Prospective randomized trial comparing endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins with a 2-year follow-up

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Background: **Endovenous laser therapy (EVLT) for ablation of the great saphenous vein (GSV) is thought to minimize postoperative morbidity compared with high ligation and stripping (HL/S). Only a few randomized trials have reported early results. This prospective randomized trial compared EVLT (980 nm) and HL/S results at 1 and 2 years after the intervention.**

Method: **Patients with symptomatic varicose veins due to GSV insufficiency were randomized to HL/S (100 limbs) or EVLT (104 limbs). Four EVLT procedures failed primarily and were excluded. Phlebectomy and ligature of incompetent perforators were performed whenever indicated in both groups. Patients were re-examined clinically and by duplex ultrasound imaging preoperatively and at 12 days and at 1 and 2 years after treatment. Closure rate, complication rate, time to return to normal activity, the Aberdeen Varicose Vein Symptom Severity Score (AVVSS), the Varicose Venous Clinical Severity Score (VVCSS), and the Medical Outcome Study Short Form-36 scores were also recorded.**

Results: **There were no differences in patient demographics, CEAP class, Widmer class, or severity scores between the groups. Simultaneous interventions did not differ between the groups. Similar times for the return to normal activity and scores for postoperative pain were reported. No major complications after treatment were recorded. HL/S limbs had significantly more postoperative hematomas than EVLT limbs, and EVLT patients reported more bruising. Follow-up at 1 year was 100% for HL/S and 99% for EVLT. Two GSVs in the EVLT group reopened and three partially reopened. No open GSVs occurred in HL/S limbs. Ninety-eight percent of the limbs in both groups were free of symptoms. VCSS, AVVSS, and Short Form-36 scores did not reveal any group differences. At 2 years, no differences compared with 1-year results were observed, except that two more GSVs in the EVLT group were partially reopened.**

Conclusions: **Abolition of GSV reflux and improvement in quality of life was similar after HL/S and EVLT. After EVLT, however, two GSVs were found completely reopened and five were partially reopened, which was significantly higher than after HL/S. A prolonged follow-up is ongoing. (J Vasc Surg 2010;52:1234-41.)**

Varicose veins caused by great saphenous vein (GSV) insufficiency and reflux are common, and until recently, high ligation and stripping (HL/S) of the GSV has been the standard treatment.[1] HL/S has been reported to improve disease-specific and general quality of life of the patients,[2,3] with a low incidence of postoperative complications. Less invasive techniques have been developed in recent years, including radiofrequency ablation, endovenous laser (EVLT) ablation, foam sclerotherapy, and cryostripping, and are reported to achieve control of insufficient truncal vein.

The most commonly used procedure so far has been EVLT. EVLT is thought to minimize morbidity after treatment compared with HL/S, including avoidance of a groin incision and dissection at the saphenofemoral confluence, which has been reported to result in a lower complication rate and reduce posttreatment discomfort and pain, with a faster resumption of normal activity.[4-7] Early recanalization has been reported to occur in 5% to 9% after EVLT,[8] and long-term results from randomized controlled trials (RCTs) are still lacking. However, a recent systemic review found very few studies have actually compared HL/S with EVLT,[9] and of those, only three randomized controlled studies have thus far reported early results.[10-12]

This prospective randomized trial compares EVLT with the standard HL/S surgical procedure of the GSV to identify differences between these ablation techniques in efficacy concerning permanent GSV closure and absence of detectable venous reflux up to 2 years after the procedure,

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as well as in technical considerations, complications, and patient satisfaction.

PATIENTS AND METHODS

The study was approved by the hospital's ethical committee (05-014 [NAC 05-004]), and all participating patients signed an informed consent form.

The study design. This was a prospective randomized clinical trial with two treatment arms of 100 limbs each. Group 1 received conventional HL/S surgery for GSV insufficiency, and group 2 received EVLT ablation using a 980-nm diode laser (Endovenous Laser OptoLight 25 W/980 nm Endosysteme, Villeurbanne, France).

Inclusion criteria. Patients in good general health presenting with progressive superficial venous insufficiency (Widmer class 0 to III) and/or $C_{2\text{-}6}$, S, Ep, $As_{2\text{-}3} \pm As_1$ and $Ap_{17\text{-}18}$, Pr, according to the CEAP classification,[13] were eligible for enrollment if pretreatment duplex ultrasound (DUS) scanning demonstrated reflux at the saphenofemoral confluence during Valsalva maneuver together with a GSV diameter of 5 to 15 mm at 3 cm from the saphenofemoral junction with the patient prone and truncal reflux >0.5 seconds, where an active intervention was indicated.

Exclusion criteria. Venous reoperations, pregnant or breast-feeding women, patients aged <18 years; a history of deep vein thrombosis or pulmonary embolism, or both, or postthrombotic changes observed at DUS examination; patients with cancer, coagulopathy, and ongoing anticoagulation therapy; patients with pacemakers; and patients with symptomatic arterial disease or no peripheral arterial pulse on clinical examination.

Once a patient was eligible to participate in the trial, randomization was performed using a computerized randomization tool. The study design adhered to the Consolidated Standards of Reporting Trials (CONSORT) model[14] (Fig 1). Enrollment for the study started in March 2006.

All EVLT or HL/S procedures, including additional phlebectomies and ligature of incompetent perforators, were done by the same surgeon (J. T. C.). All preoperative and postoperative clinical evaluations, postoperative interviews, and clinical examinations were done by the same surgeon (J. T. C.). An independent angiologist (S. G.) performed the preoperative and postoperative DUS scanning with the patient standing, following a standardized protocol that evaluated abolition of the GSV or presence of reflux, or both. Flow was defined as being antegrade. Reflux was defined as retrograde flow of >0.5 second after Valsalva maneuver or manual compression and decompression of the distal vein. Even a slight reflux in the proximal segment of an occluded GSV was assessed as pathologic. The DUS examination was performed preoperatively, immediately after the intervention and at 4 to 6 hours, at 12 days, and at 1 and 2 years.

The Medical Outcome Study Short Form 36 (SF-36) health-related quality-of-life score,[15] the Aberdeen Varicose Vein was Symptom Severity Score (AVVSS), and the Varicose Venous Clinical Severity Score (VVCSS)[16] were

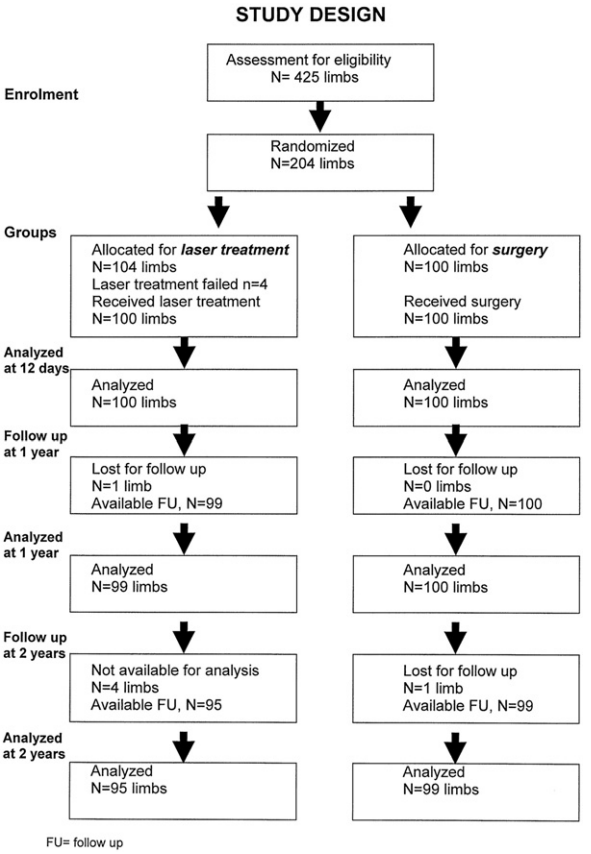

Fig 1. This randomized prospective trial compared endovenous laser and surgical ablation of primary great saphenous vein incompetency. This Consolidated Standards of Reporting Trials (CONSORT)[14] diagram shows trial recruitment, randomization, and treatment allocation for limbs evaluated and studied as well as follow-up (*FU*) analysis.

recorded for each patient preoperatively and postoperatively during the follow-up.

High ligation and stripping. Ligation of the saphenofemoral junction together with ligation of all tributary veins was performed through a 1- to 2-cm groin incision. A standard stripper was inserted in the GSV, and the vein was stripped top down either to just below the knee or at the ankle (4-mm skin incision). Stab evulsions using small skin incisions of marked varicose branches and ligation of grossly incompetent perforators was performed whenever needed. The groin and distal incisions were closed by an intradermic continuous suture with 3-0 Monocryl (Ethicon, Johnson & Johnson, Neuchâtel, Switzerland).

EVLT. The EVLT ablation was performed using a 980-nm diode laser under DUS guidance. In the initial 49 patients, the optic fiber was introduced using a sheath and guidewire, and in 51 patients, a direct puncture of the GSV was used to introduce the optic fiber (denuded, 600-μm, 0.038-inch; Endosysteme, Villeurbanne, France). Four patients required a small surgical cutdown. EVLT was not

Table I. Outcomes in 100 limbs undergoing great saphenous vein *(GSV)* ablation by endovenous laser therapy *(EVLT)* for primary varicose veins

Variables	*No. or mean ± SD (range)*
Difficult access for percutaneous fiber insertion[a]	8
Surgical cutdown	4
Sheath and guidewire use for optic fiber insertion	49
Direct puncture and placement of optic fiber	51
Distance of GSV treated, cm	35.5 ± 6.3 (18-50)
Energy delivered, J	2724.4 ± 703.0 (1236-4254)
Energy delivered, J/cm[b]	75.9 ± 12.8 (40.4-108.0)
Distance to saphenofemoral confluence, cm	1.63 ± 1.6 (0.4-28.2)

[a]Extremely obese patients and/or rolling veins which prolonged the procedure or surgical cutdown was necessary (n = 4).
[b]Eleven limbs were treated with <70 Joules/cm. The GSVs in all of these limbs were successfully obliterated, and none of these GSVs reopened during the follow-up.

Table II. Patient characteristics in 100 legs undergoing great saphenous vein *(GSV)* ablation by surgery *(HL/S)* and 100 legs by endovenous laser therapy *(EVLT)*

Variables	*HL/S*	*EVLT*
Limbs, No.	100	100
Female sex	71	67
Age, y		
Mean ± SD	46.3 ± 13.3	44.6 ± 10.5
Range	24-86	24-79
BMI, kg/m^2		
Mean ± SD	26.0 ± 5.1	26.2 ± 4.8
Range	16.9-40.5	18.2-42.2
Obesity (BMI >30 kg/m^2), No.	12	17
Size of GSV at 3 cm from SFJ, mm		
Mean ± SD	6.6 ± 1.7	6.9 ± 2.0
Range	4.4-12.8	4.2-12.5
Reflux time, s	2.4 ± 1.1	2.5 ± 0.9
Deep venous reflux	4/26	2/24

BMI, Body mass index.
P values were not statistically significant.

performed in another four patients due to severe GSV spasm. These patients were excluded from the trial.

The desired position of the laser optic fiber tip (1 to 2 cm distal to the saphenofemoral junction) was confirmed with DUS scanning. Tumescent anesthesia[17] was administered in all patients with a syringe under US guidance to ensure a homogenous layer of tumescent fluid around the GSV, using approximately 250 mL per treatment. The laser energy (10 to 12 W) was delivered during a stepwise retraction of the optic fiber (1.5-second impulse and 1.5-second pause). Laser treatment data are given in Table I.

Stab evulsions of marked varicose branches and ligation of grossly incompetent perforators was performed whenever needed and were equally distributed between the two treatment groups.

All HL/S and EVLT procedures were performed with general or spinal anesthesia, in 90% as an ambulatory procedure, without group difference. After the procedure, the leg was wrapped in sterile absorbent bandages and covered with a double-layered elastic bandage that was changed before discharge (4 to 6 hours after the treatment). After 48 hours, the patient removed the bandage and continued using a class II (30 mm Hg) below-knee elastic stocking (Sigvaris; Ganzone & Cie AG, St Gallen, Switzerland) for 3 weeks during the day only. Depending on weight, the patient received thrombosis prophylaxis using enoxaparin (20 or 40 mg; Clexane, Sanofi-Aventis, Meyrin, Switzerland) subcutaneously 6 hours after the treatment once daily for 10 days.

Patient characteristics. Patient demographics are presented in Table II. There were no group differences regarding sex, age, body mass index, or size of the GSV 3 cm below the saphenofemoral junction.

Technical results and complications were recorded, and the patients completed the scoring forms. Technical success was defined as absent GSV in the HL/S group and closed GSV without any flow in the EVLT group. During the first 12 days postoperatively, the patients were asked to indicate the maximum area of hematomas or bruising, the exact date of return to normal activity, to indicate pain using a visual analog scale from 0 to 10, and to record intake of analgesics. The primary end point was closed or absent GSV with reflux, and secondary end points were return to normal activity, treatment-related complications, and scores for VVCSS, AVVSS, and SF-36.

Statistics. Data are presented as mean ± standard deviation. Continuous variables were analyzed with *t* test and categoric variables using the χ^2 test. A value of $P < .05$ was considered statistically significant. Sample size calculations by a biostatistician before the start of the trial revealed that a group size of 100 limbs in each group had a statistical power of 80%, with the confidence interval set at 96%, to detect a difference in the primary study end point between EVLT and HL/S of ≥0.05.

RESULTS

During the enrollment phase, 425 limbs were assessed for eligibility, 204 limbs were randomized, and 4 limbs were excluded in the EVLT group, leaving 100 limbs in each group for analysis. All limbs were examined on postoperative day 12. At 1 year after treatment, 1 limb was lost to follow-up in the EVLT group, leaving 99 limbs for evaluation. At the 2-year follow-up, another 4 limbs in the EVLT group (3 limbs operated on and 1 limb lost to follow-up) and 1 limb in the HL/S group were lost to follow-up, thus allowing 2-year analysis of 95 and 99 limbs, respectively (Fig 1).

There was no significant difference between the groups regarding treatment time (31.4 ± 7.8 minutes [HL/S] and 32.0 ± 7.4 minutes [EVLT], respectively). In the HL/S group, there were no perioperative complications, whereas

Table III. Pretreatment varicose vein symptoms and classifications in 100 legs undergoing great saphenous vein *(GSV)* ablation for primary varicose veins by high ligation and stripping *(HL/S)* and 100 legs by endovenous laser therapy *(EVLT)*

Variables	*HL/S*	*EVLT*	P
Pain, No.	100	100	>.1
Heaviness, No.	90	89	.823
Edema, No.	72	61	.099
Dermatitis, No.	24	8	<.002
Skin changes			
With open venous ulcer	3	0	.123
With healed venous ulcer	2	1	>.1
ABI, mean ± SD	0.9 ± 0.1	0.9 ± 0.1	>.1
Primary varicose veins of GSV, No.	100	100	1.0
CEAP, No.			
C_2	26	34	.218
C_3	51	58	.393
C_4	18	7	.031
C_5	2	1	1.0
C_6	3	0	.123
C_4-C_6	23	8	.041
VVCSS			>.1
Mean ± SD	5.2 ± 2.7	5.2 ± 2.5	
Range	2-18	2-16	
AVVSS			>.1
Mean ± SD	22.0 ± 7.5	22.5 ± 6.5	
Range	10-46	12-42	

ABI, Ankle-brachial index; *AVVSS,* Aberdeen Varicose Vein Severity Score; *VVCSS,* Varicose Vein Clinical Severity Score.

one patient sustained a small accidental skin burn at the fiber insertion site.

Pretreatment varicose vein symptoms and severity classifications (CEAP, VVCSS and AVVSS) are reported in Table III and revealed no group differences. The HL/S group had a higher incidence of dermatitis compared with the EVLT group, whereas there were no significant differences between the groups regarding severity classifications (Table III).

The postoperative DUS examination 6 hours and at 12 days revealed absence or abolishment of the GSV in all treated legs in both groups. One limb in the EVLT group showed reflux at the level of the thigh. Time to return to normal activity was 6.6 days for HL/S vs 6.9 days for EVLT (Table IV). Pain scores were without significant group differences throughout the first 12 postoperative days, with an average pain score of 4.6 for HL/S and 4.3 for EVLT on day 1, 2.9 vs 2.2 on day 3, and 1.8 vs 1.7 on day 12. There was no group difference in the mean use of analgesics during the initial 12 postoperative days. Few complications occurred after treatment (Table IV). All patients were specifically asked about any neurologic symptoms at each follow-up visit. The area of maximum hematoma or bruising was marked by the patient in addition to a nonquantifiable observation by the examiner. More hematomas occurred after HL/S than after EVLT, which was counteracted by significantly more bruising in the EVLT group than in the HL/S group.

Table IV. Technical results and complications after great saphenous vein *(GSV)* ablation by high ligation and stripping (*HL/S*) and endovenous laser therapy *(EVLT)* at 12 days postoperatively

Variables	*HL/S*	*EVLT*	P
Limbs, No.	100	100	
GSV absent or abolished, No.	100	100	1.0
Detectable reflux, No.	0	1	>.1
Symptoms, No.	18	23	.380
Time to return to normal activity, d			>.5
Mean ± SD	6.6 ± 2.1	6.9 ± 2.7	
Range	2-14	3-21	
Complications, No.			
Infection	0	0	1.0
Superficial localized phlebitis	1	4	.369
Deep vein thrombosis	0	0	1.0
Hematoma	12	5	.076
Transient paresthesia	1	1	1.0
Bruising	2	15	.002

No limbs were lost to follow-up during the first year, but one limb was lost during the second year in the HL/S group. In the EVLT group, one limb was lost to follow-up during the first year because the patient withdrew from the study. Another four limbs in the EVLT group were not available for analysis during the second year of follow-up because three underwent surgery due to a reopened GSV, thus leaving us with completed follow-up of 99% in the HL/S group and 95% in the EVLT group.

Outcomes at 1 and 2 years after ablation of the GSV by HL/S or EVLT are presented in Table V. The mean VVCSS and AVVSS in the HL/S group were significantly decreased, from 5.2 ± 2.7 and 22.0 ± 7.5 preoperatively to 0.23 ± 0.57 and 4.17 ± 1.97, respectively, 1 year after treatment. At 2 years, no further significant improvement was noted. Similar development was noted for the EVLT group (Tables III and V).

In the HL/S group, there was a 100% absence of the GSV at 1 and 2 years postoperatively. At the 1-year follow-up in the EVLT group, two GSVs had reopened (with symptoms, reoperated on, and lost to further follow-up) and three GSVs had partially reopened (with mild symptoms). At 2 years, an additional 2 GSVs had partially reopened, one with symptoms, and underwent subsequent surgical ablation. However, the difference in treatment failure at 2 years between EVLT (7 of 98) and HL/S (0 of 99) did not reach statistical significance ($P = .051$, Table V).

In four limbs, intention to treat by EVLT was abandoned because severe spasm prevented introduction of the optic fiber. These patients were excluded. If, however, failure of intention to treat is addressed, there was a highly significant difference between the treatment groups in favor of HL/S (0 of 99) compared with EVLT (11 of 102; $P = .016$).

Quality-of-life measurement, using SF-36, showed improvement in most parameters comparing preoperative and

Table V. Outcomes in 100 legs undergoing great saphenous vein *(GSV)* ablation by high ligation and stripping and 100 legs by endovenous laser therapy for primary GSV insufficiency

Variables	*Follow-up period*	
	12 days to 1 year	*1 to 2 years*
High ligation and stripping		
Total limbs, No.	100	100
Lost to follow-up, No.	0	1
Available for follow-up, No.	100	99
Analyzed, No.	100	99
GSV absent, No.	100	99
Reflux, No.	1	1
Limbs with symptoms, No.	1	0
Retouch miniphlebectomy, No.	3	4
GSV reoperation, No.	0	0
VVCSS, mean ± SD (range)	0.23 ± 0.57 (0-3)	0.23 ± 0.59 (0-3)
AVVSS, mean ± SD (range)	4.17 ± 1.97 (2-14)	3.54 ± 2.30 (2-20)
Distance to SF confluence, mean ± SD (range), mm	6.21 ± 3.34 (0-21)	5.46 ± 3.25 (0-20)
Endovenous laser therapy		
Total, No.	100	99
Lost to follow-up, No.	1	4
Available for follow-up, No.	99	95
Analyzed, No.	99	95
GSV completely occluded, No.	94	88
GSV open, No.	2	0
GSV partially open, No.	3	2
Reflux, No.	4	4
Limbs with symptoms, No.	5	4
Retouch miniphlebectomy, No.	8	6
GSV reoperation, No.	2	1
VVCSS, mean ± SD (range)	0.26 ± 0.68 (0-3)	0.23 ± 0.54 (0-2)
AVVSS, mean ± SD (range)	4.53 ± 3.10 (3-22)	3.82 ± 1.35 (1-10)
Distance to SF confluence, mean ± SD (range), mm	9.54 ± 7.49 (0-50)	9.28 ± 6.89 (0-45)

ABI, Ankle-brachial index; *AVVSS,* Aberdeen Varicose Vein Severity Score; *SF,* saphenofemoral; *VVCSS,* Varicose Vein Clinical Severity Score.

1-year results, without a group difference. Bodily pain (BP), vitality (VT), and physical functioning (PF) were the dimensions most markedly improved at 1 year in both groups (Fig 2). There were no differences between results at 1 and 2 years in either group.

A comparison of HL/S and EVLT ablation of the GSV for primary incompetency 2 years later revealed a significantly higher incidence of completely reopened and partially reopened GSVs after EVLT than after HL/S (7 vs 0, $P < .051$), more limbs with symptoms (9 vs 1), and a longer distance to the saphenofemoral junction (9.3 vs 5.5 mm, $P < .001$). However, there were no significant group differences in quality-of-life or venous severity scoring at 2 years after GSV ablation (Table VI).

DISCUSSION

Initial and short-term good results have been published in the literature with the use of various endovenous treatment modalities of varicose veins, but few RCTs have been reported so far. High-quality large comparative RCTs on long-term clinical efficacy (recurrent varicose veins), safety, and quality-of-life outcomes would be required before considering endovenous techniques as a validated alternative treatment, even though some authors have stated EVLT as the standard of care on the basis of long-term observational single-center studies.[17,18]

One RCT has reported no difference in pain score, but less bruising and edema after EVLT compared with HL/S.[19] Another recent RCT showed a similar short-term efficacy and safety of EVLT and HL/S.[10] Comparable efficacy and disease-specific quality of life has been reported after EVLT and HL/S, but earlier return to normal activity is reported after EVLT.[12] We report here the largest study comparing EVLT and HL/S with a 2-year complete follow-up.

We first confirmed from available data that HL/S and EVLT for GSV reflux are initially similarly effective for treating GSV reflux.[10,12] Also corresponding with earlier reports[10,12] were improvement of quality of life and significant improvement in clinical severity scores (VVCSS and AVVSS) and in CEAP classification, which was documented during follow-up for both treatment groups. In contrast to previous reports, however, the two groups had similar postoperative pain scores and time for return to normal activity because the HL/S group experienced more postoperative hematomas, and the EVLT patients had significantly more bruising. Perhaps these results will change with the use of new types of optical fibers[20] and lasers with different wavelengths,[21] but long-term results from RCTs are still lacking for such refinements of EVLT.

We, importantly, did not observe any major complications, such as deep vein thrombosis or wound infection, in

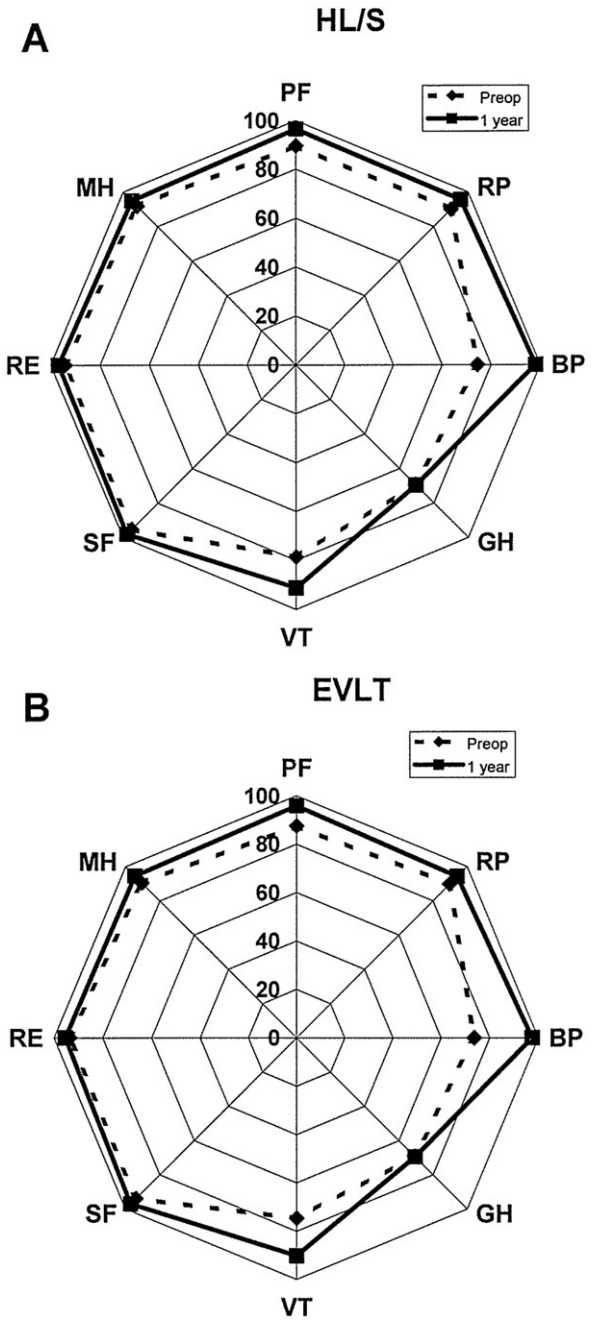

Fig 2. Medical Outcomes Study Short Form-36[15] results preoperatively and at 1 year after ablation of great saphenous vein by **(A)** high ligation and stripping (*HL/S*) or **(B)** endovenous laser *(EVLT)* in limbs presenting with primary GSV reflux. Dimensions measured were physical functioning (*PF*), role-physical (*RF*), bodily pain (*BP*), general health (*GH*), vitality (*VT*), social functioning (*SF*), role-emotional (*RE*), and mental health (*MH*). Mean data are presented.

either group. Mild complications were few: one patient in each group experienced transient paresthesia, and superficial localized thrombophlebitis in a nontruncal side branch was observed in one limb in the surgery group and in four

Table VI. Outcomes comparison between high ligation and stripping *(HL/S)* and endovenous laser therapy *(EVLT)* for abolition of primary great saphenous varicose veins at the 2-year follow-up

Variables	*HL/S*	*EVLT*	P
Limbs lost to follow-up, No.	1	5	.212
Limbs analyzed, No.	99	95	.212
Primary end point			
Great saphenous vein, No.			
Absent/completely closed	99	88	1.0
Completely reopened		2	
Partially reopened		5	
Completely + partially reopened or detectable	0	7	.051
Reflux, No.	2	8	.050
Limbs with symptoms, No.	1	9	.007
Limbs reoperated on, No.	0	3	.102
VVCSS, mean ± SD	0.23 ± 0.59	0.23 ± 0.54	>.1
AVVSS, mean ± SD	3.54 ± 2.30	3.82 ± 1.35	>.050
Distance to SF confluence, mean ± SD, mm	5.46 ± 0.25	9.28 ± 6.89	<.001

AVVSS, Aberdeen Varicose Vein Severity Score; *SF,* saphenofemoral; *VVCSS,* Varicose Vein Clinical Severity Score.

limbs after laser ablation. All treatments were performed by a highly specialized and experienced surgeon, which may have contributed to the low incidence of complications. One surgical failure occurred in the HL/S group, where a thigh reflux was observed at the 1-year control, probably due to a missed duplication of the GSV. This contrasts with earlier reports, well keeping in mind that the postoperative period of 2 years is most likely too short for neorevascularization at the saphenofemoral confluence.[12,22]

In our series, the initial closure rate immediately postoperatively and at 12 days was 100%, without detectable reflux in both groups. High success rates after EVLT have been reported. A 2-year recurrence rate of <10% was reported by Min et al[23] in 2003. Proebstle et al[24] showed that the energy delivery had an important effect on recurrence, where low-energy delivery had worse results and more recurrences than higher-energy doses.[24] Yet in a recent study, Pannier and Rabe[25] demonstrated that large vein diameter, when moderate energy delivery was used (48.6 J/cm) was associated with nonocclusion of the treated vein. The mean laser energy delivery in the present series was 75.9 ± 12.8 J/cm, which has been reported to achieve permanent GSV ablation.[24,26]

At 1-year follow-up, GSV abolishment, without detectable DUS GSV reflux, was observed in 99% in the surgery group. Contrary to the HL/S group, recanalization with a completely reopened GSV with GSV reflux was diagnosed in two limbs in the EVLT group. DUS scanning in both limbs showed a completely obstructed GSV immediately postoperatively and at the 12-day follow-up. Because these two patients presented with recurrent symptoms, both

underwent HL/S and were excluded from further follow-up. A partially reopened GSV with reflux from the saphenofemoral junction to midthigh was found in another three limbs. These patients were asymptomatic at the 1-year control, in keeping with earlier reports.[10,12,23,24]

At 2 years, an additional limb in the surgery group revealed mild, short reflux at the saphenofemoral junction, with no visible recurrence of varicose veins and no symptoms. Yet another two limbs in the EVLT-group showed long reflux in partially opened GSVs. These patients were asymptomatic, however, and required no further treatment. One patient with a partially reopened GSV to the distal part of the thigh at 1 year became severely symptomatic with recurrent varicosities and underwent HL/S at 1 year and 7 months after the initial treatment.

None of the patients with complete or partial recanalization of their GSV after EVLT had received a laser energy delivery <67 J/cm at the initial treatment. Even though early recanalization of EVLT could mimic recanalization seen after thrombophlebitic occlusion, as described by Proebstle et al,[27] the later recanalization that was seen in our series is more difficult to explain. The distance to the saphenofemoral junction may play a role, because the distance was significantly shorter in the HL/S group than in the EVLT group. The distance from the saphenofemoral confluence to the ligature and the obliteration, respectively, diminished slightly but remained significantly different. This may have an important effect on the rate of neorevascularization later on, even though some evidence has been presented in the literature suggesting that EVLT, unlike surgery, is associated with a very low incidence of neorevascularization.[28,29] However, long-term follow-up would be required to correctly address this issue.

The recanalization rate of symptomatic limbs at 2 years was 3.2% (3 of 95), which corresponds to the 3% recanalization rate after EVLT reported in a large series of 1250 patients[28] and the 3.7% reported by Darwood et al[12] in 2008. However, if one also considers partially reopened, nonsymptomatic GSVs, the recanalization rate increases to 7.4%, which is in the range of the 10% reported by Min et al[23] and close to being significantly higher than after adequate surgery performed by expert surgeon ($P = .051$).

CONCLUSION

Abolition of GSV reflux, safety, improvement in quality of life, and clinical severity score were similar after HL/S and EVLT. At 2 years after treatment, however, two GSVs were completely reopened and five were partially reopened after EVLT, which was significantly higher than after HL/S. Three of these patients required a reintervention due to recurrent symptoms. Follow-up is continuing to evaluate the rate of neorevascularization after the two treatments.

AUTHOR CONTRIBUTIONS

Conception and design: JC, HB
Analysis and interpretation: JC, GG
Data collection: JC, GG, SG
Writing the article: JC
Critical revision of the article: SG, GG, HB
Final approval of the article: JC, SG, GG, HB
Statistical analysis: JC
Obtained funding: Not applicable
Overall responsibility: JC

REFERENCES

1. Beale RJ, Gough MJ. Treatment options for primary varicose veins: a review. Eur J Vasc Endovasc Surg 2005;30:83-95.
2. Durkin MT, Turton EPL, Wiesinghe LD, Scott DJA, Berridge DC. Long saphenous vein stripping and quality of life—a randomized trial. Eur J Vasc Surg 2001;21:545-49.
3. MacKenzie RK, Paisley A, Allan PL, Lee AJ, Ruckley CV, Bradbury AW. The effect of long saphenous vein stripping on quality of life. J Vasc Surg 2002;35:1197-203.
4. Agus GB, Mancini S, Magi G, IEWG. The first 1000 cases of Italian Endovenous-EVL Working Group (IEWG). Rationale, and long-term outcomes for the 1999-2003 period. Int Angiol 2006;25:209-15.
5. Morrison N. Saphenous ablation: what are the choices, EVL or RF energy. Semin Vasc Surg 2005;18:15-8.
6. Mundy L, Merlin TL, Fitridge RA, Hiller JE. Systematic review of EVL treatment for varicose veins. Br J Surg 2005;92:1189-94.
7. Min RJ, Khilnani N, Zimmet SE. Endovenous EVL treatment of saphenous vein reflux: long-term results. J Vasc Interv Radiol 2003;14:991-6.
8. Proebstle TM, Gul D, Lehr HA, Kargl, A Knop J. Infrequent early recanalization of greater saphenous vein after endovenous EVL treatment. J Vasc Surg 2003;38:511-6.
9. Hoggan BL, Cameron AL, Maddern GJ. Systemic review of endovenous laser therapy versus surgery for the treatment of saphenous varicose veins. Ann Vasc Surg 2009;23:277-87.
10. Rasmussen LH, Bjoern L, Lawaerts M, Blemings A, Lawaertz B, Eklof B. Randomized trial comparing endovenous laser ablation of the great saphenous vein with high ligation and stripping in patients with varicose veins: short-term results. J Vasc Surg 2007;46:308-15.
11. Kaltels M, Berger I, Messie-Werndl S, Pistrich R, Schimetta W, Polz W, Hieller F. High ligation combined with stripping and endovenous laser ablation of the great saphenous vein: early results of a randomized controlled study. J Vasc Surg 2008;47:822-9.
12. Darwood RJ, Theivacumar N, Dellagrammaticas D, Mavor AID, Gough MJ. Randomized clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous varicose veins. Br J Surg 2008;95:294-301.
13. Eklof B, Rutherford RB, Bergan JJ, Carpentier PH, Glowiczki P, Kistner RL, et al. American Venous Forum International ad Hoc Committee for revision of the CEAP classification. Revision of the CEAP classification for chronic venous disorders: consensus statement. J Vasc Surg 2004;40:1248-52.
14. Boutron I, Moher D, Altman DG, Schultz KF, Ravaud P; CONSORT Group. Extending the CONSORT statement to randomized trials of non-pharmacologic treatment: explanation and elaboration. Ann Intern Med 2008;148:295-309.
15. McHorney CA, Ware JE Jr, Lu JF, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Test of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care 1994;32:40-66.
16. Rutherford RB, Padberg FT Jr, Comerota AJ, Meissner MH, Moneta GL. Venous severity scoring: an adjunct to venous outcome assessment. J Vasc Surg 2000;31:1307-12.
17. Min RJ, Khilnani NM. Endovenous laser ablation of varicose veins. J Cardiovasc Surg 2005;46:395-405.
18. Mekako AI, Hatfield J, Bryce J, Lee D, McCollum PT, Chettar I. A nonrandomized controlled trial of endovenous laser therapy and surgery in the treatment of varicose veins. Ann Vasc Surg 2006;20:451-7.
19. Medeiros CAF, Luccas GC. Comparison of endovenous treatment with an 810 nm laser versus conventional stripping of the great saphenous vein in patients with primary varicose veins. Dermatol Surg 2005;31:1685-94.

20. Sroka R, Weick K, Sadeghi-Azandaryani M, Steckmeier B, Schmedt CG. Endovenous laser therapy-application studies and latest investigations. J Biophotonics 2010;3:269-76.
21. Pannier F, Rabe E, Maurins U. First results with a new 1470-nm diode laser for endovenous ablation of incompetent saphenous veins. Phlebology 2009;24:26-30.
22. Turton EP, Scott DJ, Richards SP, Weston MJ, Berridge DC, Kent PJ, et al. Duplex-derived evidence of reflux after varicose vein surgery: neoreflux or neorevascularization? Eur J Vasc Endovasc Surg 1999;17:230-3.
23. Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long-term results. J Vasc Interv Radiol 2003;14:991-6.
24. Proebstle T, Krummenauer F, Gul D, Knop J. Nonocclusion and early reopening of the great saphenous vein after endovenous laser treatment is fluence dependent. Dermatol Surg 2004;30:174-8.
25. Pannier F, Rabe E. Mid-term results following endovenous laser ablation (EVLA) of saphenous veins with a 980nm diode laser. Int Angiol 2008;27:475-81.
26. Timperman PE, Sichlau M, Ryu R. Greater energy delivery improves treatment success of endovenous laser treatment of incompetent saphenous veins. J Vasc Interv Radiol 2004;15:1061-3.
27. Proebstle TM, Gül D, Lehr HA, Kargl A, Knop J. Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. J Vasc Surg 2003;38:511-6.
28. Theivacumar N, Dellagrammaticas D, Beale R, Mavor AID, Gough MJ. The fate and clinical significance of sapheno-femoral junction tributaries following endovenous laser ablation of great saphenous vein. Br J Surg 2007;94:722-75.
29. Ravi R, Rodriguez-Lopes JA, Trayler EA, Barrett DA, Ramaiah V, Dietrich E. Endovenous ablation of incompetent saphenous veins: a large single-center experience. J Endovasc Ther 2006;13:244-8.

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