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Early clinical improvement in chronic venous insufficiency symptoms after laser ablation of saphenous veins

Uğur Özkan, Çağla Sarıtürk

PURPOSE
We aimed to assess the degree of improvement in chronic venous disease-related symptoms after endovenous laser ablation (EVLA) for saphenous vein insufficiency.

MATERIALS AND METHODS
The study was conducted as a single-center, single-arm prospective cohort study. The series was comprised of 55 limbs of 38 patients (24 [63%] females, 14 [37%] males; mean age, 45±14 years; range, 22–78 years). All patients were clinically evaluated for limb pain, fatigue, heaviness, itchiness, night cramps, burning sensation, swelling, varices, and the presence of venous ulcers. Post-procedure changes in each symptom were categorized as full recovery, improvement, no change, or worsened.

RESULTS
Clinical improvement in one or more symptoms was observed in 96% of the limbs, and full recovery from each symptom ranged from 36% to 80%. The best clinical response was observed in night cramps, with full recovery in 80% of the limbs, while the least responsive was pain, with full recovery in 36%. Overall 25% of limbs showed full recovery from all symptoms. The venous clinical severity score was significantly decreased from a median of 5 (range, 1–21) before treatment to a median of 3 (range, 0–12) after treatment ($P < 0.001$). A significant association was found between full recovery from pain and older age ($P = 0.016$) and combined ablation of both saphenous veins ($P = 0.010$), and between full recovery from burning sensation and the presence of new incompetent perforator veins ($P = 0.048$) on multivariate analysis.

CONCLUSION
EVLA effectively improves clinical symptoms in patients with chronic venous disease. The degree of symptomatic improvement varies for each symptom.

Key words: • *varicose veins* • *venous insufficiency* • *laser ablation* • *saphenous vein*

Varicose veins that develop due to chronic venous insufficiency are a common problem that can worsen an individual's quality of life. The most common reason for the development of chronic venous insufficiency and varicose veins is saphenous vein insufficiency (1, 2). Symptoms may differ among patients, but the most commonly reported include limb pain, fatigue, heaviness, itchiness, night cramps, burning sensation, and swelling. In some advanced cases, eczema, hyperpigmentation, and leg ulcers may be seen.

Traditional treatment for saphenous vein insufficiency is surgical ligation and stripping. In recent years, however, endovenous ablation techniques have become a standard treatment. In many studies comparing treatment techniques for this disease, saphenous vein surgery and endovenous ablation have been shown to improve quality of life in the long term (3–6). Although numerous studies have been published on endovenous ablation, most have concentrated primarily on technical success or quality of life. Further, no data has been reported regarding the improvement of specific symptoms after the procedure (7–9).

The aim of this prospective study was to evaluate early clinical benefits in specific symptoms of chronic venous insufficiency following endovenous laser ablation (EVLA) without any concomitant procedures, such as sclerotherapy, phlebectomy, or perforating vein surgery.

Materials and methods

The study was approved by the institutional review board and conformed to the reporting standards outlined by the joint statement of the American Venous Forum and the Society of Interventional Radiology (10). Thirty-eight consecutive patients who had saphenous vein insufficiency and symptoms of chronic venous disease were included in this prospective study; from the 38 patients, a total of 55 limbs were examined. Patients were diagnosed using color Doppler ultrasonography (CDUS) to detect insufficiency in the great and/or small saphenous veins. Patients with a history of deep venous thrombosis (n=2), previous varicose vein surgery or injection sclerotherapy (n=3), or who did not return for follow-up evaluations (n=3) were excluded.

Patients were questioned clinically about leg pain, fatigue, heaviness, itchiness, night cramps, burning sensation, swelling, varices, and the presence of venous ulcers. After the treatment, each symptom was re-evaluated and categorized as "full recovery", "improvement", "no change", or "worsened". Venous clinical severity scores (VCSS) were documented for each limb and compared before and after the procedure. All patients underwent clinical and CDUS examinations in the outpatient clinic. CDUS exams were performed in the standing position. Superficial (great and small saphenous veins), deep (femoral and popliteal veins), and calf perforator veins were evaluated in detail for the presence of insufficiency

From the Departments of Radiology (U.Ö. ✉ *radugur@yahoo.com*) and Biostatistics (Ç.S.), Başkent University School of Medicine, Adana, Turkey.

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or previous venous thromboses. The types of perforator veins for the purpose of the study are defined in Table 1. Reflux with a duration of >500 ms in the saphenous veins and the calf perforators, and >1000 ms in the femoral and popliteal veins while performing calf compression or the Valsalva maneuver were considered pathologic.

Prior to the EVLA procedure, the risks and benefits of the procedure was discussed in detail with patients, and informed consent was obtained from each patient. Legs were prepared in a sterile fashion before the procedure. The great saphenous vein was catheterized on or under the knee region, and the small saphenous vein was catheterized near the ankle. The veins were punctured with a 21-gauge needle under ultrasonography (US) guidance and a 5-Fr catheter was introduced over a guide wire. A bare-tipped 600 µm laser fiber (Dornier, MedTech Laser GmbH, Germering, Germany or Biolitec, Jena, Germany) was threaded inside the catheter with the tip of the wire 1 to 2 cm distal from the saphenofemoral or saphenopopliteal junction. US guidance was used to confirm the correct placement of the laser fiber. Next, tumescent anesthesia was applied around the saphenous vein by US guidance; normal saline (500–1000 cc) and 2% prilocaine (10–20 cc) were used for tumescent anesthesia. After tumescent anesthesia, EVLA was performed with continuous laser at 10 W power. Each cm of the vein had laser energy for 6–10 s, resulting in treatment with 60–100 J per cm of vein. Our standard procedure consisted of 100 J/cm for the proximal part of the great saphenous vein, 80 J/cm for the middle part of the great saphenous vein, 60 J/cm for the distal part of the great saphenous vein and for the entire small saphenous vein.

No adjunctive procedure, such as sclerotherapy or phlebectomy, was performed on the patients at any point during the study. According to the guidelines on complications by the Society of Interventional Radiology Standards of Practice Committee, ecchymosis, pain, induration, dysesthesia, superficial thrombophlebitis, and hematoma were classified as minor complications occurring after EVLA, while deep vein thrombosis, pulmonary embolism, and nerve injury were classified as major complications. Patients were advised to use non-steroidal anti-inflammatory medications, class II (30–40 mmHg) stockings for three to four weeks and to abstain from heavy exercise.

Follow-up appointments were scheduled for one, three, and six months post-procedure. At the one-month follow-up, patients were only evaluated by CDUS. Clinical evaluations and CDUS exams were later performed at three and/or six months post-procedure, as pain usually persisted in the localized areas at one month. CDUS was used to evaluate all saphenous veins and calf perforators in limbs treated with EVLA. When recanalization of the saphenous vein was found, clinical evaluation was performed after successful treatment of the recanalized segment using repeated EVLA or foam sclerotherapy.

Statistical Package for the Social Sciences (SSPS) software (SPSS for Windows, version 17.0, SPSS Inc., Chicago, Illinois, USA) was used to perform all statistical analyses. The following variables were included in the analyses: age, gender, CEAP classification, duration of symptoms, variables related to the great and small saphenous veins (diameters, number of saphenous veins treated, energy delivered per cm and limb, length of treated segment, recanalization), popliteal and femoral insufficiencies, and variables related to the perforator veins (presence of new perforator veins, new competencies, and new incompetencies). Comparisons were performed with the Student *t* test, Wilcoxon test or Mann-Whitney *U* test for continuous variables; the Pearson X^2 test was used for discrete variables. Clinical variables found significant by univariate analysis were selected as risk factors for multivariate analysis using linear and logistic regression. *P* values less than 0.05 were considered significant.

Table 1. The types of calf perforator veins

Calf perforator vein	Description
Original	Any perforator vein noted before endovenous laser ablation
New	Any perforator vein not seen prior to the procedure (new ultrasonography-detectable perforator vein)
New competency	A perforator vein observed as incompetent previously, but competent after the procedure
New incompetency	A perforator vein observed as competent previously, but incompetent after the procedure

Results

The study group included 24 female (63%) and 14 male (37%) patients with a mean age of 45±14 years (range, 22–78 years). The most common complaints prior to the EVLA procedure were the presence of varicose veins (96%) and pain (91%). Fatigue and heaviness (89%), night cramps (81%), burning (64%), itchiness (64%), and swelling of the legs (54%) were less common complaints. Two patients (4%) had active ulcers before the procedure. Great and small saphenous vein insufficiencies were detected in 52 (94%) and 28 (51%) limbs, respectively. Of the 55 limbs, 27 (49%) had isolated great saphenous vein insufficiency, three (5.5%) had isolated small saphenous vein insufficiency, and 25 (45.5%) had both saphenous vein insufficiencies. Preoperative deep venous reflux was also detected in the femoral vein of 21 (39%) limbs and in the popliteal vein of 12 (28%) limbs. The median number of incompetent perforator veins and of all perforator veins per limb preoperatively was two (range, 0–7) and eight (range, 3–16), respectively. Patients' demographic and clinical data are summarized in Table 2.

Single saphenous vein ablation was performed in 51% of limbs (n=28). Both great and small saphenous veins were ablated in 49% of the limbs (n=27). The mean lengths of the great and small saphenous veins treated by EVLA were 56±11 cm (range, 28–88 cm) and 28±6 cm (range, 15–40 cm), respectively. A mean energy of 4635±990 J/limb (82±9 J/cm) for the great saphenous vein and 2091±569 J/limb (74±12 J/cm) for the small saphenous vein were delivered. Initial technical success was obtained in all EVLA procedures. However, follow-up CDUS revealed partial recanalization of two great saphenous veins and one

small saphenous vein, all of which were successfully treated with repeated EVLA or localized sclerotherapy. The median time to follow-up was 12 weeks (range, 3–27 weeks). After the procedure, 24 new US-detectable perforators in 20 limbs (34%), 31 new competent perforator veins in 22 limbs (40%), and 46 new incompetent perforator veins in 29 limbs (53%) were found.

In the follow-up period after the EVLA, clinical improvement in one or more symptoms was observed in 53 (96%) of the 55 limbs; full recovery from all symptoms was observed in 25% of the limbs, and 71% improved significantly. Table 3 summarizes the symptom changes after EVLA. Full recovery from each symptom was more common in older patients, and in univariate analysis, age was related to full recovery from pain, burning, swelling and itchiness. However, age was an independent predictor of full recovery from only pain in multivariate analysis. The associations between age and clinical improvement of each symptom of chronic venous insufficiency are shown in Table 4. After the procedure, the median VCSS improved significantly, falling from a 5 (range, 1–21) to 3 (range, 0–12) at a median follow-up of 12 weeks. A statistically significant difference was found between VCSSs before and after the procedure ($P < 0.001$).

Full recovery from pain was observed in 36% of the limbs, while significant improvement was observed in 56% of the limbs. Full recovery from pain was more pronounced in older patients (median, 53 years; range, 22–78 years) than in younger patients (median, 39 years; range, 25–74 years; $P = 0.012$), and in limbs with combined ablation of both saphenous veins compared to limbs with ablation of only one saphenous vein (54% vs. 19%, respectively; $P = 0.010$). Ablation of both saphenous veins ($P = 0.010$) and age ($P = 0.016$) were independent predictors of full recovery from pain in multivariate analysis.

The elimination of burning sensation was associated with age and the presence of new incompetent perforator veins after treatment. Frequency of full recovery from burning sensation was significantly higher in limbs with new incompetent perforator veins after the procedure than in limbs without new incompetent perforator veins (65% vs. 28%; $P = 0.028$). Full recovery

Table 2. The characteristics of the study population

Variable	Result
Age (years), mean±SD	45±14
Female/male, n (%)	24 (63)/14 (37)
Right/left limb, n (%)	26 (47)/29 (53%)
Duration of symptoms (years), median (range)	10 (1–50)
CEAP , n (%)	
1–3	39 (71)
4–6	16 (29)
Insufficiency, n (%)	
GSV	52 (94)
SSV	28 (51)
Femoral vein	21 (39)
Popliteal vein	12 (28)
Diameter of GSV (mm), mean±SD	6.5±2.2
Diameter of SSV (mm), mean±SD	3.7±2.0
Length of ablated GSV (cm), mean±SD	56±11
Length of ablated SSV (cm), mean±SD	28±6
VCSS of patients, median (range)	
Before EVLA	5 (1–21)
After EVLA	3 (0–12)

CEAP, clinical-etiological-anatomical-pathological classification; GVS, great saphenous vein; SSV, small saphenous vein; VCSS, venous clinical severity scores; EVLA, endovenous laser ablation; SD, standard deviation.

Table 3. Changes in the symptoms of chronic venous insufficiency after the EVLA procedure

Symptom	Full recovery n (%)	Improvement n (%)	No change n (%)	Worsened n (%)
Pain	18 (36)	28 (56)	4 (8)	–
Fatigue	20 (41)	25 (51)	4 (8)	–
Cramps	36 (80)	6 (13)	1 (2)	2 (4)
Itchiness	15 (43)	10 (29)	7 (20)	3 (8)
Burning	16 (46)	11 (31)	6 (17)	2 (6)
Swelling	18 (46)	16 (41)	4 (10)	1 (3)
Varicose veins	3 (6)	33 (69)	10 (21)	–

Table 4. The median ages of chronic venous insufficiency patients with or without full recovery from each symptom after the EVLA procedure

	Median age (range)		*P*	
Symptom	Patients with full recovery	Patients without full recovery	Univariate analysis	Multivariate analysis
Pain	53 (22–78)	39 (25–74)	0.012	0.016
Fatigue	45 (22–78)	39 (25–74)	0.935	–
Cramps	42 (22–78)	36 (30–74)	0.921	–
Itchiness	48 (30–78)	34 (24–38)	0,019	0,053
Burning	51.5 (33–78)	38 (24–74)	0.035	0.107
Swelling	50 (27–78)	38 (25–74)	0.045	–

from burning sensation also occurred more often in older patients (median, 51.5 years; range, 33–78 years) than in younger patients (median, 38 years; range, 24–74 years; $P = 0.035$). The presence of newly emerged incompetent perforator veins was the only independent predictor of full recovery from burning sensation in multivariate analysis ($P = 0.048$).

Of the limbs, 43% experienced a total recovery from itchiness, and 29% improved significantly after the treatment. The percentages of limbs with no change or an increase in itchiness were 20% and 8%, respectively. Older patients (median, 48 vs. 34 years; range, 30–78 vs. 24–48 years, respectively; $P = 0.019$) and a longer duration of symptom complaints (median, 13 vs. 6 years; range, 1–34 vs. 1–50 years, respectively; $P = 0.041$) were associated with full recovery from itchiness in univariate analysis, but these risk factors were not independent predictors in multivariate analysis.

After the treatment, full recovery from swelling was observed in 46% of the limbs, and significant improvement was seen in 41% of the limbs. A significantly higher frequency of full recovery from swelling was found in older patients (median, 50 years; range, 27–78 years) than in younger patients (median, 38 years; range, 25–74 years, $P = 0.045$). For other symptoms, including limb fatigue, cramps, and heaviness, changes were not related to any variables investigated after treatment.

After the EVLA procedure, no major complications, such as skin burn, deep vein thrombosis, superficial thrombophlebitis, or nerve injury, were encountered. However, minor complications, including postoperative pain (42%), ecchymosis (33%), and dysesthesia (26%) were common. No additional treatment was required for these complications.

Discussion

Lower extremity venous insufficiency and varicose veins secondary to venous insufficiency are significant health problems that lower patients' quality of life. Surgical or endovenous ablation of saphenous veins improves quality of life in the long term and helps symptoms subside. Comparison of saphenous vein ablation and surgery regarding change in quality of life showed similar results in the long term (1–6). However, in the early postoperative period, patients who had laser ablation experienced a greater improvement in quality of life, a faster return to work and a quicker return to normal activities (3–8).

Previous studies have demonstrated that both surgical and endovenous ablation of the saphenous veins greatly improve clinical symptoms. Rasmussen et al. (7) reported a 90% improvement in clinical symptoms after endovenous laser ablation, and Pittaluga et al. (11) reported a 91% improvement in clinical symptoms after surgery. Similarly, 96% of patients in the present study showed significant clinical improvement. Although clinical improvement has been reported in the great majority of cases in previous studies, the rate of full recovery from all symptoms is not clear. In the current study, 25% of limbs experienced a full recovery from all symptoms after EVLA without concomitant procedures. A recent prospective study reported a clinical improvement rate of 97% and a full recovery rate of 69% from symptoms of venous insufficiency after EVLA with concomitant sclerotherapy (9). Difference in the rate of full recovery may have resulted from the additional concomitant therapies performed on the patients. Our purpose in this study was to disclose full recovery from EVLA alone, therefore we did not perform additional methods, such as sclerotheraphy, varisectomy or perforator vein ablation. However, additional methods such as sclerotheraphy, varisectomy, and perforator vein ablation have been shown to add to the improvement in quality of life obtained through endovenous laser ablation (12–14). Carradice et al. (15) reported that the venous clinical severity scores of patients who had only laser ablation were lower than those who also underwent phlebectomy. Hence, we speculate that most of the symptoms remaining for our patients after the procedure may be due to residual varices and/or perforator vein insufficiency.

In our study, age seems to be the most prominent risk factor affecting total elimination of symptoms of chronic venous insufficiency. Full recovery from all symptoms was commonly seen in older patients, and significant associations between some symptoms (including pain, burning sensation, swelling, itchiness, and age) were found through univariate analysis. However, only age was found to be an independent predictor for full recovery from pain through multivariate analysis. Additionally, multivariate analysis revealed significant associations between combined ablation of both saphenous veins and recovery from pain, and between the presence of new incompetent perforator veins and recovery from swelling. To our knowledge, there is no data in the literature regarding elucidating factors that influence clinical improvement after the EVLA.

Studies on the results of saphenous vein surgery and laser ablation, or comparing these procedures, are abundant. However, we could not find any study in the literature regarding the change of symptoms after treatment. An interesting finding of our study was the variation in symptomatic improvement in response to the procedure. For example, pain, the most common and important symptom, showed significant improvement in 92% of limbs. However, only 36% of limbs showed full recovery from pain. Cramps, which responded the best to treatment, had a 93% significant improvement rate and an 80% full recovery rate. The percentage of patients who experienced a worsening of symptoms after laser treatment was very low (3%–8%; Table 2). In these cases, we believe that the worsening of clinical symptoms was due to inflammation of the vessel wall and perivascular structures secondary to saphenous and varicose veins thrombosis. Determining the cause of the worsening of symptoms warrants further investigation.

The absence of long term follow-up and the small size of the patient population were the most important limiting factors of the current study. In the literature, the greatest clinical benefit was reportedly obtained in the first three to six months after treatment, with no further clinical improvement possible after six months (3–7). Therefore, the best time to evaluate the response to treatment appeared to be at month six. The median follow-up time for clinical evaluation in this study, however, was three months—another limitation of the study.

To conclude, saphenous vein laser ablation is an effective method to alleviate or cure symptoms in patients with saphenous vein insufficiency. The

majority of these patients experience significant improvement in their clinical symptoms and noticeable change in their venous clinical severity scores. However, total elimination of symptoms occurs in only 25% of limbs. Therefore, patients with residual symptoms may need to undergo varisectomy, sclerotherapy, or perforator vein surgery, in addition to laser ablation.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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