

# Endovenous laser ablation: Does standard above-knee great saphenous vein ablation provide optimum results in patients with both above- and below-knee reflux? A randomized controlled trial

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**Background:** Following above-knee (AK) great saphenous vein (GSV) endovenous laser ablation (EVLA) 40% to 50% patients have residual varicosities. This randomized controlled trial (RCT) assesses whether more extensive GSV ablation enhances their resolution and influences symptom improvement.

**Method:** Sixty-eight limbs (65 patients) with varicosities and above and below-knee GSV reflux were randomized to Group A: AK-EVLA (n = 23); Group B: EVLA mid-calf to groin (n = 23); and Group C: AK-EVLA, concomitant below-knee GSV foam sclerotherapy (n = 22). Primary outcomes were residual varicosities requiring sclerotherapy (6 weeks), improvement in Aberdeen varicose vein severity scores (AVVSS, 12 weeks), patient satisfaction, and complication rates.

**Results:** EVLA ablated the treated GSV in all limbs. Sclerotherapy requirements were Group A: 14/23 (61%); Group B: 4/23 (17%); and Group C: 8/22 (36%);  $\chi^2 = 9.3$  (2 df)  $P = .01$  with  $P_{A-B} = 0.006$ ;  $P_{B-C} = 0.19$ ;  $P_{A-C} = 0.14$ . AVVSS scores improved in all groups as follows: A: 14.8 (9.3-22.6) to 6.4 (3.2-9.1), ( $P < .001$ ); B: 15.8 (10.2-24.5) to 2.5 (1.1-3.7), ( $P < .001$ ); and C: 15.1 (9.0-23.1) to 4.1 (2.3-6.8), ( $P < .001$ ) and  $P_{A-B} = 0.011$ ,  $P_{A-C} = 0.042$ . Patient satisfaction was highest in Group B. BK-EVLA was not associated with saphenous nerve injury.

**Conclusions:** Extended EVLA is safe, increases spontaneous resolution of varicosities, and has a greater impact on symptom reduction. Similar benefits occurred after concomitant BK-GSV foam sclerotherapy. (J Vasc Surg 2008;48:173-8.)

Minimally invasive ablation techniques are increasingly used to treat varicose veins, which are most commonly (70%) the result of sapheno-femoral and great saphenous vein (GSV) incompetence.<sup>1</sup> Endovenous laser ablation (EVLA) relies on thermal injury to promote occlusion of the vein and is successful in 88% to 100%<sup>2</sup> of limbs. In the original description of the technique, the GSV was ablated from the knee to the groin<sup>3</sup> without treatment of the below-knee great saphenous vein (BK-GSV) regardless of its reflux status. Although concomitant phlebectomy is advised by some authors,<sup>4</sup> others favor deferred treatment of residual varicosities (phlebectomy<sup>5</sup> or foam sclerotherapy) once they have had the opportunity to shrink following abolition of superficial venous reflux. In a previous study, we found that 44% patients required treatment for residual varicosities, and this seemed to be more likely when there was persistent reflux in the BK-GSV.<sup>6</sup> This randomized controlled trial compares the efficacy of two different techniques for correcting both above and below-knee GSV reflux against the standard above-knee EVLA technique. The hypothesis was that ablation of a longer segment of incompetent GSV would reduce the requirement for treat-

ing residual varicosities (foam sclerotherapy) and provide additional symptom improvement.

## METHODS

The study was approved by our institutional ethics committee and was registered as a Current Controlled Trial (ISRCTN 31316759). It was conducted between October 2005 and June 2007 in a single center. Patients with below-knee varicosities associated with both above and below-knee GSV reflux were invited to participate provided that they wished to undergo EVLA and were suitable for the technique.<sup>6</sup> Patients were excluded from the study if they had recurrent varicose veins, concomitant reflux in another axial vein or perforator incompetence, allergy to sodium tetradecyl sulphate (STD), BK-GSV tortuosity precluding EVLA, a competent BK-GSV, age <18 years, and did not give informed consent. Participants were recruited from 114 consecutive patients with varicose veins due to isolated sapheno-femoral and GSV reflux. They were randomized to one of three treatment groups (Fig).

## Treatment

Group A underwent standard above-knee GSV (AK-GSV) EVLA and in group B, EVLA was used to ablate the incompetent GSV from midcalf to groin. Patients in group C received above-knee EVLA with concomitant catheter-delivered foam sclerotherapy for their BK-GSV reflux. No patients were given synchronous sclerotherapy to their superficial varicosities at the time of EVLA. As EVLA was

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Competition of interest: none.

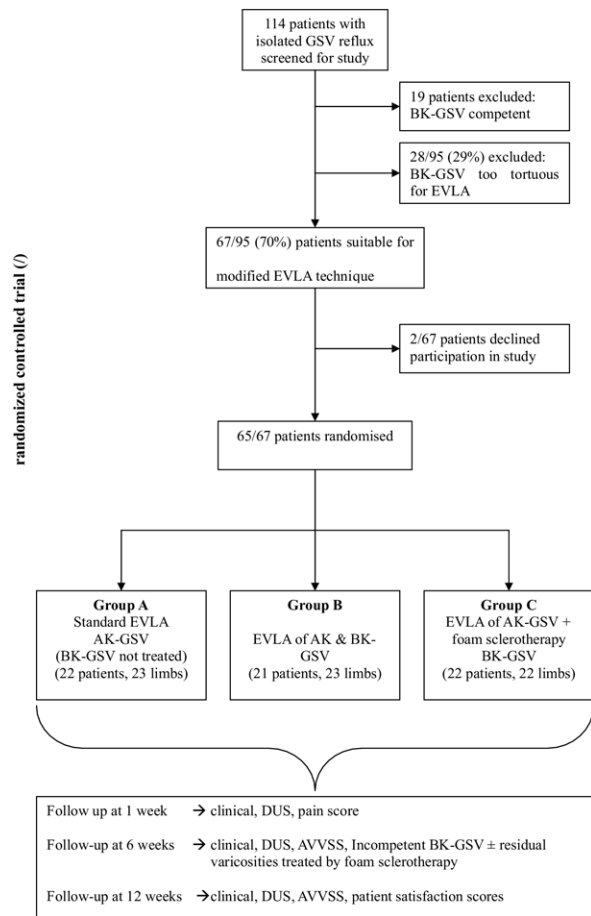
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**Fig.** Details of randomization and randomized controlled trial (RCT) protocol.

performed using local anesthesia with immediate mobilization, DVT prophylaxis was not used.

**Group A: standard above-knee EVLA.** The GSV was cannulated at or just above (<5 cm) the knee joint and a 5F (1.67 mm) endovenous catheter (ELVeS Plus Katheter; Biolitec Group, Bonn, Germany) was passed over a guidewire. The catheter tip was positioned 1 cm distal to the sapheno-femoral junction (SFJ). Following infiltration of tumescent anesthesia (0.1% lignocaine) a 220  $\mu$ m bare tipped laser fiber (ELVeS Plus Biolitec) was used to deliver 810 nm diode pulsed laser energy (12 W power) at an energy density of 60 to 70 J/cm. The efficacy of this protocol has been documented previously.<sup>7</sup> A compression bandage was applied from foot to groin with a length of foam sponge placed over the treated vein to augment compression over the GSV. The bandage remained in situ for 1 week and a compression stocking (23 to 32 mm Hg) was worn for a further week.

**Group B: above and below-knee EVLA.** The technique was identical to that for group A except that the GSV was cannulated in the calf, either below the lowest incompetent tributary or 70 cm from the sapheno-femoral junc-

tion if GSV reflux persisted beyond this point (catheter length 70 cm). Laser energy was again delivered at 60 to 70 J/cm.

**Group C: AK-GSV EVLA and concomitant BK-GSV foam sclerotherapy.** The GSV was cannulated as in group B and positioned 1 cm distal to the SFJ. Tumescent anesthesia was infiltrated only from the knee upwards and EVLA performed from groin to knee. The laser fiber was then removed and the catheter gradually pulled back towards the cannulation site in the calf whilst administering 2.5 to 3 ml of 1% STD foam (Fibroven, STD Pharmaceutical Products Ltd, Hereford, UK) to the below-knee GSV. The foam was prepared according to the Tessari method.<sup>7</sup> A compression bandage was again applied. Group C was included in the study to assess the combined effect of AK-EVLA and BK-GSV sclerotherapy as this technique would be appropriate in patients in whom BK-GSV tortuosity precludes laser ablation. This technique might also provide optimum treatment if group B patients report excessive rates of saphenous nerve injury.

#### Data collection and follow-up

Pretreatment clinical severity was assessed using CEAP grading<sup>8</sup> and Aberdeen varicose vein severity scores (AVVSS).<sup>9</sup> The GSV diameters in mid thigh and mid calf were recorded whilst standing as were the length of vein treated, laser energy details, and the time taken to complete the procedure (skin preparation to off-table time). Following treatment, patients completed a visual analogue scale (1-100) to assess pain, daily for 1 week and were reviewed at 1, 6, and 12 weeks. At each visit, the study limbs were assessed clinically and by duplex ultrasound (DUS) to ascertain the reflux status (significant reflux = >1 s measured by spectral trace analysis) of the SFJ and both the AK- and BK-GSV. Absence of flow in a noncompressible vein represented successful ablation. GSV diameters were recorded at each visit.

At 6 weeks, patients were assessed for the presence of residual varicose veins (visible, palpable superficial varicosities  $\geq 3$  mm diameter) and varicosities associated with BK-GSV reflux were treated by foam sclerotherapy of this vein. For isolated varicosities without axial vein reflux, foam sclerotherapy was administered to the varicosities themselves. Sclerotherapy was not performed for BK-GSV reflux (ultrasound) in the absence of visible varicosities. The AVVSS was repeated at the 6-week visit.

At 12 weeks, limbs were again assessed for the presence of residual varicosities. Ablation or patency of the treated axial vein was confirmed by DUS and patient satisfaction with treatment determined using a visual analogue scale (1-100). A log of complications was maintained throughout the study, and all data were collected and recorded prospectively. Patients were specifically questioned about neurological symptoms which were objectively assessed if present.

**Table I.** Patient demography and disease severity scores (C of CEAP)

	Group A	Group B	Group C
Age (range) y	40 (30-69)	42 (27-70)	46 (31-68)
Male	9	8	10
Female	13	13	12
Total number of limbs	23 (22 patients)	23 (21 patients)	22 (22 patients)
C2	16	15	14
C3	3	3	3
C4	3	4	4
C5	1	0	1
C6	0	1	0

CEAP, Clinical, etiology, anatomy, pathology.

**Table II.** Treatment details

Groups	A	B	C
Length of vein treated by EVLA (cm)	31 (29-34)	52 (49-60)	30 (28-33)
Length of vein treated by catheter guided foam sclerotherapy at primary treatment	Nil	Nil	19 (17-22)
Laser energy density (J/cm)	64 (60-71)	61 (59-70)	62 (58-71)
Duration of the procedure (min)	39 (32-47)	45 (40-56)	44 (40-56)

EVLA, Endovenous laser ablation.

### Study end points

The primary end-points were the presence of residual varicosities requiring sclerotherapy and an improvement in the Aberdeen varicose vein symptom severity score (AV-VSS), a disease specific quality of life measure. The secondary end-points were pain scores, patient satisfaction, and complication rates.

### Statistical analysis

The sclerotherapy requirement for each group was compared using a  $\chi^2$  test. AVVSS improvement within a group was tested using the Wilcoxon test and compared between groups by a Mann-Whitney U test. Pain scores and patient satisfaction were compared using a Student *t* test (unpaired) and a  $\chi^2$  test employed to compare complication rates between the groups. A *P* value of  $< .05$  was considered significant. Data are presented as medians ( $\pm$ interquartile range) unless stated otherwise. All analyses were performed with the statistical package SPSS for Windows (SPSS 14, Chicago, Ill).

## RESULTS

Demographic details are given in Table I and treatment details in Table II. At both 1 and 6 weeks, DUS showed no retrograde SFJ flow and no groin tributary reflux in any patient. The AK-GSV was ablated (noncompressible, no flow) in all limbs of all three groups. In group A, the BK-GSV remained patent in all instances and 15/23 (65%)

showed persistent reflux ( $>1s$ ) at 1 week. Examination at 6 weeks confirmed that reflux ( $>1s$ ) was still present in 12/23 (52%) limbs. For these, catheter-directed foam sclerotherapy was administered to the BK-GSV.

In group B, the BK-GSV was ablated in all cases (23/23) compared with 19/22 (86%) in group C. The three patent BK-GSVs in group C had persistent reflux, and these were retreated (ultrasound guided foam sclerotherapy) at 6 weeks.

At 12 weeks, the SFJ remained competent and the AK-GSV ablated (noncompressible shrunken vein with no flow) in all limbs. Similarly, the BK-GSV remained occluded in all group B and C patients but two limbs in group A showed significant below-knee reflux despite previous foam sclerotherapy. Sequential DUS showed that following laser ablation (AK-GSV in all groups, BK-GSV in group B), there was a progressive, significant, reduction in vein diameter. After BK-GSV sclerotherapy (groups A and C), this had not occurred by 12 weeks. The results are summarized in Tables III and IV.

The overall sclerotherapy requirements (to the BK-GSV or directly into superficial varicosities) by 12 weeks were 61% (14/23) in group A, 17% (4/23) in group B, and 36% (8/22) in group C. These difference were highly significant ( $\chi^2 = 9.39$  [2 *df*]), *P* = .01 for overall data). The difference between groups A and B was also significant (*P* = .006) but not those between B and C (*P* = .19), or A and C (*P* = .14).

Compared with pre-EVLA, there was a significant improvement (*P*  $< .001$ ) in the AVVSS score in all groups at 6 weeks (before sclerotherapy). These results are shown in Table V. The percent improvement in AVVSS at 6 weeks was 55.4%, 84.2%, and 72.8% for groups A, B, and C, respectively, and this was greater in groups B and C compared with group A (*P*<sub>A-B</sub> = 0.011, *P*<sub>A-C</sub> = 0.015). Following foam sclerotherapy at 6 weeks, all groups showed a further improvement in AVVSS at 12 weeks which was greater in group A (Table V).

Median pain scores (out of 100) at 1 week were 32 (12-45), 34 (10-40), and 36 (12-50) in groups A, B, and C, respectively, with no difference between the groups [*P* = .12 (A-B), 0.16 (B-C), 0.11 (A-C)]. Although some tenderness was recorded along the treated GSV in most limbs at 1 week, only two patients in group C reported persistent

**Table III.** Vein diameters (mm) of the GSV (IQR) before and after EVLA: *P* values relate to comparison with previous measurement within the same group (1 week vs pre-EVLA; 6 weeks vs 1 week; 12 weeks vs 6 weeks)

	Group A		Group B		Group C	
	AK-GSV	BK-GSV	AK-GSV	BK-GSV	AK-GSV	BK-GSV
Pre-EVLA	7.9 (5.9-9.2)	5.4(4.8-6.0)	7.8 (6.0-8.9)	5.9 (4.7-6.3)	7.7 (6.1-9.1)	5.5 (4.7-6.1)
At 1 wk	7.4 (5.9-8.9)	5.5 (4.9-6.1)	7.6 (6.0-8.7)	5.7 (4.6-6.2)	7.5 (6.1-9.0)	5.4 (4.5-6.1)
	<i>P</i> = .46	<i>P</i> = .36	<i>P</i> = .38	<i>P</i> = .47	<i>P</i> = .37	<i>P</i> = .32
At 6 wk	5.2 (3.6-6.4)	5.4 (4.8-6.1)	5.2 (3.5-6.4)	4.0 (3.1-4.8)	5.3 (3.6-6.5)	5.4 (4.3-6.0)
	<i>P</i> = .04	<i>P</i> = .32	<i>P</i> = .03	<i>P</i> = .03	<i>P</i> = .02	<i>P</i> = .49
At 12 wk	3.2 (2.1-4.0)	5.3 (4.6-6.0)	3.1 (2.2-3.9)	2.8 (2.1-3.3)	3.2 (2.2-4.1)	5.0 (4.0-5.9)
	<i>P</i> = .03	<i>P</i> = .34	<i>P</i> = .02	<i>P</i> = .01	<i>P</i> = .04	<i>P</i> = .09

EVLA, Endovenous laser ablation; GSV, great saphenous vein; IQR, interquartile range; AK-GSV, above-knee great saphenous vein; BK-GSV, below-knee great saphenous vein.

**Table IV.** Reflux status of vein segments after EVLA (data for 12 weeks represent the combined effect of EVLA and delayed foam sclerotherapy)

	Group A (n = 23)		Group B (n = 23)		Group C (n = 22)	
	AK-GSV	BK-GSV	AK-GSV	BK-GSV	AK-GSV	BK-GSV
At 1 wk						
Ablated/occluded	23 (100%)	0	23 (100%)	23 (100%)	22 (100%)	19 (86%)
Patent, no or flash reflux	0	8 (35%)	0	0	0	0
Patent, reflux >1s	0	15 (65%)	0	0	0	3 (14%)
At 6 wk						
Ablated/occluded	23 (100%)	0	23 (100%)	23 (100%)	22 (100%)	19 (86%)
Patent, no or flash reflux	0	11 (48%)	0	0	0	0
Patent, reflux >1s	0	12 (52%)	0	0	0	3 (14%)
At 12 wk						
Ablated/occluded	23 (100%)	10 (43%)	23 (100%)	23 (100%)	22 (100%)	22 (100%)
Patent, no or flash reflux	0	11 (48%)	0	0	0	0
Patent, reflux >1s	0	2 <sup>a</sup> (9%)	0	0	0	0

EVLA, Endovenous laser ablation; AK-GSV, above-knee great saphenous vein; BK-GSV, below-knee great saphenous vein.

<sup>a</sup>Two limbs in group A required further duplex ultrasound guided foam sclerotherapy at 12 weeks.

**Table V.** Aberdeen varicose veins symptom severity scores (AVVSS) before and after EVLA

	Pre-EVLA	6 wk	12 wk
Group A	14.8 (9.3-22.6)	6.4 (3.2-9.1)	3.2 (0.5-4.9)
		<i>P</i> (pre-6 wk) <.001	<i>P</i> (6-12 wk) =.023
Group A (appearance of veins excluded from score)		5.8 (3.2-8.1)	2.9 (0.4-4.7)
			<i>P</i> (6-12 wk) =.001
Group B	15.8 (10.2-24.5)	2.5 (1.1-3.7)	1.9 (0.5-2.4)
		<i>P</i> (pre-6 wk) <.001	<i>P</i> (6-12 wk) =.073
Group C	15.1 (9.0-23.1)	4.1 (2.3-6.8)	2.4 (0.6-3.9)
		<i>P</i> (pre-6 wk) <.001	<i>P</i> (6-12 wk) =.064

EVLA, Endovenous laser ablation.

pain due to BK-GSV thrombophlebitis for which diclofenac sodium was prescribed.

Skin staining over the BK-GSV was visible at 6 weeks in 2/22 (9%) limbs in group C. No skin staining occurred after BK-GSV EVLA. Of the 26 limbs requiring foam sclerotherapy at 6 weeks (15 BK-GSV; 11 isolated varicosities), four (15%) developed marked tenderness of the treated vein and six (23%) skin staining.

Patient satisfaction rates at 12 weeks were 90% (A), 94% (B), and 90% (C) with no difference between the groups.

Complications other than "phlebitis" were uncommon with one patient in group C reporting transient numbness in the distribution of saphenous nerve. There were no instances of DVT (common or superficial femoral veins, popliteal vein) on the DUS performed at 1 week.

## DISCUSSION

Compared with standard above-knee EVLA, concomitant ablation (laser or sclerotherapy) of an incompetent below-knee GSV results in fewer residual varicosities and

superior symptom relief 6 weeks. These techniques reduced the requirement for delayed foam sclerotherapy. This study also confirms that both below-knee GSV EVLA and foam sclerotherapy are safe. Although randomization of more patients might have resulted in significant differences in symptom improvement (AVVSS) and sclerotherapy requirements between groups B and C, this was considered unnecessary once it became apparent that EVLA of the BK-GSV was not associated with saphenous nerve injury.

Previous experience with EVLA indicates that some 44% of the patients require delayed foam sclerotherapy for residual varicosities following ablation of the above-knee GSV.<sup>6</sup> The greater proportion (61%) of limbs requiring sclerotherapy following standard EVLA in this study is explained by the presence of both above and below-knee GSV reflux in all limbs and mirrors the findings of Monahan<sup>10</sup> who reported a similar rate of residual varicosities following GSV radiofrequency ablation. Clearly, although ablation of the above-knee GSV will abolish SFJ and proximal GSV reflux, it only abolished reflux in the below-knee GSV in half of the limbs. In the presence of persistent reflux varicosities that connect directly to the below-knee GSV will almost certainly remain. Conversely, ablation of both the above and below-knee GSV should disconnect most if not all of the varicosities from the axial vein and thus, ablation of the GSV from midcalf to groin is more likely control the varicose veins. In limbs where this was achieved by EVLA, only 17% required subsequent sclerotherapy.

This study has also shown that concomitant catheter guided below-knee GSV foam sclerotherapy following above-knee laser ablation was also successful in abolishing GSV reflux 19/22 (86%) and reduced the requirement for subsequent sclerotherapy (36%), although this technique was not as effective as full length EVLA. The failure of chemical ablation in three patients in this group might be explained by the use of 1% STD rather than 3% STD. Nevertheless previous reports indicate that GSV ablation with STD foam is unsuccessful in about 10% of patients.<sup>11-14</sup> Although two patients in group C developed symptomatic phlebitis, the combination of sclerotherapy and thermal ablation is otherwise safe and more effective than standard above-knee EVLA alone. In addition to reducing the subsequent requirement for treating residual varicosities, it was also accompanied by a greater improvement in the AVVSS.

The frequency of skin staining following sclerotherapy to either the BK-GSV or to residual varicosities was relatively high. Although this has only been assessed at 12 weeks, and may have subsequently improved, it provides further justification for laser ablation of both the above and below-knee GSV when this is incompetent and technically feasible.

Although about 85% of limbs with primary varicose veins due to SFJ/GSV reflux are suitable for standard above-knee EVLA,<sup>15</sup> only 70% (67/95, Fig) with below-knee GSV reflux were suitable for longer length EVLA from midcalf to groin because of below-knee GSV tortuosity. In these patients, concomitant above-knee EVLA and

below-knee foam sclerotherapy would seem to offer the most effective initial therapy.

Following above-knee EVLA persistent reflux in the below-knee GSV was successfully treated by DUS guided foam sclerotherapy and this explains the greater improvement in AVVSS in group A between 6 and 12 weeks. Although this might be partly explained on the basis that these patients had more residual varicosities that were subsequently ablated by foam sclerotherapy, they also had persisting BK-GSV reflux prior to further treatment. Recalculation of AVVSS for group A at 6 and 12 weeks after excluding the scores representing the extent of the residual varicosities confirms that the improvement during this period remained significant and thus reflects the symptomatic benefit of abolishing BK-GSV reflux.

The impact of persistent below-knee reflux upon symptoms has been described previously<sup>6</sup> and was the rationale for designing this trial. However, we have also shown that foam sclerotherapy directed only at the residual varicosities did not provide additional symptom relief following successful ablation of above-knee EVLA.<sup>16</sup> The findings of these studies suggest that when residual varicosities are associated with below-knee GSV reflux following standard EVLA further treatment should be directed at the below-knee GSV rather than the varicosities themselves. This would suggest that above-knee EVLA combined with multiple phlebectomies may not be as effective as some suggest<sup>4</sup> when below-knee GSV reflux is present. Further, it requires the use of an operating theater, thus reducing the cost-effectiveness of EVLA.

It is also clear that concomitant phlebectomy results in the excision of some varicosities that would have resolved spontaneously following abolition of GSV reflux particularly in group B patients, only 17% of whom required delayed sclerotherapy. Such a policy of delayed intervention for persistent varicose veins is also promoted by Welch.<sup>5</sup>

Although the presence of residual varicosities has been used as one of the end-points of this study, it should be considered that following abolition of below-knee GSV reflux, the residual varicosities are unlikely to be responsible for symptoms. Thus, their further treatment with sclerotherapy is only of cosmetic value. When such intervention is offered the risk of pigmentation, the frequency which has been reported as 0% to 67%<sup>17</sup> must be considered.

A potential drawback to performing EVLA from midcalf to groin is the greater time required for the procedure. This largely relates to the administration of the tumescent anesthesia. Compared with the standard technique treatment times for patients in groups B and C were an average of 5 minutes longer. It might also be considered that the risk of thermal injury to the saphenous nerve might be greater following below-knee EVLA because of the more intimate relationship of the nerve to the vein. We found no evidence to suggest this.

Given that this study supports the concept that varicosities that are directly connected to a refluxing axial vein will improve after ablation of the axial vein, provided that the point of communication is disrupted, is logical to suggest

that an incompetent axial vein should be ablated from a point below the last point of branch reflux. This will usually require cannulation of a segment of competent axial vein that will be of smaller diameter than the incompetent proximal vein. Whilst more experienced clinicians may find this relatively easy, this procedure can be facilitated by cannulating the vein with an 18 G intravenous catheter which is smaller than the 5 G needle supplied with the laser fiber, but will allow insertion of the guidewire. Alternatively, the vein can be hooked to the skin surface through a small stab incision and cannulated under direct vision.

Although patients in group B had a higher satisfaction rate compared with the other two groups, this difference was statistically not significant. Similarly there was no difference in average pain scores during the first week indicating that the three treatment methods are equally acceptable to patients.

In conclusion, longer length laser ablation of the great saphenous vein from midcalf (or the lowest point of reflux) to groin is safe and more effective than standard AK-GSV ablation when treating patients with below-knee varicose veins due to reflux in both the above and below-knee segments of the GSV. Although the follow-up in this study is short and does not provide any new data on the long-term efficacy of EVLA, it seems logical that this technique should be adopted whenever possible. Further, standard EVLA can be combined with catheter guided foam sclerotherapy to the below-knee GSV, and this method would seem to offer the optimum therapy when tortuosity of the below-knee GSV makes it unsuitable for EVLA.

#### AUTHOR CONTRIBUTIONS

Conception and design: NT, MG, AM

Analysis and interpretation: NT, MG,

Data collection: NT, DD, AM, MG

Writing the article: NT

Critical revision of the article: MG, DD, AM

Final approval of the article: NT, DD, AM, MG

Statistical analysis: NT, DD

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