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Endovenous Laser Ablation for Incompetent Saphenous Vein Combined With Fluoroscopy-Guided Endovenous Foam Sclerotherapy in Varicose Tributaries: Long-Term Follow-up Results

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The aim of this study is to describe the long-term results of 980-nm endovenous laser ablation (EVLA) combined with fluoroscopy-guided endovenous foam sclerotherapy using a microcatheter into varicose tributaries. This report reviewed experiences with fluoroscopy-guided endovenous foam sclerotherapy using a microcatheter followed by EVLA, from July 2005 to November 2007. The sclerosing foam was injected through the microcatheter using 1% polidocanol or sodium tetradecyl sulfate. Patients were evaluated clinically and with duplex ultrasound from 1 week to 3 years to assess treatment efficacy and adverse reactions. Technical success was seen in 460 of 461 limbs (99.8%). Continued closure of the saphenous veins and complete sclerosis of varicose tributaries were noted in 351 of 408 limbs (86%) at 1-month follow-up, all 328 limbs at 3-month follow-up, all 299 limbs at 6-month follow-up, all 146 limbs at 1-year follow-up, all 94 limbs at 2-year follow-up, and all 32 limbs at 3-year follow-up. No serious complications were noted.

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Bruising was noted in 79.0%, and pain or tightness was noted in 68.4%. Hyperpigmentation was noted in 54.2%. EVLA for incompetent saphenous vein combined with endovenous foam sclerotherapy appears to offer the obvious benefits of less additional percutaneous sclerotherapy. However, many problems, like long-lasting pain and hyperpigmentation, can lessen the value of this procedure.

Key words: Varicose vein – Laser – Sclerotherapy – Fluoroscopy – Ultrasound

Surgical ligation and stripping is the traditional method of eliminating incompetent saphenous veins. In recent years, a number of minimally invasive treatments for varicose veins have been developed.[1] In 1999, Bone first reported the delivery of endoluminal laser energy.[2] Since then, endovenous laser ablation (EVLA) has been demonstrated to close the saphenous vein through thermal damage to the endothelium, with subsequent thrombosis and reabsorption of the damaged vein. In the last few years, EVLA has evolved into an accepted option for eliminating truncal reflux. Laser systems, including a 980-nm wavelength laser, have been used for incompetent great or small saphenous veins (GSV or SSV), with reported rates of saphenous vein occlusion ranging from 88% to 100% at the end of follow up.[1,3–5]

Although EVLA has been demonstrated to effectively occlude incompetent saphenous veins, it does not treat branch varicosities directly, thus requiring an ambulatory phlebectomy or follow-up sclerotherapy. For the treatment of leg veins smaller than 4 mm in diameter, sclerotherapy has been considered to be the criterion standard.[5] The sclerosing foam, which is composed of a mixture of air and a sclerosant, such as polidocanol or sodium tetradecyl sulfate, has been introduced in sclerotherapy, with the aim of increasing the effectiveness and safety of the treatment. However, percutaneous sclerotherapy has some shortcomings, including risks associated with intra-arterial injection during injection into large veins and the need for multiple needle punctures and therapeutic sessions.[6]

Therefore, we performed venogram, followed by selection of the varicose tributaries using a microcatheter. Directed endovenous foam sclerotherapy was then performed through a microcatheter, followed by EVLA in the incompetent saphenous veins, not only to reduce the need for additional follow-up percutaneous sclerotherapy, but also to prevent multiple punctures. The purpose of this study was to report the long-term follow-up results of endovenous foam sclerotherapy followed by EVLA with a 980-nm diode laser.

Patients and Methods

Patient selection and evaluation

From July 2005 to November 2007, patients with varicose veins (CEAP classification: C2-C6) in one or both lower extremities who were presented to the vascular surgery and thoracic and cardiovascular surgery outpatient departments were examined to elicit an accurate history, symptoms, duration, and possible causes. All patients underwent duplex ultrasound examination. Reflux in duplex ultrasound was defined as reverse flow in the saphenous vein for >0.5 seconds after releasing calf or thigh compression with the patient standing, and after the Valsalva maneuver in the supine position.

Patients with an incompetent saphenous vein were given the choice of surgical ligation and stripping with phlebectomy, or EVLA combined with sclerotherapy.

We excluded patients younger than 18 years and those with impalpable pedal pulses, evidence of previous deep vein thrombosis, inability to ambulate, poor general health, and pregnancy, as well as those who were nursing or who planned to become pregnant during the course of treatment.[5] A total 336 patients (M:F = 149:187; mean age, 46.2 years; range, 21–71 years) were included in this study. Written informed consent that delineated the predictive result and potential complications of this new method was obtained, and the Institutional Review Board approved the study.

Procedure

The patient was draped in the usual sterile fashion from the groin to the ankle in the case of treating GSV, or from the posterior midthigh to the ankle for SSV. After the saphenous vein was successfully accessed, a 0.018-inch wire and a 4-Fr or 5-Fr microsheath were introduced into the puncture site

under ultrasound and fluoroscopy guidance. A venogram was performed to verify the exact orifice of varicose tributaries from the saphenous vein. A guiding catheter was advanced over a 0.035-inch guide wire into the saphenous vein of the orifice area of varicose tributaries. Thereafter, a 2.3∼2.6-Fr microcatheter was placed into the guiding catheter coaxially, and selective catheterization into varicose tributaries followed by venogram through the microcatheter was performed to ascertain the connection to the deep venous system and the exact extent of varicose tributaries.[5]

The sclerosing foam to be injected through the microcatheter was produced using the Tessari method using 1% polidocanol or sodium tetradecyl sulfate mixed with contrast medium. Two syringes including sclerosant and air (1:4∼5), respectively, were attached using a 3-way stopcock, and the stable sclerosing foam was obtained by mixing them through multiple passages between the 2 syringes.[7] After mixing, a homogeneous white foam was created, and 2 to 2.5 mL of the foam was aspirated using a 3-mL syringe. Under fluoroscopy, the foam was injected into the tributaries, and external compression was done for about 5 minutes.

After completion of endovenous sclerotherapy, the microcatheter was removed and the guiding catheter was advanced below the saphenofemoral or saphenopopliteal junction (SFJ or SPJ). A 600-μm bare-tipped laser fiber of 980-nm wavelength was inserted into the guiding catheter and placed within 1 to 2 cm of the SFJ or SPJ. Using ultrasound guidance, a tumescent solution consisting of 100 to 250 mL of 0.05% lidocaine was delivered along the course of the saphenous vein within the fascial envelope. The EVLA was performed using the pull-back method. Linear endovenous energy density was from 50 to 120 J/cm in the continuous mode.

After the procedure, the patient was discharged, and a class II full-thigh graduated support stocking was worn for at least 1 month at all times except during sleep or showering. Patients were given a prescription for analgesics and antibiotics for 3 days.

Follow-up and assessment

The technical success of EVLT was defined as a procedure with successful access, crossing the segment to be ablated, adequate administration of tumescent anesthesia, and delivery of laser energy to the incompetent saphenous vein. The technical success of endovenous sclerotherapy was defined as successful selective catheterization and adequate injection of the foam into varicose tributaries.

Patients were evaluated clinically and using duplex ultrasound at 1 week; at 1, 3, and 6 months; at 1 year; and then annually. The duplex ultrasound criteria for successful treatment were defined as noncompressible veins and no blood flow seen within the entire ablated saphenous vein and varicose tributaries.

Results

A total of 336 patients and 461 limbs (GSV, 351; SSV, 110) were managed using endovenous foam sclerotherapy followed by 980-nm EVLA. The technical success in accessing the saphenous vein, selective catheterization, injection of the foam into varicose tributaries, exact positioning of the tip of the laser, tumescent anesthesia, and EVLA was seen in 460 of 461 limbs (99.8%). In 1 limb, we failed to advance the guide wire into the GSV, and this was transferred to the referring physician. When the orifice of varicose tributaries was selected with a microcatheter, vascular spasm appeared in 117 of 460 limbs (25.4%), which made it difficult to advance the microcatheter to the intended site of the tributaries, but all microcatheters were successfully advanced to their orifice using gentle manipulation of the wire under fluoroscopy.

The tip of the laser was unclear in 19 limbs (2 SFJ, 17 SPJ) under ultrasound imaging, but correct positioning of the tip of the laser was easily achieved after verification of the SFJ and SPJ using a venogram under fluoroscopy.

Follow-up results at 1 week were obtained in 443 of 460 limbs (96.3%), and 429 of 443 limbs (96.8%) at 1-week follow-up showed complete closure in the treated saphenous veins. These 14 limbs that were not shown to be occluded on duplex ultrasound at 1-week follow-up still showed recanalization with obvious reflux on duplex ultrasound at 1-month follow-up. A total of 394 of 408 limbs (96.6%) showed complete occlusion at 1-month follow-up. Continued closure of the treated saphenous veins was seen in all 328 limbs (100%) at 3-month follow-up, and all 299 limbs (100%) at 6-month follow-up, all 146 limbs (100%) at 1-year follow-up, all 94 limbs (100%) at 2-year follow-up (Fig. 1), and all 32 limbs (100%) at 3-year follow-up (Table 1). No limbs with complete occlusion in the saphenous vein at 1-week follow-up demonstrated the reappearance of blood flow and compressibility during later follow-ups.

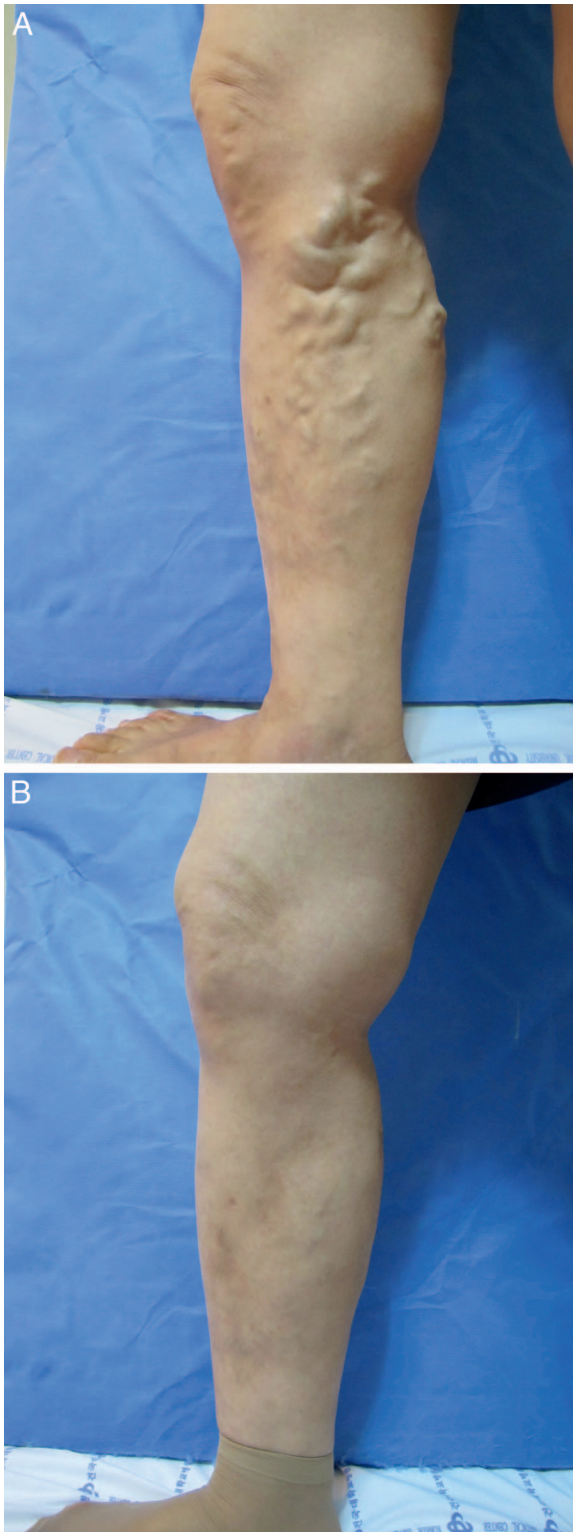

Fig. 1 A 62-year-old woman with varicose veins in the right lower extremity. (A) Typical feature of varicose veins due to incompetent GSV in the right lower extremity. (B) Marked improvement in the appearance of varicose veins at 2-year follow-up after EVLA combined with endovenous foam sclerotherapy.

Varicose tributaries treated using endovenous foam sclerotherapy demonstrated no visible vascularity and no compressibility along their entire courses in 351 of 408 limbs (86%) at 1-month follow-up. The volume of the foam that was used for sclerotherapy ranged from 1 to 14 mL (mean, 4.8 mL). A total of 57 limbs with incomplete sclerosis in varicose tributaries showed partial blood flow on 1-week follow-up duplex ultrasound. A total of 48 of 57 limbs received additional percutaneous sclerotherapy. Any limbs with complete sclerosis in varicose tributaries at 1-month follow-up did not show any blood flow during further follow-ups.

Of 460 limbs that achieved adequate cannulation of the saphenous vein as an initial access route, complications such as venous perforation and dissection did not occur during the passage of the guide wire or the placement of the guiding catheter in the saphenous vein; the guide wire or guiding catheter was easily advanced into SFJ or SPJ.

Two common side effects, such as bruising and pain or tightness, were noted after EVLA. Bruising was noted in 79.0% at 1-week follow-up, but this was asymptomatic and resolved completely in all followed-up limbs by 1-month follow-up. Pain or tightness over the treatment site was complained of in 68.4% at 1-month follow-up. These symptoms were greatly improved or resolved by 3 or 6 months. However, 77 of 146 limbs (52.7%) still had pain in varicose tributaries that was treated by endovenous foam sclerotherapy even at 1-year follow-up, although all 94 limbs did not complain of pain any more at 2-year follow-up (Table 2).

Hyperpigmentation was noted in 221 of 408 limbs (54.2%) at 1-month follow-up. It was increasingly improved during further follow-ups. However, 38 of 146 limbs (26%) still had obvious hyperpigmentation at 1-year follow-up, and furthermore, long-lasting hyperpigmentation was noted in 11 of 94 limbs (11.7%) even at 2-year follow-up. At 3-year follow-up, 32 limbs did not show any remnant hyperpigmentation.

Paresthesia was detected in 16 of 408 limbs (3.9%) at 1-month follow-up, and this symptom was relatively mild and well tolerated and completely disappeared by 6-month follow-up.

One patient (0.3%) noted a transient visual disturbance like a flash after sclerotherapy. Mild headache was noted in 6 patients (1.76%). These symptoms were mild and completely resolved within 30 minutes. Mild edema in the calf without evidence of deep vein thrombosis was noted in 9 limbs (2.2%). Itching sensation was complained of in

Table 1 Closure rate of GSV

	1 wk	1 mo	3 mo	6 mo	12 mo	24 mo	36 mo
GSV, n (%)	429/443 (96.8)	394/408 (96.6)	328/328 (100)	299/299 (100)	146/146 (100)	94/94 (100)	32/32 (100)

8 patients (2.4%). These were completely resolved by 6-month follow-up.

There were no significant complications, such as skin burns, skin necrosis, pulmonary embolism, cerebral infarction, or allergic reaction.

Discussion

Minimally invasive methods for ablation of the saphenous vein have gained increasing popularity in the treatment of varicose veins. Worldwide, endovenous techniques have more or less replaced conventional surgery.[8] Different laser systems have been used with wavelengths of 810, 940, 980, 1320, and 1470 nm, with reported success, and the rates of saphenous vein occlusion ranging from 87.9% to 100% at the end of follow-up.[8–19] The saphenous occlusion rate was 96.8% at 1-week follow-up in this study, which was comparable to other studies. However, the complication rates of both bruising and pain or tightness were relatively higher than in previous reports. We assumed that the higher bruising rate resulted from the high linear endovenous energy density greater than 100 J/cm that was used during EVLA in some patients. Also, combined endovenous foam sclerotherapy using a microcatheter might have induced higher pain or tightness. In fact, it is not usual for pain or tightness after EVLA to last more than 1 year. This might be a significant drawback of endovenous foam sclerotherapy using a microcatheter.

Currently, the 1470-nm endovenous laser has been developed and used popularly because it demonstrates a marked reduction in postoperative pain and ecchymosis through minimal vein wall perforation and dramatic reduction in energy compared with the 980-nm wavelength.[20] However, the first article regarding a 1470-nm endovenous laser was published in 2009,[18] and it is a bit difficult to find an article dealing with its long-term follow-up data. This laser was not available for use in our institution while this study was going on. Bruising and pain may be reduced in this study if the 1470-nm endovenous laser is used instead.

In general, EVLA was performed just under ultrasound guidance, and fluoroscopy was limited for its use during EVLA because of its radiation hazard and unnecessariness. However, sometimes it is difficult to visualize the tip of the laser under ultrasound guidance even if its red light is turned on. This could be accentuated in SSV because of its acute angle draining into the popliteal vein. We also experienced 19 cases where the tip of the laser was unclear under ultrasound image, and of these, 17 cases occurred in SSV. EVLA and endovenous foam sclerotherapy were successfully completed in all of these 19 cases using venogram and fluoroscopy guidance. Another problem during EVLA under ultrasound guidance is failure of guide wire advancement because of the tortuous and enlarged saphenous vein.[4,21] Difficulty in advancing the wire and guiding the catheter into the intended site of the saphenous vein due to venospasm and tortuosity of the saphenous vein was encountered in this study, but these problems were solved using fluoroscopy guidance through the gentle wire technique in all cases except one. Therefore, only in terms of technique, fluoroscopy guidance can be used in situations when the exact location of the laser fiber is unclear on ultrasound imaging, or in the presence of a tortuous saphenous vein. However, we routinely used fluoroscopy as guidance because of endovenous foam injection using a microcatheter under fluoroscopy guidance, and it is obviously inevitable to make some argument regarding the overuse of radiation even in patients whose cases were easy enough to use only ultrasound as guidance without the need for fluoroscopy guidance.

Endovenous laser is commonly used for the treatment of patients with an incompetent saphenous vein rather than for the management of varicose tributaries. Park *et al*[3] tried to treat varicose tributaries with a 980-nm endovenous laser. They

Table 2 Side effects after endovenous sclerotherapy followed by EVLA

Side effects	%
Bruise or ecchymoses	79
Pain	52.7
Hyperpigmentation	54.2
Paresthesia	3.9
DVT	0
Skin burns or necrosis	0
Pulmonary embolism	0

DVT, deep vein thrombosis.

reported its high failure and complication rates and did not recommend direct laser ablation for varicose tributaries. Disselhoff *et al*[21] reported that, despite anatomic and functional success after EVLA, remnant varicosities that needed additional sclerotherapy or phlebectomy were noted in 21.5% of patients. Therefore, how to treat remnant varicosities after successful EVLA for incompetent saphenous veins could be one of the important issues in the completion of elimination of varicose vein.

It is well known that sclerotherapy is a good choice for the treatment of nonsaphenous varicose veins, residual veins after endovenous or surgical correction of axial vein reflux, and spider telangiectasia.[22] Liquid sclerosant using sodium tetradecyl sulfate or polidocanol has been used for a long time, but foam sclerosant has been gaining more popularity. In fact, liquid sclerosant can be diluted by blood, and its concentration can be reduced in the vein wall. Foam, on the other hand, has obvious benefits over liquid sclerosant. First, it can displace the blood and allows direct contact with the endothelium so that it can follow the efficacy of a given concentration of a sclerosant that can be enhanced with foam therapy. In addition, there is increased safety with foam preparations because lower concentrations of sclerosant are used and because extravasated foam is much better tolerated than liquid extravasation. Finally, the air contained in the foam is echogenic and thus increases the visibility and accuracy of placement when performing duplex-guided sclerotherapy.[23] In fact, there have been several articles elucidating the superiority of foam sclerotherapy over liquid sclerotherapy.[24–26]

However, although many authors have reported that the success rate of sclerotherapy is around 90%,[27–29] sclerotherapy itself has some drawbacks, including risks associated with the need for multiple needle punctures and multiple visits to the hospital, thrombophlebitis, and pulmonary embolism. Also, the problem of recanalized veins was encountered in up to one quarter of patients after 1 year with percutaneous sclerotherapy.[4,30] In addition, prominent bulging varicosities that present while patients stand can collapse when they lie down, and this makes it difficult to cannulate the varicosities briskly despite marking them before lying down.[31]

Therefore, we tried to perform endovenous foam sclerotherapy using a microcatheter just before doing EVLA instead of follow-up percutaneous foam sclerotherapy, and we obtained 86% complete sclerosis that did not need additional percutaneous sclerotherapy at 1-month follow-up.

However, this study showed 54.2% of hyperpigmentation at 1-month follow-up, which lasted until 2 years in 11 limbs. Patients comprising a total of 77 limbs (52.7%) complained of pain and tenderness at sites where they received endovenous foam sclerotherapy using a microcatheter at 1-year follow-up. These results suggested that endovenous foam sclerotherapy using a microcatheter produces greater and long-lasting pain and hyperpigmentation than previous percutaneous foam sclerotherapy, although foam sclerotherapy is reported to produce more pain and hyperpigmentation than liquid sclerotherapy.[32]

We presume that these higher rates of pain and hyperpigmentation in this study could be induced by the following. First, inappropriate compression could be performed at sites after endovenous foam sclerotherapy, because we should perform EVLA immediately after completion of endovenous foam sclerotherapy, although manual compression was conducted at varicose tributaries where endovenous foam sclerotherapy was applied. Second, injection of foam sclerosant using a microcatheter into varicose tributaries could sometimes cause overexpansion of tributaries and it can result in damage to the vein and lead to pain. Third, the amount of foam injected into varicose tributaries could be overused locally, which would cause long-lasting pain and hyperpigmentation, although its total amount is not so high (mean, 4.8 mL).

This study has obvious shortcomings other than some mentioned above. First, there is a risk of allergic reaction of contrast media in patients because venogram is routinely used in endovenous foam sclerotherapy. Second, the cost of the procedure is expensive because of the routine use of microcatheters and contrast media. Third, the number of limbs for more than 2-year follow-up is small; particularly, there were just 32 limbs in 3-year follow-up.

In conclusion, EVLA for incompetent saphenous vein combined with endovenous foam sclerotherapy using a microcatheter appears to offer the obvious benefits of less additional percutaneous sclerotherapy. However, many problems, like long-lasting pain and hyperpigmentation, its high cost, and radiation hazard, can lessen the value of this procedure.

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