CLINICAL STUDY

A Comparison of Concomitant Tributary Laser Ablation and Foam Sclerotherapy in Patients Undergoing Truncal Endovenous Laser Ablation for Lower Limb Varicose Veins

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ABSTRACT

Purpose: To compare outcomes of patients who received simultaneous tributary endovenous laser ablation (EVLA) or foam sclerotherapy (FS) with EVLA of the great saphenous vein (GSV) trunk.

Methods and Materials: This study recruited 418 patients (542 legs) with diagnosed varicose veins. Patients in the EVLA/FS group (255 patients, 327 legs) received concomitant FS for the tributaries with truncal lasering. For the EVLA-alone group (163 patients, 215 legs), tributaries (8W) were ablated with EVLA in addition to the GSV trunk (14W). Complications, Aberdeen Varicose Vein Questionnaire (AVVQ), EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D), numerical rating scale (NRS) scores, and condition of residual varicosities were assessed at 3 days, 4 weeks, and 6 months after procedure. All residual varicosities were identified and treated with a staged FS at 6 months.

Results: Except for ecchymosis, incidence of other complications was not significantly different between both groups at 6 months. Pain NRS scores of the EVLA/FS group were remarkably elevated at 4 weeks and then, at 6 months, declined to a level similar to the EVLA-alone group. The EVLA/FS group exhibited more significant improvement in both AVVQ and EQ-5D scales than the EVLA group at 6 months, while exhibiting poor improvement at 4 weeks. The EVLA/FS group had a significantly lower rate of residual varicosities than the EVLA group, thus reducing the need for the staged FS.

Conclusions: These results confirm the feasibility and safety of simultaneous tributary EVLA and FS. In addition, they indicate better early quality-of-life improvement and a reduced reoperation rate of simultaneously combined truncal EVLA and tributary FS.

ABBREVIATIONS

AVVQ = Aberdeen Varicose Vein Questionnaire, CEAP = clinical, etiological, anatomic, pathological classification system, CVI = chronic venous insufficiency, EQ-5D = EuroQol Group 5-Dimension Self-Report Questionnaire, EVLA = endovenous laser ablation, FS = foam sclerotherapy, GSV = great saphenous vein, NRS = numerical rating scale, QoL = quality of life, RCT = randomized control trial

With the advent of therapeutic techniques, practices are moving away from traditional open surgery toward minimally invasive alternatives (1–3), including endovenous laser ablation (EVLA) and foam sclerotherapy (FS). However, residual varicose veins-associated symptoms and cosmetic issues are becoming a matter of clinical controversy (4). In recently published randomized controlled trials (RCTs), concomitant phlebectomy with truncal treatment

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reduced the need for staged procedures and improved quality of life (QoL) (5,6). In addition, several articles reported on combined minimally invasive treatments (EVLA or FS) for simultaneously treating varicose veins (7–10). Simultaneous treatment of varicose veins may increase operative time and outpatient discomfort. However, this combination procedure significantly reduces the number of patients who need a staged treatment of residual varicose veins for cosmetic and symptomatic reasons (5). Because of this, National Institute for Health and Care Excellence guidelines recommend simultaneous treatment of varicose veins in patients undergoing truncal treatment for varicose veins (11).

Compared to phlebectomies, both EVLA and FS are less invasive and therefore more acceptable to patients. However, to date, no evidence has been reported showing which concomitant method—FS or EVLA—is superior. In addition, clinical safety, feasibility, and effectiveness of simultaneous tributary EVLA and FS have not yet been fully confirmed in clinical studies (12). The aim of this study was to compare the outcomes of patients who received simultaneous tributary EVLA or FS with truncal lasering.

MATERIALS AND METHODS

This prospective cohort study was designed to understand the feasibility, effectiveness, and safety of simultaneous tributary EVLA or FS with truncal EVLA. Before this study was initiated, the protocol and informed consent were approved by the local hospital's institutional ethics committee. This study was registered in the Chinese Clinical Trial Registry (ChiCTR-INR-16009204). Patients with confirmed diagnoses were recruited by clinical presentation and venous ultrasound examination. Before receiving treatment, patients were fully informed about current mainstream techniques, details of the perioperative situation, and both advantages and disadvantages of combination procedures.

Between January 2010 and June 2015, 418 patients (542 legs) with diagnosed lower limb varicosity were enrolled in this nonrandomized cohort study. Comparisons of baseline characteristics between the 2 groups are listed in **Table 1**. Of the enrolled patients, 72% were classified as C-3 and C-4, and most patients had venous reflux in 1 or more deep veins in the lower extremity. Patients in both the EVLA-alone and EVLA/FS cohorts were matched except for the frequency of C5 disease, deep venous reflux, and disease history (**Table 1**). The EVLA/FS group exhibited a higher frequency of iliac veins reflux than the EVLA-alone group, while exhibiting a significantly lower proportion of femoral vein reflux. In addition, disease history of patients in the EVLA/FS group was 2.83 years longer than that of patients in the EVLA-alone group.

Inclusion criteria were as follows: age between 18 and 75 years at enrollment; clinical, etiological, anatomical, and pathophysiological (CEAP) clinical type 2-6; primary signs and symptoms of great saphenous vein (GSV) incompetence, further confirmed by reflux time of 1 second or more on Doppler ultrasonic analysis; and diameter of varicose vein less than 15 mm. Exclusion criteria were as follows: any previous treatment, such as surgery, EVLA, radiofrequency ablation, or FS, for ipsilateral varicosity; lower limb varicosity caused by deep venous occlusion or other venous diseases; diameter of the truncal or nontruncal varicose vein larger than 15 mm; absolute contraindications for lumbar or general anesthesia; and inability to commit to post-procedure follow-up. In total, 1642 patients refused to participate or were excluded because they met exclusion criteria (**Fig 1**). Of these excluded patients, 1615 chose to receive high ligation/stripping (n = 1293), endovenous microwave ablation (n = 210), or single FS (n = 112). Four hundred eighty-five patients (485 legs) consented to participate in the trial. Forty and 27 patients were excluded from the EVLA-alone and EVLA/FS groups (**Fig 1**), respectively, for a variety of reasons.

Eligible patients themselves chose their concomitant treatment: tributary EVLA or FS. For patients with bilateral legs that needed treatment, only a single leg was randomly selected for the final analysis (to avoid significant intrapatient correlation, **Fig 1**). Before treatment, a standardized ultrasonic examination was performed with a duplex imaging system (12L5 probe, 8 MHz, Osaka, Japan) by a certificated ultrasound physician in the Department of Ultrasound Imaging, to define GSV reflux time and any existence of venous occlusion.

Endovascular Laser Ablation

Patients in both the EVLA-alone and EVLA/FS groups underwent corresponding procedures in a dedicated operative theater under general anesthesia. Tributaries in the EVLA-alone group were treated with EVLA as well as the GSV trunk, whereas tributaries in the EVLA/FS group were treated with FS only. Both procedures were designed to simultaneously eliminate the tributaries with a successful truncal ablation during the first-stage operation. Laser power (14W for GSV trunk, 8W for tributaries) was applied along the length of the vein by withdrawing laser fiber. Before the procedure, both sides of the tributaries (target varicosities) were marked with dotted lines in the dependent position, and pictures of marked lower limbs of each patient were taken for preoperative versus postoperative comparison.

Before laser therapy, tumescent anesthetic solution was locally injected to protect the tissues and nerves around the truncal or nontruncal varicosities (13). Ultrasound-guided access of the varicose vein was followed by advancement of a vascular sheath containing the laser fibers to a location of 2 cm below the saphenofemoral vein junction. During ablation, the tip of the laser fiber was always 1–2 cm outside the end of the sheath to ensure successful ablation. In the EVLA-alone group, tributaries with diameter larger than 1.5 mm were also treated with laser by a method similar to the standard EVLA technique but at less power. The local vessel wall, where the vessel started to be tortuous, was pushed to make the tributary less tortuous (thus facilitating the