## **CLINICAL INVESTIGATION**

# **Endovenous Laser Ablation and Concomitant Foam Sclerotherapy: Experience in 504 Patients**

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Received: 11 October 2011/Accepted: 13 November 2011

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#### **Abstract**

Purpose To investigate the value of endovenous laser ablation (ELA) and concomitant ultrasound-guided foam sclerotherapy (USGFS) in patients with chronic venous insufficiency.

Methods During a 6-year period, concomitant USGFS of the varicose veins were performed in 504 out of 610 patients who underwent ELA for truncal or perforating vein insufficiency. In these 504 patients (944 legs; bilateral in 440 patients), the incompetent veins were greater saphenous vein in 615 legs, small saphenous vein in 118 veins, perforating veins in 42 legs, and a combination of these in 169 legs. In all patients, after ELA of the incompetent veins, USGFS was performed for the remaining varicosities with 1–3% polidocanol foam. Patients were followed up clinically and with color Doppler ultrasound at 1, 6, and 12 months.

Results ELA was technically successful in all cases, although another venous puncture was necessary in 29 legs. Concomitant USGFS was also technically successful in all cases, but one to three additional sclerotherapy sessions were performed in 203 legs with persistent varicosities. During the follow-up, recanalization of the laser-ablated refluxing veins occurred in 16 legs (1.7%) and was treated with repeat ELA or USGFS. Major complications occurred in 1.4% of the treated legs and included skin necrosis and calf vein thrombosis.

Conclusion ELA and concomitant foam sclerotherapy is feasible and effective. The procedures are associated with a low complication rate and can be performed in both legs in the same session. Concomitant use of laser and foam may potentially decrease the recanalization rate of laser-ablated vessels.

**Keywords** Sclerotherapy · Varicose veins · Venous intervention

#### Introduction

Endovenous laser ablation (ELA) is a well-established alternative to surgery in the treatment of truncal and perforating vein insufficiency. After the refluxing truncal or perforating vein is ablated, the remaining varicosities are removed with phlebectomy or alternatively treated with sclerotherapy [1–3]. Sclerotherapy is traditionally performed with liquid agents, but ultrasound (US)-guided foam sclerotherapy (USGFS) is becoming more popular [4]. In the literature, there are few data on the concomitant use of USGFS after ELA [5, 6]. In this single-center series, we present our experience in 504 patients in whom ELA and USGFS were performed in the same session.

### **Materials and Methods**

We retrospectively reviewed the data of 610 patients who underwent ELA for truncal and/or perforating vein insufficiency at our institution between July 2005 and June 2011. Of these patients, 106 underwent either phlebectomy or USGFS after ELA at another session and were excluded from the study. The remaining 504 patients underwent concomitant USGFS after ELA and constituted our study group. The demographic and clinical data of these 504 patients are presented in Table 1.

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Published online: 14 December 2011



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Table 1 Demographic and clinical aspects of 504 patients who underwent ELA and concomitant USGFS

Characteristic	Value
No. of patients	504
No. of affected legs	
Total	944
Bilateral	440
Sex, M/F	74/430
Clinical classification (CEAP) in 944 total legs	
C1	77 (8.2%)
C2	418 (44.4%)
C3	192 (20.3%)
C4a	93 (9.8%)
C4b	72 (7.6%)
C5	56 (5.9%)
C6	36 (3.8%)
Refluxing veins in 944 total legs	
GSV	615 (65.2%)
Small saphenous vein	118 (12.4%)
PV	42 (4.5%)
Combined	169 (17.9%)

CEAP Classification: C0 no visible or palpable signs of venous disease, C1 telangiectasias/reticular veins, C2 varicose veins, C3 edema, C4a pigmentation or eczema, C4b lipodermatosclerosis, C5 healed venous ulcer, C6 active venous ulcer

Before all procedures, potential risks and benefits were explained in detail, and informed written consent was obtained from each patient. Also, throughout the study, the principles of the Helsinki Declaration were strictly followed. Institutional review board approval was not obtained because it is not required for retrospective studies at our institution.

In all patients, the ELA procedure was performed with US guidance under local tumescent anesthesia. In the last 244 patients, a femoral or sciatic nerve block was also performed to provide better analgesia. In patients with bilateral disease (n = 440), ELA was performed in both extremities in the same session (n = 415) or in a separate session (n = 25), depending on patient preference.

For the ELA, the patient was placed supine on the table in the reverse Trendelenburg position to distend the veins. After intradermal injection of a small amount of local anesthetic (0.2–0.6 ml), the incompetent vein was punctured with an 18-gauge needle under US guidance. An angled-tip 0.035-inch guide wire was then advanced and passed through the junction of the incompetent vein with the deep veins. The laser catheter (or sheath) was advanced over the guide wire and placed near to the junction. The guide wire was then removed and the tumescent solution was injected around the vein under US guidance by means

of a power pump (Klein pump). After tumescent anesthesia, a laser fiber (980 or 810 nm) was inserted into the catheter and its tip positioned several centimeters below the junction. For portal vein (PV) incompetence, we tried to advance the catheter and laser as deeply as possible, close to the junction with the deep veins. In patients where this was not possible because of the tortuosity of the PV, we ablated at least a several-centimeter-long straight portion of the PV.

Depending on the diameter of the refluxing veins, 50–120 J/cm energy was provided during the laser ablation. We intentionally provided more energy in the region of the reflux (near the junctions) to enhance the ablation, then lowered the energy when the laser tip was below the knee to avoid nerve damage.

After all ELA procedures were completed (unilateral or bilateral), the remaining varicosities were treated with USGFS. For USGFS, first, multiple butterfly needles were placed into the varicosities under US guidance with the patient in the reverse Trendelenburg position. In patients with small varicose veins, we placed the butterfly needles shortly before the tumescent anesthesia because afterward, these small veins may become much smaller or even disappear, making it difficult to place a needle. Then a thick foam was prepared according to the Tessari method, with a mixture of 1–3% polidocanol solution and air in a 1:4 ratio. The foam was then injected via the butterfly needles into the varicosities under US guidance with the patient in a slight Trendelenburg position (Fig. 1).

Whenever possible, the foam was intentionally directed into the laser-ablated veins to create additional ablation of the refluxing veins with the foam. We preferred to inject small volumes of foam (generally 3 ml) at multiple sites rather than a large volume through a single site, and we avoided injection close to the competent perforating veins. When all the varicosities were filled with echogenic foam,



Fig. 1 USGFS of the varicose veins after ELA in a patient with GSV insufficiency



the injection was stopped. The patient then put on compression stockings and walked for 20–30 min. Follow-up color Doppler US procedures were performed routinely at 1, 6, and 12 months, and depending on patient complaints thereafter.

#### Results

ELA was technically successful in all cases, although another venous puncture was necessary in 29 legs as a result of tortuosity or venous spasm. Concomitant foam sclerotherapy was also technically successful in all cases. But the follow-up (1–64 months, during mean  $\pm$  SD  $19 \pm 6$  months), persistent reflux was seen in the varicose veins in 203 legs. These veins were treated with repeat US-GFS performed one to three times. In 16 of these legs (1.7% of total), there was also recanalization of the laser-ablated refluxing veins (10 greater saphenous vein [GSV], four small saphenous vein, two PV), which were later treated with repeat ELA (n = 4) or USGFS (n = 12). In the remaining 187 veins, laser-ablated veins were still closed; in these legs, persistent reflux in the varicose veins was attributed to a de novo distal PV incompetence in 41 and pelvic vein incompetence in 64; no source could be identified in the remaining 82. De novo PV incompetence was treated with ELA (n = 24) or USGFS (n = 17), while de novo pelvic vein incompetence was treated with USGFS in all cases. In all our patients, repeat ELA and USGFS were continued until no reflux was identified in the treated veins (Fig. 2).

During USGFS, we continued the injection until all varicose veins were filled with foam. Therefore, we did not have a dose limit for foam sclerotherapy. The data on the amount of foam were available for 76% of the USGFS sessions. In these, the foam injected per session ranged 5–45 ml (median 20.0 ml, mean  $\pm$  SE 21.2  $\pm$  0.3 ml). After USGFS, a varying degree of trapped hematoma was observed at control examinations in some patients with large varicosities. None of these patients had any sign of superficial thrombophlebitis, but despite this, we preferred to perform drainage with a no. 11 surgical blade or an 18-gauge needle in 22 legs (2%) to reduce pigmentation and improve cosmesis.

After the initial concomitant ELA and USGFS, all the ablated truncal or perforating veins were found to be closed at the 1-month Doppler US controls; recanalization of these veins was invariably observed at 6- or 12-month follow-up (seven at 6 months, nine at 12 months). Likewise, recurrent reflux in the varicose veins in 203 legs occurred more often after 1 month; it was observed at 1 month in 18 legs, at 6 months in 84 legs, and at 12 months in 101 legs.

After the procedures, a number of complications occurred; minor complications were quite common and



Fig. 2 A 37-year-old woman with a C4b venous insufficiency. A, B Preoperative images reveal marked edema and large varicosities in the anterior thigh and lateral calf in the right leg due to combined GSV (anterolateral branch), small saphenous vein, and pelvic venous insufficiency. C, D Six months after combined ELA and USGFS, images reveal almost complete disappearance of the varicose veins and a remarkable reduction in edema, with a slight pigmentation over the course of the varicose veins

included dry coughing, nausea/vomiting, hyperpigmentation, telangiectatic matting, visual disturbances, and paresthesia, which were transient and generally required no treatment. Major complications were extremely rare (14 of 944 legs, 0.14%) and included skin necrosis and calf vein thrombosis (Table 2).

## Discussion

In truncal and perforating vein insufficiency, the traditional method to treat remaining varicosities after ELA is ambulatory phlebectomy [3, 7]. Although excellent cosmetic results can be obtained in experienced hands, ambulatory phlebectomy has some drawbacks. First, it is a surgical procedure that requires special surgical instruments, which is not suitable in the office setting. Second, it is a time-consuming treatment, and most interventional radiologists are not familiar with this technique. Third, although large varicose veins can be successfully removed,



**Table 2** Complications and their outcome after ELA and foam sclerotherapy in 504 patients (944 legs)

Complication	No. of patients or legs	%	Outcome
Dry coughing	299 patients	59.3	Disappeared spontaneously within 15 min
Nausea/vomiting	31 patients	6.1	Disappeared spontaneously in 28, antivomiting drug provided in 3
Hyperpigmentation	102 legs	10.8	Disappeared in 95, persisted after 1 y in 7
Telangiectatic matting	57 legs	6.0	Disappeared in 50, persisted after 1 y in 7
Skin necrosis	9 legs	0.9	Healed within 4 mo in 8, skin graft implanted in 1
Calf vein thrombosis	5 legs	0.5	Resolved within 2 mo
Transient paresthesia	32 legs	3.4	Resolved within 5 mo in 31 and in 18 mo in 1
Visual disturbances	3 patients	0.6	Resolved within 15 min

small reticular and spider veins remain after ambulatory phlebectomy, and these veins require treatment with sclerotherapy. Fourth, some patients do not like the idea that their veins are being removed with hooks.

Another method to treat remaining varicosities after ELA is sclerotherapy. Sclerotherapy is traditionally performed by injecting sclerosing liquids into the varicosities. Liquid sclerotherapy has been an excellent treatment for spider and reticular veins but has proved unsuccessful for large varicose veins [4]. Thus, until recently, the only option for such varicose veins has been ambulatory phlebectomy.

In the last decade, foam sclerotherapy was introduced and has become increasingly popular. Foam sclerotherapy has some advantages over liquid sclerotherapy. First, because the liquid mixes instantly with blood, its concentration drops and its ablative effect diminishes rapidly. Instead, foam pushes the blood rather than mixing with it, and it thus may retain its concentration over a long distance in the vein lumen. As a result, its ablative effect is several times stronger than the liquid, and for this reason, it is suitable for the treatment of even large varicose veins. Second, because it is mixed with air, it contains less drug, but it becomes more effective. As a result, the amount of sclerosant and the number of injections to obtain a certain ablative effect are reduced. Third, foam is readily visible on US, and because it is lighter than blood, it can be easily directed into the target vessels by manual massage and by putting the leg into certain positions [2, 4, 5].

Although successfully used in truncal and perforating vein ablation instead of endovenous laser or radiofrequency, foam sclerotherapy is most commonly preferred in the treatment of pelvic–gonadal vein insufficiency and for the ablation of remaining varicosities after ELA of truncal and perforating veins [4]. In the literature, we could find only two studies reporting the results of concomitant use of foam sclerotherapy after endovenous ablation [5, 6]. In both, the combined treatment was associated with a high success rate (98–100% closure of the refluxing veins) and a low complication rate. Similarly, during the 1–64-month follow-up, there was only 1.7% recanalization of the

refluxing veins in our study. This compares favorably with the 3–12% recanalization rates reported in the literature [4–11]. We believe that routine Doppler US follow-up of all patients, including the asymptomatic ones; repeated foam sclerotherapy of varicosities until no reflux was seen; and intentional manipulation of the foam into the laserablated veins to create additional ablation after ELA may have reduced the recanalization rate in our series.

In our study, we observed persistent reflux in the varicose veins in 20% (n = 187) of the legs after the successful treatment with combined ELA and USGFS, although the refluxing truncal or perforating veins were still closed. This phenomenon was also observed in 16-22% of the patients after ligation and stripping of the incompetent GSV and found independent from the proximal GSV as well from insufficient perforating veins [12]. In our study, with a detailed color Doppler US examination, we were able to find a de novo incompetence of either a pelvic vein or a PV in 56% of these patients, while no source could be identified in the rest. Regardless of their origin, these remaining varicose veins were successfully treated with USGFS in our study, as in others in the literature [13, 14]. Both persistent reflux and recanalization of the laser-treated veins were generally observed at late (6 and 12 months) follow-up in our study, which is also the case in the literature [8–14]. We believe, therefore, that a Doppler US control at 6–12 months should be routinely performed in such patients to detect recanalization and persistent varicose veins.

In our study, we saw some minor complications immediately after foam sclerotherapy, including coughing, nausea/vomiting, and transient visual disturbances, which resolved within 15–20 min after the procedure. Other minor complications included hyperpigmentation and telangiectatic matting (due to foam sclerotherapy), which mostly resolved within 1 year, and transient paresthesia (due to ELA), which mostly resolved within 5 months. In our study, major complications occurred in 14 legs (1.4%), which is comparable to that reported in the literature [2, 3, 5, 15, 16]. Skin necrosis was observed in nine legs, which may be due to foam extravasation or to foam intravasation



into a small artery. All except one of the necrotic wounds healed within 4 months, although systemic and topical antibiotics were necessary. Calf vein thrombosis was seen in at least one of the crural veins in five legs (0.5%). All the patients had ankle swelling several days after the procedure, which was successfully treated with low-molecular-weight heparin.

The rate of deep vein thrombosis (DVT) after ELA has been reported to be 0-5.7% in the literature. Although theoretically the risk of DVT is expected to increase with concomitant foam sclerotherapy, this was not the case in our study (0.5% DVT) and that of King et al. (0.1% DVT) [5]. In our study, we took some measures to reduce the risk of DVT, as follows. First, instead of injecting a large volume of foam via a single puncture, we injected small volumes via multiple punctures. Second, we avoided injection near perforating veins. Third, when we saw filling of the deep veins with foam, we stopped the injection at that site and continued the injection via another puncture. Fourth, we always performed foam sclerotherapy after all ELAs were finished, and we made the patient walk for 20 min immediately after the procedure. Fifth, we instructed the patient to be active (walking or performing foot exercises) for at least 4 h after each foam sclerotherapy session.

In our experience, concomitant use of USGFS with ELA provides some advantages. First, because the refluxing vein and the varicosities are treated in the same session, the total duration and also the cost of the treatment are reduced, because sterile materials used in ELA (e.g., injectors, stopcocks) can also be used for the USGFS, and the amount of foam is reduced because the large varicose veins become smaller after tumescent anesthesia. Second, the period spent in compression stockings is shorter after combined ELA and USGFS compared with the separate treatment, which is preferred by the patient. Third, if the varicose veins are left untreated after ELA, they may be thrombosed as a result of stagnation. This may complicate or interfere with the subsequent sclerotherapy (or phlebectomy) and may require anticoagulant treatment. Foam sclerotherapy performed shortly after ELA prevents this complication. Fourth, passage of the foam from the varicosities into the laser-ablated refluxing truncal or perforating veins creates an additional ablation, and this may result in a more durable occlusion.

In conclusion, ELA and concomitant foam sclerotherapy is feasible and effective. The procedures are associated with a low complication rate and can be performed in both legs in the same session. Concomitant use of laser and foam may potentially decrease the recanalization rate of laser-ablated vessels.

**Acknowledgment** We thank the Akdeniz University Scientific Research Projects Unit for supporting this study.

**Conflict of interest** The authors declare that they have no conflict of interest.

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