From the Vascular and Endovascular Surgery Society

A randomized clinical trial of endovenous laser ablation versus conventional surgery for small saphenous varicose veins

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Background: **This randomized clinical trial compared endovenous laser ablation (EVLA) and surgical ligation with attempted stripping in the treatment of small saphenous vein (SSV) insufficiency. The early results demonstrated that EVLA was more likely to eradicate axial reflux and was also associated with a faster recovery, lower periprocedural pain, and fewer sensory complications. The aim of this 2-year follow-up was to establish whether these benefits remained stable over time and whether these improved technical outcomes were associated with less clinical recurrence.**

Methods: **Patients with primary saphenopopliteal junction and SSV reflux were randomized to EVLA or saphenopopliteal junction ligation and attempted stripping/excision. Outcomes assessed at 2 years included the presence of residual or recurrent reflux, clinical recurrence, sensory complications, the need for secondary intervention, and patient-reported quality of life on the Aberdeen Varicose Veins Questionnaire, SF-36, and EuroQol.**

Results: **Of 106 patients who were equally randomized and successfully treated according to the protocol, 88 (83%) were successfully assessed at 2 years. The groups were comparable at baseline. At 2 years, EVLA remained superior to surgery in eradicating axial reflux in 36 patients (81.2%) compared with 29 (65.9%) in the surgery group ($P = .002$). There was no significant difference in clinical recurrence (EVLA: seven of 44 [16%] vs surgery: 10 of 44 [23%]; $P = .736$), sensory disturbance (EVLA: one [2.4%] vs surgery vs three [6.8%]; $P = 1.000$) or any quality of life domain.**

Conclusions: **The results of treatment of SSV insufficiency with EVLA appear durable up until 2 years. The study does not appear to suggest that the improved abolition of reflux after EVLA compared with surgery is associated with superior outcomes than those seen after surgery by this time point, because equal effect was shown in both groups. The sensory disturbance associated with surgery appears to settle over this time frame. EVLA is therefore superior in the short-term and not inferior by 2 years. (J Vasc Surg 2015;61:741-6.)**

Superficial venous insufficiency (SVI) is a very common cause of disease. Symptomatic varicose veins affect up to half of the adult population[1-4] and have been shown to have a significant detrimental effect upon physical elements of quality of life (QOL).[3,5,6] Treatment is associated with significant improvement.[7-9] There is also emerging evidence that without treatment, the disease severity tends to progress over time.[2,10] Most of this evidence is based on treatment of the most common pattern of SVI, insufficiency of the great saphenous vein (GSV). However, ~3% to 33% have insufficiency of the small saphenous vein (SSV),[11-14] and much less is known regarding the outcomes after treatment of this axis.[15] It cannot simply be assumed that the evidence pertaining to the GSV can be applied to insufficiency of the SSV. For instance, the latter may be more significant because it seems to have a stronger association with venous ulceration,[16,17] and existing evidence suggests that saphenopopliteal junction (SPJ) reflux and SSV axial reflux may result in a greater effect on the patient's QOL than that of the GSV reflux when analyzed in isolation.[18]

This was the only randomized trial that was designed to study the outcome of treatment specifically in this group

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of patients. The short-term results demonstrated that patients randomized to receive endovenous laser ablation (EVLA) were more likely to have total abolition of axial reflux, less pain, a faster recovery, and less sensory complications than those randomized to surgery featuring saphenopopliteal ligation and attempted stripping of the SSV.[19] The aim of this 2-year follow-up was to establish whether these benefits remain stable over time and whether these improved technical outcomes are associated with less clinical recurrence.

METHODS

The detailed methodology of this randomized clinical trial has been previously reported.[19] Briefly, the trial included adults presenting with primary, symptomatic, unilateral, isolated SPJ and SSV insufficiency. Exclusion criteria included small tortuous SSVs, pregnancy, nonpalpable foot pulses, and inability to give informed consent or complete the follow-up visits. All eligible patients were consented for participation in line with local and national ethical consent approval processes. Each patient received detailed information to allow him or her to make an informed decision to participate in this study. Willing and consenting participants were randomized equally using a sealed opaque envelope selection system to receive EVLA or surgical treatment. The study was approved by the UK Health Research Authority (www.hra.nhs.uk) through the National Research Ethics Service. This is a similar rigorous ethical approval process to the Institutional Review Board within the United States.

Interventions. Full intraoperative details have previously been published.[19] In summary, all patients underwent preoperative duplex ultrasound (DUS) imaging of the SPJ, SSV, tributaries, and perforators in line with the international consensus protocol.[20] Interventions were performed by three senior vascular surgical consultants with 10 to 25 years' experience post-training, and EVLA was performed by a consultant vascular surgeon or a senior fellow with a special interest in the management of venous disease.

Those participants allocated to surgery underwent formal exploration under general anesthesia as a day-case procedure. SPJ ligation was performed, followed by attempted inversion stripping of the SSV. The sural nerve was protected where seen, and retractors were used cautiously.

EVLA was similarly done as a day-case procedure under perivenous local anesthesia. Ultrasound-guided percutaneous cannulation was performed with the patient prone in the reverse Trendelenburg position. The SSV was cannulated at the most distal point of reflux. A bare-tipped 600-nm laser fiber was then introduced through the catheter, and laser energy was delivered using an 810-nm diode laser generator (Diomed/Angiodynamics, Queensbury, NY) at 14 W power aiming for an energy delivery of 80 to 100 J/cm ablating from the SPJ to the cannulation point. Perivenous tumescent anesthesia, consisting of 2% levobupivacaine (20 mL) in 1000 mL 0.9% saline was infiltrated along the vein and tributaries.

Both groups underwent ambulatory phlebectomy of all clinically evident incompetent tributaries. Phlebectomy wounds and cannulation sites were closed with Steri-Strips (3M, St. Paul, Minn), and cotton wool and a Panelast (Lohmann & Rauscher International GmbH & Co. KG, Rengsdorf, Germany) elastic adhesive bandage was applied from ankle to midthigh. At the first follow-up week, this was exchanged for a T.E.D. stocking (Tyco Healthcare, Gosprot, United Kingdom) for 5 weeks. Participants who underwent surgery followed the same postoperative compression regimen as the EVLA patients.

The groups received identical postprocedural instructions regarding activity, mobilization, and driving. Each group was supplied with the same analgesia (diclofenac, 50 mg, twice daily, regularly; paracetamol 1 g four times daily for breakthrough pain).

Outcomes. Patients were assessed at 1, 6, and 12 weeks and then at 1 and 2 years. Assessors were consultants or research registrars with a special interest in venous disease. Each patient underwent a detailed clinical assessment, followed by a DUS assessment protocol, based on international consensus.[20] The primary outcome for the study was the abolition of SSV reflux. Further outcomes included clinical recurrence, disease severity, reintervention rates, sensory disturbance, patient satisfaction, and QOL.

Sensory disturbance was defined as clinically evident alteration of cutaneous sensation, irrespective of whether there was any effect on QOL or indeed, whether the patient had independently noticed it. This encompassed all kinds of disturbance, including hypoesthesia, anesthesia, hyperesthesia, dysesthesia, and neurogenic pain. Clinical recurrence was defined as the presence of clinically evident varicose veins of $\geq$3 mm in diameter that were not present at 1 and 6 weeks. For the purposes of the study, clinical recurrence was reported irrespective of the presence or absence of associated symptoms. In the presence of clinical recurrence, the DUS pattern of reflux was studied. The disease severity in each participant was reviewed using the Venous Clinical Severity Score (VCSS), which has previously been shown to be a valid measure of disease severity and is designed to be responsive to changes in status over time.[21,22] Participants independently completed QOL and satisfaction assessment questionnaires. Disease-specific QOL was assessed using the Aberdeen Varicose Vein Questionnaire (AVVQ), a reliable, responsive, and valid method of assessing the QOL effect of venous disease directly on patients.[7,23,24] Generic QOL effect was assessed individually by domains using the SF-36 UK version 1 and index QOL using the EuroQol 5-Domain instrument (EQ-5D, Rotterdam, Netherlands). Both are popular validated instruments in the assessment of generic QOL across a range of disease states, including venous insufficiency. Finally satisfaction with the cosmetic result and with the treatment overall was indicated by placing a cross on an unmarked 10-cm visual analog scale (0, completely unsatisfied; 10, completely satisfied).

Sample size. A power calculation performed before recruitment was based on the presence of persistent SSV reflux on DUS after surgery with post-EVLA. This was based on a local unpublished pilot study. Each group

Table I. Baseline parameters

Variables[a]	*Surgery*	*EVLA*	P *value*[b]
Age, years[c]	7.5 (12.9)	47.8 (12.2)	.890[d]
Women	40 (76)	34 (64)	.204
BMI,[c] kg/m^2	24.9 (5.3)	25.9 (3.2)	.376[d]
CEAP			.444
C2	46 (87)	40 (75)	
C3	1 (2)	2 (4)	
C4	4 (8)	9 (17.0)	
C5	2 (4)	2 (4)	
VCSS	3 (2-4)	3 (2-4.5)	.299[e]
AVVQ[c]	14.53 (6.02)	13.22 (5.97)	.215[d]
EQ-5D	0.877 (0.796-1.0)	0.808 (0.726-1.0)	.249[e]
SF-36 Domains			
Physical Function	90 (70-100)	90 (75-100)	.891[e]
Physical Role	100 (50-100)	100 (50-100)	.969[e]
Bodily Pain	74 (42-88)	74 (51-84)	.826[e]
General Health	77 (52-87)	77 (53.2-84.2)	.606[e]
Vitality	65 (50-80)	55 (46.2-75)	.072[e]
Social Function	100 (75-100)	100 (75-100)	.420[e]
Emotional Role	100	100	.820[e]
Mental Health	80 (72-88)	78 (60-87)	.167[e]

AVVQ, Aberdeen Varicose Vein Questionnaire; *BMI,* body mass index; *EQ-5D,* EuroQol 5D; *EVLA,* endovenous laser ablation; *VCSS,* Venous Clinical Severity Score.
[a]Values for categoric data are expressed as number (%), and values for continuous data are mean (interquartile range [IQR]) unless otherwise specified.
[b]By χ^2 test unless otherwise specified.
[c]Data are mean (standard deviation).
[d]By Student *t*-test.
[e]By Mann-Whitney *U* test.

required 48 limbs to detect a statistically significant difference between the two groups at 6 weeks with an $\alpha = .05$ (5% significance) to a power of 80%. Each group required 53 patients to allow for 10% loss to follow-up. Outcomes at 2 years and the focus of this report are discussed below.[19]

Analysis. Data were recorded into a designated Access database (Microsoft Corp, Redmond, Wash) on a secure server. Data were tested for normality, and normally distributed data are presented as mean (standard deviation). Hypothesis testing was performed by paired and unpaired *t*-tests. Non-normally distributed data are presented as median (interquartile range [IQR]) values and were analyzed using the Mann-Whitney *U* test for unrelated samples and the Wilcoxon signed rank test for paired samples. Multiple related sample analysis was performed using the Friedman test across the study interval. Categoric data were analyzed using the χ^2 test or the Fisher exact test when necessary. Time-to-event analysis was also performed at 1 and 2 years by using a Kaplan-Meier survival plot. Significance levels were calculated using a log-rank analysis. All analysis was performed according to the principle of intention to treat.

RESULTS

Of the initial 767 screened patients, 106 were successfully recruited and enrolled in the study at baseline. These were randomized equally, and both groups were comparable at baseline[19] (Table I). At 1 year, there were 99 limbs followed up with 88 attending at 2 years. Each group contained 44 patients achieving an 83% follow-up rate; the Consolidated Standards of Reporting Trials[25] diagram depicts the participant follow-up (Fig 1).

Primary outcome. The proportion of patients with no axial reflux remained significantly higher in the EVLA group from 6 weeks until 2 years ($P = .047$; Fig 2). The number without reflux at 6 weeks was 51 (96.2%) in the EVLA group and 38 (71.7%) in the surgery group ($P < .001$), at 1 year was 45 (88.2%) vs 38 (71.7%), and at 2 years was 36 (81.2%) vs 29 (65.9%; $P = .002$).

Secondary outcomes. The number of patients with clinical recurrence over the 2-year period was similar ($P = .952$; Fig 3). Overall, seven patients (16%) after EVLA and 10 (23%) after surgery demonstrated some evidence of clinical recurrence by 2 years. There was no difference in secondary procedures between the groups by 2 years, with four (9%) in both groups ($P = .670$). One patient in the EVLA group had further EVLA, and three had ultrasound-guided foam sclerotherapy, compared with three undergoing EVLA and one ultrasound-guided perforator ligation in the surgery group. All were performed under local anesthetic. Both groups saw the same improvement in the VCSS scores (Table II), which were maintained until 2 years, with no difference between the groups ($P = .348$).

The significant proportion of patients with postintervention sensory disturbance seen in the surgery group at 6 weeks continued to show spontaneous resolution from 14 individuals (26.4%) to five (9.8%) at 1 year and three (6.8%) at 2 years. No significant difference was seen in the EVLA group over time ($P = 1.000$).

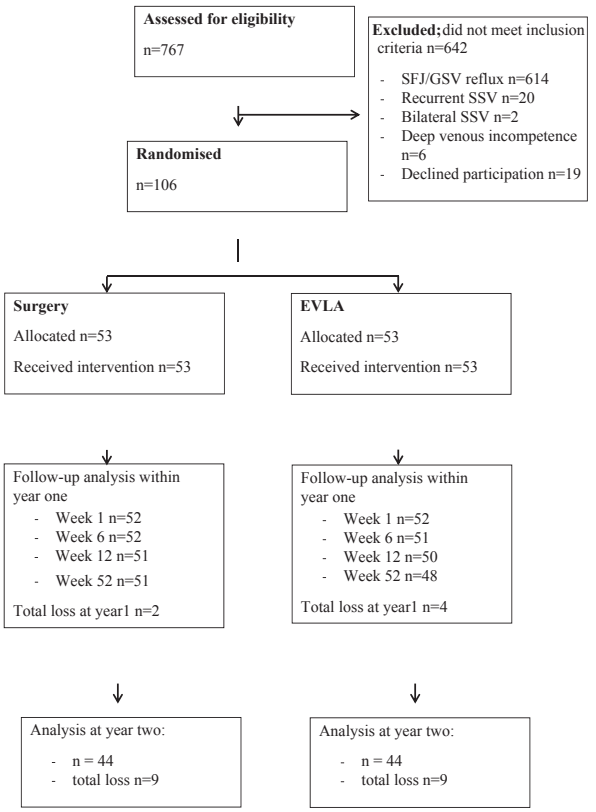


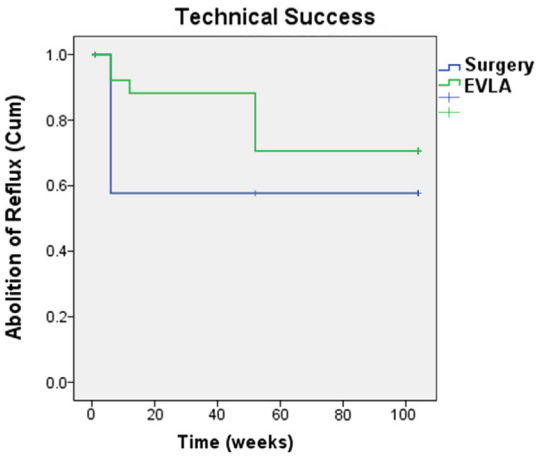
Fig 1. Consolidated Standards of Reporting Trials (CONSORT) diagram. *EVLA,* Endovenous laser ablation; *GSV,* great saphenous vein; *SFJ,* saphenofemoral junction; *SSV,* short saphenous vein.

Both groups saw a large decrease in AVVQ scores (Table III) after treatment, and these were maintained until 2 years. No differences were seen between the groups in this or in the SF-36 or EQ-5D scores ($P > .050$). Participants remained highly satisfied in both groups at 2 years, with both groups scoring a median of 9.0 (IQR, 8.0-10.0) for cosmetic satisfaction and 10 (IQR, 9.0-10.0) for the treatment received. There was no difference between the groups at 2 years ($P = .462$).

DISCUSSION

The short-term benefits of EVLA over open surgery are well documented in the treatment of the great saphenous axis.[9,26,27] Pain and disability are less, allowing a more rapid recovery. Similar findings were observed in the small saphenous axis in this small Randomized Clinical Trial.[19] A further benefit seen in this study was that EVLA was more successful in the abolition of axial reflux in the SSV, but whether this finding would be robust over time or would translate into lower recurrence rates was not known.

The DUS findings at 2 years demonstrated the continued superiority of EVLA compared with surgery in the abolition of reflux. These results are comparable to previously published series featuring ablation of the SSV.[28-31] Those patients undergoing SPJ ligation did



Abreviated Kaplan-Meier Technical Success Data for Surgery

Time	Abolition of Reflux (Cumulative)	No. Cases at Risk	Loss to Follow-up	Standard Error
6	50	52	0	0.069
12	47	51	1	.
52	45	51	0	.
104	36	44	7	.

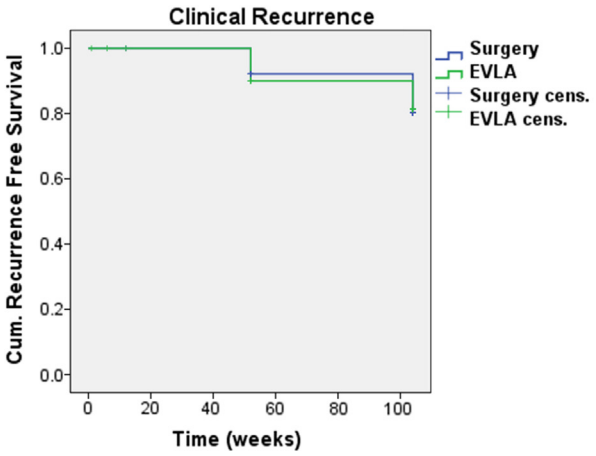
Abreviated Kaplan-Meier Technical Success Data for EVLA

Time	Abolition of Reflux (Cumulative)	No. Cases at Risk	Loss to Follow-up	Standard Error
6	38	52	0	0.038
12	38	51	1	0.045
52	38	51	0	0.064
104	29	44	7	

Fig 2. Kaplan-Meier plot shows postintervention technical success over the study period. *EVLA,* Endovenous laser ablation.

develop incompetent neovascularization at the junction, which then feeds the axial remnant SSV; hence, the DUS assessment demonstrating reflux in the remnant vein due to the refluxing neovascularity. In comparison, the EVLA cohort demonstrated recanalization alone. The sample size was not large enough here to detect a true statistical difference, but these patterns of recurrent reflux appear to be congruent with the present theories in the literature.[32,33]

Both treatments have proved to be equally clinically effective over a 2-year period. Despite the difference in the apparent technical efficacy of the two techniques, no differences were observed in the number of clinical recurrences or the number of secondary procedures between the groups by 2 years. Both groups saw equivalent improvement in disease severity and QOL, and this naturally led to very high patient satisfaction scores. Whether these appearances on DUS imaging will lead to a clinical difference in the future is impossible to say, and longer-term follow-up is required.



Abreviated Kaplan-Meier Technical Success Data for surgery

Time	Recurrence (Cumulative)	No. Cases at Risk	Loss to Follow-up	Standard Error
6	0	52	0	0.038
12	0	51	1	0.059
52	5	51	0	.
104	10	44	7	.

Abreviated Kaplan-Meier Technical Success Data for EVLA

Time	Recurrence (Cumulative)	No. Cases at Risk	Loss to Follow-up	Standard Error
6	0	52	0	0.042
12	0	51	1	0.056
52	2	51	0	.
104	7	44	7	.

Fig 3. Kaplan-Meier plot shows cumulative recurrence-free survival over the study period. *EVLA*, Endovenous laser ablation.

Table II. Venous Clinical Severity Score (*VCSS*)

Assessment	*Surgery, median (IQR)*	*EVLA, median (IQR)*	P *value*[a]
Baseline	3 (2-4)	3 (2-4.5)	.299
Week 52	0 (0-1)	0 (0-1)	.413
Week 104	0 (0-1)	0 (0-1)	.459

EVLA, Endovenous laser ablation; *IQR*, interquartile range.
[a]By Mann-Whitney *U* test.

The resolution of sensory disturbance rates from 1 year to 2 years is an interesting finding. This suggests that nerve injury during treatment continues to spontaneously improve over time, even after 1 year. This finding is difficult to explain but may result from the gradual improvement over time in fascial inflammation and scarring or indeed healing of the nerve structure. These rates demonstrate that significant ongoing sensory disturbance is low after surgery and EVLA, despite the proximity of the sural nerve to the SPJ, and these figures appear very similar to those seen after treatment of the GSV.[27]

Table III. Aberdeen Varicose Vein Questionnaire (*AVVQ*) scores over the 2-year follow-up

AVVQ	*Surgery mean (SD)*	*EVLA mean (SD)*	P *value*[a]
Baseline	14.5 (6.0)	13.2 (6.0)	.215
Week 6	8.8 (5.5)	8.8 (7.2)	.996
Week 12	5.2 (5.3)	5.1 (5.0)	.787
Week 52	5.3 (5.7)	4.2 (6.0)	.327
Week 104	4.2 (4.4)	5.3 (6.3)	.344
Week 52 to 104 *P* value	.614	.671	

EVLA, Endovenous laser ablation; *SD*, standard deviation.
[a]Student *t*-test.

The strength of this study is that it is the only randomized clinical trial to compare minimally invasive venous ablation with conventional surgery in the small saphenous axis. Patients with isolated, unilateral disease and no previous treatment were selected to minimize unwanted variability in disease or outcome and this enabled a clear picture of the relative strengths and weaknesses of these treatments. The open surgical arm was designed to represent current conventional practice at the time of the study, and therefore, the procedures were performed under general anesthesia and did not use innovations such as tumescent anesthesia and cryostripping. Indeed, some have argued that stripping of the SSV is a radical procedure and only perform open ligation in their practice.

Blinding was not possible in this study due to the nature of the interventions, but in an effort to minimize possible bias, assessor-reported outcomes were produced by protocol-based assessments or objective and validated scoring systems. Patient-reported outcomes were also included and were completed independently before the assessments to further reduce bias.

Another limitation is the sample size. Although the trial was powered to detect differences in technical efficacy, these numbers may miss intergroup differences in generic QOL analysis due to the large amount of unsystematic variation seen in these outcomes; however, obtaining meaningful numbers of such a small, but important subset of patients with SVI was challenging, and a large multicenter study would be required to do this within a reasonable timeframe. The popularity of venous ablation is such that large studies comparing techniques with conventional surgery may be a thing of the past, because the equipoise of many physicians and patients has been compromised.

CONCLUSIONS

This randomized clinical trial has shown that patients with symptomatic incompetence of the SSV report less pain, less sensory disturbance, and recover faster after treatment with EVLA and phlebectomy compared with open surgical ligation, SSV stripping, and phlebectomy. Both treatments are highly effective until at least 2 years, improving both clinical status and QOL. Although EVLA results in lower rates of residual reflux, recurrence and reintervention are the same up to 2 years, as is patient satisfaction.

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AUTHOR CONTRIBUTIONS

Conception and design: DC, NS, IC
Analysis and interpretation: SN, JE, PS, NS, TW
Data collection: SN JE, GS, NS, TW, PS
Writing the article: SN, JE, DC, PS
Critical revision of the article: SN, DC, GS
Final approval of the article: IC, DC
Statistical analysis: SN, DC, JE
Obtained funding: NS,
Overall responsibility: IC

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