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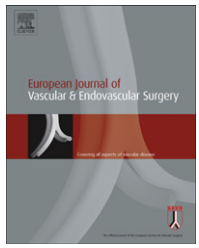

Randomised Controlled Trial Comparing Sapheno-Femoral Ligation and Stripping of the Great Saphenous Vein with Endovenous Laser Ablation (980 nm) Using Local Tumescent Anaesthesia: One Year Results

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KEYWORDS
Great saphenous vein insufficiency;
High ligation and stripping;
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Abstract *Objectives:* Comparison of sapheno-femoral ligation and stripping (SFL/S) versus endovenous laser ablation (EVLA, 980-nm) in the treatment of great saphenous vein (GSV) insufficiency, using local tumescent anaesthesia.
Design: Randomised, single centre trial.
Materials and methods: Patients with GSV incompetence and varicose veins were randomised to either SFL/S or EVLA. At days 1, 2, 3, 7, 10, and 14 post-treatment, patients completed questionnaires on pain and quality of life. Recurrent varicose veins were evaluated by Duplex ultrasound (DUS) performed at 1 and 6 weeks, and 6 and 12 months.
Results: 130 legs in 121 patients were treated by SFL/S ($n = 68$) or EVLA ($n = 62$). Significantly more post-treatment pain was noted after EVLA at days 7, 10 and 14 ($p < 0.01$; $p < 0.01$; $p = 0.01$), more hindrance in mobility at days 7 ($p < 0.01$) and 10 ($p = 0.01$), and in self care ($p = 0.03$) and daily activities ($p = 0.01$) at day 7 compared to SFL/S. DUS at 1-year follow-up showed 9% recurrences (5/56) after EVLA and 10% (5/49) after SFL/S.
Conclusion: Both SFL/S and EVLA, using local tumescent anaesthesia, were well tolerated, with no difference in short-term recurrence rate. In the second week after EVLA, patients experienced significantly more pain resulting in restricted mobility, self care and daily activity compared to SFL/S.
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Introduction

Varicose veins is a common health problem in Western countries, with a prevalence between 10 and 50%.[1–3] Several risk factors for the development of varicose veins have been described, such as age, sex, positive family history, and pregnancy.[4–6] Varicose veins may be asymptomatic but many patients have symptoms such as pain, heaviness, ankle oedema, skin changes, or venous leg ulcers. The most frequent cause of varicose veins is incompetence of the sapheno-femoral junction (SFJ) and the great saphenous vein (GSV).

The surgical method of sapheno-femoral ligation and stripping (SFL/S) is considered the gold standard in the treatment of the insufficient GSV. However, during the last decade several minimal invasive techniques have been developed to treat the incompetent GSV, such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA). These new techniques have become an increasingly popular alternative to surgical treatment.

Several studies of endovenous treatments for varicose veins have demonstrated less postoperative complications and a better quality of life (QoL) score compared conventional surgery by SFL/S, and a high occlusion rate.[7–10] However, up to now only one randomised trial has been published that compared short-term post-treatment outcome after SFL/S and EVLA in the treatment of the incompetent GSV under tumescent anaesthesia.[11]

The aim of this study was to compare post-treatment QoL and pain score, complications, and post-treatment GSV recurrence rate after SFL/S and EVLA performed under local tumescent anaesthesia, for a total follow-up period of 10 years. This article presents our findings covering one year post-treatment follow-up, focussing on QoL and pain.

Materials and methods

This study was designed as a prospective, non blinded, randomised, active controlled trial in an outpatient clinic specialising in venous disease (more than 1200 surgical procedures per year, performed under local tumescent anaesthesia only). The study protocol was approved by the regional ethics committee. The main outcome measure of this trial was recurrent varicose veins seen in a follow-up period of 10 years. Secondary outcome measures included QoL, postoperative pain and complications. This article describes the one year results, focussing on QoL and post-procedural pain.

Patients

All patients included were referred for treatment of primary varicose veins by their general practitioner. At their first visit patients were seen by an experienced phlebologist, who recorded the medical history and performed a physical examination and lower limb duplex ultrasound (DUS) (Biosound Esaote MyLab® 25). DUS of the lower limbs was performed in an upright position, using manual compression of the calf and the Valsalva manoeuvre to visualise flow and reflux. Incompetence of the GSV was defined as reflux > 0.5 s in duration following either calf compression and release or a Valsalva manoeuvre. Patients eligible for surgery, who agreed to have local tumescent anaesthesia, and met with the inclusion criteria, were invited to participate in the study. Inclusion criteria included age > 18 years at randomisation, CEAP (clinical class, etiology, anatomy, pathophysiology) classification $\geq$ C2,[12] GSV and sapheno-femoral junction (SFJ) incompetence defined as reflux > 0.5 s seen on DUS imaging with an intrafascial length of at least 15 cm measured from the SFJ downwards, and GSV diameter between 0.3 and 1.5 cm. Exclusion criteria included previous surgical treatment of the GSV, intrafascial GSV reflux length ≤ 15 cm measured from the SFJ downwards, GSV diameter ≤ 0.3 or ≥ 1.5 cm, pregnancy, immobility, intolerance of lidocaine, active superficial phlebitis, previous or active deep venous thrombosis, deep venous insufficiency. After written informed consent was obtained and patients agreed to inclusion in a post-treatment follow-up study, computer randomisation (1:1) was performed per patient for either SFL/S or EVLA. All data collected were to be evaluated in accordance with the Declaration of Helsinki. Patients with bilateral GSV incompetence were randomised only once.

Methods

During the patients' initial visit, information on medical history was collected, followed by physical examination, DUS, and documentation of the CEAP classification. After randomisation, the presence and severity of complaints caused by chronic venous disease were recorded by using the questionnaires. At their second visit, patients underwent treatment and were then given questionnaires. Pain score was measured using a visual analogue scale ranging from 0 (no pain) to 10 (most severe pain).[13,14] Quality of life was measured using the EuroQol-5D questionnaire that is assigned to 5 dimensions: mobility, self care, daily activities, pain and discomfort, and anxiety.[15] The response to each question was rated on a scale from 1 to 3, in which 1 represented no difference and 3 represented severe worsening in comparison with the pre-treatment situation. Treatment failure and post-treatment complications were documented. Complications included prolonged bleeding, wound infection, skin burns, paraesthesia, thrombus at SFJ, and deep vein thrombosis.[16,17]

Follow-up visits were scheduled 1 and 6 weeks, and 6 and 12 months post-treatment. During all follow-up visits, physical examination and DUS were performed to assess recurrence of varicose veins. CEAP classification was documented at one year follow-up. After both treatments, clinical recurrence of varicose veins was defined as visible or palpable varicosities in the area of the treated GSV, classified as CEAP $\geq$ C2. DUS was performed with the patient in the upright position, using manual compression of the calf and the Valsalva manoeuvre to detect flow and reflux. After SFL/S, a recurrent varicose vein on DUS was defined as a tortuous vein in the GSV area with a diameter ≥ 3 mm, originating in the groin and connected with the femoral vein, and showing reflux > 0.5 s. A new refluxing vein < 3 mm and clinically visible was also considered as a recurrence.[18,19] After EVLA, a recurrent varicose vein on DUS was defined as the ability to compress the GSV, or as reflux > 0.5 s in a vein originating in the groin and connected with the femoral vein.[20]

Procedures

Treatments were performed by surgeons experienced in both procedures (>250 procedures/year). Treatment procedures were scheduled to last between 45 and 60 min. DUS was performed in an upright position and the GSV was marked. The diameter of the GSV was documented. A single daily prophylactic dose of low-molecular weight heparin for 1 week was only given to high-risk patients, such as patients with inherited coagulation disorders and patients with a medical history of deep vein thrombosis.

Sapheno-femoral ligation and stripping

Perivenous tumescent anaesthesia (lidocaine 0.1% with 1:1 000 000 adrenalin) was administered by infiltrating 300–400 ml along the length of the GSV (Nouvag Dispenser DP20) starting at the groin. After a groin incision, high ligation of the GSV (0.5 cm distal of the sapheno-femoral junction) and ligation of all tributaries were performed, followed by insertion of a Pin stripper. Access to the GSV was achieved through a small incision just below or above the knee. Inversion stripping was followed by closure of the groin and the distal wound.

Endovenous laser ablation

After the patient was positioned on the operating table DUS-guided percutaneous access to the GSV was obtained and followed by positioning of the laser fibre tip 2 cm below the SFJ. Perivenous tumescent anaesthesia (lidocaine 0.1% with 1:1 000 000 adrenalin; 300–400 ml) was administered under ultrasonographic guidance (Nouvag Dispenser DP20). Manual compression was applied over the GSV while the 980-nm diode laser (Biolitec) gave 12 W continuous laser energy. The proximal 10 cm of the incompetent GSV was treated with an energy dose of 100 J/cm, followed by a targeted energy dose that was determined by the diameter of the GSV (0.3–0.4 cm = 50 J/cm, 0.4–0.5 cm = 60 J/cm, 0.5–0.6 cm = 70 J/cm, >0.6 cm = 80 J/cm). Peroperative data such as diameter of GSV, length of the treated GSV, and total amount of energy delivered was recorded. Directly after SFL/S and EVLA treatment, sclerotherapy (Aethoxysclerol 0.5–3.0%, Kreussler) of residual superficial varicose veins was performed by a phlebologist. Short-stretch bandages (Panelast®, Lohman–Rauscher) were applied on the whole leg for one week. In the second week patients were advised to apply a foam bandage (Rosidal®, Lohman–Rauscher) during daytime. Patients were asked to complete post-treatment questionnaires focussing on QoL, pain and patient satisfaction. For the management of post-treatment pain, patients were advised to take non-steroid anti-inflammatory drugs (NSAID) after EVLA, or paracetamol after SFL/S. The SFL/S group was advised to avoid long and heavy exercise the first day after treatment.

Sample size and statistical methods

Sample size calculations were based on detecting a 10 percent difference in recurrent varicose veins on duplex imaging between the treatment groups. α (type I error) = 0.05 and β (type II error) = 0.20, 137 patients were required in each group.

Analyses were performed using SPSS. Nominal variables were tested by the χ^2 test. For group comparisons of the ordinal variables the Mann–Whitney *U* test or the Kruskall–Wallis test was used. Continuous variables were compared using the *T*-test or ANOVA. For comparison of two ordinal variables the test of Wilcoxon was used. A $p < 0.05$ was considered significant. The study design included performing a yearly interim analysis. The one year interim analysis focussed on post-treatment pain and QoL after SFL/S and EVLA. Considering the measured VAS results of pain seen at day 7 (SD1 = 1.9, $n1 = 68$ and SD2 = 2.7, $n2 = 62$, and delta = 2) a power of >99% was calculated.

Results

Between June 2007 and December 2008 312 patients (333 legs) were invited to participate in the study. One hundred and thirty legs in 122 patients with GSV insufficiency were randomised to SFL/S ($n = 68$) or EVLA ($n = 62$). Two patients were lost to follow-up after 6 weeks (Fig. 1). The groups were homogenous for demographic characteristics, summarised in Table 1, also showing CEAP classification at initial visit, EVLA energy applied, and complaints of chronic venous disease at randomisation. No difference between the two treatments was found in pain experience during the administration of local tumescent anaesthesia. During treatment, patients in the SFL/S group experienced significantly more pain (VAS mean of 3.39 (SD 2.57)) compared to the EVLA group (VAS mean 2.21 (SD 2.40; $p = 0.02$)). All patients were mobilised immediately and were discharged after 1–2 h. During the first post-treatment day, patients treated with SFL/S experienced significantly more hindrance in daily activities ($p = 0.01$). However, the pain score at day 7 ($p < 0.01$), day 10 ($p < 0.01$) and day 14 ($p = 0.01$) was significantly higher after EVLA (Table 2). Also, patients treated with EVLA were significantly less mobile at day 7 ($p < 0.01$) and day 10 ($p = 0.01$), and they experienced significantly more hindrance in their daily activity ($p = 0.01$) and in self care at day 7 ($p = 0.03$).

In both treatment groups, patients resumed daily activities after 3 days (SFL/S mean 3.2, SD 4.0; EVLA mean 3.2, SD 4.3), returned to work after 4 days (SFL/S mean 4.2, SD 3.7; EVLA mean 4.4, SD 5.4), and restarted sporting activities after 10 days (SFL/S mean 10.6, SD 7.0; EVLA mean 10.5, SD 7.1) (Table 2).

Overall, patient satisfaction was good. 79% (53/67) of the patients in the SFL/S group and 77% (47/61) patients in the EVLA group replied that they were willing to undergo the same treatment again. 88% (59/67) and 84% (51/61) in the SFL/S and EVLA group respectively, would recommend the treatment to a friend or relative. All treatments were performed successfully. No major complication such as wound infection and deep vein thrombosis was encountered. Postoperative bleeding was recorded in only two patients (3%) after SFL/S, and this was effectively treated with a pressure bandage. A thrombus at the SFJ was seen on DUS in 3 patients (5%) one week after EVLA. In all cases the thrombus dissolved without treatment and could not be detected on DUS at 6 weeks follow-up. Self-limiting paraesthesia was seen in one patient (1%) after SFL/S and in two patients (3%) after EVLA. One year after SFL/S a persistent neurosensory deficit,

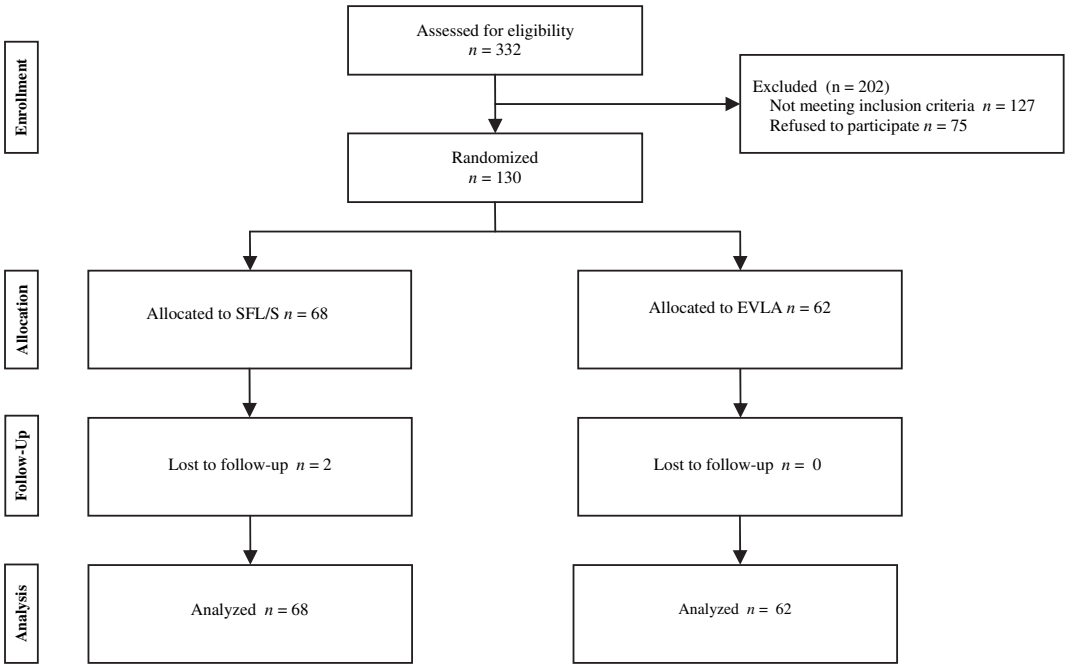

Figure 1 CONSORT diagram showing trial recruitment, randomisation and treatment allocation, in terms of legs. SFL/S: sapheno-femoral ligation and stripping. EVLA: endovenous laser ablation. Six weeks post-treatment two patients in the SFL/S group were lost to follow-up, but as they complete their postoperative questionnaires, these could be analyzed.

Table 1 Patient characteristics of study population, complaints and CEAP classification.

Variable	SFL/S*	EVLA*	χ^2 test
	$n = 68$	$n = 62$	p-value
Male/female (n)	15/53	16/46	0.62
Left/Right leg (n)	27/41	27/35	0.66
Age, mean (SD)	50 (10.5)	49 (11.0)	0.68[a]
BMI*, mean (SD)	24.5 (3.7)	25 (3.3)	0.57[a]
Diameter of SFJ*, cm mean (SD)	0.92 (0.27)	0.88 (0.22)	0.43[a]
Diameter GSV* at knee level, cm mean (SD)	0.64 (0.14)	0.64 (0.16)	0.90[a]
Length of treated GSV, cm mean (SD)		40.8 (7.45)	
Total joules, mean (SD)		2605 (428.4)	
Joules/cm, mean (SD)		64.5 (6.8)	
Pre-operative complaints			
Tired legs, n (%)	35 (52)	31 (50)	0.87
Oedema, n (%)	32 (47)	21 (34)	0.13
Itching, n (%)	26 (38)	20 (32)	0.48
Cosmetic n (%)	13 (19)	13 (20)	0.79
Pain, n (%)	13 (19)	9 (15)	0.49
Restless legs n (%)	6 (9)	11 (18)	0.13
Calf cramps, n (%)	8 (12)	8 (13)	0.84
Other, n (%)	7 (10)	9 (15)	0.46
Course of complaints before operation (range)	7.0 (0.5/50)	6.5 (0/40)	0.73[a]
CEAP classification			
C2, n (%)	26 (38)	29 (47)	0.29
C3, n (%)	36 (53)	29 (47)	0.43
C4, n (%)	5 (7)	4 (6)	0.86
C5, n (%)	1 (1)	0 (0)	0.34

SFL/S* sapheno-femoral ligation and stripping, EVLA* endovenous laser ablation, BMI* Body Mass Index, SFJ* sapheno-femoral junction, GSV* great saphenous vein, Other* f.e. restless legs, cosmetic, tingling.
[a] t-test.

Table 2 Peri- and postoperative pain and Quality of Life.

Peri- and postoperative pain (VAS 1–10)	SFL/S $n = 68$ mean (SD)	EVLA $n = 62$ mean (SD)	*T*-test MW[a] *p*-value
During tumescent	4.85 (2.48)	4.69 (2.48)	0.72
During operation procedure	3.39 (2.57)	2.21 (2.40)	0.02
Day 1	4.00 (2.34)	3.58 (2.60)	0.38
Day 2	3.12 (2.38)	3.05 (2.48)	0.86
Day 3	2.38 (2.11)	2.76 (2.53)	0.37
Day 7	1.78 (1.94)	3.74 (2.72)	<0.01
Day10	1.18 (1.49)	2.65 (2.21)	<0.01
Day 14	0.77 (1.46)	1.66 (2.04)	0.01
Restart daily activities, no. of days	3.20 (±4.01)	3.16 (±4.34)	0.96
Restart work, no. of days	4.15 (±3.72)	4.38 (±5.43)	0.80
Restart sport, no. of days	10.62 (±6.96)	10.52 (±7.12)	0.95
Daily activities (scale 0, 1, 2)	mean rank	mean rank	
Mobility day 7	53.7	76.0	<0.01[a]
Mobility day 10	58.3	71.1	0.01[a]
Self care day 7	60.9	68.3	0.03[a]
Daily activity day 1	71.4	57.1	0.01[a]
Daily activity day 7	57.4	72.1	0.01[a]
Anxiety	64.0	64.0	0.98[a]

SFL/S: sapheno-femoral ligation and stripping, EVLA: Endovenous laser ablation.
[a] MW = Mann–Whitney.

caused by saphenous nerve injury, was found in one patient (1%). Six months after treatment, patients documented a significant cosmetic improvement ($p < 0.01$), without differences between SFL/S or EVLA (Fig. 2). After one year, both groups showed a significant improvement in symptoms of chronic venous disease ($p < 0.01$) (Table 3) and in CEAP classification ($p < 0.01$). No difference in symptoms and CEAP classification between treatment groups was noted before operation ($p = 0.28$) and after one year follow-up ($p = 0.87$) (Table 4).

One year post-treatment, no significant difference in the development of recurrent varicose veins was seen after SFL/S or EVLA. Five of 56 patients (9%) treated with SFL/S showed reflux in a vein, originating in the groin and connected with the femoral vein, of which three (5.4%) were clinically visible. After EVLA, reflux was recorded in five of 49 patients (10%), of which three (6%) were clinically visible. In two patients complete recanalization of the GSV was seen, and in another patient partial recanalization was detected, starting 11 cm distal to the groin.

Discussion

In recent years minimally invasive endovenous treatments of the incompetent GSV have become increasingly popular alternatives to conventional open varicose vein surgery (SFL/S), not only among surgeons but also among patients. Patients favour avoidance of SFL/S under general anaesthesia, assuming that this would cause more postoperative discomfort and slower recovery compared with the endovenous techniques. Recruitment for the present study was more difficult than expected because of patients' preference for endovenous procedures.

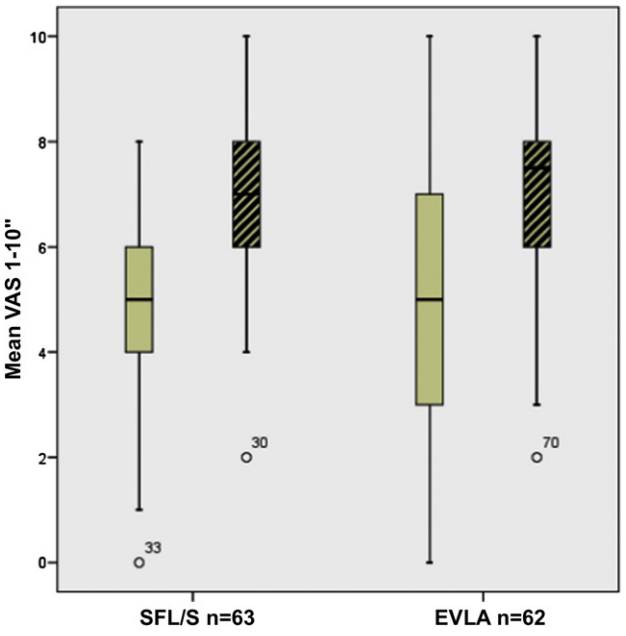

Figure 2 Quality of life: cosmetic results (VAS 1–10) before sapheno-femoral ligation and stripping (SFL/S) and endovenous laser ablation (EVLA), and at 6 months follow-up. Six months after treatment, patients documented significant cosmetic improvement ($p < 0.01$), without differences between SFL/S or EVLA. Pre-operative median VAS was 5 in both groups (IQR = 2 for SFL/S; IQR = 4 for EVLA). After 6 months median VAS was 7 (IQR = 2) for SFL/S, and median VAS was 7.5 (IQR = 2) for EVLA.

Table 3 Pre-operative complaints and complaints after one year.

	Pre-operative		χ^2-test	One year		χ^2-test	pre/one year
	SFL/S $n = 68$	EVLA $n = 62$	p-value $n = 130$	SFL/S $n = 62$	EVLA $n = 56$	p-value $n = 118$	p-value
Tired legs, n (%)	35 (52)	31 (50)	0.87	8 (13)	5 (9)	0.49	<0.01
Oedema, n (%)	32 (47)	21 (34)	0.13	10 (16)	6 (11)	0.39	<0.01
Itching, n (%)	26 (38)	20 (32)	0.48	6 (10)	3 (5)	0.50[a]	0.01[a]
Cosmetic, n (%)	13 (19)	13 (20)	0.79	8 (13)	4 (7)	0.31	<0.01
Pain, n (%)	13 (19)	9 (15)	0.49	6 (10)	1 (2)	0.12[a]	0.02[a]
Restless legs, n (%)	6 (9)	11(18)	0.13	4 (6)	7 (13)	0.43	<0.01
Calf cramps, n (%)	8 (12)	8 (13)	0.84	2 (3)	5 (9)	0.25[a]	0.01[a]
Other, n (%)	7 (10)	9 (15)	0.46	1 (2)	2 (4)	0.60[a]	0.52[a]

SFL/S: Sapheno-femoral ligation and stripping, EVLA: Endovenous laser ablation.
[a] 1 or 2 cells have expected count less than 5 so Fisher Exact test (2-sided) is performed.

However, the results of our study demonstrate that conventional surgery by SFL/S, when performed under local tumescent anaesthesia, was well tolerated and the amount of post-treatment complications after both treatments was equally low.

The suggestion of more post-treatment pain in the EVLA group was confirmed by the one year interim analysis. The significantly higher rate of post-treatment pain after 980-nm laser treatment was considered of such clinical relevance, that we decided to stop further inclusion of patients in this trial. Our observation of elevated pain and more hindrance in daily activities in the second week after EVLA is in contrast with results reported in other publications. To our knowledge, a comparison of SFL/S with EVLA, using a laser with similar wavelength and both treatments performed under local tumescent anaesthesia, has been described in only one other randomised study, i.e. by Rasmussen et al.[11] In their study, significantly more pain and bruising 12 days post-operative was noted after SFL/S in comparison with EVLA, but time to resume normal activity (SFL/S mean 7.7; EVLA mean 6.9 days) and work was equal after both treatments (SFL/S mean 7.6; EVLA mean 7.0 days).

Darwood et al. compared two forms of EVLA performed under tumescent anaesthesia (810-nm; continuous and stepwise laser withdrawal) with SFL/S performed under general anaesthesia. They found no difference in post-operative pain after SFL/S or EVLA, but return to normal activity, as well as return to work, was significantly faster after both forms of EVLA than after SFL/S.[21] Kalteis et al. compared high ligation combined with either EVLA (810-nm) or stripping, both performed under general anaesthesia. They found no difference in postoperative pain, but EVLA combined with high ligation was associated with a longer period of time needed to return to work compared with SFL/S.[22]

Post-procedural pain, bruising and some restrictions in normal daily activities after SFL/S and EVLA have been well described[10,23] These are known symptoms and are of short duration. However, pain and bruising after EVLA are especially common after treatment with lasers that use haemoglobin-specific wavelengths (810 nm, 940 nm, 980 nm).[8,23,24] It has been demonstrated that those endovascular laser techniques can cause vein perforations.[25,26] Such vein perforations lead to extravasation of blood into the surrounding tissues, which causes bruising and pain.[27]Although these symptoms are mostly of mild intensity and self-limiting after one or two weeks, they may lead to hindrance in daily activities. We therefore speculate that these observations might well be the underlying cause of our findings of more pain and delay in starting in daily activities after EVLA. Due to these findings, we decided to stop the inclusion for this trial, but we will continue the follow up of the reported patients. We prefer the use of other endovenous techniques such as radiofrequency ablation (VNUS ClosureFAST®) and 1470 nm laser (Biolitec).

Additionally, in our study, the post-treatment pain after SFL/S may have been reduced by the local tumescent anaesthesia. Compression of the GSV tunnel and the local

Table 4 CEAP classification before and one year postoperative.

	CEAP preoperative			χ^2-test	CEAP one year postoperative			χ^2-test
	SFL/S	EVLA	total	p-value	SFL/S	EVLA	total	p-value
	68	62	130		61	56	117	
C0, n (%)	0	0	0		21 (34)	19 (31)	37 (46)	0.96
C1, n (%)	0	0	0		22 (36)	20 (36)	34 (33)	0.97
C2, n (%)	26 (38)	29 (47)	55 (42)	0.33	11 (18)	9 (16)	16 (16)	0.78
C3, n (%)	36 (53)	29 (47)	65 (50)	0.48	6 (10)	7 (13)	13 (13)	0.65
C4, n (%)	5 (7)	4 (7)	9 (7)	0.84	0	1 (2)	1 (1)	
C5, n (%)	1 (1.5)	0	1 (1)		1 (2)	0	1 (1)	

SFL/S: Sapheno-femoral ligation and stripping, EVLA: Endovenous laser ablation.

application of lidocaine and adrenalin have been found to reduce haematoma and to diminish postoperative pain.[11,28]

After SFL/S, complication rates up to 30% are described, however, in the present study postoperative complications were recorded in only 3% of the patients.[29] No deep vein thrombosis was seen, despite the fact that no routine perioperative anticoagulant therapy was administered. In public literature, the recurrence rate after varicose vein surgery has been reported to vary between 6 and 62%, depending on the follow-up period and the definition of the condition.[19,30–32] In the present study, the prevalence of recurrent varicose veins one year after SFL/S was 9%.

In a prospective, non-randomised study, Proebstle et al. demonstrated less than 10% recanalization of the GSV up to one year after EVLA (940 nm).[10] In another prospective, non-randomised study, Min et al. reported a recurrence rate, defined as recanalization of the GSV on DUS, of less than 7% at 2-year follow-up after EVLA (810 nm).[24] These percentages resemble ours, as we found complete recanalization of the GSV in 2 of 49 patients (4.1%) at one year follow-up after EVLA, and partial recanalization of the GSV in one patient. It has been debated whether a correlation exists between the EVLA induced occlusion rate of the incompetent GVS and the amount of energy administered during the procedure. In the study of Theivacumar et al. an energy density $>$ 60 J/cm is recommended. In the present study EVLA was performed with an average energy density of 64.5 SD 6.8 J/cm.

This study had some limitations. Due to practical difficulties in scheduling follow-up visits in our clinic, it was not possible to invite consecutive patients for recruitment in this study. Neither the patients, nor the doctors could be blinded for the treatment. Therefore, patients' expectations might have influenced the outcome measures regarding post-treatment pain and QoL. Because of practical drawbacks, the assessment of recurrent varicose veins during the follow-up visits was not performed by an independent observer.

In conclusion, both conventional surgery by SFL/S and endovenous laser ablation (EVLA), performed under local tumescent anaesthesia, were well tolerated, with no differences in complications, short-term cosmetic results, CEAP classification, and recurrence rate. However, in the second week of post-treatment QoL assessment, patients in the EVLA group experienced significantly more pain resulting in a restriction of mobility, self care and daily activities than noted after SFL/S.

Conflict of Interest

None.

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