

Endovenous laser ablation for saphenous vein insufficiency: immediate and short-term results of our first 60 procedures

Saim Yılmaz, Kağan Çeken, Ahmet Alparslan, Timur Sindel, Ersin Lüleci

PURPOSE

To present the immediate and short-term results of our first 60 endovenous laser (EVL) ablation procedures.

MATERIALS AND METHODS

Between July 2005 and December 2006, 60 EVL ablations were performed in 36 symptomatic patients (26 females, 10 males; mean age \pm SD, 46 ± 14 years). The incompetent veins included the great saphenous vein (GSV) ($n=52$), small saphenous vein ($n=6$), and major branches of the GSV ($n=2$). In all cases incompetent veins were punctured under ultrasound (US) guidance and the laser fiber was placed into these veins through a vascular sheath or with the help of a catheter. After tumescent anesthesia was administered, the veins were ablated with laser by delivering 50–100 joules/cm energy to the vein wall. Following EVL ablations, 29 patients also underwent foam sclerotherapy to treat the remaining varicosities. After the EVL ablation \pm sclerotherapy, patients were followed-up with Doppler US at 1 week, and then 3, 6, and 12 months post procedure.

RESULTS

In all patients EVL ablation was technically successful. Complications were minor and included transient visual disturbance due to foam sclerotherapy ($n=1$), bruising/ecchymoses ($n=24$), postoperative pain ($n=16$), and superficial thrombophlebitis ($n=6$). All patients returned to normal activity within 2 days. During the 7 ± 5 months (mean \pm SD) of follow-up, recurrent reflux was seen in only one patient, in both GSVs, which was successfully treated with foam sclerotherapy.

CONCLUSION

EVL ablation is a safe and effective method for the management of saphenous vein insufficiency.

Key words: • varicose veins • catheter ablation • laser coagulation • endovenous laser ablation

Chronic venous insufficiency (CVI) affects approximately 20%–40% of people in the western world (1). Its prevalence is higher among the elderly, females, and people living in developed countries (2). CVI occurs due to dysfunction of the venous valves. In normal individuals, these valves prevent blood, which is pumped to the lungs, from returning into leg veins. When these valves become incompetent due to some genetic or environmental causes, the blood refluxes into the leg veins and increases venous pressure. This venous hypertension results in gradual dilatation and tortuosity of the incompetent vein, as well as its subdermal venous branches, which are then called varicose veins (1, 2).

CVI and varicose veins have a detrimental effect on patient quality of life; most patients have significant pain, cramping, burning sensations, and leg fatigue, which increase in the evening and after standing for long periods of time. In severe cases, leg edema, skin discoloration, and venous ulceration may develop. In rare cases, varicose veins may thrombose (superficial thrombophlebitis) and cause pulmonary embolism, or may bleed spontaneously, which could be dangerous if the leg is not promptly elevated (3, 4). Despite these problems, most patients did not undergo any treatment because until recently the only therapeutic options were surgery, which is invasive and has a high recurrence rate, and conservative measures, which are difficult for patients to comply with (2). This attitude, however, is expected to change with the widespread use of new treatment methods, such as endovenous laser (EVL) ablation and ultrasound (US) guided sclerotherapy.

The modern management of CVI includes treatment of both the cause (reflux) and result (varicose veins). Naturally, reflux should be treated before varicosities because if the cause is not eliminated varicose veins will eventually recur (2). Elimination of reflux has been classically accomplished with surgery (2, 5); however, thermal ablation methods, such as EVL and radiofrequency ablation, are gradually becoming the treatment of choice (5). In this study, we present our single center experience with the first 60 EVL ablations, along with the immediate and short-term results.

Materials and methods

Between July 2005 and December 2006, 36 patients with CVI were treated with EVL ablation, with or without sclerotherapy. These patients were not consecutive; rather, they constituted roughly half of the patients to whom EVL ablation was recommended by radiologists, based on duplex Doppler findings. The remainder of the patients either refused the procedure or did not come to their appointments, mainly because of their skepticism about EVL ablation or its high cost. Patients with deep venous obstruction, predominant deep venous insufficiency, and acute

From the Department of Radiology (S.Y. ✉ ysaim@akdeniz.edu.tr), Akdeniz University School of Medicine, Antalya, Turkey.

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superficial thrombophlebitis were not offered EVL ablation.

All the treated patients were symptomatic; the most common symptom was visible varicose veins, which were present in at least one extremity in all patients. Other symptoms included pain, night cramps, restless leg, variceal bleeding, and skin discoloration. Five patients had previous treatments for varicose veins (3 sclerotherapy and 2 phlebectomy), and the remainder had no previous treatment.

On duplex Doppler examination, all the patients were found to have incompetent saphenous veins in one (n=15) or both limbs (n=21) (3 limbs had 2 incompetent veins each). In these examinations significant reflux (>1 s duration) was seen in the great saphenous vein (GSV) (n=52), small saphenous vein (SSV) (n=6), or anterior lateral/posterior medial branches of the GSV (n=2) (Fig. 1). In some patients, reflux was also present in the

deep venous system at the level of the common femoral vein (n=6) or popliteal vein (n=2). Other demographic and clinical details of our patients are given in Table.

In all patients, the potential risks and benefits of EVL ablation and sclerotherapy were explained, and informed consent was obtained. Additionally, throughout the study the principles of the Helsinki Declaration were strictly followed. Before the procedure, a final Doppler US examination was performed and the course of each incompetent vessel was marked on the skin. The leg was disinfected with betadine and alcohol, and then was covered with sterile cloths. The transducer (7.5–10 MHz linear) of the US machine was similarly disinfected, and a suitable puncture point was chosen along the course of the incompetent vein. GSV and its branches were punctured either at the level of the knee or near the saphenofemoral junction

(SFJ), whereas the SSV was punctured approximately 10 cm proximal to the ankle. Based on our experience with initial cases, we generally preferred to use a micropuncture set (Cook, Bloomington, IN, USA) because puncturing with larger needles can be problematic in these low-pressure veins. The veins were punctured with a 21-gauge needle under US guidance as the patient was performing the Valsalva maneuver to distend the vein. The transducer was held in the transverse position because this enabled a more precise puncture into the center of the vein. After the needle tip was seen in the vein, the transducer was placed in the longitudinal position, which improved the visualization of the needle tip and the posterior wall of the vein, as well as the guidewire exiting the needle and advancing in the vein lumen (Fig. 2).

After the vein was successfully punctured, a 0.018-inch guidewire was inserted into the vein, which was then exchanged with a 0.035-inch standard guidewire through the sheath of the micropuncture set. This guidewire was then placed across the SFJ and a 4–5F sheath or diagnostic catheter was advanced over it. The guidewire was removed and the tip of the sheath/catheter was placed 2–3 cm distal to the SFJ. At this stage, tumescent anesthesia was administered. The anesthetic solution included 500 ml saline, 5 ml 10% lidocaine, 10 ml 8.4% sodium bicarbonate, and 1 ml adrenaline. This solution was injected just outside the vein wall along its entire course, so that it provided local anesthesia, compressed the vein, and isolated it from the surrounding structures (Fig. 3).

After administering the tumescent anesthesia, a 300–600- μ m laser fiber was inserted into the sheath/catheter, advanced 1–2 cm beyond, and fixed to the sheath/catheter via its valve or a Y connector. We made sure that the tip of the laser fiber was located several cm distal to the SFJ. The parameters of the laser machine were then adjusted so that it delivered 10 joules per pulse. These parameters were power (W), pulse duration (s), and pulse interval (s). We generally preferred 10–12 W power, 1 s duration, and 1 s interval, so that the machine would deliver 10–12 joules per pulse at 1-s intervals. The machine was then turned on and the fiber-sheath/catheter assembly was slowly withdrawn. Since 50–100 joules/cm la-

Demographic and clinical data of 36 patients in whom 60 endovenous laser ablations were performed

Age	Years
Mean \pm SD	46 \pm 14
Median	49
Range	20–68
Sex	n
Male	10 (28%)
Female	26 (72%)
Treated limb	n
Right	27 (45%)
Left	33 (55%)
CEAP classification	n
Clinical	
C0: no visible venous disease	0
C1: telangiectatic or reticular veins	0
C2: varicose veins	45 (75%)
C3: edema	0
C4: skin changes without ulceration	15 (25%)
C5: skin changes with healed ulceration	0
C6: skin changes with active ulceration	0
Etiology	
Congenital	0
Primary	60 (100%)
Secondary	0
Anatomy	
Telangiectasias or reticular veins	0
Great saphenous vein above the knee	12 (20%)
Great saphenous vein below the knee	40 (67%)
Small saphenous vein	6 (10%)
Saphenous branch veins	2 (3%)
Pathology	
Superficial reflux	52 (87%)
Superficial + deep reflux	8 (13%)
Deep reflux	0
Obstruction	0

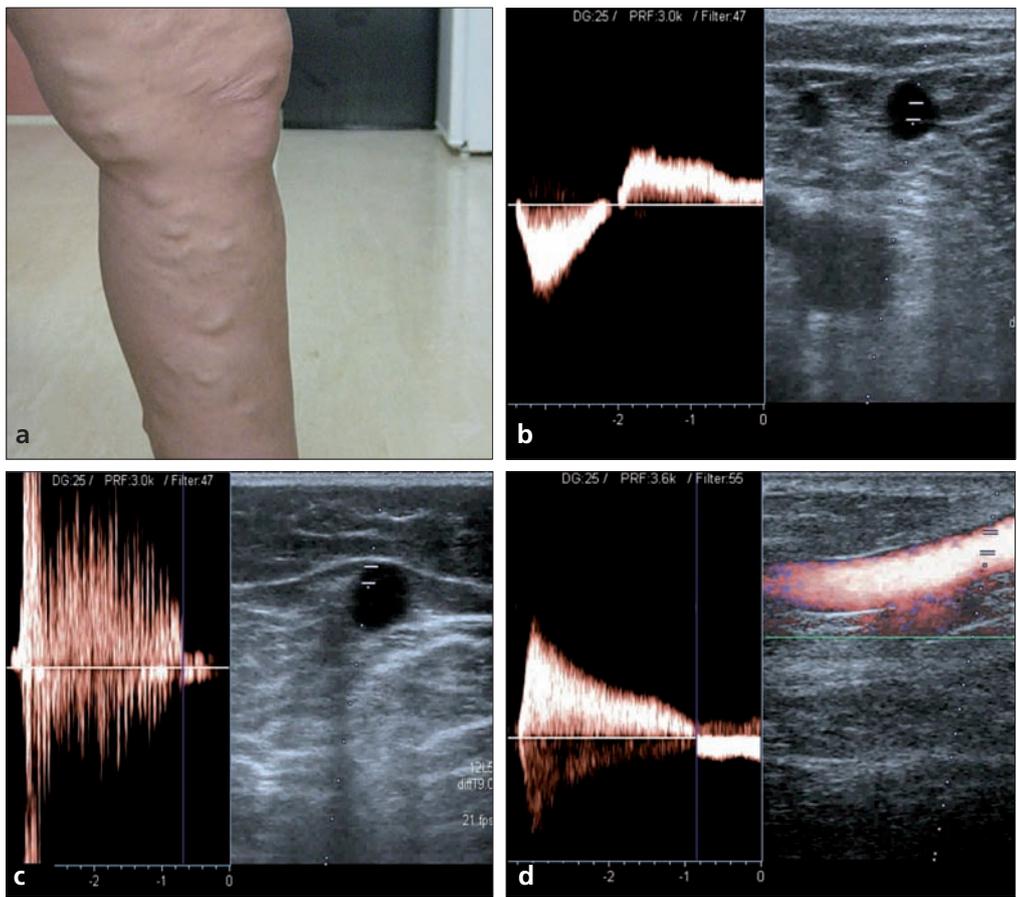


Figure 1. a-d. A 40-year-old woman with symptoms of venous insufficiency. Photograph of the left leg (a) showing typical varicosities located in the medial calf suggestive of great saphenous vein (GSV) insufficiency. Duplex Doppler US (b) shows reflux in the GSV near the saphenofemoral junction with distal manual compression. First deflection is created by the prograde flow upon distal manual compression and the second deflection is created by the retrograde flow (reflux) upon release of the compression. Duplex Doppler US (c) shows reflux with the Valsalva maneuver. Note that the flow is typically unidirectional (retrograde only) and is created by the Valsalva maneuver, which increases pressure in the central veins. The appearance of reflux on color Doppler US (d) with the Valsalva maneuver. Color and power Doppler US may facilitate the identification of refluxing segments; however, they are not routinely used since they are known to underestimate the degree of reflux in patients with venous insufficiency.

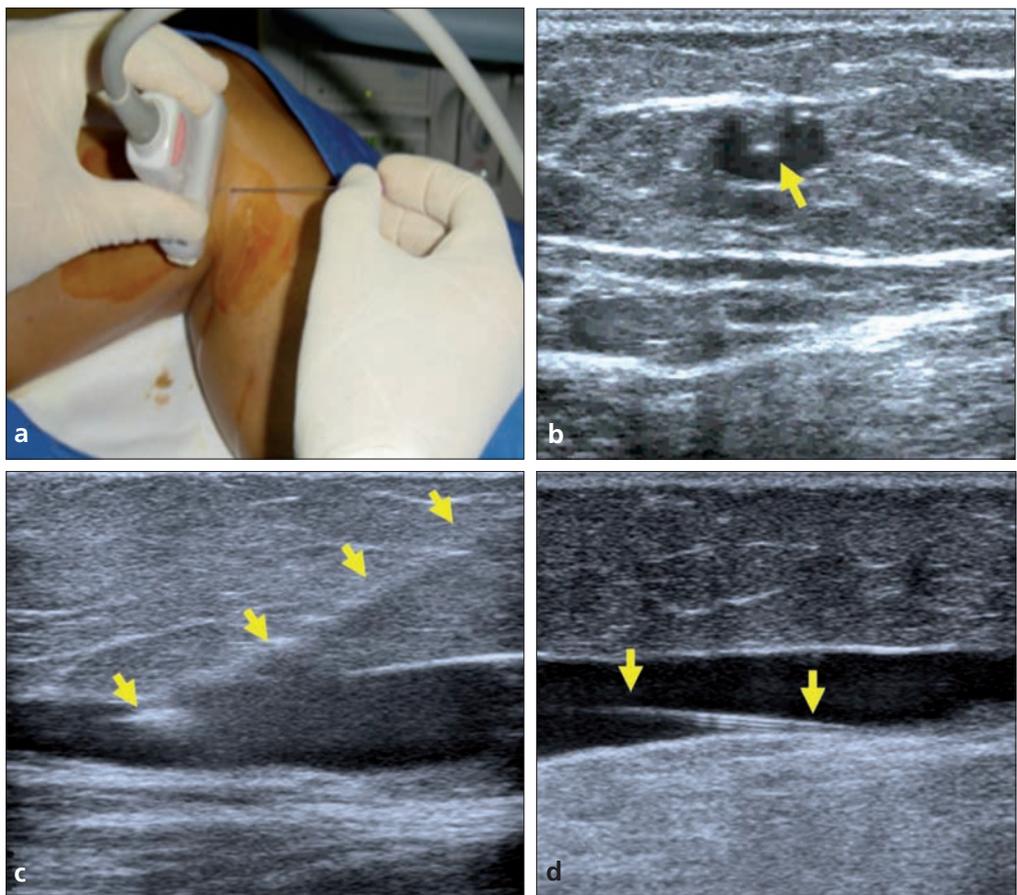


Figure 2. a-d. Typical stages of venous puncture in a patient with great saphenous vein (GSV) insufficiency. The GSV is punctured with a 21–22-gauge needle under US guidance (a) while the patient is performing the Valsalva maneuver. US image (b) showing the transducer held in the transverse position and the needle is introduced towards the center of the vein (arrow). After the vein is successfully punctured, the transducer is put into the longitudinal position (c). In this position, the exact locations of the needle tip (arrows, c) and the guidewire, in relation to the vessel walls, are visualized more accurately. Before the micropuncture sheath is advanced, it is better to confirm the intravascular location of the guidewire on the longitudinal US view (arrows, d). Otherwise, the sheath may perforate the vessel, leading to extensive venous spasm and perivascular hematoma, in which case it may be extremely difficult to repuncture the saphenous vein since it becomes virtually invisible on US.

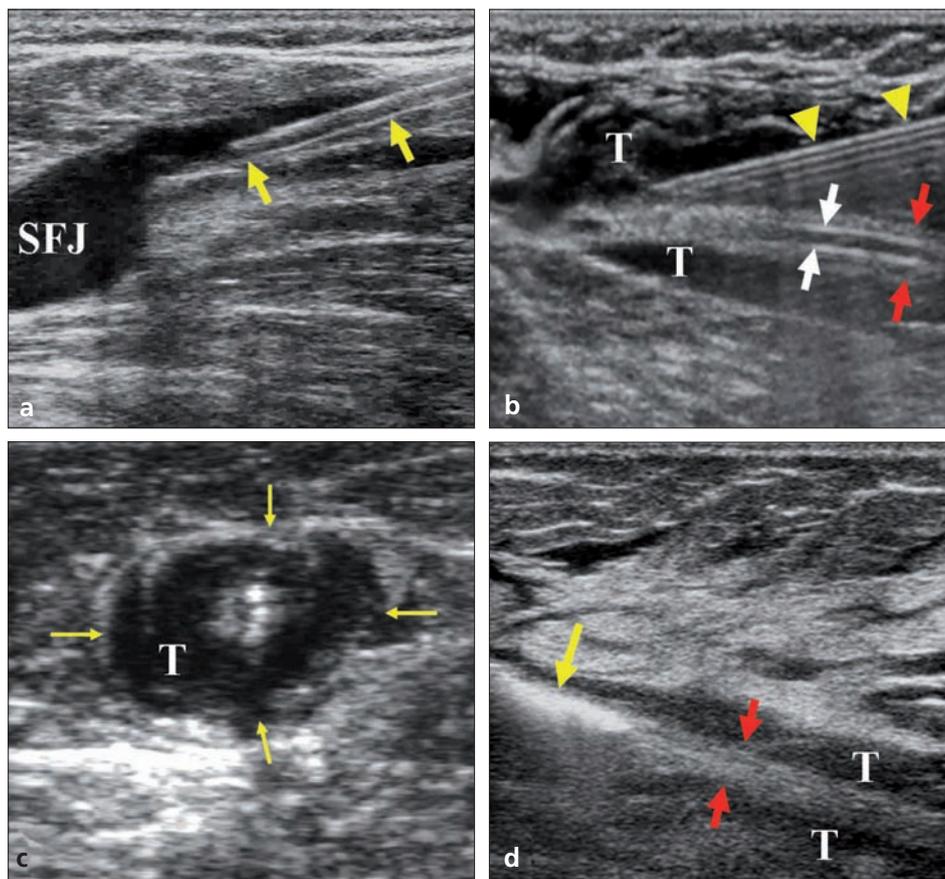


Figure 3. a–d. After the great saphenous vein (GSV) is punctured successfully, the sheath/catheter is placed across the saphenofemoral junction (SFJ) over a 0.035 guidewire. The sheath/catheter (arrows) is withdrawn so that its tip is located several centimeters distal to the SFJ (a). In this location, the deep venous system and superficial epigastric vein are protected from heat damage. Tumescent anesthesia is then administered under US guidance with the transducer in the longitudinal position (b). The needle (yellow arrowheads) is advanced into the vein wall and the tumescent solution (T) is injected only around the vessel. The tumescent anesthesia compresses the vein and apposes its walls (red arrows) onto the sheath (white arrows); as a result, there is little blood in the vein and the vein walls are very close to the laser beam. The tumescent solution (T) also isolates the saphenous vein from the surrounding soft tissues (arrows, c). Therefore, the patient experiences no pain and the soft tissues are protected from heat damage. During laser ablation, the laser energy is absorbed by the blood and steam bubbles are produced (d). These bubbles (yellow arrow) can be seen on US and are believed to be the key factor leading to intimal damage. Red arrows point to the saphenous vein, which is surrounded by the tumescent solution (T).

ser energy is recommended during EVL ablation (5), the fiber was withdrawn at such a rate that the machine produced 5–10 pulses/cm. We used lower energy levels for small size veins and higher energy levels for larger veins. After each vein was ablated all along, the fiber and the sheath/catheter were removed, and the puncture hole was covered with sterile tape. An elastic bandage was then wrapped around the leg and patients were immediately requested to walk for 20–30 min.

After EVL ablation, patients were given a non-steroidal anti-inflammatory drug for 1–2 weeks, depending upon the severity of their complaints. They wore elastic bandages for 1 week and class II (30–40 mmHg) stockings for at least 1 month. They were also advised to walk at least 1 h per day, but to avoid intense exercise, high temperatures, and standing for a long period of time.

In 29 patients (40 legs), after the incompetent saphenous vein was ablated, sclerotherapy was performed for varicosities. Since almost all patients had large (>4–5 mm) varicose veins, foam sclerotherapy was preferred rath-

er than the liquid form. We prepared foam according to the Tessari method (6); two 5–10 ml sterile injectors were attached via a 3-way stopcock. One injector contained one volume (1–2 ml) polidocanol and the other, 4 volumes (4–8 ml) air. The sclerosant and air were then mixed (15–30 times) until thick foam was obtained. The foam was immediately injected into the varicosities at 1–3 sites under US guidance. The injection was stopped when the target varicosities were filled and the echogenic foam passed into the deep veins (Fig. 4). The leg was wrapped with elastic bandages just as it was done after EVL ablation, and the patient was immediately asked to walk for 20–30 minutes. Early in our experience, we performed sclerotherapy 1–2 weeks after EVL ablation (n=15). Later, we generally did it during the same session, shortly after EVL ablation (n=25). This was more acceptable to the patients since they had to wear elastic bandages only once.

Patients were followed-up with Doppler US at 1 week, and then 3, 6, and 12 months post procedure. The 1-week follow-up was performed to check for

thrombus formation at the SFJ or saphenopopliteal junction (SPJ), and the subsequent follow-ups were to evaluate the effectiveness of the procedure(s). In our study, technical success was defined as successful catheterization and complete ablation of the incompetent saphenous veins. Complications were defined as minor when they required only minor therapy and overnight observation, or major when they required major therapy, prolonged hospitalization, or an unplanned increase in the level of care. At follow-up, success was defined as the persistent occlusion and gradual narrowing/disappearance of the treated vessel.

Results

In all procedures, EVL ablation was technically successful. In our very first case, it took about one hour to successfully puncture the GSV at the knee. In this patient, we tried to enter the vein with a standard 18-gauge needle after local anesthesia, which resulted in multiple failed attempts, venospasm, and rupture. In subsequent cases, we punctured the veins with a micropuncture set, without local anesthesia, and

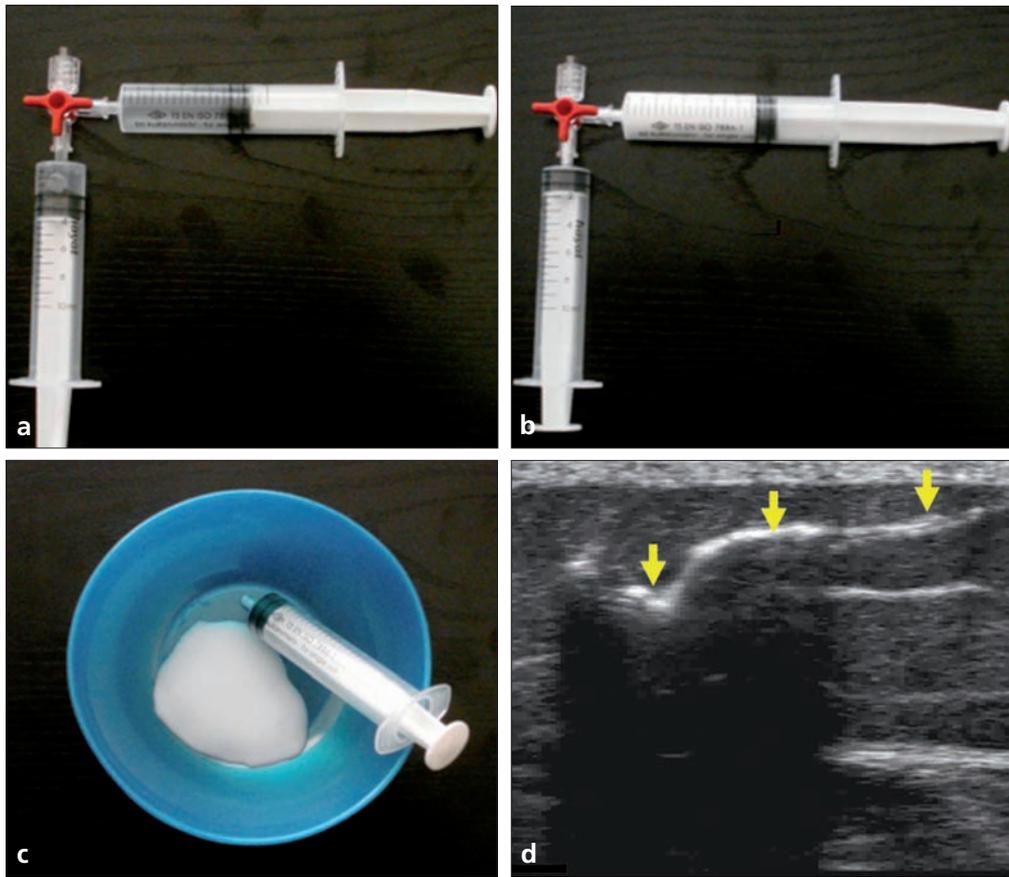


Figure 4. a–d. After endovenous laser ablation (EVL) ablation, the remaining varicose veins are generally treated with sclerotherapy (liquid or foam) or phlebectomy to decrease the recurrence rate and increase patient satisfaction. Foam is usually preferred to liquid in the sclerotherapy of varicose veins, and is prepared according to the Tessari method (6). One volume of polidocanol and 4 volumes of air are aspirated into the injectors, and the 2 injectors are attached via a 3-way stopcock (a). The sclerosant and air are mixed by pushing the pistons of the injectors 15–30 times, sequentially, until a thick foam is created (b). This foam should be injected immediately since it liquefies approximately 90 s after its preparation (c). US image showing the foam (arrows, d). It can be directed into the target veins by elevating and rotating the leg. Since it advances in the vein like an air column, and pushes the blood rather than mixing with it, it creates sufficient intimal damage for most varicosities, even from a single injection site.

were generally able to enter the veins on the first attempt.

After the EVL ablation±sclerotherapy, no major complications occurred. Minor complications, however, were quite common and included transient visual disturbance due to foam sclerotherapy (n=1), bruising/ecchymoses (n=24), postoperative pain that required analgesics (n=16), and superficial thrombophlebitis (n=6), all of which disappeared within one month. Skin burn and paresthesia did not occur. All patients returned to normal activity within 2 days.

After the procedures, symptoms of venous insufficiency decreased (n=10) or disappeared (n=25) in all but one patient. In this particular patient the persistence of symptoms was attributed to coexistent severe gonarthrosis. At one-week Doppler US follow-up, none of the patients had deep venous thrombosis or extension of thrombus into the deep venous system. During the 7±5 months (mean±SD; range, 1–17 months) of follow-up, recurrence was not seen, except in a patient who underwent EVL ablation for bilateral GSV insufficiency. In this patient, re-

canalization was seen in both GSVs on Doppler US 8 months post procedure, and both vessels were successfully treated with foam sclerotherapy. In the remaining 35 patients, follow-up Doppler US showed gradual narrowing or disappearance of the treated vessels (Fig. 5).

Discussion

For more than a century, the classic treatment for saphenous vein insufficiency has been surgical ligation and stripping (L&S) (2). This procedure is associated with an excellent early outcome since the incompetent vessel is totally removed. In the long term, however, 20%–40% of the cases present with recurrent reflux within 5 years, mainly because of the neovascularization that occurs in the saphenous compartment (7, 8). In addition, L&S has a number of disadvantages that make it undesirable to patients, such as general anesthesia, risk of deep venous thrombosis, paresthesia, hospitalization, prolonged return to daily activities, and postoperative scarring (2, 3).

EVL ablation was introduced as an alternative to L&S by Navarro et al.

in 2002 (9) and has rapidly become the treatment of choice for treating saphenous vein insufficiency. This procedure is based on the thermal ablation of the incompetent vein with laser energy via a fiber placed in the vein lumen. This laser energy leads to intimal damage, which results in permanent occlusion with subsequent fibrosis of the vein (5, 10). EVL ablation is proven to be very successful and durable in the treatment of saphenous vein insufficiency. In a number of large case series, the technical success rate was close to 100%, and the long-term success rate (up to 5 years) ranged from 90% to 100% (11–13). Likewise, in our study the technical success of EVL ablation was 100% and the short-term success rate was 97%. These figures are clearly superior to those of L&S, although they have not yet been confirmed with prospective randomized studies (2, 10).

From the technical point of view, venous puncture and tumescent anesthesia are the most crucial components of EVL ablation. Venous puncture is important because if it is not successfully performed in initial attempts, venos-

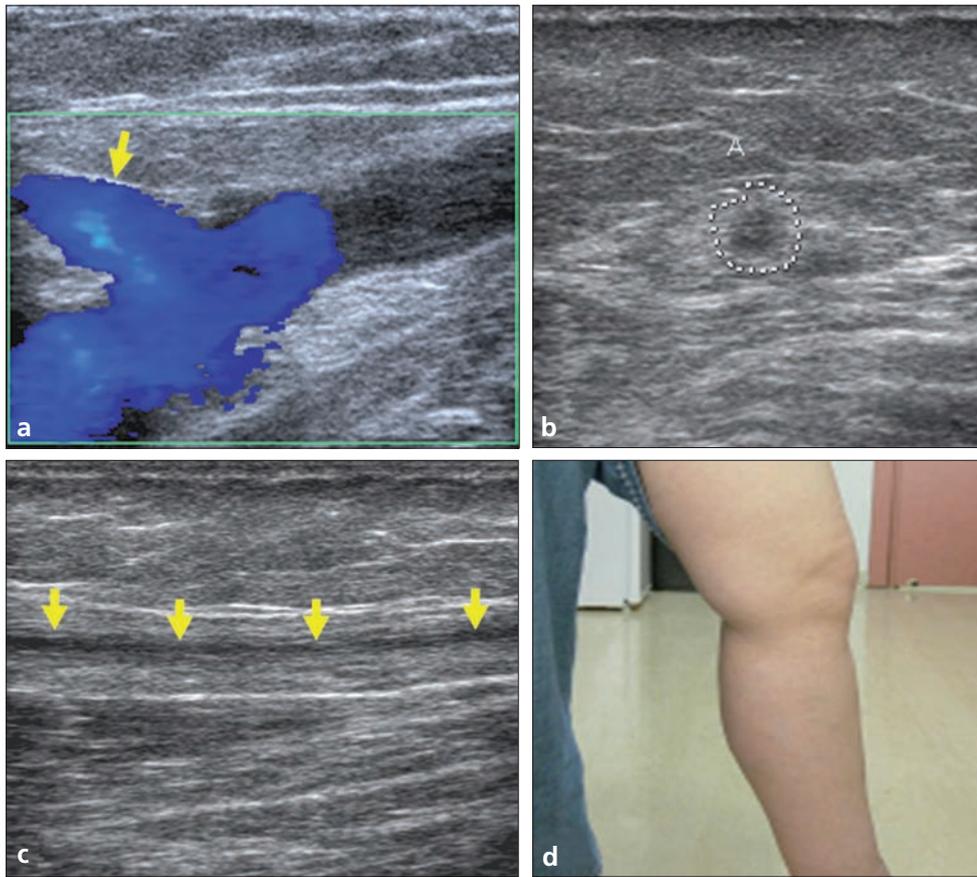


Figure 5. a–d. The follow-up of the patient in Fig. 1a. Color Doppler US (a) at one week post procedure demonstrates the occlusion of the great saphenous vein (GSV) distal to the superficial epigastric vein (arrow). There is no thrombus at or near the saphenofemoral junction. Transverse US image at one month (b), shows that the GSV is still occluded and its diameter is reduced, with an increase in luminal echogenicity. Longitudinal US image at 3 months (c), shows that the GSV looks remarkably shrunken (arrows). At 9 months after endovenous laser ablation and 3 sessions of sclerotherapy, varicose veins almost disappear, and the patient becomes asymptomatic (d).

pasm or rupture can frequently develop and the procedure may have to be abandoned. Successful puncture of the saphenous vein may be very challenging for several reasons: first, the saphenous veins are rather mobile in the fat tissue, particularly in obese patients; second, in the standing position, blood pressure in superficial veins is around 100 mm Hg, and therefore the veins are very distended. In the supine position, however, this blood pressure drops to virtually 0 mm Hg, making these veins very thin and easily compressible (13, 14). Thus, if puncture of the saphenous veins are attempted in the usual manner, it is likely to fail. There are, however, a number of maneuvers that may facilitate the puncture. First, blood pressure in the saphenous vein may be increased by putting the patient in the reverse Trendelenburg position or getting the patient to perform the Valsalva maneuver. Second, use of a micropuncture set with a small gauge needle and guidewire may decrease trauma to the vein and thus lower the risk of venospasm. In our patients, we did not use the reverse Trendelenburg because our patient table did not tilt; instead,

we routinely punctured the veins with a micropuncture set while the patient was performing the Valsalva maneuver and did not experience any puncture failures.

Tumescent anesthesia is another important stage of EVL ablation. It is useful in 3 ways: first, it provides local anesthesia, making EVL ablation a virtually painless procedure; second, it isolates the saphenous veins from the surrounding soft tissues and prevents heat damage to the skin and accompanying nerves [these first 2 points increase patient comfort and decrease the risk of complications, such as skin burn and paresthesia (13)]; third, tumescent anesthesia compresses the vein and drains the blood from inside the lumen, thus decreasing thrombus formation and increasing intimal damage by bringing the vein wall into close contact with the laser fiber. This last point may directly affect the long-term success of EVL ablation, as during the procedure the laser energy is completely absorbed by all the blood within <1 mm of the fiber, which results in extremely high intraluminal temperatures (700–1300°C). These

high temperatures produce steam bubbles, which induce both intraluminal thrombosis and intimal damage (15). For a durable saphenous occlusion, there must be maximal intimal damage and minimal thrombosis, because a thrombosed vein without intimal damage will eventually recanalize. Thrombosis is favored when there is too much blood in the vein and relatively less laser energy is given to the vein wall; intimal damage is favored when there is little blood in the lumen and sufficient laser energy is delivered; thus, more heat is transferred to the intima by steam bubbles. Tumescent anesthesia creates maximal intimal damage by attaching the vein walls to the laser fiber, and decreases thrombosis by compressing the vein and emptying its blood content; therefore, it improves the long-term outcome of EVL ablation (5, 13, 16, 17). For ideal tumescent anesthesia administration, the tumescent needle should touch the outer surface of the vein without perforating it. In this position, the injected local anesthetic goes just around the saphenous vein and the surrounding soft tissues

are pushed away (Fig. 3b, c). If the tumescent solution is given at a distance from the vein, these tissues are not pushed away, but are attached to the vein wall and thus may be exposed to some degree of heat damage (13). In our patients, we strictly followed these rules during the use of tumescent anesthesia, and think that it has contributed to the low complication and recurrence rates in our series.

Both venous puncture and tumescent anesthesia require extensive US skills and experience, and this is the reason why EVL ablation should be performed by interventional radiologists (IRs) who are trained on ultrasound and experienced in percutaneous techniques. For instance, in cases such as a tortuous saphenous vein, it is very important to have had the necessary training/experience to manage placing the tip of the catheter in the proper position. Likewise, it is important to see the tip of the laser fiber at the SFJ or SPJ with US, because if the fiber tip is in or near to the deep veins it may lead to deep vein thrombosis (DVT). Some operators inexperienced with US-guided procedures usually perform surgical cut down for accessing the GSV, perform tumescent anesthesia without US guidance, or use spinal or general anesthesia, all of which can decrease the technical success and increase complication rates. Accessing the vein with single/multiple cut-downs instead of the percutaneous technique transforms EVL ablation into a more invasive, semi-surgical procedure. Tumescent anesthesia performed without US guidance will not effectively compress and isolate the saphenous veins from the surrounding tissues, which may increase complications and negatively affect long-term outcome (5, 13, 17). Use of general/regional anesthesia will increase the risk of DVT because the patient will not be able to stand and walk immediately (11, 13) post procedure. In our patients, we always performed EVL ablation with local anesthesia, without premedication, and made the patients walk immediately post procedure. We believe that this is the primary reason why there was no DVT in our series, despite the simultaneous use of foam sclerotherapy in some patients.

Before the advent of EVL ablation, radiologists were mainly interested in

the diagnosis and follow-up of patients with venous insufficiency. After the introduction of EVL ablation, some radiologists (mainly IRs) were also involved in treatment. It is known that EVL ablation is performed by a variety of specialties, including interventional radiology, vascular surgery, general surgery, dermatology, etc. (2, 5, 15) In our opinion, however, IRs should be actively involved in EVL ablation and other phlebologic procedures for the following reasons:

- 1) IRs are the only interventionalists who are officially trained in US and US-guided interventions, and EVL ablation is a typical US-guided percutaneous intervention.
- 2) US is extremely important for the diagnosis and post treatment follow-up of venous insufficiency; it detects the incompetent vein(s), localizes the point(s) of reflux, shows varicosities, and excludes venous or arterial obstruction, providing virtually all the necessary information for the treatment. After EVL ablation, US provides an objective evaluation of success, and demonstrates complications and recurrence (if any) (14); thus, IRs have already been doing a great deal of the work in the diagnosis and follow-up of venous insufficiency, and it is only natural that they are also interested in its treatment.
- 3) EVL ablation was first introduced by an IR (Min) and 2 other physicians (9) (there were no vascular surgeons in this group). IRs have also produced a considerable number of scientific publications on EVL ablation (5, 11, 13, 17–23). It is evident, therefore, that IRs have also been very active from the research point of view.
- 4) EVL and sclerotherapy procedures are far safer than other percutaneous procedures, and thus surgical back-up is not necessary.
- 5) Clinical aspects of venous insufficiency are, of course, important, but they are relatively easy to learn. Moreover, clinical examination can never compete with a good duplex Doppler US examination in the diagnosis and treatment planning of venous insufficiency.

- 6) Patient referral is a problem as in every field of interventional radiology; however, venous insufficiency is a highly prevalent disorder, patients are interested in new noninvasive treatments, and because of the genetic aspect of the disease, most patients have relatives suffering from saphenous vein insufficiency. As a result, patients are generally referred by other patients who have been satisfied with EVL ablation.

In conclusion, EVL ablation is a safe and effective method for the management of saphenous vein insufficiency. Due to a number of reasons, IRs must be actively involved, not only in the diagnosis and follow-up, but also in the treatment of this disorder.

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