency, who were pregnant or breastfeeding, who were extremely debilitated and who had a history of allergy against local anesthetic substances or sclerosing substances were not included in the study.

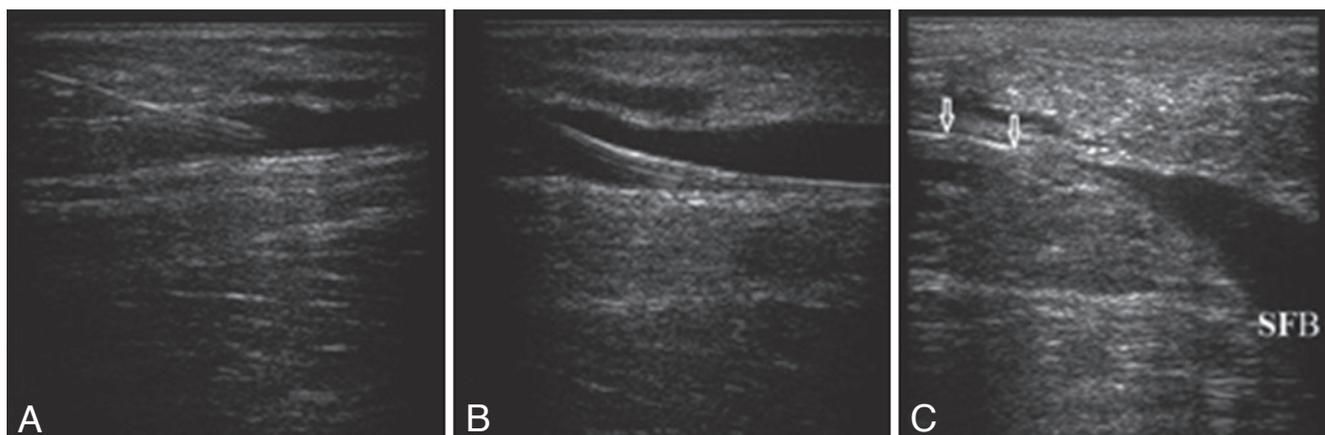


Fig. 1. — Entrance into the saphenous vein percutaneously with a 21 G needle (A), placement of the 5F catheter over the guidewire into the lumen of the saphenous vein and advancement until approximately 2 cm away from the SFJ (B, C).

Table I. — VAS scoring.

VAS:	0	1	2	3	4	5	6	7	8	9	10
	(No pain)				(moderate)				(very severe)		

Endovenous laser ablation technique

Diode laser source (Intermedic, Endolazer, Spain) with 980 mm wavelength and a maximum power of 15W was used for EVLA procedure.

The patients were prepared by sterilizing the legs, soles and inguinal regions. Under local anesthesia, the saphenous vein where reflux was found was entered distally using a 21 G needle under ultrasonographic guidance. A 0.018 inch guidewire was sent through the needle and the needle was removed. The catheter system which is composed of two parts (sheath and dilatator) was sent over the guidewire and the dilatator inside was removed together with the wire. With the assistance of the sheath which stayed in the vascular lumen, a 0.035 inch J-tip guidewire was advanced along the saphenous vein. A 5 F 70 cm-marked catheter was placed 2 cm distal to the SFJ/SPJ over the guidewire (Fig. 1).

Tumescent local anesthesia was prepared as a mixture of 500 cc physiologic serum (+4 C°), 10 ml 10% lidocaine, 20 ml 8.4% sodium bicarbonate and 0.5 mg adrenaline. It was injected under US guidance using a 21G micropuncture needle such as to cover the surrounding of the venous segment on which the procedure would be performed 360 degrees (Fig. 2). After the tumescent local anesthesia was performed opti-

mally, the guidewire was removed, the laser fiber bound to a laser source was advanced inside the catheter and the naked tip of the laser fiber was placed 2 cm distal to the SFJ/SPJ under US guidance.

Laser energy was applied as 12 J in each shot with a pulse mode of 1 sec intervals in proportion with the vascular diameter more intensely in the areas close to the SFJ/SPJ by adjusting the laser parameters. Lower energy amounts were preferred in the superficial segments to prevent skin burns. The length of the saphenous vein which would be treated was calculated on the 5F 70 cm-marked catheter and recorded. At the end of the procedure, the total laser energy applied and showed on the laser source was recorded. The laser energy applied in each centimeter (J/cm) was calculated by dividing the total laser energy to the length of the saphenous vein treated.

After EVLA procedure, foam sclerotherapy was applied directed to the superficial varicose veins using 1-3% polidocanol as the sclerosing agent. Dilution of the sclerosing agent with air was provided with proportions of 1:2, 1:3 or 1:4 according to the diameter and extension of the varicose veins using a three-way tap and two injectors. After the foam was produced it was applied percutaneously into the varices. The distribution of the sclerosing agent which was transformed to foam was monitored by US and its distribution in

the varicose vein segments was provided with the assistance of a probe, when necessary. After the procedure a tight bandage was applied to the extremity to be kept for 5-6 days and the patients were mobilized. The patients were made to walk for 30 minutes without stopping and they were monitored for 2 hours following the procedure. Analgesic drugs were prescribed to be used for one week. The patients were encouraged to wear Class 2 support socks for one month.

The patients were followed up clinically and by Doppler US in the 1st and 2nd week and 1st month and 6th month. Occlusion and recanalization of the saphenous veins and the status of the varicose veins were evaluated. Complications were investigated. At the six-month follow-up visit, vessel diameter measurements, VCSS evaluation and VAS scoring were repeated.

Statistical analysis

The descriptive statistics for the groups in terms of the properties emphasized were expressed as mean, standard deviation, minimum and maximum values. Student's-t test was used to examine if there was a difference between the groups before and after treatment in terms of these properties. The statistical significance level was considered as 5% and calculated. The analyses were done using SPSS version 13.0 package programme.

Results

EVLA procedure was applied only to the LSV in 37 extremities, only to the SSV in 4 extremities and both to

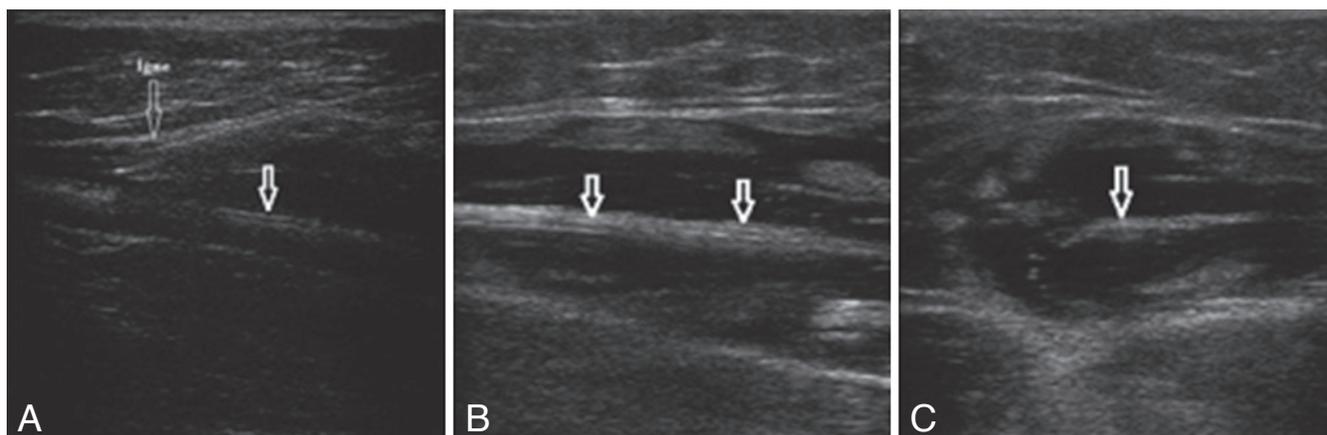


Fig. 2. — On longitudinal (A, B) and transverse (C) US images, tumescent local anesthesia can be observed around the saphenous vein.

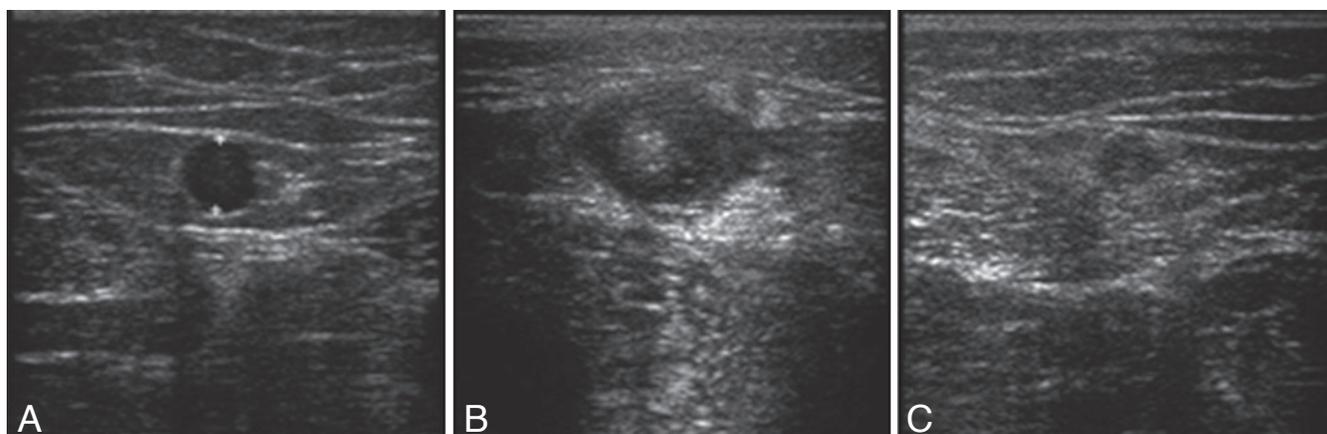


Fig. 3. — Appearance of the LSV before EVLA (A), after EVLA (B) and 6 months after treatment (C)

the LSV and SSV in one extremity in a total of 43 saphenous veins in 42 lower extremities. In two patients, bilateral LSVs were treated. Simultaneously with EVLA treatment, foam sclerotherapy was applied with 1-3% polidocanol directed to the superficial varicose veins in 33 (78.7%) of 42 extremities.

On colored doppler US examination before the procedure, insufficiency was present at the level of the SFJ along the trace of the LSV in 35 extremities and at the level of the SPJ along the trace of the SSV in 5 extremities. In 3 extremities, insufficiency was found in the Hunter's perforator vein and in the LSV distal to this level.

CEAP clinical scores of the patients in whom treatment was applied were as follows: C2 in four extremities (95%), C3 in 12 extremities (28.5%) and C4 in 26 extremities (62%). In all 42 extremities, the etiology was primary and the pathophysiology was related with reflux. Superficial venous insufficiency was found in

39 extremities (92.8%) and both superficial and perforating vein insufficiencies were found in 3 extremities (7.2%).

The diameters of the saphenous veins ranged between 3,5 mm and 8,5 mm (mean $4,9 \pm 0,8$). The lengths of the saphenous veins ranged between 16 cm and 50 cm (mean $30,2 \pm 7,6$).

Laser energy ranging totally between 950 joule and 3940 joule (mean $2545 \pm 669,6$ J) and between 59.3 and 97.1 joule/cm was applied in the saphenous veins treated.

Varying degrees of tenderness and ecchymosis were observed in 34 extremities (81%) at the one-week follow-up visit. Ecchymosis and tenderness were not observed in the follow-up visit at the second week.

In one extremity (2.3%), superficial thrombophlebitis which required treatment was observed in the varicose veins in the first week. The patient was treated with appropriate medications. Varying degrees of increased pigmentation was observed

at the six-month follow-up visit in 7 (21%) of 33 patients in whom foam sclerotherapy was applied in the superficial veins.

No major complications including skin burns or deep vein thrombosis were found in the patients in whom the procedure was applied.

Recanalization was observed in 2 (4.6%) of the saphenous veins (in the LSV). Complete occlusion was observed in 41 (95.4%) of 43 saphenous veins treated (Fig. 3).

After EVLA procedure, the diameters of the saphenous veins ranged between 1.4 and 3.2 mm at the six-month follow-up visit (mean 2.2 ± 0.4 mm). When the vein diameters measured before the procedure and 6 months after the procedure were compared, the decrease in the diameters after treatment was found to be statistically significant ($p < 0.05$).

While the VAS score of the patients was 6.95 ± 1.2 before the procedure, it was found to be 1.60 ± 1.0 6 months after the procedure. The decrease in the VAS score 6 months

Table II. – Descriptive statistics according to student's-t test and comparison results.

	Pre-treatment VAS	Post-treatment VAS	Pre-treatment VCSS	Post-treatment VCSS
Number	42	42	42	42
Mean value	6,95	1,60	6,98	1,0
Maximum	9	3	10	3
Minimum	4	0	3	0
Standard deviation	1,2	1,0	1,7	0,9
P.	0.003		0,001	

after the procedure compared to the value before the procedure was statistically significant ($p < 0.05$).

While the VCSS value of the patients was 6.98 ± 1.7 before the procedure, it was found to be 1.0 ± 0.9 6 months after the procedure. The decrease in the VCSS value 6 months after the procedure compared to the value before the procedure was statistically significant ($p < 0.05$, Table II).

No statistically significant difference was found between the patients in whom foam sclerotherapy was performed and not performed following EVLA therapy in terms of the reduction in VAS and VCSS values.

Discussion

Chronic venous insufficiency is an important clinical condition which may affect the quality of life of individuals. It gains importance with its high prevalence, marked workforce loss and its effects on the quality of life of the patient (1, 2).

Most of the venous problems in the lower extremities originate from the LSV and SSV. Insufficiency in the valves of the saphenous vein, weakness in the walls of the veins and arterovenous fistulas are among the most important causes of varices (4).

In treatment of venous insufficiency, the classical method is surgical. The most commonly performed operation in this area is the L&S operation which is used in eliminating LSV insufficiency. In this operation, the LSV is ligated at the level of the SFJ and the part of the LSV above the knee is removed. Thus, the vessel which leads to venous insufficiency and varices is eliminated. However, the L&S operation is performed under general anesthesia and the time to go back to normal life after the operation is long (5, 6).

The current developments in treatment of varicose veins using minimally invasive interventions include radiofrequency ablation, EVLA

and foam sclerotherapy under US guidance (3). Laser therapy for treatment of varicose veins was defined in 1985 for the first time (7). EVLA has "Food and Drug Administration" approval since 2002 and it has been used gradually widely as its efficiency became prominent (8). The most important advantages of this method include performance under local anesthesia, absence of pain, absence of wound or scar and mobilization of the patient immediately after the procedure (9, 10).

The EVLA method can be applied in approximately 70% of the patients with complaints of varice. The success rate of the intervention is above 90%. Obesity, low energy distribution per cm vein, larger saphenous vein diameter and higher central venous pressures in deep veins are related with higher failure rates (11-13). In our study, the early success rate at the six-month follow-up visit was found to be 95.4% which was compatible with the literature.

Minor complications of EVLA therapy include pain, paresthesia, superficial thrombophlebitis, hematoma and skin pigmentation. Major complications include deep vein thrombosis, peripheral nerve injury and pulmonary embolus (1, 3). In a series, 3 thrombosis cases extending inside the femoral vein and carrying a possibility of pulmonary embolus were found. It was reported that a case of septic thrombophlebitis which developed following EVLA therapy resulted in phlegmon which required surgical drainage and antibiotic treatment (14). Deep vein thrombosis prophylaxis may be considered above the age of 50 years (15). In a serial study performed by Ravi et al (16), pulmonary embolus was observed in an obese patient after EVLA treatment on the 4th day. Transient cutaneous numbness may occur as a result of injury of the saphenous or sural nerve (17). Nerve injury may originate directly from increased perivenous heat or

thrombosis in the vaso nervosum. EVLA treatment of the small saphenous vein may be related with a higher rate of nerve injury because of adjacency to the sural nerve (18). In our study, varying degrees of tenderness and ecchymosis were observed in 34 (81%) extremities at the one-week follow-up visit. No ecchymosis or tenderness was observed at the two-week follow-up visit. Superficial thrombophlebitis was observed in the varicose veins in the 1st week in one extremity (2.3%). Treatment was provided with appropriate medication. Major complications including skin burn and deep vein thrombosis were not observed.

In a study performed by Desmyttere et al (19) in which 500 patients (436 women, 64 men) were included, treatment with 511 LSV 980 nm EVLA was applied and occlusion with a rate of 98% was obtained immediately after the intervention. At the four-year follow-up visit, this rate was found to be 97.1%. At the one-week follow-up visit, moderate pain was observed with a rate of 9.3%. In the one-year follow-up visit, the LSV was completely eliminated or reported as a minimal fibrous cord. No major complication was observed. Ecchymosis was observed in 60% of the patients and transient paresthesia was observed in 7% of the patients.

Sharif et al (20) reported a success rate of 85.5% for EVLA treatment which they performed in 145 extremities of 136 patients who had LSV insufficiency. At the three-month follow-up visit, complete occlusion was found with a rate of 89.7% and partial occlusion was found with a rate of 7.7%. At the 12-month follow-up visit, complete occlusion was observed with a rate of 76% and partial occlusion was found with a rate of 18%. At the one-year follow-up visit, residual or recurrent varices were found in 31% of the patients. Only 5% of these required further treatment. Among

complications, saphenous vein injury was observed in one patient and superficial skin burn was observed in another patient.

Min et al (9) reported the long-time success rate of EVLA treatment to be 93.4% in the second year in a study they conducted with 499 extremities. LSV was not observed on doppler US examination in the regions where treatment was applied. The most commonly observed symptom was tenderness with a rate of 90% and the most commonly observed finding was ecchymosis with a rate of 30%. No major complication was observed.

In a randomized controlled study, the results and costs of EVLA and high ligation and stripping were compared. Post-operative pain and ecchymosis were observed with a higher rate after open operation and inguinal wound infection developed in one patient. The quality of life was found to be similar in the 3rd month. The total costs of the procedures were found to be similar in both groups (21).

In a study in which 67 perforating veins were included, it was shown that EVLA could also be successfully used in insufficiency of the perforating veins. In this study, a laser fiber was placed 1 cm away from the deep veins below the fascia and complete occlusion was reported on the first day with approximately 250 J 1320 nm laser with a power of 10 W in 66 perforating veins (22).

Higher doses of laser energy have been reported to result in 100% success and significantly reduced recanalization (11). It has been reported that laser wavelengths do not affect the efficiency of this procedure (8). In a prospective, randomized, controlled study which compared ablation therapy of the LSV with 980 and 810 nm, it was reported that there was no difference on the 3rd day, but less ecchymosis was observed in the entrance region on the 7th day in the 980 nm group compared to the 810 nm group (23).

Conclusively, EVLA is a safe method which can be performed under local anesthesia in superficial venous

insufficiency with high patient satisfaction and low complication rates.

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