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