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ORIGINAL ARTICLE

Endovenous ablation with a 940 nm laser for the treatment of great saphenous vein insufficiency: short- to mid-term results

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PURPOSE
We aimed to present the short- to mid-term results of endovenous laser ablation (EVLA) procedures that were used to treat great saphenous vein (GSV) insufficiency.

MATERIALS AND METHODS
This prospective study was conducted between December 2009 and January 2011. A total of 112 incompetent GSVs were treated using EVLA with a 940 nm wavelength laser. Ninety patients were treated for varicose veins with saphenous reflux, including 36 females (40%) and 54 males (60%). These patients' ages ranged from 17 to 79 years (median, 48 years). After the EVLA, the patients were monitored using duplex ultrasonography and were assessed clinically at 1 week and 1, 3, 6, and 12 months after the surgery. The patients were scheduled for a three-day examination after the EVLA to assess the level of pain that each patient was experiencing in each limb.

RESULTS
At the end of a one-year follow-up period, the postprocedural duplex scans revealed a total occlusion of the treated GSVs in 88 (97%) patients and a sub-total occlusion in two (2%) patients. The average modified clinical, etiological, anatomical, and pathological score was significantly decreased at 12 months. The following complications were observed in the present study: hypoesthesia (11%), swelling and induration (5%), skin pigmentation (5%), deep vein thrombosis (1%), erythema (1%), and bleeding (1%). The mean visual analog pain score for the entire procedure was 3.14±1.06.

CONCLUSION
Our short- and mid-term results of the EVLA procedure were satisfactory, and the results of this study reaffirmed the safety and effectiveness of an EVLA using a 940 nm wavelength for the treatment of GSV insufficiency.

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

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Venous disease, which affects 40% to 55% of the population, is a common clinical problem that can significantly affect a patient's quality of life. Common symptoms of this disease include leg pain, swelling, and skin pigmentation (1).

The majority of varicose veins are due to great saphenous vein (GSV) incompetence, with or without incompetent perforators. The conventional treatment for great-saphenous-system varicose veins is the ligation of the saphenofemoral junction and stripping of the GSV. This conventional treatment includes the use of general or spinal anesthesia. In many centers, patients undergoing this operation are hospitalized for at least one day. An endovenous obliteration of the GSV is an alternative procedure to the conventional treatment.

The present study aimed to evaluate the efficacy of endovenous laser ablation (EVLA) with a 940 nm laser and to analyze the short- to mid-term results of 112 separate EVLA procedures to treat GSV insufficiency.

Materials and methods

Between December 2009 and January 2011, we performed EVLAs in 90 patients. Patients who had a documented GSV insufficiency after a duplex venous examination and who were classified as "clinical, etiological, anatomical, and pathological" (CEAP) class II or greater were included in the present study (Table 1).

The duplex scanning was performed by a radiologist using an Acuson 120XP10 (Aspen, California, USA) device to document the patency of the deep veins and to evaluate the extent and severity of the reflux in the superficial venous system (the GSV, small saphenous vein, and perforators) of patients in the standing position. The competence of the leg perforators was also assessed during this examination. Venous reflux was defined as a reverse flow with a duration of longer than 0.5 s, whereas a perforator was considered to be incompetent if its diameter was 4 mm or greater and/or its outward directional flow exceeded 0.5 s.

The GSV diameter was measured at a location that was 3 cm below the saphenofemoral junction. In addition, the small saphenous vein (SSV) diameter was measured at a location that was 1.5 cm below the saphenopopliteal junction (SPJ) while the patient was standing.

Patients were excluded from the study if there was any evidence of deep venous thrombosis (DVT), superficial thrombophlebitis, non-healing ulcers or non-palpable pedal pulses. The patients with very superficial or tortuous GSVs were also excluded from the present study. The patients were warned about vein thickening and tenderness along the tributaries after the EVLA, and during our study, the principles of the Helsinki Declaration were strictly followed.

There were 90 patients who were treated for varicose veins with saphenous reflux, including 36 (40%) females and 54 (60%) males,

with ages ranging from 17 to 79 years (median, 48 years). The mean body mass index for these patients was 26 kg/m^2.

Twenty-two patients underwent EVLA for both of their legs. In total, 112 GSVs were treated using EVLAs.

The most common symptoms were cramping and pain in the lower limbs, which occurred in 65 (72%) of the patients. Other symptoms included lower limb swelling in 16 (18%) of the patients and skin pigmentation in 5 (6%) of the patients (Table 1). Twenty-five (27%) of our patients chose to undergo the surgery for cosmetic reasons. GSVs and SSVs were treated in the same limb in 12 (13%) of the patients using an EVLA for the GSV and foam sclerotherapy by ultrasonography (US) guidance for the SSV. A phlebectomy and injection sclerotherapy for the leg and ankle were performed while the patient was under local anesthesia in 52 (58%) of the patients.

We used a spinal anesthesia needle (Spinocan, 0.53×88/25 gauge) and an intravenous solution device to administer the tumescent anesthesia solution using US guidance. The anesthetic solution for the tumescent anesthesia consisted of 500 mL saline, 5 mL 10% lidocaine, 10 mL 8.4% sodium bicarbonate, and 1 mL adrenaline.

Table 1. Preoperative clinical presentations and characteristics of the patients (n=90)

	Result
Age (years, mean [range])	48 (17–79)
Gender	
Female	36 (40%)
Male	54 (60%)
Limbs (n [%])	
Total number of limbs	112
Unilateral limbs	68 (76%)
Bilateral limbs	22 (24%)
Premorbid conditions (n [%])	
Hypertension	5 (6%)
Diabetes mellitus	3 (4%)
Hypertension+diabetes mellitus	2 (3%)
CEAP clinical class (n [%])	
II	69 (77%)
III	16 (17%)
IV	5 (6%)
V/VI	0
Varicose veins (n [%])	
Few	12 (13%)
Calf	25 (28%)
Calf and thigh	13 (14%)
Pain/cramping (n [%])	
Occasional	60 (66%)
Daily	5 (6%)
Edema	16 (18%)
Pigmentation (n [%])	
Small area	4 (5%)
Large area	1 (1%)

CEAP, clinical, etiological, anatomical, and pathological.

The GSV was punctured using a 17-gauge needle. After the saphenous veins were punctured, the laser fiber was inserted and moved to the proper location (1 to 2 cm below the saphenofemoral junction). The length of the treated vein was measured using the markings on the fiber. Using US guidelines, 250 to 500 mL of the tumescent anesthesia solution was administered. After administering the tumescent anesthesia, we performed an EVLA (940 nm, delivering 50–100 joules/cm of energy). The fiber was withdrawn at a rate at which the laser produced 5–10 pulses/cm. An avulsion phlebectomy or a foam sclerotherapy for the leg and ankle were performed (if indicated) under local anesthesia. After each vein was ablated, the fiber and the sheath/catheter were removed, and the puncture area was covered using sterile tape. Tinzaparin 100 anti-Xa IU/kg was administered subcutaneously. An elastic bandage was then wrapped around the leg, and the patients were immediately asked to walk for 20 to 30 min.

After the endovenous ablation, the patients were administered a non-steroidal anti-inflammatory drug (diclofenac 100 mg/daily) for three days. The patients wore elastic bandages for three days and class II (30–40 mmHg) stockings for at least one month. The patients were also advised to walk for at least one hour/day and were warned to avoid intense exercise and standing for a long period of time.

The patients were monitored after the surgery using duplex US and were clinically assessed at the first week and the first, third, sixth, and twelfth month after surgery. The tibial and popliteal veins of the treated legs were also examined for duplex evidence of DVT. All of the patients were given a postprocedural duplex examination and attended clinical follow-ups.

The patients were scheduled to attend a three-day examination after the EVLA procedure to assess their level of pain. Their levels of pain intensity were measured using a 10-point visual analog pain (VAP) scale, with numerical grades from 0 (no pain) to 10 (worst pain that the patient had ever experienced). The pain score was assessed

for each leg separately in the patients who had an EVLA administered to both legs. This pain score evaluation was conducted on 63 legs of male patients and on 49 legs of female patients (Table 2).

The Mann-Whitney *U*-test and Spearman correlation test were used for the statistical analyses. $P < 0.05$ (two-sided) was considered to be statistically significant.

Results

The lengths of the GSVs that were treated in the present study ranged from 25 to 50 cm (median, 35 cm), and the diameter of the SSV ranged from 6 to 18 mm (median, 9 mm). The mean operating time and mean amount of energy delivered per unit length were 40 min (range, 25–62 min) and 60 joules/cm (range, 50–100 joules/cm), respectively. A mean of 402 mL tumescent solution was injected in the areas around the GSVs. The median follow-up period for all of the patients was 8 months (range, 0–13 months). The following premorbid conditions were present in these patients: hypertension (6%), diabetes mellitus (3%), and hypertension in addition to diabetes mellitus (2%) (Table 1). The patients' mean age was 49.67±14.89 years. The mean age of the male patients was 52.57±14.31 years, and the mean age of the female patients was 45.94±14.92 years. The mean age of the male patients was greater than that of the female patients ($P = 0.017$).

After the EVLA procedure, two (2%) patients complained of pain that lasted longer than three days; these patients were administered oral analgesia (diclofenac 100 mg/daily), which was followed by paracetamol (1 g/tablet), four times a day on demand.

The mean VAP score for the male patients was 3.13±1.04, and the mean VAP score for the female patients was 3.16±1.087). The mean VAP score for all legs was 3.14±1.06. No differences were observed in the mean pain scores with respect to gender ($P = 0.821$) or age ($P = 0.073$) (Table 3).

Table 2. The distribution of the number of legs according to gender

	Female	Male
Number of patients	36	54
Number of legs assessed with respect to the pain score	49	63

Table 3. Age and pain score of subjects whose number of legs assessed with respect to the pain score

	Female (n=49)		Male (n=63)		
	Mean	SD	Mean	SD	*P*
Age	45.94	14.89	52.57	14.31	0.017
Pain score	3.16	1.087	3.13	1.039	0.821

SD, standard deviation.

Table 4. Complications of the EVLA procedures

Complications	n (%)
Hypoesthesia	10 (11%)
Pigmentation	4 (5%)
Swelling and induration	4 (5%)
Bleeding	1 (1%)
Erythema and bruising	1 (1%)
Deep vein thrombosis	1 (1%)

EVLA, endovenous laser ablation.

At the end of the one-year follow-up period, the postprocedural duplex scans revealed a total occlusion of the treated GSVs for 88 patients (97%) and a sub-total occlusion for two (2%) patients.

At the three-month duplex examination, the patients who were treated using an EVLA had visible GSVs; however, the diameters of the GSVs were decreased by approximately 50%. At the twelve-month duplex examination, 8 of the 20 patients (40%) with GSVs who were treated using an EVLA no longer exhibited GSVs that were detectable using US. In addition, no new reflux in the treated segments and no recurrent varicose veins were observed.

There was no mortality in our study. During the follow-up visit, the varicosities of all of the patients were resolved, and all of the patients experienced an improvement in their symptoms postoperatively. The mean modified CEAP score decreased from 3 to 0.7.

The complications of EVLA that were experienced by our patients included hypoesthesia of the affected lower limbs in 10 (11%) patients, swelling and induration in 4 (5%) patients, skin pigmentation in 4 (5%) patients, erythema in 1 (1%) patient, and bleeding from the GSV puncture site in 1 (1%) patient (Table 4). The hypoesthesia in the laser-ablated limbs resolved in less than one month after the procedure without treatment. The swelling, induration, erythema and local pain also resolved spontaneously in less than two weeks after the procedure. The mean body mass index in the patients with skin pigmentation following the EVLA was 18 kg/m^2. The mean body mass index in the patients without skin pigmentation was 26 kg/m^2.

For one patient, the first duplex scan revealed a thrombus at the saphenofemoral junction that protruded approximately 1 mm into the femoral vein (Fig.). We diagnosed this patient with endovenous heat induced thrombosis (EHIT) and began treatment. Low molecular heparin (tinzaparin sodium 20 000 IU/day) was then administered for five days. One week later, on the follow-up duplex scan, the thrombus was no longer observed. There was no evidence of recanalization in the postprocedural duplex scans of our patients.

No patient underwent a secondary surgical procedure, and none of

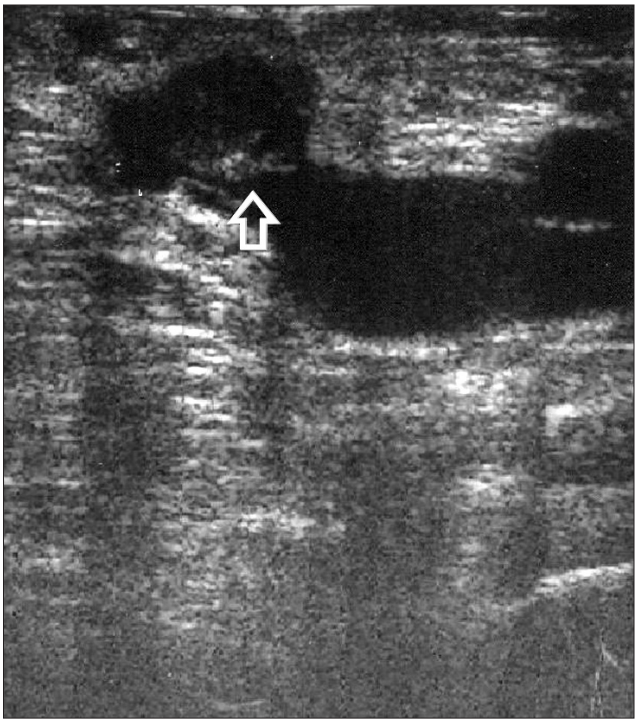

Figure. The thrombus at the saphenofemoral junction, protruding approximately 1 mm into the common femoral vein *(arrow)*.

the patients developed a pulmonary embolism.

Discussion

EVLA has a high success rate of over 90%, as demonstrated by several years of follow-up studies, and this procedure has a lower complication rate than traditional ligation with stripping (2). EVLA for the treatment of saphenous vein insufficiency has been successfully used for 10 years.

EVLA damages blood-filled vessels as a result of steam formation, leading to endothelial denudation, collagen contraction, and vein wall fibrosis (3).

The results of the prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVeS Study) included greater quality-of-life scores after endovenous treatment compared with conventional treatment for varicose veins at the one- and two-year assessment time points (4).

Endovenous ablation has advantages over conventional surgery, including a lower level of postoperative pain, shorter periods of sick leave, an earlier return to normal activities, and a reduction in the overall cost to society (5). In several large case studies, the technical success rate was approximately 100%, and the long-term success rate (up to 5 years) ranged from 90% to 100% (5–7).

The postprocedural duplex US evaluations for the patients in the present study revealed that a total occlusion of the treated GSVs occurred in 88 patients (97%) and that a sub-total occlusion in 2 (2%) patients.

Lasers of various wavelengths, including 810 nm (8), 940 nm (9), 980 nm (10), 1320 nm (11), and 1470 nm (12), have been used to ablate the GSV. A prospective randomized study (13) that compared the use of 980 nm and 810 nm lasers for endovenous obliteration procedures and a study (14) that compared the use of 810, 940, and 980 nm diode lasers did not find any significant differences in their levels of effectiveness and complication rates. We used a 940 nm laser in our study because it was readily available at our hospital.

Thromboembolic complications may occur after any type of treatment for varicose veins. DVT is a serious complication of varicose vein surgery, with an associated risk of a pulmonary embolism. Prospective duplex screening identifies DVT in 5% of patients, compared to a clinical incidence of approximately 1% (15). Van Rij et al. (16) documented DVT in 5.3% of their patients' limbs after varicose vein surgery; however, the majority of these thrombi were localized to the tibial veins. As demonstrated by previous trials and case studies, DVT in patients who have undergone EVLA is rare, with a reported incidence of 0% to 6% (6, 17).

EHIT is thrombus extension into a deep vein after a superficial venous thermoablation that usually carries a benign prognosis (17). Marsh et al. (17) observed an incidence of DVT of 1% after EVLA. In their study, which included 350 patients, three cases of EHIT (0.9%) were recorded.

We observed an incidence of DVT of 1% in our EVLA study, and this case of DVT was an EHIT. This patient was asymptomatic, and the diagnosis of EHIT was based solely on the routine postprocedural US examination.

Yoshioka et al. (18) observed a DVT incidence of 8.3% in their spine surgery study, in which regional anesthesia was used. However, to our knowledge, no reports exist in the literature about the DVT incidence after EVLA performed using an anesthesia method other than tumescent anesthesia.

In our EVLA study, general/regional anesthesia and intravenous sedation were not used; we used tumescent anesthesia. All of our patients were administered prophylactic heparin and compression therapy after the ablation procedure.

Heparin prophylaxis, early mobilization, and wearing compression stockings that were worn for at least one month postoperatively were effective at maintaining a low DVT incidence. This result was similar to those of other studies. To reduce the level of preoperative pain, the use of general/regional anesthesia or intravenous sedation during EVLA instead of tumescent anesthesia may increase the risk of DVT because the patient will not be able to stand and walk immediately after the procedure.

To relieve the intraoperative and postoperative pain of the patients, we avoided using needles larger than 25 gauge for the administration of the tumescent anesthesia; however, using smaller gauge needles prolongs the duration of the procedure.

The mean pain score in our EVLA study was similar to the value reported in Ho et al. (19). These authors used a similar pain scale for a study of EVLA (940 nm) that included 24 patients. In addition, we observed that the pain

scores in our EVLA were independent of age and gender.

Serious complications following an EVLA are uncommon (5). The incidences of hypoesthesia, swelling, bruising, and discomfort following an EVLA are not low; however, these impairments are usually self-limited and often improve within several months (5, 20). In our study, the most common complication was hypoesthesia. The minor complications observed during our EVLA study were resolved in less than one month after the procedure, except for pigmentation.

Hyperpigmentation along the course of the treated vein may also be observed, especially when the vein is located above the fascial level or if the patient is thin. However, this pigmentation gradually fades over time (5). The mean body mass index of our patients with hyperpigmentation following the EVLA was significantly lower than that of the other patients. This factor may have contributed to the skin discoloration that was observed following the EVLA.

In conclusion, our EVLA study's short- to mid-term results and associated major complications were satisfactory in point of major complications associated with EVLA. However, to observe the major complications that are associated with this procedure, long-term results from large-scale patient studies are necessary.

The results of the present EVLA study using a 940 nm laser indicate that this procedure is safe and effective in all suitable patients, especially in terms of the level of postoperative pain, regardless of the patient's age and gender.

Conflict of interest disclosure

The authors declared no conflicts of interest.

References

1. Fiebig A, Krusche P, Wolf A, et al. Heritability of chronic venous disease. Hum Genet 2010; 127:669–674.
2. Bos R, Arends L, Kockaert M, Neumann M, Nijsten T. Endovenous therapies of lower extremity varicosities: a meta-analysis. J Vasc Surg 2009; 49:230–239.
3. Shepherd AC, Gohel MS, Lim CS, Hamish M, Davies AH. Pain following 980-nm endovenous laser ablation and segmental radiofrequency ablation for varicose veins: a prospective observational study. Vasc Endovascular Surg 2010; 44:212–216.
4. Lurie F, Creton D, Eklof B, et al. Prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVeS): two-year follow-up. Eur J Vasc Endovasc Surg 2005; 29:67–73.
5. van Groenendael L, Flinkenflögel L, van der Vliet JA, Roovers EA, van Sterkenburg SM, Reijnen MM. Conventional surgery and endovenous laser ablation of recurrent varicose veins of the small saphenous vein: a retrospective clinical comparison and assessment of patient satisfaction. Phlebology 2010; 25:151–157.
6. Spreafico G, Kabnick L, Berland TL, et al. Laser saphenous ablations in more than 1,000 limbs with long-term duplex examination follow-up. Ann Vasc Surg 2011; 25:71–78.
7. Ravi R, Trayler EA, Barrett DA, Diethrich EB. Endovenous thermal ablation of superficial venous insufficiency of the lower extremity: single-center experience with 3000 limbs treated in a 7-year period. J Endovasc Ther 2009; 16:500–505.
8. Goode SD, Chowdhury A, Crockett M, et al. Laser and radiofrequency ablation study (LARA study): a randomised study comparing radiofrequency ablation and endovenous laser ablation (810 nm). Eur J Vasc Endovasc Surg 2010; 40:246–253.
9. Tan KK, Nalachandran S, Chia KH. Endovenous laser treatment for varicose veins in Singapore: a single centre experience of 169 patients over two years. Singapore Med J 2009; 50:591–594.
10. Ergenoglu MU, Sayin M, Kucukaksu S. Fate of vena saphena magna stump after endovenous laser ablation with 980-nm diode laser: 12-month follow-up. Photomed Laser Surg 2010; 28:659–662.
11. Proebstle TM, Herdemann S. Early results and feasibility of incompetent perforator vein ablation by endovenous laser treatment. Dermatol Surg 2007; 33:162–168.
12. Rathod J, Taori K, Joshi M, et al. Outcomes using a 1470-nm laser for symptomatic varicose veins. J Vasc Interv Radiol 2010; 21:1835–1840.
13. Kabnick LS. Outcome of different endovenous laser wavelengths for great saphenous vein ablation. J Vasc Surg 2006; 43:88–93.
14. Proebstle TM, Sandhofer M, Kargl A, et al. Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood. Dermatol Surg 2002; 28:596–600.
15. Bhogal RH, Nyamekye IK. Should all patients undergo postoperative duplex imaging to detect a deep vein thrombosis after varicose vein surgery? World J Surg 2008; 32:237–240.
16. Van Rij AM, Chai J, Hill GB, Christie RA. Incidence of deep vein thrombosis after varicose vein surgery. Br J Surg 2004; 91:1582–1585.
17. Marsh P, Price BA, Holdstock J, Harrison C, Whiteley MS. Deep vein thrombosis (DVT) after venous thermoablation techniques: rates of endovenous heat-induced thrombosis (EHIT) and classical DVT after radiofrequency and endovenous laser ablation in a single centre. Eur J Vasc Endovasc Surg 2010; 40:521–527.
18. Yoshioka K, Kitajima I, Kabata T, et al. Venous thromboembolism after spine surgery: changes of the fibrin monomer complex and D-dimer level during the perioperative period. J Neurosurg Spine 2010; 13:594–599.
19. Ho P, Poon JT, Cho SY, et al. Day surgery varicose vein treatment using endovenous laser. Hong Kong Med J 2009; 15:39–43.
20. Theivacumar NS, Dellagrammaticas D, Mavor AI, Gough MJ. Endovenous laser ablation: does standard above-knee great saphenous vein ablation provide optimum results in patients with both above- and below-knee reflux? A randomized controlled trial. J Vasc Surg 2008; 48:17–38.