CLINICAL STUDY

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 (≥ 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

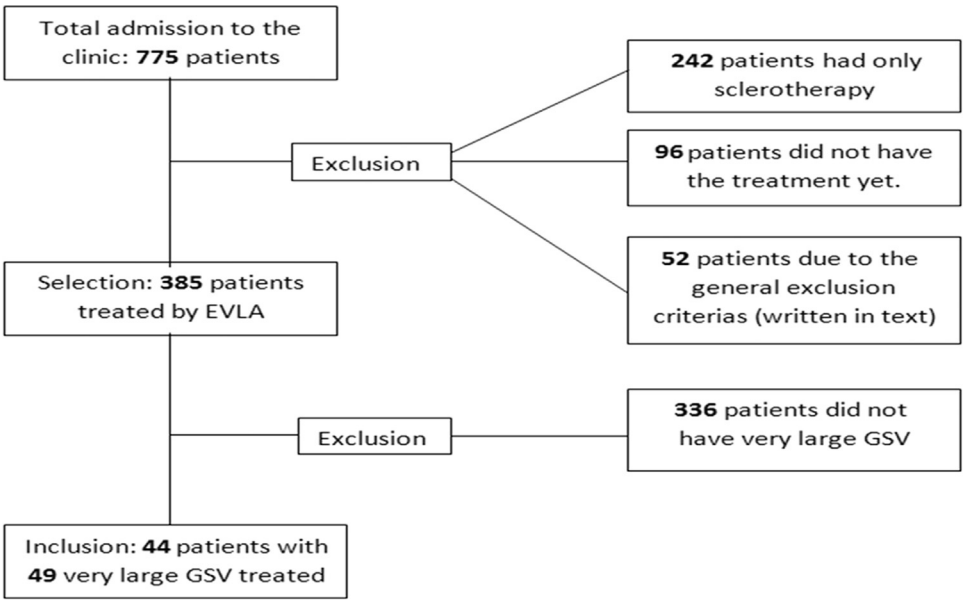

Figure 1. Patient disposition flowchart.