

Six-year follow-up of endovenous laser ablation for great saphenous vein incompetence

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Objective: Treatment of chronic venous insufficiency of the great saphenous veins by endovenous laser ablation yields good short- and medium-term results, as assessed clinically and technically by echo-color-Doppler. At present, scarce data are available on the long-term results of endovenous laser ablation. We wanted to assess the long-term efficacy of endovenous laser ablation.

Methods: We performed a prospective 6-year follow-up cohort study, with recruitment between 2003 and 2004, and the follow-up completed in 2010. The setting was an ambulatory care/day surgery. Of 209 consecutive patients who underwent endovenous laser ablation at our institution during the recruitment period, five (2.4%) did not complete the procedure due to technical reasons. Of 204 patients who successfully completed the intervention, 14 (6.8%) were lost for follow-up, and 190 completed the planned 6-year follow-up. The intervention was an endovenous laser ablation using a 980-nm laser diode. Clinical and echo-color-Doppler evaluations were regularly scheduled for all patients during the planned follow-up period. The incidence of clinical and echo-color-Doppler confirmed endovenous laser ablation failures over a 6-year follow-up period. Potential

associations between failures and patients' characteristics, echo-color-Doppler findings, or surgical features were also investigated.

Results: Symptomatic clinical endovenous laser ablation failures occurred in 22 (11.6%; 95% confidence interval [CI], 7.4-17.0%) patients; while 57 (30.0%; 95% CI, 23.6-37.1%) had echo-color-Doppler-confirmed failures. Only two patients (1.1%; 95% CI, 0.1%-3.8%) had both symptomatic clinical and echo-color-Doppler-confirmed failures. Three features of the great saphenous vein: an "atypical" junction, a junction diameter ≥ 8 mm, and a mean trunk diameter ≥ 8 mm, were independently associated with echo-color-Doppler-confirmed failures on multivariate logistic regression analysis.

Conclusions: Six years after endovenous laser ablation, most patients were improved on clinical grounds, and more than two-thirds had no saphenous insufficiency at echo-color-Doppler. Only a minority had both clinical and echo-color-Doppler-confirmed failures. Anatomical features of the junction and the saphenous diameter both at the junction and at the trunk independently predicted echo-color-Doppler-confirmed failures. (J Vasc Surg: Venous and Lym Dis 2013;1:20-5.)

Venous diseases, and especially varicose veins, are counted among the most frequent diseases in industrialized countries.¹ In recent years, the standard approach to saphenous vein insufficiency (ie, surgical ligation and stripping) was replaced, in suitable patients, by less invasive techniques such as sclerotherapy, radiofrequency, or endovenous laser ablation (EVLA).^{2,3}

Since the late 1990s, a number of studies,⁴⁻⁹ albeit with some methodological flaws, such as small sample size, short follow-up period, and lack of information about clinical and echo-color-Doppler (ECD) outcomes, established EVLA as a viable alternative to vascular surgery in this setting.

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The aim of this study was to prospectively assess the clinical and technical outcomes of EVLA for treatment of great saphenous vein incompetence, over a 6-year follow-up period. In addition, we sought to determine if demographical, physical, anatomical, technical, or surgical features could forecast clinical and technical EVLA failures.

METHODS

We undertook a prospective cohort study to assess the efficacy of endovenous laser ablation for treatment of great saphenous vein insufficiency over a 6-year follow-up period.

The study was conducted at the Multidisciplinary Centre of Day Surgery - University Hospital, in Padua. Patients were recruited for the study between January 2003 and July 2004, and the follow-up phase lasted until July 2010. Finally, it took about 10 months for the data collection, the statistical analysis, and the manuscript drafting.

The study protocol was reviewed by our Institution's Ethical Board.

Participants. All consecutive patients with suspected great saphenous vein insufficiency, referred for evaluation to our center during the study period, were considered for the study. Patients were excluded if they were pregnant or breastfeeding, if they had an American Society of

Anesthesiologists classification score >2 , if they were not eligible for ambulatory treatment, or were technically unsuitable for EVLA. To evaluate this latter issue, all patients underwent ECD to assess for the presence of the following EVLA feasibility criteria: a saphenous vein reflux due to saphenous-femoral junction incompetence (ie, reverse venous flow lasting more than 0.5 seconds after Valsalva, augmentation maneuvers, or both), a navigable (ie, patent and straight) saphenous vein trunk, and a saphenous vein diameter >4.5 mm at the puncture site, measured in the standing position. The presence of venous dilatations either along the saphenous trunk or near the confluence of the superficial inguinal veins (CSIV) did not constitute an exclusion criterion for the study. At the same visit, patients were interviewed using a standardized questionnaire detailing all other necessary information, including age, gender, body mass index, leg symptoms, and signs, according to "C" of CEAP classification.

Patients without exclusion criteria were informed about the study purposes, and were asked to participate in the study. Only those who formally agreed to undergo EVLA and committed to attend the planned follow-up visits were included in the study.

Surgical procedures. All EVLA procedures were performed at our day-surgery unit, using tumescent ECD-guided peri-venous anesthesia, according to a standardized protocol.¹⁰ A 980-nm diode Laser (ELVeS, Biolitec AG, Jena, Germany), and a commercial kit (ELVeS kit, Biolitec AG) containing all the equipment for the procedure (19G needle for percutaneous introduction, J guide-wire 0.035", 5 Fr 55-cm introducer catheter, 600- μ m bare fiberoptic) was used in all patients. The most prominent varices were treated with stab-vein avulsion directly at the end of the EVLA procedure, according to the Muller technique. Patients with residual (ie, still clearly visible, despite successful EVLA) varicose veins were proposed post-operative sclerotherapy, usually scheduled at 12 weeks after surgery.

Low-molecular-weight heparin prophylaxis, unless contra-indicated, was administered for 6 days following the procedure in patients with adjunctive risk factors for venous thromboembolism (VTE; increasing age, prolonged immobility, stroke or paralysis, previous VTE, cancer and its treatment, major surgery, trauma, obesity, varicose veins, cardiac dysfunction, indwelling central venous catheters, inflammatory bowel disease, nephrotic syndrome, pregnancy or estrogen use), at the dose suggested for moderate risk surgery according to American College of Chest Physicians guidelines 2001.¹¹ Namely, the most frequently encountered risk factors were age, obesity, and varicose veins. Furthermore, all patients had to wear a 35-mm Hg elastic compression stocking (Struva 35, Medi, Bayreuth, Germany) for 24 hours a day, during the first week after EVLA, and then switch to second-class graduated elastic compression stocking for another 4 weeks. All patients, unless contraindicated, were prescribed ketoprofene, 200-mg tablets (Orudis retard), for pain relief.

Follow-up. Patients were scheduled for clinical and ECD assessments at 3, 7, 30, and 90 days after EVLA; and thereafter once yearly, for 6 years.

Patients with ECD-confirmed EVLA failure were proposed sclerotherapy based on the ECD pattern, and the presence of visible varices. Sclerotherapy was performed, with the intention to treat both the ECD-confirmed EVLA failures (ECEf) and the varicosities, using sodium tetradecyl sulfate foam 1% to 3%. The procedure was always performed according to the patients' preferences.

Variables. The main study outcome was the incidence of clinical and ECD-confirmed EVLA failures during the planned 6-year follow-up period. Clinical failures were defined as lack of improvement or worsening of leg symptoms after EVLA, as compared with pre-EVLA status.

ECEf were defined as the finding of measurable venous reflux in the treated segment, with or without recurrent varices, either clinically symptomatic or asymptomatic; and were categorized according to a similar classification of ECD failures.¹²

Additionally, potential associations between clinical and ECD-confirmed EVLA failures and patients' characteristics, ECD findings, or surgical features were investigated by logistic regression analysis.

Data sources/measurement. All clinical and ECD examinations were carried out by medical doctors (G.S., A.P., P.P., E.G., M.F., A.N.), in a standardized fashion. The interobserver variability for clinical and ECD evaluations, assessed on a sample of 50 consecutive patients before the start of the study, was fairly good (Kappa = 0.78, and 0.81; respectively).

To assess the incidence of clinical failures, both the side effects of EVLA (ie, paresthesias, varicophlebitis, pigmentation, etc.) and the evolution of symptoms or signs affecting the patients before the procedure (ie, heaviness, edema, skin changes, presence of visible varices, etc.) were systematically recorded at each follow-up visit, as applicable. To this purpose, a standardized questionnaire was employed, based on the following set of questions: (a) did EVLA improve your leg symptoms? (If yes: partially or completely? If no: are the symptoms unchanged or worsening?) (b) did you notice new varicose veins in the treated leg? (If yes: with or without new symptoms?)

To assess the incidence of ECEf, ECD examinations were performed at each follow-up visit. ECD assessments were performed by six experienced vascular physicians (G.S., A.P., P.P., E.G., M.F., A.N.), employing either a Technos or an Au-5 ultrasound machine (Esaote, Genova, Italy), equipped with 7.5- to 10.0-MHz linear probes. Testing was carried out in orthostatism, following a standardized protocol. First, the saphenous junction competence was assessed, defined as absence of venous reflux, or presence of venous reflux lasting for <1 second after Valsalva or augmentation (ie, muscle-squeezing) maneuvers. Notably, we choose a different time cut-off from the preoperative assessment in order to account for the normal pseudo-reflux that can be occasionally detected

after EVLA, due to blood flow through the venous stump. Secondly, the saphenous trunk patency was assessed. If, despite EVLA, the trunk was still patent, then its diameter was recorded, and venous reflux, if present, evaluated with Valsalva and augmentation maneuvers. Finally, varicose veins were evaluated to distinguish between residual or recurrent varicose veins, the latter defined as refluxing varices fed by an unsuccessfully treated venous segment. Specifically, ECEF were categorized as type 1 (venous reflux limited to the junction and/or the residual saphenous stump, for a maximum length of 5 cm from the junction, without reflux in the collaterals of the junction); type 2 (reflux at the junction, or in the treated trunk or in a collateral vein of the junction for more than 5 cm from the junction, without clinically evident recurrent varices); or type 3 (reflux at the junction site, or into the treated trunk, or on a collateral to the junction for a length of more than 5 cm from the junction, with clinically evident recurrent varices, either symptomatic or asymptomatic).

In addition, we sought to investigate if potential associations between demographical (age, gender), physical (body mass index, "C" of CEAP classification), presurgical ultrasonographic findings (CSIV aspect, diameter, and saphenous trunk mean diameter), and surgical features (length of the treated trunk, energy delivered, and power), could allow us to forecast ECEF. To this purpose, we standardized beforehand several ultrasonographic variables, as follows: the saphenous CSIV was defined as the proximal part of the saphenous vein, starting from the sapheno-femoral junction and extending distally through the trunk for a maximum of 5 cm. The CSIV diameter was measured with a longitudinal scan, at a distance of 2 cm from the junction, having the patient standing. The CSIV was defined as "competent" if no venous reflux could be recorded at the level of the terminal saphenous valve. The CSIV was labeled as "enlarged" when its diameter was >10 mm, and "atypical" if the sapheno-femoral junction was more than 2 cm deep from the skin surface; or if the CSIV featured an eccentric aneurismatic dilatation, was kinked on transverse or longitudinal scans, or if venous reflux towards the collaterals was recorded. Finally, the saphenous trunk diameter was defined as the average diameter of nonlocally-enlarged segments of the vein, measured every 10 cm from the junction to the puncture site, with transverse scans, having the patient standing.

Statistical analysis. Descriptive statistics were calculated for all variables. Time to event analysis was estimated using the Kaplan-Meier method.

Factors associated with the probability of failure were determined by univariate analyses using a logistic regression model. Variables included in the analysis were age, gender, body mass index, "C" of CEAP classification, and CSIV and trunk diameters. The assessment of the functional relationship between age, CSIV and trunk diameters, and the outcome was visually checked by grouping the continuous variables into deciles and plotting the mean covariate value within each decile against the

proportion of patients experiencing a failure. Subsequently, age was treated as a continuous variable, while CSIV and trunk diameters were categorized. Multiple logistic regression analysis was used to determine the adjusted association between clinical factors and the probability of failure. Covariates were removed using backward elimination according to a selection stay criterion of .05. Data analyses were performed using the SAS statistical package (release 9.1; SAS, Cary, NC).

RESULTS

Between January 2003 and July 2004, 209 consecutive patients underwent EVLA at our institution. Five patients (2.4%) did not complete EVLA due to technical reasons (ie, failure to catheterize the saphenous trunk or the CSIV), and were therefore excluded from the analysis. Within the same EVLA session, 124 patients (60.8%) also underwent stab-vein avulsions (median number: four per patient, range, 1-12). Another 65 patients (32.8%) with residual varicose veins, received sclerotherapy within 12 weeks from the procedure.

Of 204 patients who successfully completed EVLA, two (0.98%) developed asymptomatic endovenous heat-induced thrombosis at the sapheno-femoral junction, diagnosed by routine ECD control 3 days after surgery; and one (0.49%) patient had persistent lower limb paresthesias, fully recovered 12 months later.

Fourteen (6.8%) of 204 patients were lost for follow-up, either because they could not be contacted ($n = 3$; two patients at 1 month, and one patient at 1 year after EVLA), or because they declined further examinations ($n = 11$; nine patients at 1 month, and two patients at 1 and 3 years after EVLA); hence, 190 patients completed the planned 6-year follow-up period. No deep vein thrombosis was detected during the follow-up period, while two patients (1.1%; 95% confidence interval [CI], 0.1-3.8%) developed superficial vein thrombosis of the anterior accessory saphenous vein (ASSV) at 1 and 2 years after EVLA. Demographic, anatomic, and surgical features of the patients who completed the planned follow-up observation are reported in Table I.

Outcomes

Clinical failures. At the end of the planned follow-up period, 168 (88.4%) of the patients reported a symptomatic improvement; of them, 87 patients had no residual symptoms, and 81 experienced a significant reduction of their leg complaints. Therefore, the primary clinical outcome occurred in 22 (11.6%; 95% CI, 7.4-17.0%) patients. Of them, 14 complained of persistent symptoms, six reported unsatisfactory aesthetic results (four new telangiectasias, one visible scars, and one skin pigmentation), and two patients had worsened skin alterations (one lipodermatosclerosis and one ulcer recurrence).

Interestingly enough, only two (0.9%; 95% CI, 0.1%-3.8%) of these 22 patients had also an ECEF; namely,

Table I. Demographics, clinical, surgical and echo-color-Doppler characteristics of the 190 patients who completed the 6-year follow-up period

Female gender	144 (76)
Age (years), mean (SD; range)	51.5 (\pm 13.7; 21-90)
Body mass index (kg/m ²), n (%)	
\leq 24.9	110 (58)
25-29.9	61 (32)
\geq 30	19 (10)
CEAP class, n (%)	
C2	153 (81)
C3	3 (2)
C4	20 (11)
C5	10 (5)
C6	4 (2)
Vein treated, n (%)	
Great saphenous	190 (100)
Echo-color-Doppler variables	
Great saphenous terminal valve, n (%)	
Incompetent	171/196 (87)
Competent	25/196 (13)
CSIV diameter (mm) ^a , mean (SD; range)	8.8 (\pm 2.3; 6-16)
Trunk diameter (mm), mean (SD; range)	7.1 (\pm 1.2; 6-12)
Refilling time, n (%)	
Normal (>25 seconds)	38/126 (30)
Abnormal (<25 seconds)	88/126 (70)
Laser variables	
Continuous mode, n (%)	228 (100)
Power (Watts), median (range)	10 (8-12)
Linear endovenous energy density (J/cm), mean (SD; range)	56.9 (\pm 11.7; 31-101)
Treated saphenous trunk (cm), mean (SD; range)	39.6 (\pm 8.9; 10-63)

CSIV, Confluence of the superficial inguinal vein; SD, standard deviation.
^aMeasured at 2 cm from the junction.

they developed clinically evident recurrent varices, all of them associated with type 3 ECEF.

ECD-confirmed EVLA failures. After 6 years, the proportion of patients with a competent saphenous junction and a persistently occluded saphenous trunk was 70.0% (133/190); therefore, 57 (30.0%; 95% CI, 23.6-37.1%) had an ECEF. Of them, 20 patients had a type 1 ECEF, 18 had a type 2 ECEF, three of which were at the ASSV; and 19 had a type 3 ECEF, 12 of which were at the ASSV. All 15 patients with ASSV reflux post-treatment had a competent ASSV at the preoperative ECD evaluation. ASSV reflux was diagnosed in nine patients at the 1-month follow-up visit, in four patients at 1 year, and in two patients at 2 years. Of all ECEFs, 43 (75.7%) were diagnosed during the first year of follow-up, whereas 14 (24.6%) were recorded during the second year of follow-up (Fig).

Logistic regression analysis. At the univariate analysis, the following clinical and ECD variables were significantly associated with ECEF: age, treated as a continuous variable (odds ratio [OR], 1.05; 95% confidence interval [CI], 1.02-1.08; $P = .0021$); male gender (OR, 2.23; 95% CI, 1.11-4.45; $P = .0236$), body mass index \geq 30 (ie, morbid obesity [OR, 3.78; 95% CI, 1.38-10.32; $P =$

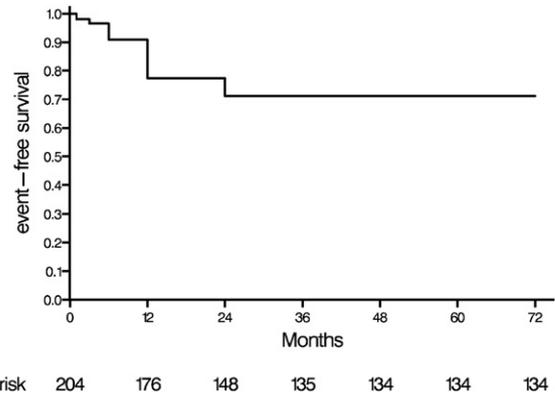


Fig. Kalpan-Meyer plot of echo-color-Doppler-confirmed endovenous laser ablation failures.

.0095]); presence of skin changes (OR, 3.83; 95% CI, 1.47-9.96; $P = .0059$), or presence of skin changes with signs of healed ulceration (OR, 4.7; 95% CI, 1.26-17.57; $P = .0213$); atypical (OR, 9.14; 95% CI, 3.14-26.67; $P \leq .0001$) or enlarged CSIV (OR, 4.69; 95% CI, 2.3-9.57; $P < .0001$); mean CSIV diameter 8.9 mm (OR, 8.53; 95% CI, 2.38-30.56; $P = .0010$); mean CSIV diameter \geq 10 mm (OR, 28.17; 95% CI, 7.81-101.55; $P < .0001$); and mean trunk diameter \geq 8 mm (OR, 11.69; 95% CI, 5.45-25.08; $P < .0001$).

At the multivariate logistic regression analysis, an atypical CSIV or a CSIV with a diameter \geq 8 mm, and a mean trunk diameter \geq 8 mm were highly significantly associated with ECEF (Table II).

Additional findings. During an average period of 2 years from EVLA, four of 20 (20%) patients progressed from type 1 to type 2 ECEF; and eight of 18 (44.4%) patients with type 2 proceeded to type 3 ECEF; half of these patients being free from recurrent symptoms.

Ultrasound-guided foam sclerotherapy of recurrent varices was performed in 17 patients with either type 2 EF ($n = 6$), or type 3 EF ($n = 11$), on average for 2.3 sessions per patient. Interestingly, none of those 17 patients reported clinical complaints.

Finally, no patients with EVLA failure underwent high tie and/or saphenous vein stripping.

DISCUSSION

To our knowledge, this is the first study of patients treated with EVLA featuring a 6-year follow-up time. In our cohort, postoperative complications were rare and mild, confirming the good safety profile of EVLA.¹³

Expected EVLA results, either by the clinical or the technical (ECD) point of view, were obtained in 88.4% and 70.0% of our patients, respectively; and persisted throughout the 6-year follow-up period. All failures were observed within the first 2 years from EVLA (Fig).

Only a minority (2/190; 1.1%) experienced both clinical and technical failure. Actually, most patients with ECEF were clinically asymptomatic.

Table II. Results of the multivariate logistic regression analysis, covariates statistically significantly associated with endovenous laser ablation failures at the end of the 6-year follow-up period

Covariates	OR	95% CI	P (logical regression)
CSIV characteristics			.0009
Typical	1		
Atypical	13.2	2.9-60.1	
CSIV diameter			.0017
6-7 mm	1		
8-9 mm	14.4	3.2-64.9	
≥10 mm (enlarged)	13.3	2.7-66.4	
Trunk mean diameter			.0002
6-7 mm	1		
≥8 mm	8.1	2.7-24.7	

CI, Confidence interval; CSIV, confluence of the superficial inguinal vein; OR, odds ratio.

Our clinical findings are supported by other published studies,^{14,15} reporting the disappearance or the improvement of preoperative symptoms in the vast majority of patients undergoing EVLA, though based on a shorter follow-up.

On the other hand, the unexpectedly high (57/190; 30.0%) rate of ECEF, contrasting with the published data, deserves careful discussion. First, the systematic application of the Valsalva maneuver during ECD, to assess for venous competence, probably accounts for the high rate of type 1 ECEF. Actually, 87% of type 1 ECEF identified in our study would not even have been adjudicated, had ECD-testing been based on augmentation maneuvers only. This is indirectly supported by the observation that type 1 ECEF was never associated with recurrent symptoms or varices; and, although in four patients a progression to type 2 ECEF was observed, the clinical picture remained stable during the 6-year period of observation. Notably, during follow-up evaluations, in nine of 20 patients with type 1 ECEF, we observed an ECD pattern of small vessel neo-angiogenesis, similar to that sometimes encountered after high-ligation and stripping. This may be of interest for the long-term outcome of EVLA, because it is well known from the surgical literature that neo-angiogenesis may lead to the development of junctional recurrence. In this respect, an additional follow-up period (up to at least 10 years) of type 1 ECEF would probably clarify this issue. Besides, we suggest that type 1 ECEF could contribute to the development of type 2 or 3 ECEF of the junction collaterals (eg, the ASSV). Second, the elevated number of Type 2 and 3 ECEFs detected in our study likely represents a sort of historic finding, owing to the standards for laser procedures recommended in 2003 through 2004. Specifically, the linear endovenous energy density (LEED) routinely employed at the time our patients were enrolled (50 joules/cm) was subsequently established as unable to permanently occlude a number of saphenous trunks, especially the larger ones. Indeed, with the higher LEED (at least 70 joules/cm) subsequently suggested by

Timperman et al,¹⁶ trunk patency has become uncommon. For instance, we recently reported on a group of 145 consecutive patients who underwent EVLA at our Institution, employing a mean LEED of 91 joules/cm. Interestingly enough, no type 2 or 3 ECEF were observed at the end of an 18-month follow-up.¹⁷

From multiple logistic regression analysis, we learned that the finding of an atypical CSIV, a CSIV diameter ≥8 mm, and mean trunk diameter ≥8 mm are statistically significantly associated with ECEF. Notably, the probability of ECEF increases as the number of these variables increase, reaching 95% in the case of a patient older than 60 years, with an atypical CSIV, a CSIV diameter ≥10 mm and a mean trunk diameter ≥8 mm.

The importance of the CSIV morphology and of the CSIV and the trunk diameters as potential risk factors for ECEF should urge an international standardization and validation of the methods employed to record these variables, given the current broad variability in the literature to this respect, and the consequent impossibility to compare data across different studies.

We believe our results were obtained using adequate methodology. We carried out a long-term prospective follow-up study, on a wide number of consecutive patients treated with a standardized endovenous laser technique. Clinical and technical outcomes were defined beforehand, and very few patients were lost to follow-up. Clinical and ECD findings were recorded using a standardized examination protocol, followed by all investigators, that turned out to be adequately reproducible as assessed by the Kappa statistic (0.78 and 0.81, respectively).¹⁸

Regarding clinical data, we did not employ validated questionnaires available from the literature, addressing either patient-reported outcomes or clinical severity, not commonly used when the study was planned; however, the vast majority of follow-up visits were not conducted by the operating surgeons (G.S., U.B.), therefore reducing the potential for assessment bias. Therefore, we trust our results are generalizable, provided a similar methodology is employed.

In conclusion, EVLA of great saphenous vein insufficiency is a safe and effective procedure, both by the clinical (ie, the patient's) and the technical (ie, the physician's) point of view, with persistent benefits after 6 years of follow-up. It is likely that most of the technical failures we observed will soon be eliminated, due to the use of adequate LEED (at least 70 joules/cm) and to the newer implements now available.^{19,20}

AUTHOR CONTRIBUTIONS

Conception and design: GS

Analysis and interpretation: GS, AP, EB, RB

Data collection: GS, AP, EG, PP, MF, UB

Writing the article: GS, AP, EB

Critical revision of the article: GS, AP, EB, EG, PP, RB, MF, UB

Final approval of the article: GS, AP, EB, EG, PP, RB, MF, UB

Statistical analysis: EB, RB

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REFERENCES

1. Callam MJ. Epidemiology of varicose veins. *Br J Surg* 1994;81:167-73.
2. Luebke T, Brunkwall J. Systematic review and meta-analysis of endovenous radiofrequency obliteration, endovenous laser therapy, and foam sclerotherapy for primary varicosis. *J Cardiovasc Surg (Torino)* 2008;49:213-33.
3. Beale RJ, Gough MJ. Treatment options for primary varicose veins—a review. *Eur J Vasc Endovasc Surg* 2005;30:83-95.
4. Min RJ, Zimmet SE, Isaacs MN, Forrestal MD. Endovenous laser treatment of the incompetent greater saphenous vein. *J Vasc Interv Radiol* 2001;12:1167-71.
5. Oh CK, Jung DS, Jang HS, Kwon KS. Endovenous laser surgery of the incompetent greater saphenous vein with a 980-nm diode laser. *Dermatol Surg* 2003;29:1135-40.
6. Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long-term results. *J Vasc Interv Radiol* 2003;14:991-6.
7. Gérard JL, Desgranges P, Becquemin JP, Desse H, Mellièrre D. [Feasibility of ambulatory endovenous laser for the treatment of greater saphenous varicose veins: One-month outcome in a series of 20 outpatients]. *J Mal Vasc* 2002;27:222-5.
8. Probstle TM, Sandhofer M, Kargl A, Gül D, Rother W, Knop J, et al. Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood. *Dermatol Surg* 2002;28:596-600.
9. Van den Bos R, Arends L, Kockaert M, Neumann M, Nijsten T. Endovenous therapies of lower extremity varicosities: a meta-analysis. *J Vasc Surg* 2009;49:230-9.
10. Agus GB, Mancini S, Magi G, Italian Endovenous-laser Working Group. The first 1000 cases of Italian Endovenous-laser Working Group (IEWG). Rationale, and long-term outcomes for the 1999-2003 period. *Int Angiol* 2006;25:209-15.
11. Geerts WH, Heit JA, Clagett GP, Pincus GF, Colwell CW, Anderson FA Jr, et al. Prevention of venous thromboembolism. *Chest* 2001;119(Suppl 1):132S-75S.
12. Spreafico G, Kabnick L, Berland TL, Cayne NS, Maldonado TS, Jacobowitz GS, et al. Laser saphenous ablations in more than 1,000 limbs with long-term duplex examination follow-up. *Ann Vasc Surg* 2011;25:71-8.
13. Van Den Bos RR, Neumann M, De Roos KP, Nijsten T. Endovenous laser ablation-induced complications: review of the literature and new cases. *Dermatol Surg* 2009;35:1206-14.
14. Darwood RJ, Gough MJ. Endovenous laser treatment for uncomplicated varicose veins. *Phlebology* 2009;24; Suppl 1:50-61.
15. Mundy L, Merlin TL, Fitridge RA, Hiller JE. Systematic review of endovenous laser treatment for varicose veins. *Br J Surg* 2005;92:1189-94.
16. Timperman PE, Sichlau M, Ryu RK. Greater energy delivery improves treatment success of endovenous laser treatment of incompetent saphenous veins. *J Vasc Interv Radiol* 2004;15:1061-3.
17. Spreafico G, Giraldo E, Pavei P, Piccioli A, Ferrini M, Nosadini A, et al. Thermal ablation and sclerotherapy. Varicose vein treatment in Padova: Indications and results. In: Becquemin JP, Alimi YS, Gerard JL, editors. *Controversies and Updates in Vascular Surgery*. Torino, Italy: Edizioni Minerva Medica; 2010. p. 503-8.
18. Carletta J. Assessing agreement on classification tasks: the Kappa statistic. *Comput Linguist* 1996;2:249-54.
19. Doganci S, Demirkilic U. Comparison of 980 nm laser and bare-tip fibre with 1470 nm laser and radial fibre in the treatment of great saphenous vein varicosities: a prospective randomised clinical trial. *Eur J Vasc Endovasc Surg* 2010;40:254-9.
20. Schwarz T, von Hodenberg E, Furtwängler C, Rastan A, Zeller T, Neumann FJ. Endovenous laser ablation of varicose veins with the 1470-nm diode laser. *J Vasc Surg* 2010;51:1474-8.

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INVITED COMMENTARY

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After a decade of clinical use, the late clinical outcomes of contemporary techniques of endovenous thermal ablation are just beginning to surface, providing interesting observations and insights in the natural history of the chronic venous disease after treatment of incompetent great saphenous vein (GSV).

This single center series of 190 patients who underwent endovenous laser treatment in 2003 and 2004 confirms other reports that the reflux in the remaining proximal segment of the GSV occurs more frequently than previously thought, and progresses mostly during the first year, and exclusively within 2 years after treatment. It also showed that longer refluxing segments have higher rate of progression to clinical recurrence. Similar data has been used previously to advocate duplex surveillance for early detection of failures, and intervention in order to improve clinical results.

However, the relationship between clinical outcomes and the ultrasound findings after thermal ablation of the GSV are rather complex. Only two of the 22 patients with clinical failure also had endovenous laser ablation failure confirmed by duplex ultrasound. Conversely, only half of the patients with progressive reflux developed symptoms. Interestingly, the majority of clinically relevant recurrences were associated with reflux in previously competent anterior accessory saphenous vein. These observations raise several questions. One is whether or not currently used duplex

protocols are sensitive enough to detect reflux in anterior accessory saphenous vein and groin tributaries in the presence of significant GSV reflux. The other is how good our analysis of clinical information is. Less than half of the patients had no residual symptoms after treatment, and in 7.4%, the symptoms did not respond to treatment at all. How much of this failure is due to nonvenous nature of patients' symptoms remains unknown.

Postoperative management after venous ablations remains to be extremely variable. This includes postoperative compression therapy and prevention of thrombotic complications. A broad variety of compression materials and differences in duration of their use make analysis of this aspect of postoperative care challenging, if not impossible. The study contributes to this variability by continuing use of compression stockings during the first week after treatment. Although rare, thrombosis is the most serious complication of this otherwise safe treatment of a benign condition. Endovenous heat-induced thrombosis (EHIT) particularly appears to behave differently from spontaneous venous thromboses. Authors used prophylactic dose of low-molecular-weight heparin in 44 patients. Surprisingly, the only two cases of EHIT (both type 2) occurred in patients who received this prophylaxis. Clearly, the risk factors, and effective ways to prevent EHIT deserve further investigation.