Efficacy and Safety of Endovenous Laser Ablation in Very Large and Tortuous Great Saphenous Veins

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ABSTRACT

Purpose: To investigate the efficacy and safety of endovenous laser ablation (EVLA) with high energy delivery in large great saphenous veins (GSVs) at 1-year sonographic follow-up.

Materials and Methods: Retrospective review of 385 patients who underwent EVLA between August 2011 and September 2013 was conducted, and 44 consecutive patients (21 women [47%]; mean age, 41 y; range, 23–66 y) with 49 large GSVs were included. Vein size and clinical follow-up results were recorded. A 600-μm bare-tipped 1,470-nm laser fiber was used for the EVLA procedure. Intended energy delivery was 150 J/cm (10 sessions at 15 W) for proximal GSV segments less than 20 mm in diameter and 195 J/cm (13 sessions at 15 W) for larger veins. Improvements in clinical and quality-of-life scores at 6 months were assessed with three validated scoring systems.

Results: Mean GSV diameter was 16.95 mm (range, 15–26 mm). Five patients had GSVs at least 20 mm in diameter. Technical success was observed in 48 GSVs (97.9%) at 1-month follow-up. A second EVLA treatment was performed in one case and achieved closure, for a GSV occlusion rate of 100% at 6 months. All patients showed significant clinical improvement on all three scoring systems ($P < .001$). One-year follow-up was completed in 48 of 49 cases (98%). No recanalization was observed at 1-year follow-up, and there were no major complications.

Conclusions: Sonographic follow-up at 1 year shows that EVLA is an effective and safe procedure with excellent technical success rates in the treatment of large GSVs.

ABBREVIATIONS

CEAP = Clinical, Etiologic, Anatomic, Pathologic [classification], CIVIQ = construction and validation of a quality of life questionnaire in chronic lower-limb venous insufficiency, EVLA = endovenous laser ablation, GSV = great saphenous vein, rVCSS = revised Venous Clinical Severity Score

Endovenous laser ablation (EVLA) is a commonly used technique for saphenous vein ablation in symptomatic venous reflux, but there is still a debate regarding its efficacy and complication rates in large ($\geq$ 15 mm) veins. It is controversial whether aneurysmal dilation of the proximal great saphenous vein (GSV) at its junction with the femoral vein poses a risk of thrombus extension into the deep venous system (1). However, large-diameter veins can be safely and effectively treated with EVLA, assuming that sufficient tumescent anesthetic solution is infiltrated around the vein to collapse it (1). As the practitioner's ultrasound (US)-guided technical skills improve with tumescent anesthesia, veins larger than 20 mm in diameter can be successfully treated (2).

There are only a few reports regarding large saphenous vein ablation (2,3). The energy delivered and success and complications at long-term follow-up are still unclear for this subgroup of patients. The aim of the present study was to investigate the efficacy and safety of EVLA with high energy delivery in large veins at 1-year follow-up.

MATERIALS AND METHODS

Institutional review board approval was obtained (protocol 11.07.2014-45), and the principles of the Declaration of Helsinki were strictly followed. A retrospective review of patients who underwent EVLA of the GSV between August 2011 and September 2013 was conducted. A total of 775 patients were reviewed. All patients presenting with varicose veins were evaluated clinically

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and with Doppler sonography by a vascular interventional radiologist. Of these, 385 patients underwent EVLA treatment, including 44 patients (21 women [47%]; mean age, 41 y; range, 23–66 y) with a total of 49 large GSVs (Fig 1).

Patients with severe peripheral arterial disease, active thrombophlebitis, severe deep vein insufficiency, pregnancy, known thrombophilia or coagulation disorders, or history of deep vein thrombosis, including one case of subacute deep vein thrombosis, were not treated. Diameter and tortuosity were not exclusion criteria for EVLA treatment. The treatment procedure was explained to all patients, and all patients gave written informed consent.

Patients

Patients' demographic information and medical histories were recorded. The varicose disease was categorized by using the Clinical, Etiologic, Anatomic, Pathologic (CEAP) classification (4), and clinical severity was graded by using the revised Venous Clinical Severity Score (rVCSS) as recommended by the Society of Interventional Radiology (SIR) (5). Patient satisfaction was assessed by using a chronic venous insufficiency quality-of-life questionnaire (construction and validation of a quality-of-life questionnaire in chronic lower-limb venous insufficiency [CIVIQ-2]) before treatment (6). Veins larger than 15 mm in diameter were considered to be large at the level of the saphenofemoral junction throughout the terminal/preterminal valve of the GSV. Venous reflux lasting longer than 0.5 seconds in the GSV with compression and release or Valsalva maneuver was diagnostic for venous insufficiency (7,8). A preoperative reflux map was obtained to allow flow mapping to plan the treatment strategy.

EVLA Procedure

Each patient underwent a physical examination and Doppler sonography examination by the same physician who also performed the EVLA procedures. Doppler sonography examinations of both lower extremities were performed while the patient was standing before and after treatment. The same US device with a linear transducer (6–13 MHz; LA523; Esaote, Genoa, Italy) was used for the diagnosis, treatment, and postprocedural follow-up examination.

The procedure was performed with local anesthesia in an office-based treatment facility. A US-guided femoral nerve block was used for analgesia during EVLA for the 32 patients who were treated after June 2012. Forty to 50 mg of lidocaine diluted in 10 mL of saline solution was injected into the hyperechoic triangle lateral to the common femoral artery under US guidance with a 22-gauge needle and a short connection line (9). The other patients (12 of 44) underwent EVLA with only local anesthesia. Cold tumescent anesthetic agent (4°C) was injected around the vein under US guidance with a power pump (Klein pump; HK Surgical, San Clemente, California). A 600-μm bare-tipped laser fiber was used at 1,470 nm (Vari-Lase; Vascular Solutions, Minneapolis, Minnesota) in continuous mode for the EVLA procedure. The energy delivered was 150 J/cm (10 sessions at 15 W) for proximal GSV segments that were less than 20 mm in diameter and 195 J/cm (13 sessions at 15 W) for veins 20 mm or larger in diameter. Subcutaneous tributaries were also ablated at 80 J/cm after tumescent anesthesia just under the skin. Finally, the energy delivered was decreased to 60 J/cm below the knee because of smaller veins in this area.

For significantly tortuous GSVs, EVLA was used with multiple entry sites. The fiber was passed through large

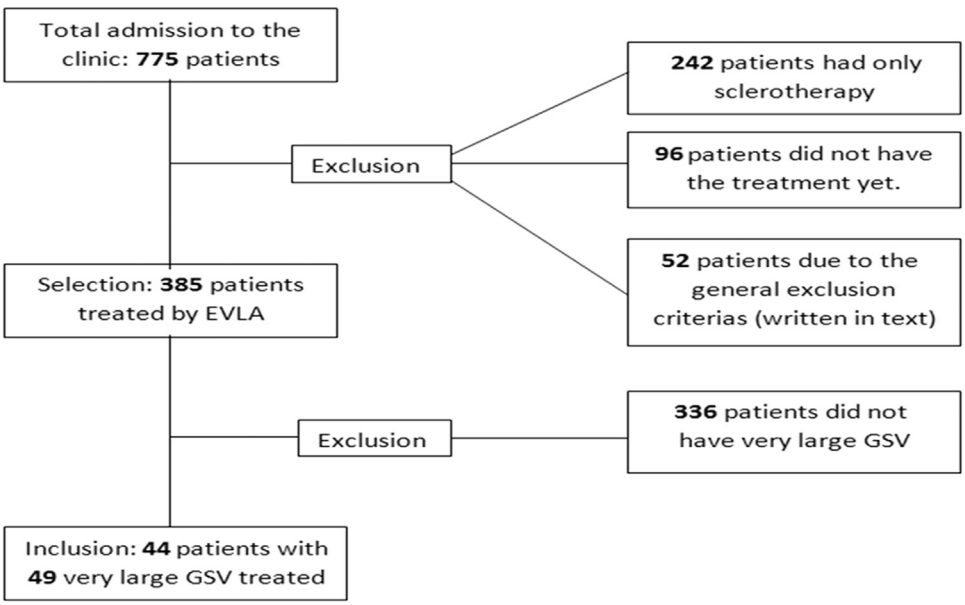

Figure 1. Patient disposition flowchart.

subcutaneous tributary veins between incompetent GSV segments if required. If there were any additional incompetent veins, a Giacomini vein, or a major tributary vein, they were also ablated in the same session. At the same session, US-guided foam sclerotherapy was used as a complementary treatment to EVLA for the residual superficial varicosities. Polidocanol (Aethoxysklerol 3%; Chemisce Fabrik Kreussler, Wiesbaden, Germany) was used as the sclerosing solution with a modified Tessari technique (1:3 sclerosant:air ratio). At the end of the sessions, compression stockings were put on the patients, who were advised to walk for 20 minutes. Nonsteroidal antiinflammatory drugs (Voltaren 50 mg twice a day [diclofenac sodium]; Novartis International AG Investor Relations; Basel, Switzerland) were recommended for 3 days as standard treatment. Pain medication was allowed according to patient requirements after 3 days. Patients were advised to wear compression stockings for at least 10 days.

Technical and Clinical Assessment

Technical success of EVLA was defined as successful access, delivery of laser energy to the incompetent GSV, and obliteration of the GSV at the first month of follow-up. The patients were evaluated clinically and with Doppler sonography at 1, 6, and 12 months after treatment and annually thereafter. Follow-up US examinations were performed by the same interventional radiologist who performed the procedure. Clinical improvements in patients were assessed by comparing CEAP, rVCSS, and CIVIQ-2 scores at 6 months versus pretreatment scores, which were available for all patients. An interventional radiology technologist who was not personally involved in the EVLA treatment administered the CEAP and rVCSS questionnaires. The technologist was unblinded as to whether a particular patient had received treatment. All patients were contacted by telephone 3 days after treatment, and pain scores were recorded on days 1 and 3 after treatment with the standard recommended medication. The scale ranged from 0 to 10, with 0 indicating no pain and 10 indicating the most severe pain imaginable. Any adverse effects, such as hyperpigmentation, skin necrosis, allergic reaction, deep vein thrombosis, or paresthesia, were also recorded according to SIR guidelines (10).

The Wilcoxon test was used for statistical analysis to evaluate clinical improvement after treatment. Analyses were performed with SPSS software (version 11.0; IBM, Armonk, New York). Null hypotheses of no difference were rejected if P values were less than .05.

RESULTS

Mean GSV diameter was 16.95 mm (range, 15–26 mm) before ablation. Five patients had GSVs at least 20 mm in diameter (Fig 2). All patients had venous reflux at the GSV. There were six patients with two entry sites and one patient with three entry sites required to completely cover the tortuous GSV (seven of 49; 14%). A total of six patients had nine additional incompetent veins. Additional incompetent veins included two small saphenous veins, two anterior thigh circumflex veins, two major tributary veins, and three perforator veins, and all were ablated in the same EVLA session as the GSV (Fig 3). The total tumescent anesthetic solution used for each patient was not recorded. The superficial varicose veins treated by US-guided foam sclerotherapy exhibited no visible vascularity and no compressibility along their entire course in all 48 available limbs (100%) at the 12-month follow-up (Fig 4). The volume of injected foam ranged from 2 to 10 mL (mean, 4.3 mL). Only five patients required an additional foam sclerotherapy session for varicose veins at the 1-month visit.

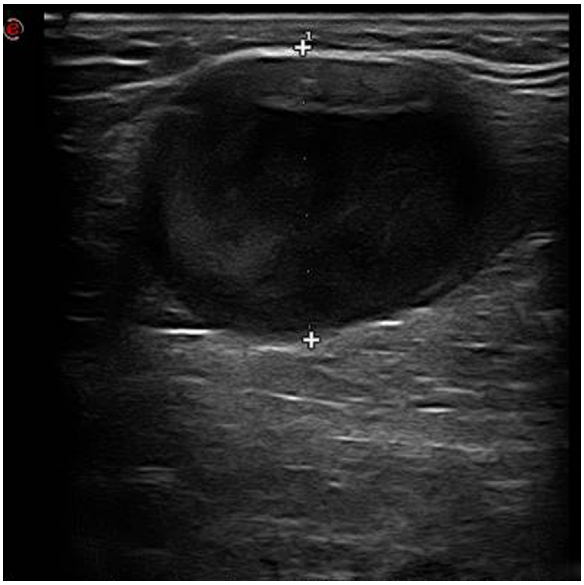

Figure 2. Pretreatment axial US image of the GSV at the saphenofemoral junction level in a 40-year-old male patient. The diameter of the large GSV is 26 mm.

At 1-month follow-up, technical success was observed in 43 of 44 GSVs (97.7%). After a second EVLA treatment in a single case, closure of the ablated GSV was observed in all 44 GSVs (100%) at the 6-month follow-up. Follow-up was completed in 97.7% of patients; only one patient missed the 12-month follow-up. At the 12-month follow-up, all treated large GSVs were completely occluded. After 1 year, 83% of the treated veins had disappeared on Doppler sonography, and no recanalization was observed.

All patients had CEAP class $\geq$ 2 disease and were symptomatic before treatment. The CEAP classification score ranged from 2 to 5 (median, 3). After 6 months, the CEAP score decreased to a range of 0–4 (median, 1; Fig 5). rVCSS values before the procedure ranged from 2 to 13 (median, 8) and decreased to 2 (range, 0–7) after treatment. All clinical outcomes were significantly improved

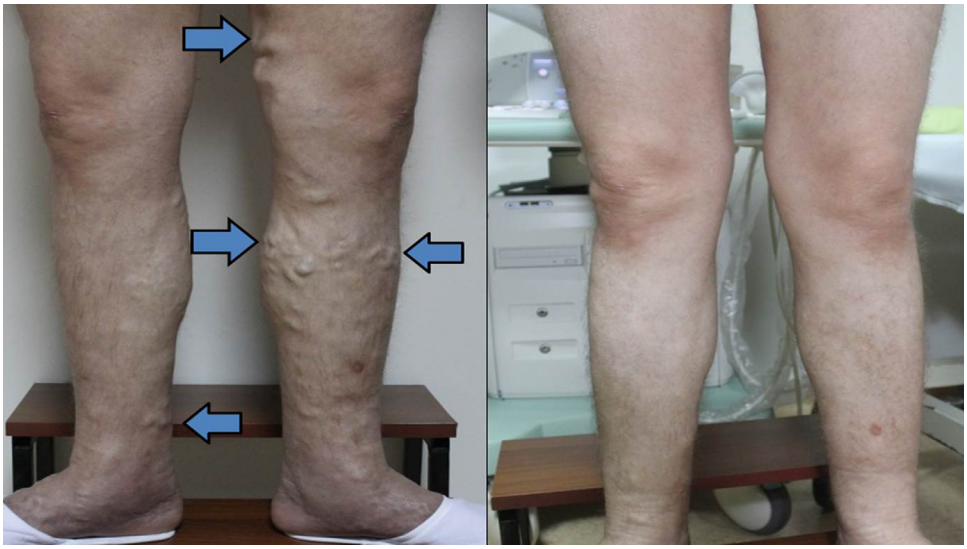

Figure 3. Photographs of the legs of a 34-year-old male patient with bilateral large GSVs before and 12 months after EVLA and sclerotherapy of associated varicosities (arrows). There is marked improvement in the appearance of the legs.

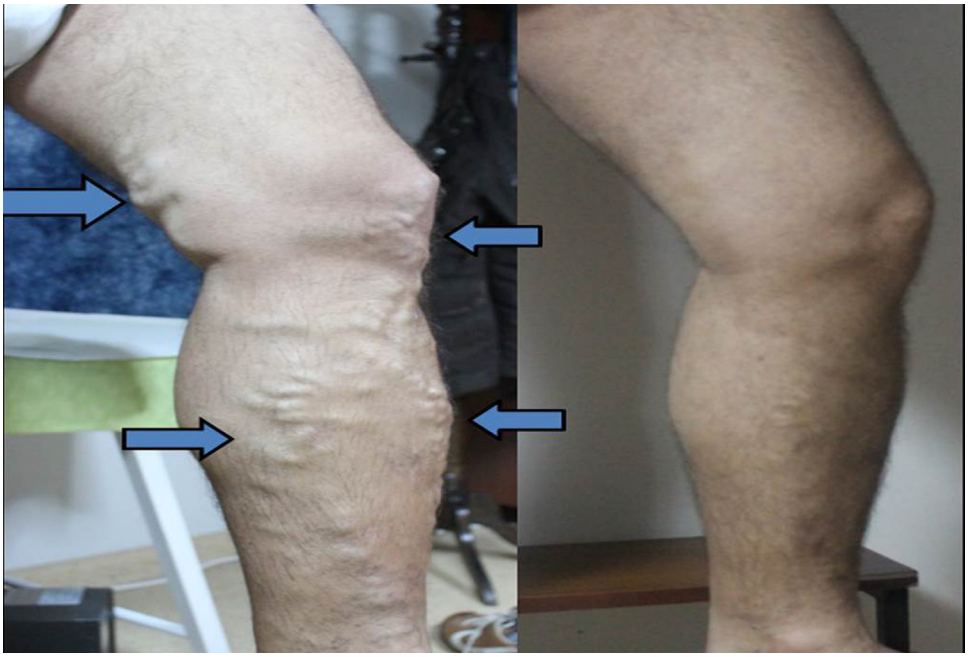

Figure 4. Photographs of the leg of a 32-year-old male patient with a large left GSV before and 6 months after EVLA and sclerotherapy of associated varicosities (arrows). There is marked improvement in the appearance of the leg.

based on the nonparametric Wilcoxon test. Analysis of differences in CEAP class, rVCSS, and CIVIQ-2 score showed significant improvement (Table). The mean preoperative CEAP score was 2.85 ± 0.95, and the mean postoperative score was 1.29 ± 1.61 ($P < .001$). The mean preoperative rVCSS was 6.62 ± 2.50, and the mean postoperative score was 1.98 ± 1.19 ($P < .001$). The mean preoperative CIVIQ-2 score was 57.51 ± 13, and the mean postoperative score was 31.69 ± 7.8 ($P < .001$). Pain scale scores were recorded on the first and third days after the procedure. Mean pain scores were 3.80 ± 0.89 on the first day and 3.96 ± 0.79 on the third day.

There were no major complications, such as skin burns, necrosis, paresthesia, deep vein thrombosis, or allergic reaction. There were only minor postprocedural complications, such as pain, bruising, and cordlike tightening along the course of the treated vein. Three patients were diagnosed with superficial vein thromboses and were treated successfully with nonsteroidal antiinflammatory agents. There was mild hyperpigmentation

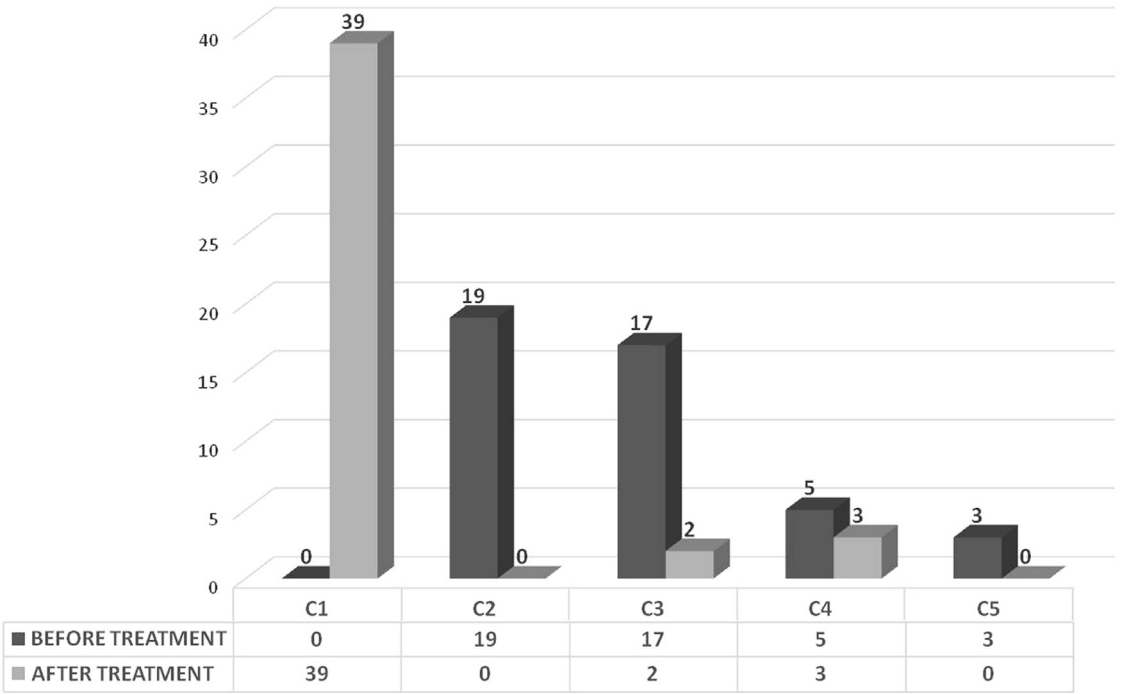

Figure 5. Clinical, Etiologic, Anatomic, Pathologic clinical scores (ie, "C" score) before and after EVLA treatment in large GSVs at 6-month follow-up.

Table. Clinical and Quality-of-Life Outcomes of EVLA Treatment in Large GSVs at 6-Month Follow-up

Time Point	rVCSS	CIVIQ-2
Preoperative	6.62 ± 2.50	57.51 ± 13
Postoperative	1.98 ± 1.19	31.69 ± 7.8
P value	< .001	< .001

CIVIQ = construction and validation of a quality-of-life questionnaire in chronic lower-limb venous insufficiency, EVLA = endovenous laser ablation, GSV = great saphenous vein, rVCSS = revised Venous Clinical Severity Score.

in three patients (6.9%) at 1-year follow-up, but none of these patients had recurrent varicose veins at this interval.

DISCUSSION

In the present study, closure of the ablated GSV was observed in all 44 patients (100%) at 6-month follow-up, and no major complications were reported. Only 14% of patients required multiple punctures because of GSV tortuosity.

Since EVLA of the GSV was initially reported in 2001 (11,12), indications for endovenous treatments have been expanding. A large GSV diameter is still considered to be a relative contraindication according to many authorities (1), but many interventionalists have recently performed EVLA on large veins without any major complications. Radiofrequency ablation or endovenous steam ablation are not used for large GSV treatment; the radiofrequency ablation catheter destroys the vein wall with the segmental conductive heating treatment of veins, and it is not recommended for veins larger than 15 mm in diameter (13). Additionally, endovenous steam ablation and radiofrequency ablation have longer plateau phases and lower maximum temperatures (14) that may not be enough to occlude large GSVs. Although the mechanism of vein wall destruction by laser remains controversial, whether it occurs by direct contact or indirectly via steam bubbles (15–17), it has been shown that EVLA with a greater energy delivery is highly effective in large veins (18).

The results of a recent study that specifically investigated the efficacy of EVLA in large veins (3) were similar to the present results. However, these investigators (3) defined a large GSV as greater than 1 cm in diameter, which is not an ideal limit value because there is no debate on the endovenous treatment of GSVs 10–15 mm in diameter. In the present study, a large GSV was defined as 15 mm or more in diameter. Additionally, higher energy (195 J/cm) was administered to GSVs greater than 19 mm in diameter. A laser with a 1,470-nm wavelength was used because it is theorized that the higher-wavelength lasers result in less postoperative bruising and discomfort for patients (19). However, it should be noted that a bare-tipped laser fiber was used; a radial fiber could be effective with a lower energy delivery.

Tortuous veins are still accepted as a relative contraindication by many interventionalists. However, tortuosity is not a problem for an interventionalist who has adequate US-guided technical skills. In the present study, only seven cases required multiple access points to completely cover the tortuous GSV. Generally, navigating tortuous vessels with angled-tip catheters was not

attempted. This catheter technique can be time-consuming and risky for vasoconstriction or vein rupture. Catheterization with support from the straight catheter of the laser set was attempted before a second access point was created. By using multiple access points, treatment failure related to tortuosity was avoided.

As the interventionalist gains more technical skills with US-guided procedures, the role of EVLA can expand to large vein ablations and reflux sources apart from the GSV. Various reflux sources that can be treated by laser ablation are isolated perforator reflux, the anterior accessory saphenous vein, major tributaries, or small saphenous vein reflux (20,21).

The present study has some limitations and shortcomings. First, EVLA is not yet accepted as a standard treatment technique for large GSVs, especially for veins larger than 20 mm in diameter. However, compared with other EVLA studies reporting the incidence of complications with standard indications, the incidence and outcome of these complications in the present study were similar or better. Second, posttreatment pain was an important issue for these patients; unfortunately, in the present retrospective study, the existing pain data include only the first 3 days after treatment. However, the first 3 days of pain data did show a statistically significant difference in patients treated with standard EVLA treatment. The third limitation is the small sample size (n = 49 veins); however, a GSV with a diameter of 15 mm or more is not a common entity. Fourth, as this is a retrospective study, it was planned as a single-arm study with no comparator group. Finally, the examiners who performed the follow-up US examinations and administered the CEAP and rVCSS scales were not blinded as to whether a particular patient had or have not received EVLA.

In conclusion, EVLA is an effective procedure with excellent technical success rates in the treatment of large GSVs without any major complications. Multiple punctures may be needed only in a minority of cases. Although more energy is used with a bare-tipped fiber, this did not translate into higher complication rates, indicating that EVLA is safe for large vein closure. More studies are required to establish a standard energy level to use in large veins ablated with different types of laser fibers.

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