Favorable long-term results of endovenous laser ablation of great and small saphenous vein incompetence with a 1470-nm laser and radial fiber

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ABSTRACT

Objective: Scarce information is available on the long-term results of endovenous laser ablation (EVLA) for great saphenous vein (GSV) or small saphenous vein (SSV) insufficiency. We sought to provide data on the status of patients at least 9 years after EVLA.

Methods: In 2018, we undertook a cross-sectional survey of ambulatory patients who had undergone EVLA in our tertiary care center in 2008-2009. Of 240 eligible patients, 5 died of causes not related to EVLA, 20 refused to participate, and 12 were lost to follow-up. Thus, 203 patients were re-evaluated; of them, 161 (79%) had GSV insufficiency and 42 (21%) had SSV insufficiency. The mean follow-up was 114 months (standard deviation, 11 months). All included patients underwent an echocardiography-color Doppler (ECD) evaluation, a clinical visit, and a standardized medical history. We assessed the competence of the junction and of the treated and untreated saphenous trunk and the presence of recurrent varicose veins. The trunk was considered ablated if it was nonvisible on B-mode or, when visible, if it was noncompressible or without flow or reflux on color flow Doppler analysis. Any recurrent varicose vein with the leakage point located in the treated saphenous vein was considered a failure. We asked patients about the effect of EVLA on their preoperative complaints and about any new or recurrent symptoms. We also recorded any complication or additional subsequent treatment and all data necessary to calculate the clinical class (C of the Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classification) and the Venous Clinical Severity Score (VCSS). Finally, we investigated potential associations between the study outcomes and variables by multiple logistic regression techniques.

Results: Some 10 years after EVLA, we performed a single clinical and ECD evaluation in 203 patients. Only one recanalization (0.5%; 95% confidence interval, 0.0-2.7) of the treated GSV trunk was observed in an otherwise asymptomatic patient. Up to 98% of patients were asymptomatic or significantly improved after EVLA. Additional subsequent treatments occurred in 21% of patients with GSV insufficiency and 5% of patients with SSV insufficiency. Three complications were observed, two in the GSV group (varicophlebitis, saphenous nerve damage) and one (varicophlebitis) in the SSV group. The mean C class of CEAP and the mean VCSS were significantly lower at the end of follow-up, both in patients with GSV insufficiency (C class, 3.2 vs 1.5 [$P = .00001$]; VCSS, 6.3 vs 1.6 [$P = .001$]) and in patients with SSV insufficiency (C class, 2.9 vs 1.1 [$P = .00001$]; VCSS, 5.4 vs 0.7 [$P = .001$]). Only the maximum diameter of the GSV at the junction independently correlated with ECD-confirmed reflux in the treated saphenous trunk or in the anterior accessory saphenous vein (odds ratio, 1.10; 95% confidence interval, 1.01-1.21).

Conclusions: EVLA using a 1470-nm diode laser with radial fibers provides stable and valuable long-term results in patients with either GSV or SSV insufficiency. (J Vasc Surg: Venous and Lym Dis 2020;■:1-9.)

Keywords: EVLA; Saphenous vein insufficiency; Long-term results

Thermoablative techniques, including endovenous laser ablation (EVLA) and radiofrequency ablation, which were introduced some 17 years ago, are currently recommended for first-line treatment of saphenous varicose disease by several international guidelines.[1-3] EVLA, although it is associated with a high rate of recurrent varicose veins (RVVs)[4] along with a non-negligible rate of persistent or recurrent reflux of the great saphenous vein (GSV) stump[5] and of the anterior accessory saphenous vein (AASV),[6] is highly efficient from both a clinical and a technical standpoint; it has a low complication rate, can be employed on an outpatient basis, and is associated with fair satisfaction of the patients. Radial emission optical fibers, used with a 1470-nm laser, were

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introduced in 2008 and represented a significant technologic advancement for the specific type of thermal damage produced,[7,8] for the high effectiveness in ablating the GSV, and for the almost uneventful postoperative course.[9-11]

Scarce information is available on the long-term results of EVLA; specifically, the average follow-up reported in the literature does not exceed 5 years.[4,5] The purpose of this study was to evaluate the status of patients undergoing EVLA for GSV or small saphenous vein (SSV) insufficiency, performed with radial emission optical fibers and a 1470-nm diode laser, at least 9 years after the procedure.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center cross-sectional study
- **Key Findings:** At a mean of 114 months after endovenous laser ablation of the great saphenous vein (GSV) in 181 limbs and small saphenous vein (SSV) in 42 limbs of 203 patients, only one GSV recanalization (0.5%; 95% confidence interval, 0.0-2.7) was observed. Recurrent varicose veins with the leakage point in the treated saphenous vein, including the junction and the untreated segment of the saphenous trunk, were observed in 17% and 2% of GSVs and SSVs, respectively. The maximum diameter of the GSV at the junction correlated independently with failure.
- **Take Home Message:** Using a 1470-nm diode laser and radial fibers, we obtained a stable occlusion of the trunk in either the GSV or SSV at a mean of 114 months.

METHODS

Design and setting. This was a cross-sectional study. Between November and December 2018, we re-evaluated all consenting patients who had undergone EVLA at the Multidisciplinary Center for Day Surgery, University Hospital of Padua (Italy), between May 2008 and December 2009. Those patients had been included in a previously published study, the inclusion criteria for which, described in detail elsewhere,[11] in summary were GSV and SSV insufficiency with a venous reverse flow lasting >0.5 second, a navigable saphenous trunk, and a saphenous trunk diameter >4 mm. Patients were excluded if they were pregnant or breastfeeding, if they were assigned to an American Society of Anesthesiologists physical status class >3, if they were not eligible for ambulatory treatment, or if they were technically unsuitable for EVLA. Patients had originally been treated with a 1470-nm diode laser and single emission ring optical fibers. The linear endovenous energy density (LEED) was patient customized on the basis of the average diameter of the saphenous vein measured on nondilated segments, according to the rule of times 10 (ie, mean vein diameter in millimeters times 10 equals LEED in joules/centimeter).

Patients consenting to participate in the cross-sectional study underwent a vascular visit and a venous echocardiography-color Doppler (ECD) evaluation of the treated limb. The study protocol was approved by our Institutional Review Board (N 109 4348/AO/17).

Vascular visit. All evaluations were performed by P.P., E.G., and M.F. A thorough medical history was collected on a standardized form (prepared by G.S., P.P., and E.G.). Patients were questioned about the perceived effect of EVLA on their preoperative complaints, choosing between a range of options, as follows: asymptomatic, significantly improved, improved, unchanged, or worsened. In addition, they were asked whether current symptoms were recurrent or of new onset. All complications and re-treatments were also recorded. In the case of RVVs, patients were asked to indicate their location (thigh, calf, or both) and to quantify their impact on everyday life, using a score of 0 to 5 (in which 0 corresponds to none and 5 to severe). This scoring system was similar to the one proposed in the Randomized study comparing Endovenous Laser Ablation with Crossectomy and Stripping (RELACS).[12] Furthermore, they were asked to state whether RVVs were symptomatic or asymptomatic and either residual (ie, present before EVLA and not corrected by the procedure) or of new onset. The patients' memories about their pre-EVLA status were double-checked by the examiner using the preoperative ECD mapping schemes.

During the vascular visit, we also recorded all useful data to define the clinical class (item C of the Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classification) and to calculate the Venous Clinical Severity Score (VCSS). To assess RVVs, examiners employed the same descriptive items used for the patient self-evaluation, complemented by palpation and ECD examination.

At the end of the visit, both the patient and the physician had to score the overall results of EVLA on a range of 1 to 10 (1 for the worst results and 10 for the best) using a numeric rating scale. Patients gave a subjective judgment, whereas the physicians based their conclusions on both subjective (ie, clinical evaluation) and objective (ECD) data. The finding of persistent or recurrent symptoms, RVV (in particular if connected to the treated saphenous vein), complications, additional subsequent treatments, or severity score of RVV ≥3 and the patient's dissatisfaction with final results (a score of <6) fostered further investigation. In particular, the examiner had to more deeply assess the dynamics, the timing, the evolution, and the impact on everyday life of the reported event along with the reasons for the patient's dissatisfaction. In doubtful cases, the judgment was defined, if possible, by consensus (P.P., E.G., and G.S.) or otherwise by majority.

ECD. The ECD evaluation of the treated limb was performed by three experienced physicians (P.P., E.G., M.F.) with standardized methods.[11,13] In summary, the examination was conducted with the patient standing; competence was tested at the junction with color flow imaging after both a Valsalva maneuver and a compression-relaxation test performed at the thigh, at the leg, or above the RVV (if visible or palpable). All venous refluxes evident at the color module were to be confirmed by pulsed Doppler analysis; any reflux lasting at least 1 second was considered pathologic.

The treated saphenous trunk was confirmed as ablated if it was nonvisible on B-mode or, if visible, if it was either noncompressible or without flow or reflux by color flow imaging or pulsed Doppler analysis. The competence of the untreated saphenous trunk, distal to the point of introduction of the optical fiber, was assessed in the same fashion. Similarly, any RVV, visible or palpable, either connected to the saphenous trunk or of an extrasaphenous venous segment, was evaluated by the same ECD protocol.

If a Doppler-confirmed reflux lasting >1 second was diagnosed, it was then followed backward toward its leakage point (RVV connected to a saphenous or extrasaphenous leakage point) or until the disappearance of either the vessel or the reflux (RVV without obvious leakage point). Any RVVs in which the reflux originated from a leakage point located in the treated saphenous vein (junction, treated saphenous trunk, and untreated residual trunk) were considered "true" recurrent RVVs, that is, a sign of a failure of EVLA. Any RVVs in which the vanishing point was not located in the treated venous segment or that did not have a leakage point were regarded as new or residual.

Final classification. At the end of the visit, the examiner assigned each patient to one of the four classes, from 0 to 3, of a scoring system for EVLA failures incorporating both clinical and ECD data, described in detail elsewhere.[11,14] Briefly, class 0 included patients with optimal clinical and ECD outcome (no symptoms or RVV; competent junction, fully occluded treated saphenous trunk, and competent untreated saphenous trunk). Class 1 included patients with RVV, either symptomatic or asymptomatic, and good results of EVLA on ECD, that is, a competent junction, a fully occluded treated saphenous trunk, and a competent untreated saphenous trunk. This class comprised patients with RVV, either residual or new, not connected to the treated saphenous trunk. Class 2 included patients with a good clinical outcome (ie, no symptoms or RVV) and an isolated, ECD-confirmed reflux at the junction or at the tributaries or on the saphenous trunk, either treated or nontreated. This class included asymptomatic, purely "technical" failures. Class 3 included patients with both clinical and ECD-confirmed failure, that is, RVV, either symptomatic or asymptomatic, connected to a leakage point located in the treated saphenous vein, namely, in a recanalized saphenous trunk, in a refluxing untreated saphenous trunk, or in a refluxing junction, either isolated or with reflux located on a tributary, often the AASV. This class included "real" RVVs due to an EVLA failure.

Outcomes. The primary outcome was the recanalization rate of the treated saphenous trunk, assessed by ECD. The secondary outcomes were both clinical and instrumental, as follows. The clinical ones were effect of EVLA on symptoms, prevalence of RVVs and the respective patient's grading, proportion of re-treatments and complications, pre-EVLA vs end of follow-up scoring of both the clinical class and VCSS, and results of the final judgment by both the patient and the physician of the EVLA treatment. The instrumental (ECD) ones were proportion of persistent or recurrent reflux at the junction or in the tributaries and on the treated and untreated saphenous trunk, degree of neovascularization at the junction, proportion of RVVs with leakage point located in the treated saphenous vein, and results of the final clinical-instrumental classification.

In the cohort of patients with GSV insufficiency, we also attempted to evaluate potential associations between true EVLA failures (ie, score of 3 at the final classification; see earlier) or the presence of ECD-confirmed reflux in the AASV and other study variables, including demographic (sex, age, body mass index), clinical (occurrence of new symptoms after EVLA, C class of CEAP, VCSS), and technical variables (diameter of the junction at 2 cm from the femoral vein, maximum diameter of the junction, mean and maximum diameter of the trunk, length of the treated vein, LEED delivered to the junction or to the trunk, and occurrence and number of re-treatments).

Statistical analysis. Differences between proportions and means were assessed by the χ^2 test or the *t*-test, as appropriate. Potential associations between either EVLA failure or the presence of reflux in the AASV and the other study variables (see earlier) were first visually explored by cross-tabulation and subsequently compared in patients with and without failure by means of the χ^2 test or the *t*-test, as appropriate. Continuous covariates were treated as such or categorized. Odds ratios (ORs) and their 95% confidence intervals (CIs) were estimated on the basis of a multiple logistic regression model to test the association between the risk of failure or the presence of reflux on the AASV, taken as dependent variables, and the variables described before. Covariates were removed by backward elimination according to a selection stay criterion of .05. Statistical significance was based on a two-sided type I error rate of .05. All statistical tests were performed by SPSS version 25.0 (IBM Corp, Armonk, NY).

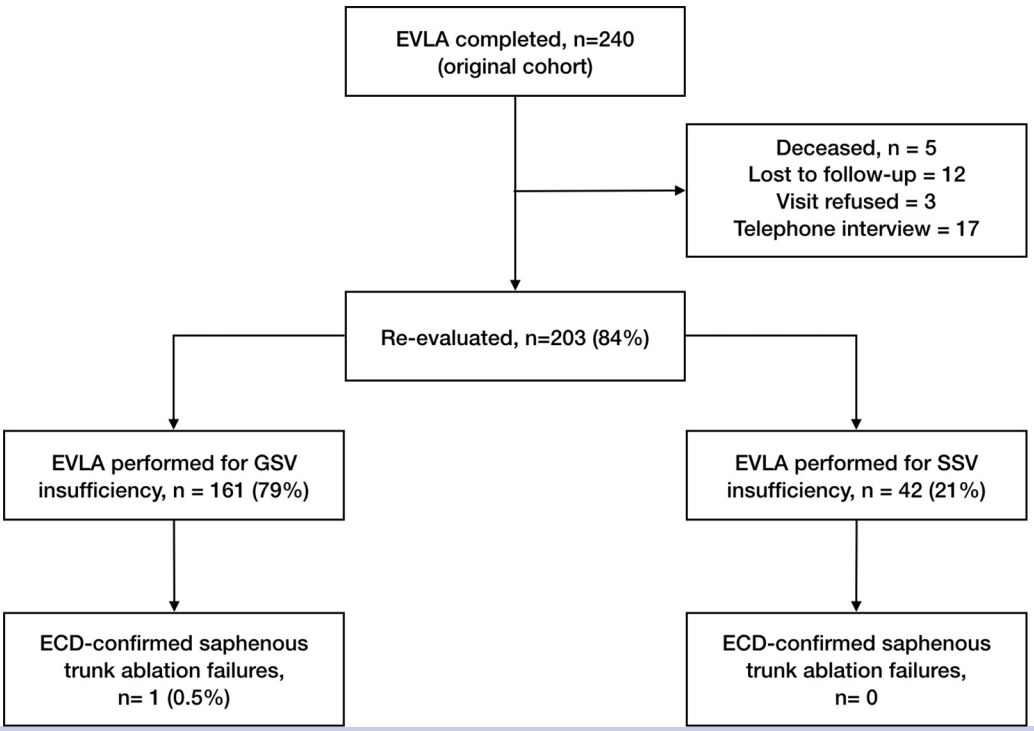

Fig. Consolidated Standards of Reporting Trials diagram. *ECD*, Echocardiography-color Doppler; *EVLA*, endovenous laser ablation; *GSV*, great saphenous vein; *SSV*, small saphenous vein.

RESULTS

The original cohort comprised 240 consecutive patients who underwent EVLA for GSV and SSV insufficiency between May 2008 and December 2009. Of them, 17 patients could not be contacted (5 died of causes unrelated to EVLA and 12 were lost to follow-up), 3 patients declined the visit, and another 17 patients refused the visit but agreed to answer a telephone interview (overall, only 2 of them reported RVVs that were asymptomatic). Thus, 203 patients (84%) of the original study cohort were re-evaluated, of whom 161 (79%) were treated at the GSV (183 limbs, 22 with bilateral treatment at different times) and 42 patients/limbs (21%) at the SSV (none with bilateral treatment). The mean follow-up was 114 months (standard deviation, 11 months). The Consolidated Standards of Reporting Trials diagram (Fig) shows the study patients' flow. Table I shows the demographic, anatomic, and surgical data of all re-evaluated patients at the time of EVLA.

Primary outcome. Only one case (0.5%; 95% CI, 0.0-2.7) of recanalization of the treated saphenous trunk with ECD-documented reflux and a small residual diameter (<4 mm) was observed in a patient with GSV insufficiency. Of note, that patient was completely asymptomatic and did not have RVV, either clinically apparent or diagnosed by ECD.

Secondary outcomes. Most patients (93% with GSV insufficiency and 98% with SSV insufficiency) were completely asymptomatic or reported a significant improvement in their complaints after EVLA (Table II). New symptoms appeared in 7% of patients with GSV insufficiency and in none with SSV insufficiency.

Of 183 limbs with GSV insufficiency, 68 (37%) had RVV according to the examiner and 72 (39%) according to the patient's judgment ($P = .4$). Patients judged the impact of RVV on their everyday life as none, mild, or moderate in the majority (89%) of cases (Table II).

Of 68 limbs with RVV, 32 (17% of 183 limbs) were true RVVs, that is, with the leakage point located in the treated vein segment. About one-third (9/32) of these patients were symptomatic, most of them reporting mild or minor complaints; only two had symptoms interfering with their personal or working life. The majority (84%; 27/32 limbs) of these true RVVs originated from the AASV.

Of 42 limbs with SSV insufficiency, 7 (16%) had RVVs as assessed by both the examiner and the patients. All of them judged the impact of RVV on their everyday life as none, mild, or moderate (Table II). Only one patient had true (class 3) RVV originating from the untreated portion of the saphenous trunk (Table II).

Of 183 limbs with GSV insufficiency, 39 (21%) underwent additional subsequent treatments, in most cases requested by the patients for cosmetic reasons and seldom suggested by the physician to prevent RVV, especially when a refluxing AASV had been diagnosed (Table II).

Additional subsequent treatments were performed within 3 years after EVLA in 86% of patients. Almost half of them (20/39) were treated for a recurrence at

Table I. Demographics

	GSV (183 limbs)	SSV (42 patients)
Female	73	74
Male	27	26
Age, years, mean (SD)	51 (13)	56 (9)
Body mass index		
Normal weight (18.5-24.9 kg/m^2)	45	60
Overweight (25-29.9 kg/m^2)	39	19
Obesity (≥30 kg/m^2)	16	21
C class of CEAP		
Varicose veins (C2)	36	38
Edema without skin changes (C3)	15	29
Skin changes: pigmentation, eczema (C4a)	31	26
Skin changes: lipodermatosclerosis (C4b)	9	5
Skin changes with healed ulceration (C5)	8	2
Skin changes with active ulceration (C6)	1	0
Junction diameter, mm (at 2 cm from the femoral vein)		
Mean (SD)	9 (2)	8 (1)
Median (IQR)	9 (8-10)	8 (7-8)
Junction maximum diameter, mm		
Mean (SD)	12 (4)	10 (3)
Median (IQR)	11 (9-13)	9 (8-11)
Junction LEED, J/cm		
Mean (SD)	216 (57)	216 (55)
Median (IQR)	216 (197-238)	209 (198-239)
Trunk diameter, mm		
Mean (SD)	7 (1)	7 (1)
Median (IQR)	7 (7-8)	7 (7-8)
Trunk maximum diameter, mm		
Mean (SD)	11 (4)	8 (2)
Median (IQR)	9 (8-12)	8 (7-8.5)
Length of treated saphenous trunk, cm		
Mean (SD)	37 (10)	19 (4)
Median (IQR)	39 (31-44)	20 (16-22)
Trunk LEED, J/cm		
Mean (SD)	82 (21)	93 (35)
Median (IQR)	78 (68-92)	86 (73-107)

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; *GSV*, great saphenous vein; *IQR*, interquartile range; *LEED*, linear endovenous energy density; *SD*, standard deviation; *SSV*, small saphenous vein.
Numbers are expressed as proportions (rounded) unless stated otherwise.

the AASV. Most limbs (35/39) underwent ultrasound-guided foam sclerotherapy (UGFS); four had either phlebectomy (three) or EVLA (one). Only two patients (5%) with SSV insufficiency underwent re-treatment, all by UGFS.

Two complications were observed in patients with GSV insufficiency: a recurrent calf varicophlebitis, treated with anticoagulants and phlebectomy; and a persistent paresthesia (numbness) in the territory of the saphenous nerve. In patients with SSV

Table II. Secondary outcome results

	GSV (183 limbs)		SSV (42 limbs)	
	Before EVLA	End follow-up	Before EVLA	End follow-up
Effects of EVLA on preoperative symptoms				
Asymptomatic	–	19 (10)	–	3 (7)
Significantly improved	–	62 (34)	–	14 (33)
Improved	–	89 (49)	–	24 (57)
Unchanged	–	12 (7)	–	1 (2)
Worsened	–	1 (0)	–	0
RRVs[a]				
Class 1	–	36 (20)	–	6 (14)
Class 3	–	32 (17)	–	1 (2)
Impact of RVV on patient's everyday life[b]				
0 (none)		37/68 (54)		0/7
1 (mild)		9/68 (13)		2/7 (29)
2 (moderate)		14/68 (21)		4/7 (57)
3 (bothersome)		6/68 (9)		1/7 (14)
4 (important)		1/68 (1.5)		0/7
5 (severe)		1/68 (1.5)		0/7
Re-treatment[c]				
Class 0		7		2
Class 1		8		0
Class 2		8		0
Class 3		16		0
C class of CEAP				
0	0	52 (28)	0	19 (45)
1	0	39 (21)	0	9 (21)
2	66 (36)	66 (36)	16 (38)	11 (26)
3	27 (15)	4 (2)	12 (29)	1 (2)
4a	57 (31)	4 (2)	11 (26)	1 (2)
4b	17 (9)	2 (1)	2 (5)	0
5	14 (8)	16 (9)	1 (2)	1 (2)
6	2 (1)	0	0	0
Mean (SD)	3.2 (1.0)	1.5 (1.4)[d]	2.9 (0.9)	1 (1.1)[d]
VCSS, mean (SD)	6.3 (2.8)	1.6 (1.1)[e]	5.4 (1.9)	0.7 (1.0)[e]
EVLA scoring				
Patients' mean (SD)	–	9.1 (1.0)	–	9.2 (0.9)
Examiners' mean (SD)	–	8.9 (1.5)	–	9.4 (0.9)
Final classification				
Class 0	–	92 (50)	–	34 (81)
Class 1	–	36 (20)	–	6 (14)
Class 2	–	23 (13)	-	1 (2)
Class 3	–	32 (17)	–	1 (2)

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; *EVLA*, endovenous laser ablation; *GSV*, great saphenous vein; *RVVs*, recurrent varicose veins; *SD*, standard deviation; *SSV*, small saphenous vein; *VCSS*, Venous Clinical Severity Score.
Numbers are expressed as number (percentages) unless stated otherwise. Class is final classification (see text).
[a]Based on clinical and echocardiography-color Doppler (ECD) results.
[b]Physician assessment.
[c]Grouped according to the results of the final classification.
[d]$P = .00001$ vs before EVLA.
[e]$P = .001$ vs before EVLA.

insufficiency, a single episode of varicophlebitis was reported, which was treated with low-molecular-weight heparin.

No occurrences of neovascularization at the junction were recorded as assessed by ECD. The mean clinical class and the mean VCSS were statistically significantly lower at the end of follow-up, both in patients with GSV insufficiency and in patients with SSV insufficiency (Table II). No differences in terms of overall EVLA scoring (Table II) were observed ($P = .3$) as assessed by both the patients and the examiner. Finally, 70% of limbs in the GSV cohort were assigned a class 0-1 final classification (optimal-good results). In the SSV cohort, the respective figure was 95% (Table II).

In patients with GSV insufficiency, several clinical and instrumental variables were statistically significantly associated with true EVLA failures and ECD-confirmed reflux in the AASV (Table III); however, only the maximum diameter of the GSV junction independently correlated with both true EVLA failures (OR, 1.10; 95% CI, 1.01-1.21) and ECD-confirmed reflux in the AASV (OR, 1.12; 95% CI, 1.02-1.23). The presence of reflux in the AASV was associated with a significantly higher risk of true EVLA failure (OR, 4.0; 95% CI, 2.3-7.0).

DISCUSSION

To our knowledge, this is the first study prospectively evaluating the long-term results of EVLA. After a >9-year mean period subsequent to EVLA, the observed recanalization rate (0.5%) was indeed low. Using analog equipment, similar results were obtained in three prospective observational studies with shorter follow-up times (up to 3 years)[9-11] and in a parallel group study with a 5-year follow-up comparing EVLA with radiofrequency ablation.[15] Higher recanalization rates ranging between 12% and 27% were instead reported by two meta-analyses.[4,5] Of all variables evaluated in the multiple logistic regression model, only the maximum GSV diameter independently predicted the development of EVLA failure.

Our results were obtained using a 1470-nm diode laser, which specifically targets water, with single emission ring optical fibers, allowing a finely controlled thermal lesion. Most important, we customized the endovenous energy used for each patient according to the rule of times 10 (ie, mean vein diameter in millimeters multiplied by 10 equals the LEED in joules/centimeter). Our technique, as we were able to demonstrate in vivo, produces homogeneously deep and circumferential thermal damage to the venous wall without contact lesions.[7]

In this study, clinical results of EVLA, evaluated by various parameters, were either good or optimal. In particular, preoperative symptoms improved in >90% of patients, and a significant downgrading of the CEAP class, in terms of means of the clinical classes, was recorded in both cohorts (GSV and SSV). Mean VCSSs were also significantly reduced at the time of re-evaluation. A similar pattern was reported by a meta-analysis, although with a shorter (5 years) follow-up time.[5] A different case has to be made for RVVs, which were clinically observed in 37% (68/183) of patients with GSV insufficiency and in 17% (7/42) of those with SSV insufficiency. Similar or higher RVV rates are reported in the literature in studies with shorter mean follow-up times (2-5 years)[12,16] and in a meta-analysis of randomized trials with a 5-year follow-up.[4] Interestingly, most

Table III. Study variables (clinical, instrumental) statistically significantly associated with either true endovenous laser ablation (*EVLA*) failures or reflux in the anterior accessory saphenous vein (*AASV*) on univariate analysis in patients with great saphenous vein (*GSV*) insufficiency

	True failures[a]	AASV reflux[b]
Any re-treatment	<.0001	<.0001
RRVs[c]	<.0001	<.0001
Any point increase of VCSS	<.0001	<.0001
Any point increase of C class of CEAP	<.0001	<.0001
Overall judgment of EVLA efficacy[c]	<.0001	<.0001
Final judgment[d]	<.0001	<.0001
Body mass index	.013	–
Maximum diameter of the GSV junction, mm	.004	.019
Maximum diameter of the GSV trunk, mm	.003	.038
LEED delivered to the GSV trunk, J/cm	.004	.043

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; *LEED*, linear endovenous energy density; *RRVs*, recurrent varicose veins; *VCSS*, Venous Clinical Severity Score.
[a]Both clinical and instrumental failures of EVLA, assigned a score of 3 at the final classification.
[b]Echocardiography-color Doppler (ECD)-confirmed reflux in the AASV.
[c]As assessed by both the patient and the physician.
[d]Made by the physician based on clinical and instrumental data.

of these patients were only slightly symptomatic, as confirmed by the low self-assigned severity scores in the two groups. Most important, the mean patients' EVLA rating was above 9 points (Table II), indicating high satisfaction with the long-term results of the procedure. This is probably due to a slowing of the progression of the varicose disease, possibly owing to a "liberal" use of UGFS in the first 3 years after EVLA, during which 86% of the re-treatments were performed, that is, when patients were to attend vascular visits on a regular basis. Another explanation may be that only 14% (31/183 limbs with GSV insufficiency and 1/42 patients with SSV insufficiency) of RVVs were truly recurrent ones, that is, due to an EVLA failure. Interestingly, only one patient with true RVV complained of worsened symptoms (patient's score = 4); the remaining patients had unchanged (n = 6), improved (n = 11), or significantly improved (n = 12) symptoms.

The issue of refluxing AASV, with or without RVV, also deserves careful discussion. The reported frequency of refluxing AASV ranges from 16% to 48% in the literature.[6,17] In our study, 49 of 183 limbs (27%) had a reflux at the saphenous-femoral stump as assessed by ECD that was limited to the junction in 14 of 183 limbs (8%) and that reached the AASV in the remaining 35 limbs (19%). Of those limbs with refluxing AASV, 27 of 183 (15%) also had RVVs, but only 7 (4%) were symptomatic. Furthermore, three-quarters (74%) of those patients with RVVs rated the impact of RVVs on their everyday life as none, mild, or moderate (0-2). Re-treatment was performed on 15 limbs, by UGFS on 14 limbs (in 2 with additional phlebectomy) and by EVLA on 1 limb.

We believe our results are valid and generalizable because we were able to investigate a large sample of consecutive patients, especially with GSV insufficiency, after a >9-year mean follow-up period. We tried to limit bias by standardizing both the clinical and instrumental (ECD) evaluation and by adopting a simple and reproducible classification for EVLA failures already employed in previously published studies.[11,14]

We are aware that our study also has some limitations, including its single-center, single-arm design, the lack of data on quality of life, the small sample of patients with SSV insufficiency, and some other favorable characteristics of the patients, including a young mean age (51 years) and no history of previous deep venous thrombosis or post-thrombotic syndrome.

Finally, patients had been scheduled for regular controls in the first 3 years after EVLA,[11] and only a minority of the patients (7/225 limbs [3%]) came back to our center after that period for re-treatment. Thus, with a mean follow-up of >9 years, our study is likely to portray the natural history of venous insufficiency (especially of GSV) after EVLA, otherwise said, to be a "real-life" study.

CONCLUSIONS

EVLA using a 1470-nm laser diode with radial fibers provides stable and valuable long-term results in patients with either GSV or SSV insufficiency.

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AUTHOR CONTRIBUTIONS

Conception and design: PP, GS
Analysis and interpretation: PP, GS, EB
Data collection: PP, EG, MF
Writing the article: PP, GS, EB
Critical revision of the article: PP, GS, EB, EG, MF
Final approval of the article: PP, GS, EB, EG, MF
Statistical analysis: EB
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