

Laser Saphenous Ablations in More Than 1,000 Limbs With Long-Term Duplex Examination Follow-Up

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Background: The goal of this study was to evaluate the duplex results of endovenous laser ablation in the treatment of incompetent great saphenous veins (GSV) and small saphenous veins (SSV) with at least 1-year follow-up.

Methods: A retrospective registry was entered by 11 centers from Europe and America, organized by the International Endovenous Laser Working Group.

Data concerning 1,020 limbs in patients with incompetence of the GSV and/or SSV, treated with the Endovenous Laser Ablation (EVLA) procedure, were collected. EVLA failures were defined on duplex imaging as reflux confined to the saphenofemoral or saphenopopliteal junction, reflux confined to the main saphenous trunk, or reflux of both junction and main trunk (totally patent saphenous vein) were analyzed at one or more years postoperatively.

Results: The mean age of patients was 54 ± 5 years (range: 18-91 years). The average body mass index was 25. There was a paucity of severe complications: One case of third-degree skin burn, six patients with postsurgical deep vein thrombosis (0.6%), and 27 cases of sensory nerve damage (2.7%). At 1-year, the rate of complete occlusion of the saphenous trunk was 93.1%. There were 79 cases of treatment failures as evidenced by duplex: 22 isolated junction failures (2.2%), 44 isolated trunk failures (4.4%), and 13 totally patent veins (1.3%). Two-year duplex results were reported for 329 limbs with the identification of 19 new cases of failure. No new cases of failure were reported at 3-year follow-up of 130 limbs. Cumulative failure rates estimated by Kaplan–Meier analysis were 7.7% at 1-year and 13.1% at 2- and 3-year follow-up.

Conclusions: On the basis of a duplex scan performed at least 1-year post-treatment, this multicenter registry confirms the safety and efficacy of the EVLA procedure in the treatment of GSV and SSV reflux. Considering the continued failure rate documented in the present study, an annual follow-up by duplex is recommended to 2 years after EVLA.

INTRODUCTION

The standard treatment performed previously for varicose veins caused by incompetence of the great

saphenous vein (GSV) or small saphenous vein (SSV) was high ligation and stripping. The past decade has contributed toward several advances in the treatment of venous disease, including but not limited to endovenous radiofrequency or laser ablation, and ultrasound-guided foam sclerotherapy.¹⁻⁴ Modern treatments aim to use less invasive and less painful procedures that can be performed in ambulatory settings. They are associated with quicker recovery and fewer complications, with efficacy similar to the traditional surgical treatments.

Endovenous laser ablation (EVLA) has been performed using different laser wavelengths (810, 940, 980, 1064, 1320, 1470 nm) and has been associated with an excellent safety and efficacy profile.¹⁻⁸ The

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ELVeS™ (EndoLaser Venous System, Biolitec, Bonn, Germany) and VenaCure EVLT™ (Angiodynamics, Albany, NY) procedure kits offer materials that can be used as part of a standardized procedure.⁹

The purpose of this multi-center, international study was to review the duplex examination results after one or more years following EVLA of the GSV or SSV.

METHODS

In 2006, the International Endovenous Laser Working Group (IEWG) promoted a multicenter retrospective registry to evaluate safety and efficacy of the EVLA procedure. The IEWG comprised international experts in endovenous laser treatment, and the objective of this group is to promote studies on endovenous laser, specifically, the EVLA procedure. A registry was formed by the phlebologists in this group by contacting 11 centers in four countries. The EVLA procedure was performed in a very similar manner between all centers.

The EVLA Procedure

In this study, EVLA was performed using an 810-nm or 980-nm diode laser (ELVeS or VenaCure- Angiodynamics, Latham, NY), EVLA kit containing a 600-micron bare-tip fiber with safety lock, a needle, a guide wire, and a 5-F sheath used to introduce the fiberoptic laser into the vein. The Seldinger technique guides the physician through a step-by-step process to complete the procedure safely and effectively as follows:⁹

- The guide wire is introduced into the saphenous vein through a percutaneous puncture or an open venous cut-down.
- The 5-F sheath is then placed over the guide wire and advanced toward the junction.
- Using ultrasound guidance, the fiberoptic laser is then placed through the sheath and positioned 2 cm from the junction.
- Once in place, the fiberoptic laser is then locked to the sheath.

Using ultrasound guidance, tumescent anesthesia is instilled into the perivenous space surrounding the saphenous vein to create a 1-cm circumferential wheal around the vessel wall. After confirming that the fiberoptic laser tip is at least 2 cm from the saphenofemoral (SFJ) junction, the energy source is activated.¹⁰ The sheath, which is locked to the fiberoptic laser, is withdrawn at a specified speed to deliver the desired energy.

The Registry

The IEWG contacted centers which were known for their experience with the EVLA procedure. By May 2006, all of the participating centers in the study (with the exception of one) had performed more than 100 EVLA procedures. The countries and participating centers are listed in Table I.

Patient inclusion criteria for this study were as follows:

1. Incompetence of the GSV and/or SSV documented by duplex ultrasound
2. No previous treatment with surgery or sclerotherapy
3. Treatment with 810-nm or 980-nm diode laser with at least 1-year follow-up by duplex ultrasound

A standard data collection spreadsheet was used by all participating centers. The requested data were consistent with the recommended reporting standards as described by Kundu et al.¹¹ (Table II).

Detailed explanation forms accompanied the spreadsheets specifying definitions of data items. Spreadsheets were collected and reviewed by the authors and, if needed, the centers were contacted for further clarification of the given data. Finally, on completion of the study in each center, a consent form was signed by the responsible physician granting permission for the collected data to be used for scientific publication. Standard statistical analysis was used with χ^2 test or Fisher's exact test applied to appropriate categorical variables by using SPSS (SPSS, Inc. Chicago, IL), and Kaplan–Meier analysis using Prism 5 (GraphPad Prism Software, Inc, La Jolla, CA). Kaplan–Meier analysis was used to estimate cumulative failure rates.

Color duplex examinations were performed using high-resolution, linear probes (>7.5 MHz) following an assessment protocol that dictated obtaining views in at least two planes of the SFJ/saphenopopliteal (SPJ) and the GSV and its tributaries in the groin and at three levels in the thigh. Examinations were performed using a Valsalva maneuver and/or calf manual compression-release to provoke and quantify reflux. Reflux was defined as >0.5 seconds of reverse flow. Initial follow-up duplex was performed within 1 week of EVLA in the United States centers and within 1 month in the European and South American centers. This study included all patients who completed at least a 1-year duplex follow-up.

Failure was defined by duplex criteria as follows:

- Isolated Junction Failure (Fig. 1A)—The presence of an open stump ≥ 5 cm in continuity with the SFJ/SPJ, with a thrombosed truncal vein.

Table I. Participating countries and centers

Country (number of centers)	Participating centers
Italy (4)	Centro Multidisciplinare Day Surgery, Azienda Ospedaliera-Università, Padova, Italy Stabilimento Ospedaliero di Latisana, Italy Angiologia-Università di Milano, Italy Clinica Santa Maria, Bolzano, Italy
France (3)	Center Hospitalier Prive Saint Martin, Caen-Cadex, France Henri Mondor Hospital University, Paris - Creteil Polyclinique du Parc, Toulouse France
United States (3)	New York University, New York, USA Vein Institute of New Jersey, Morristown, USA Vein Clinics of America, Chicago, USA
Uruguay (1)	Hospital de Clínicas, Universidad de la República, Uruguay

Table II. Data collected

Sex
Age
CEAP classification
Treated vein (GSV and/or SSV)
Diameter of the vein (specifying as standing or lying)
Length of the treated vein
Laser setting (mode, power in watts [W], energy measured in joules/cm [J/cm])
Adjuvant treatment(s) (phlebectomy, sclerotherapy) at the same time as laser procedure or staged
Skin burn
Nerve damage (sensory, motor)
Deep venous thrombosis (DVT) at the junction or outside the junction
Confirmed pulmonary embolism
Duplex failure at 1, 2, and 3 years
Isolated junction reflux
Isolated trunk reflux
Totally patent vein

- Isolated Trunk Failure (Fig. 1B)—A patent segment of ≥ 5 cm in the saphenous trunk, with a thrombosed SFJ/SPJ.
- Total Failure (Fig. 1C)—A patent saphenous vein and junction.

RESULTS

Patient Data

Data for 1,020 limbs in 961 patients were collected (Table III).

Female patients accounted for 78% of the limbs in the study. The mean age was 54 ± 5 years (range: 18-91 years). Almost half of the patients were overweight (body mass index [BMI] >25 : 45%). On the basis of the CEAP (Clinical, Etiology, Anatomy,

Physiology) classification, most of the patients were C2 (62%) and one-third were between C3 and C6 (37%). The percentage of each C class differed between centers because of a different recruitment area and/or different socioeconomic populations. In particular, three centers, C4 (75%), C5 (75%), and C6 (89%), collected most of the patients. Treated veins were mainly GSV (85%). The diameter of the saphenous vein was checked with the patient in the standing position in half of the cases (53%), with a mean diameter of 7 mm. The mean length of the treated vein was 43 cm. Two centers that treated the entire saphenous trunk, from the ankle to the junction, elevated the mean value of all the other centers, which ranged between 30 and 41 cm.

Treatment

Treatment data are summarized in Table IV.

Laser energy was administered continuously in 73% of all procedures. Five centers always used a continuous mode, two a pulsed mode; and three used both methods. In the latter, there was a trend toward the use of the continuous mode as experience developed. The mean power delivered was 11 W (± 1 , range: 10-14 W) and mean energy delivered was 59 J/cm (± 14 , range: 40-91 J/cm). A modification of laser settings was observed in all but three centers, depending on the type (GSV versus SSV) and diameter of the vein to be treated: larger veins were treated with increasing watts and joules, whereas smaller vessels were treated with less energy.

More than half of the patients (55%) underwent phlebectomies at the same treatment session, whereas only 4% underwent a staged phlebectomy. Sclerotherapy was performed as a staged procedure in 33% of patients.

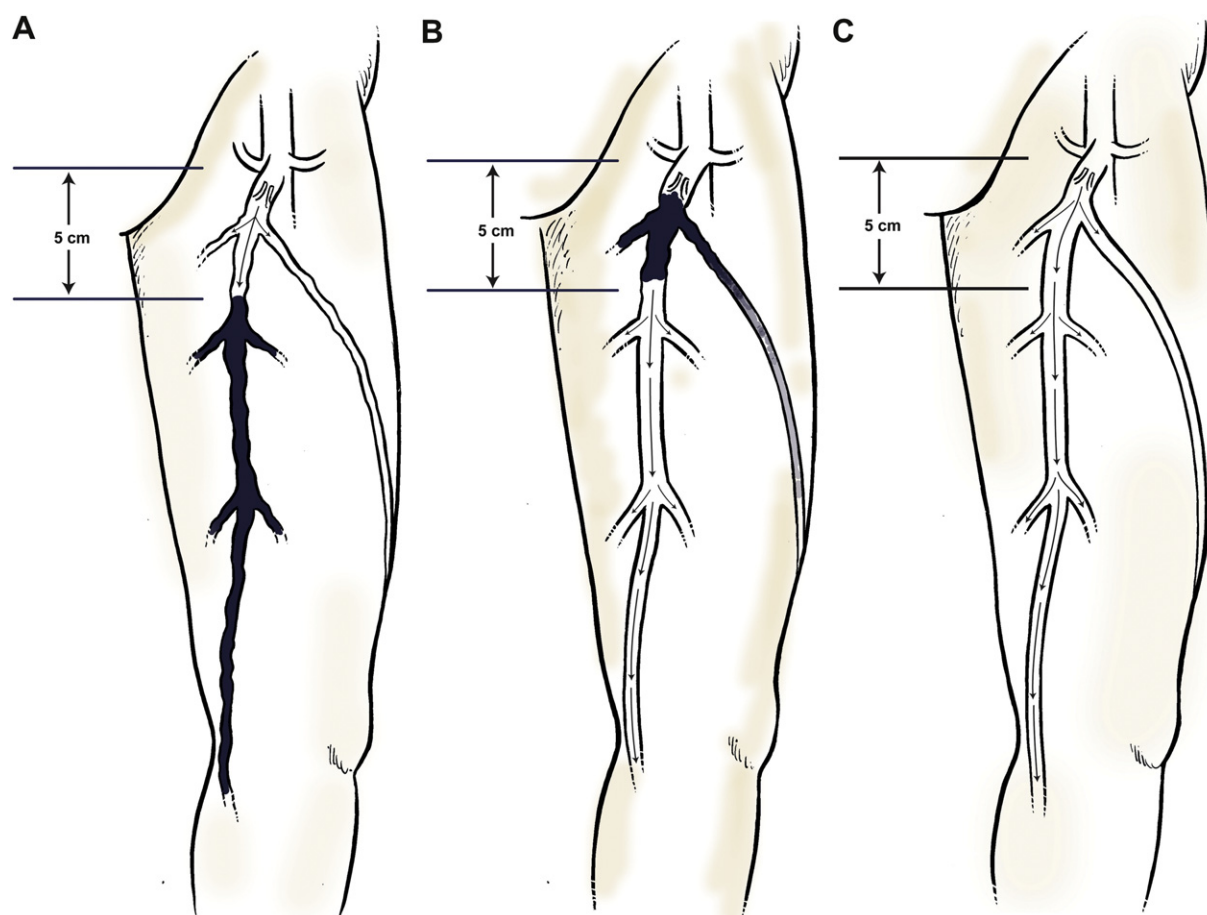


Fig. 1. **A** Isolated junction failure, **B** Isolated trunk failure, **C** Total failure.

Complications

Overall, the number of complications was as low as 3.3%. There were no reports of motor nerve damage or confirmed pulmonary embolism. Complications were as follows:

- One case of third-degree skin burn (0.1%)
- Six cases of deep vein thrombosis (DVT) (0.6%) (five at the SFJ/SPJ (0.5%); one in a gastrocnemius vein)
- 27 cases of sensory nerve involvement (2.7%)

The single case of a third-degree skin burn occurred below the knee in a setting where tumescent anesthesia had not been used. The burn healed after 3 weeks without any sequelae. Of the 27 sensory nerve complications, 22 were reported from two centers that treated GSV and SSV from ankle to junction. These 22 sensory injuries occurred after treatment of the GSV, whereas the remaining five underwent treatment of the SSV. However, at the 1-year follow-up only three patients (0.3%) showed residual sensory deficits.

Failure at 1-Year Follow-up

A 1-year venous duplex was completed on 1,020 (100%) treated lower extremities. EVLA failures are reported in [Table V](#). As defined previously, failures were categorized by duplex as being isolated junction, isolated trunk, or total failure (totally patent vein). A total of 22 (2.2%) limbs showed isolated junction failure at the 1-year follow-up, whereas 44 (4.4%) showed isolated trunk failure. However, of these cases, only 29 of the 44 limbs showed persistent reflux in the truncal vein, whereas 15 of the 44 limbs showed a competent saphenous vein. Duplex showed a total failure in 13 limbs (1.3%) with a patent, refluxing saphenous vein and junction. Seven centers reported 2-year follow-up duplex scans in a total of 329 (33%) patients. EVLA failures at 2-year follow-up are shown in [Table VI](#). Isolated junction failures were noted in 21 limbs, but only 10 of these were in patients who originally displayed a thrombosed saphenous vein at the 1-year follow-up. Although a total of 29 isolated trunk failures were reported, only eight of these were refluxing and 21 were

Table III. Patient data^a

Parameter	Number of Limbs (%)
Females ^b	791 (78%)
Males ^b	229 (22%)
Age (years)	54 ± 5 (range: 18-91)
BMI ^c	
<25	352 (54%)
25-29.9	194 (30%)
>30	106 (16%)
CEAP ^b	
C1	4 (0.5%)
C2	628 (62%)
C3	165 (16%)
C4	161 (16%)
C5	33 (3%)
C6	19 (2%)
Vein treated ^b	
GSV	861 (85%)
SSV	149 (15%)
Vein diameter (mm)	7 ± 2
Checking of vein ^b	
Standing	532 (53%)
Lying	478 (47%)
Average length treated (cm)	43 ± 15

^aTotal number of patients = 961 and total number of limbs = 1,020.

^bNumber of limbs (%).

^cData available for 652 patients.

now competent. Seven isolated trunk failures were identified in patients who had thrombosis previously documented on duplex imaging. There were five total failures, but only two of these five were new failures.

Duplex follow-up at 3 years was reported by two centers in a total of 130 limbs (12.7%). There were 16 failures reported, all of which had been previously reported on follow-up imaging.

Kaplan–Meier analysis estimated the failure rates of EVLA as defined by duplex follow-up as 7.7% at 1-year and 13.1% at 2- and 3-year follow-up (Fig. 2).

Logistic regression analysis revealed that patients with a BMI of >30 and CEAP ≥ 3 were twice as likely to have EVLA failure at the 1-year follow-up ($p = 0.027$). In two-thirds of the cases of failures, <50 J/cm was delivered to the vein; one center from which no failures were reported used a mean of 90 J/cm. There was no statistically significant difference in failure rate in men versus women. There was also no statistically significant relationship between vein diameter and failure rate.

DISCUSSION

EVLA materials and procedure have been available since 2002. Articles concerning the use and success

Table IV. Treatment

Treatment type/parameter	
Mode ^a	
Continuous	737 (73%)
Pulsed	283 (27%)
Power (W)	11 ± 1
Energy (J/cm)	59 ± 14
Adjuvant Tx—same session ^a	634 (62%)
Phlebectomy	558 (55%)
Sclerotherapy	79 (8%)
Adjuvant Tx—staged ^a	373 (37%)
Phlebectomy	43 (4%)
Sclerotherapy	332 (33%)

^aNumber of limbs (%).

Table V. Failures at 1-year follow-up^a

Failure	Limbs (%)
Total	79 (7.7%)
Isolated junction failure	22 (2%)
Isolated trunk failure	44 (4%)
Competent trunk	15 (2%)
Refluxing trunk	29 (3%)
Totally patent (refluxing)	13 (1.3%)

^aTotal number of patients = 961 and total number of limbs = 1,020.

of lasers with various wavelengths have been published with excellent results regarding safety and efficacy.^{5,6,12-14} Most of these articles report a high rate (95-100%) of occlusion of the treated truncal vein,^{2,3,7,15,16} and the results of our multi-center study echo these findings.

The aim of this registry was not only to collect a large number of treated limbs, but also to respect the scientific standard during the collection process, increasing the scientific validity of the results. The strengths of this study lay in the fact that it is multi-centered; the patients were treated with a well-standardized technique; the postsurgical duplex parameters were clearly defined and explained; the results of the treatment were validated by duplex at 1 or more years follow-up.

The overall failure rate as seen on duplex imaging at 1 year was 7.7%, most of them being isolated trunk failures. Two-year duplex follow-up data were available in 329 (33%) limbs, and this showed a continued failure rate of 5.4% at 2 years. This represented failures observed in patients in whom 1-year follow-up had shown successful treatment. Data for duplex follow-up at 3 years showed no new cases of failure. This study highlights a continued, albeit small,

Table VI. Failures at 2-year follow-up^a

Failure	Limbs (%)
Total	55 (13.1%)
Isolated junction failure	21 (6%)
Isolated trunk failure	29 (8%)
Competent trunk	21 (6%)
Refluxing trunk	8 (2%)
Totally open	5 (1.5%)

^aTotal number of patients = 307 and total number of limbs = 329.

failure rate out to 2 years and underscores the need for continued duplex follow-up in patients who have undergone EVLA.

The duplex examination at both 1- and 2-year follow-up showing cases in which the treated saphenous vein was patent and competent is noteworthy. Although this is classified as an EVLA failure in the present study, an astute clinician might consider this to be an ideal situation because the expected result of ablation would be a thrombosed saphenous vein. A patent, competent saphenous vein might represent a return to a more natural venous physiological state. The data analysis in the present study did not show any variables significantly associated with this phenomenon. We believe that this finding mandates further study.

Most of the previously published data focus on occlusion of the saphenous trunk, whereas competence of the SFJ or SPJ is not assessed. The optimal means of testing the competence of the junction has not yet been defined, especially when the saphenous trunk is occluded. We consider that the compression and/or release (augmentation) method seems to be more sensitive than the Valsalva maneuver in revealing reflux, but this was not examined in this study. Isolated junction failure was reported in 22 limbs (2.2%) and might reflect cases in which the position of the laser fiber was very distal to the SFJ/SPJ.

The rate and types of failures varied between centers. This might suggest that technical aspects and different indications for EVLA are important in determining or predicting specific types of failures. However, the data in the present study do not allow any conclusions to be drawn at this point. The registry showed many differences in the practice between centers regarding patient selection (BMI, class C of the CEAP classification), saphenous vein diameter, and laser settings (mode, power, energy). Furthermore, an evolution in the choice of laser settings was observed over time, specifically with respect to power and energy delivered.

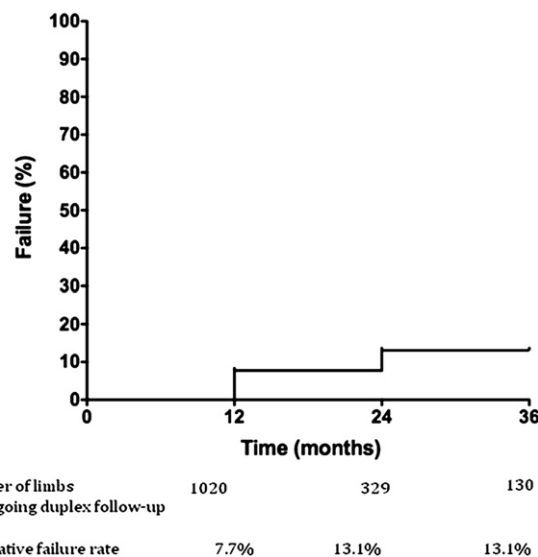


Fig. 2. Kaplan—Meier analysis of cumulative percentage of failure of EVLT as assessed by US duplex follow-up at 12, 24, and 36 months.

Neither the use of continuous or pulsed laser mode, nor the homogenous power setting at a mean of 11 ± 1 W, seem to be important factors in the appearance of failures. On the contrary, delivered energy, measured in J/cm, seems to be a significant factor in treatment efficacy. Energy of <50 J/cm was reported in two-thirds of the EVLA failures. It is our belief that the delivery of an optimal amount of energy to the vein wall is the key to thrombosis of the vein and durable treatment success. Timperman et al. reported that treatment with >70 J/cm markedly reduces the number of recanalized trunks.¹⁷ Interestingly, in the present study, one registry center where patients were consistently treated with >90 J/cm reported no cases of trunk failure. Proebstle et al. reported that laser fluence, or laser energy as it relates to the square centimeter of vein treated, is inversely correlated with EVLA failure and early recanalization.¹⁸ This registry data showed a tendency to customize treatment, particularly in the European centers: The power and energy parameters used for the treatment of the SSV were lower than those used for the GSV. The tendency to use higher powers and energy has also been described for the treatment of larger veins and vice versa for the smaller ones. However, it is impossible to draw any conclusions on the basis of the wide-ranging variability and heterogeneity of our patient population. This includes, but is not limited to, the unreliable diameter measurements of the saphenous veins; half of the centers performed the measurements with the patients in the standing position, and half in the supine position.

The number of reported complications was as low as 3.3%. These data are in agreement with the previous publications¹⁹⁻²¹; however, it is important to note that complications might tend to be under reported in registry studies such as this. There were no cases of severe complications, such as pulmonary embolism and motor nerve damage reported. The single case of a skin burn might have been because of the treatment of a superficial vein (<1 cm from skin) and/or insufficient administration of tumescent anesthesia before energy source activation.

Because of the low incidence of thrombus extension DVTs (0.6%) in this study, we were not able to identify risk factors for this complication. Potential risk factors to be considered include: the use of general anesthesia, same session bilateral treatment, and treatment of the entire length of the GSV. Although there are reports on numerically significant experiences with a zero-incidence of DVT,² the incidence assessed by this registry was very low and quite similar to the one reported by the American College of Chest Physicians for low risk surgical interventions.²² To minimize the risk of DVT, it is important to ascertain both a medical history and family history of thrombotic risk, with consideration of the use of prophylactic heparin in high-risk patients. Furthermore, positioning of the laser tip 2 cm from the SFJ junction should be confirmed by ultrasound before laser activation. Ideally, patients should mobilize immediately after the procedure. General anesthesia is not favored in particular for the inability of patients to ambulate immediately.²³

Sensory nerve damage (2.7%) was the most common complication reported in this study. Our data confirm the increased risk of sensory nerve damage with treatment of the GSV at the ankle, especially when performed under general anesthesia. However, in most of the cases, sensory nerve injuries resolved spontaneously after several weeks and persisted for 1 year after the procedure in only three of the 1,020 ablations. Sensory nerve damage in high risk areas such as the lower two-thirds of the saphenous trunk in the leg might possibly be prevented if the nerve is identified during the procedure and adequate tumescent anesthesia is injected, or if EVLA is avoided in this region. Additionally, it is our feeling that whether the treatment is to be performed, local anesthesia should be preferred over general anesthesia to allow prompt detection of signs of an early nerve injury.

CONCLUSION

The data collected through this multicenter registry support the conclusion that the incompetent

saphenous trunk of the GSV and SSV can be treated effectively using the EVLA technique. This is accomplished with a low rate of significant complications and high rate of occlusion of the treated vein, confirmed by a duplex examination at 1, 2, and 3 years postsurgically. Although small, the continued failure rate observed in the limbs at 2- and 3-year follow-up suggests the need for long-term duplex follow-up in patients undergoing EVLA.

The few reported complications and the moderate number of EVLA failures could help improve technique and/or modify the indications. In particular, the use of >60 J/cm might reduce the total and partial recanalization rate of the trunk. The natural history and the possible causes of the isolated junction reflux and the phenomenon of recanalized and competent saphenous veins merit further investigation. The data collected with this registry might be considered the benchmark for further prospective studies on the safety and effectiveness of EVLA.

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