Original article

Endovenous laser ablation of great saphenous veins using a 1470 nm diode laser and the radial fibre – follow-up after six months

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Abstract

***Background*:** Endovenous laser ablation (EVLA) is an efficient method to treat insufficient great saphenous veins (GSV) with high occlusion rates.[1–5] Most studies used 810, 940 or 980 nm diode lasers and a bare fibre.[1,2,6] Moderate postoperative pain and bruising are frequent findings.[2,6] Laser systems with higher wavelengths like 1470 nm with a higher absorption in water show less pain and bruising after the procedure.[7–9] A newly-developed fibre (radial fibre, Biolitec) emits the laser energy radially around the tip directly into the venous wall contrary to the bare fibre.[9] The aim of this study was to demonstrate the outcome and side-effects after EVLA of GSV with a 1470 nm diode laser (Ceralas E, Biolitec) by using the radial fibre.

***Methods*:** Non-randomized, prospective study including 50 unselected limbs of 50 patients with a duplex sonographically verified incompetent GSV. EVLA was performed with a 1470 nm diode laser (Ceralas E, Biolitec) and a radial fibre. In the same session all insufficient tributaries were treated by phlebectomy. Tumescent local anaesthesia with 0.05% lidocaine was applied perivenously. Laser treatment was carried out in a continuous mode with a power of 15 W. Compression stockings (30 mmHg) were applied for one month. Postinterventional checkups took place one, 10, 30 days and six months after the procedure.

***Results*:** Three patients were lost to follow-up. The average linear endovenous energy density (LEED) was 90.8 J/cm vein (SD 35.3). At the six month follow-up all treated veins remained occluded and no new reflux in the treated segments occurred. No recurrent varicose veins had occurred so far. No severe complications such as deep venous thrombosis could be detected. In four patients at 30 days and three patients at six months local paresthesia occurred in the region of EVLA. Forty-four percent of patients did not have any pain after the treatment and 50% did not take any analgesic tablets at any time after the procedure. Postoperative ecchymoses in the track of the treated GSV was rare. In 80% of the limbs, no ecchymoses was observed after the treatment.

***Conclusion*:** EVLA of GSV with a radially emitting laser fibre by using a 1470 nm diode laser is a safe and efficient treatment option.

Keywords: EVLA; great saphenous vein; 1470 nm; endovenous laser; radial fibre

Background

Endovenous laser ablation (EVLA) is an effective method to treat insufficient great saphenous veins (GSV).[1–5] Occlusion rates were demonstrated to reach about 95%.[1] Most of the studies used 810, 940 or 980 nm diode lasers and a bare fibre.[6] Moderate postoperative pain and bruising are frequent

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findings.[2,6] Laser systems with higher wavelengths, such as 1320 or 1470 nm, have a higher absorption in water and show less pain after the procedure and less bruising.[7–9] A newly-developed fibre (radial fibre, Biolitec, Bonn, Germany) emits the laser energy 360° radially around the tip directly into the venous wall contrary to the bare fibre (Figure 1). By this it is thought to have a more homogeneous effect on the venous wall with less penetration, which could lead to less pain and bruising. The aim of this study was to demonstrate the outcome and side-effects after EVLA of GSV with a 1470 nm diode laser (Ceralas E, Biolitec) by using the radial fibre.

Methods

Between April and October 2008, 50 legs in 50 consecutive patients attending the 'Health Center 4', Center of Phlebology in Riga, Latvia, were treated by EVLA for GSV incompetence. All patients agreed to be included in a non-randomized prospective study and for their data to be evaluated in accordance with the Declaration of Helsinki. We obtained permission from the ethics committee.

All patients were examined clinically and with duplex by an experienced phlebologist prior to intervention and at follow-up visits at days one, 10 and 30 for complications, occlusion, flow and reflux in the treated vein segments. Follow-up visits at six months were performed by experienced phlebologists who did not perform the initial treatment. Patient's characteristics are presented in Table 1.

Duplex was performed in upright position. Normal flow is defined as antegrade. Reflux was defined as retrograde flow of >0.5 seconds duration after a Valsalva manoeuver or manual compression and decompression of the distal limb. The entire treated vein and more extensively the sites 3, 25 and 50 cm distally to the safeno-femoral junction (SFJ) were assessed. Even a slight marginal flow or reflux in a largely occluded vein was assessed as pathological. In all cases, reflux was initially completely eliminated by EVLA. The entire deep venous system was checked for signs of deep venous thrombosis.

The clinical evaluation included clinical classification, modified clinical, aetiological, anatomical and pathological elements (CEAP) clinical severity score (the items 'corona phlebectatica', 'white atrophy' and 'ulcer scar' were added), filled in by the investigator and the presence of recurrent varicose veins. The modified clinical severity score has 12 questions with 0–2 points for each item. The minimum value of the score is 0 and the maximum is 24 points per leg. Recurrent varicose veins were

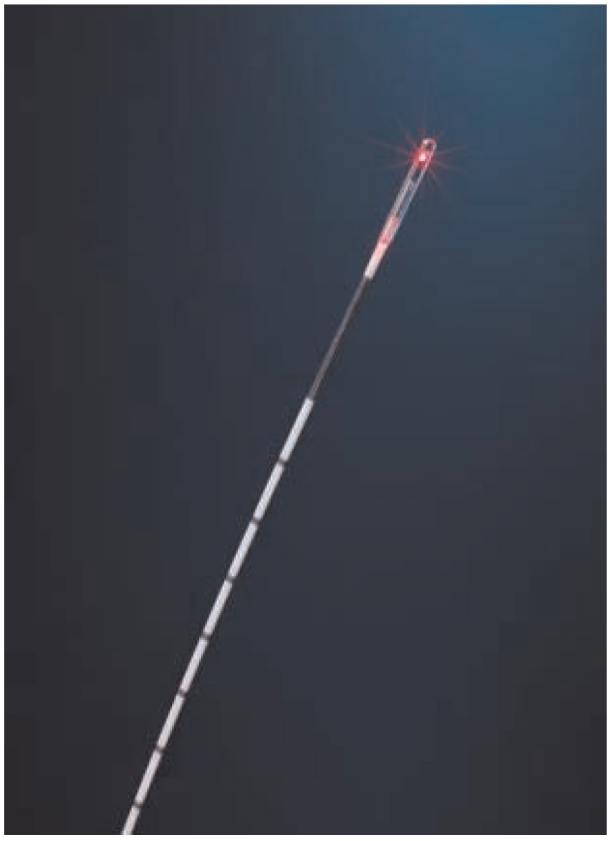

Figure 1 Radial fibre (Biolitec)

Table 1 Patient's characteristics

Variables	
Patients (*n*)	50
GSV treated (*n*)	50
Additional treatments – phlebectomies, limbs (%)	50 (100%)
Left leg, *n* (%)	29 (58%)
Female gender, *n* (%)	42 (84%)
Age (years), mean (SD)	48 (14.8)
BMI (kg/m^2), mean (SD)	26.5 (5.2)
CEAP (highest classification per limb), n	
C2	21
C3	10
C4	16
C5	3
Length of treated GSV, mean (SD)	45.4 (16.6)
TLA (mL) for ELT per limb, mean (SD)	466 (142.3)
TLA (mL) per cm GSV, mean (SD)	10.9 (2.8)
Endovenous procedure time (min), mean (SD)	14.8 (4.6)
Total OP time (min) (EVLA + phlebectomies), mean (SD)	35.8 min/leg, (11.1)
LEED (J/cm vein), mean (SD)	90.8 (35.3)
EFE (J/cm^2 vein), mean (SD)	35.5 (12.6)

GSV, great saphenous veins; BMI, body mass index; CEAP, clinical, aetiological, anatomical and pathological elements; TLA, tumescence local anaesthesia; ELT, endovenous laser treatment; EVLA, endovenous laser ablation; OP, operation; EFE, endovenous fluence equivalent; LEED, linear endovenous energy density

defined as every subcutaneous varicosity of more than 3 mm in diameter which occurred after the initial treatment. Pain was assessed on a five-point scale ranging from no pain at all (0) to very painful (5). Patient's satisfaction was assessed by a scale ranging from 0 to 4. The questions were: 'Are you satisfied with the method being used?' (0 = very satisfied, 1 = satisfied, 2 = fairly satisfied, 3 = not satisfied, 4 = extremely unsatisfied), 'would you choose endovenous laser therapy again?' (0 = definitely, 1 = probably, 2 = don't know, 3 = probably not, 4 = definitely not).

EVLA was performed with a 1470 nm diode laser (Ceralas E, Biolitec). The entire procedure was performed under duplex guidance (MicroMaxx, SonoSite, Inc) using cold (5°C) tumescent local anaesthesia with 0.05% lidocain. In the same session all insufficient tributaries were treated by phlebectomy. GSV was accessed at the most distal insufficient point with an 18 gauge needle. The 600 μm radial fibre was introduced through a puncture set and the tip was positioned 1–2 cm distal to the junction right below the epigastric vein under duplex guidance. The tumescent local anaesthesia was then applied perivenously under duplex guidance too.

The linear endovenous energy density (LEED, J/cm), which was required to achieve the occlusion of the vein, was calculated by the following formula: 10 × vein diameter (D, mm) in the upright position. For example: if D was 12 mm at 3 cm, 10 mm at 25 cm, 8 mm at 50 cm and 6 mm at the puncture level (60 cm), the treatment was started with a LEED of 120 J/cm, lowering it in the mid-thigh (25 cm) to 100 J/cm, continuing to lower LEED to 80 J/cm at knee level (50 cm) and to 60 J/cm at the end. Laser treatment was carried out in a continuous mode with a power of 15 W. LEED level was delivered by controlling pull-back time on a clock.

Eccentric compression with cotton wool rolls on the treated vein for 24 hours and 30 mmHg compression stocking for one month were applied. In addition, a prophylactic dosage of low-molecular weight heparin for seven days was given to all patients. The patients were mobilized immediately after the intervention. The NSAID Mesulid, 100 mg, was prescribed to be taken in case of postoperative pain.

Postinterventional checkups took place one, 10, 30 days and six months (187.8 days, range: 91–289 days) after the procedure.

Statistics

Mean values and standard deviations were calculated using the statistics part in Microsoft Excel 2003 version.

Results

The results are shown in Tables 2 and 3.

Follow-up data: The mean follow-up was 187.8 days (91–289). Three patients were lost to follow-up at day 30 and 10 patients at six months.

LEED: The average LEED was 90.8 J/cm vein with a minimum of 46.2 J/cm and a maximum of 188.5 J/cm (SD 35.3).

EFE: The average endovenous fluence equivalent (EFE) was 35.5 J/cm^2 vein with a minimum of 19.6 J/cm^2 and a maximum of 81.9 J/cm^2 (SD 12.6).

Occlusion and reflux: Up to six months follow-up, all treated veins remained occluded and no new reflux in the treated segments occurred. No recurrent varicose veins occurred so far.

Diameter: The diameter of the GSV at 3 cm below the SFJ reduced significantly ($P < 0.05$) from 1.0 before treatment (SD 0.4) to 0.6 cm at day 30 (SD 0.2) and 0.3 at six months (SD 0.2).

Modified CEAP clinical severity score: The modified CEAP clinical severity score improved significantly ($P < 0.05$) from 2.5 (SD 2.4) preinterventional to 1.3 (SD 1.8) at day 30 and to 1.4 at six months (SD 2.3).

Subjective assessment of treatment by patients: After 30 days, 35 patients were very satisfied and 12 were satisfied; at six months, 22 patients were very satisfied, 17 were satisfied and one patient fairly satisfied with the method. At day 30, 35 patients definitely and 11 patients probably would chose EVLA again; one patient was uncertain.

Table 2 Patient's outcome after EVLA with the radial fibre

Variables	Pretreatment	One month	Six months
Patients at follow-up (*n*)	50	47	40
Patients lost to follow-up (*n*)		3	10
Occlusion rate, *n* (%)		47 (100%)	40 (100%)
Diameter 3 cm distally to junction (cm), mean (SD)	1.0 (0.4)	0.6 (0.2)	0.3 (0.2)
Modified CEAP severity score, mean (SD)	2.5 (2.4)	1.3 (1.8)	1.4 (2.3)
Local paresthesia in track of treated GSV, *n* (%)		4 (8%)	3 (6%)
Average area of paresthesia (cm^2)		47	24
Satisfaction (day 30) patients (%)			
Very satisfied		35 (74%)	22 (55%)
Satisfied		12 (26%)	17 (43%)
Fairly satisfied			1 (2%)
Willing to choose EVLA again, *n* (%)			
Definitely yes		35 (75%)	25 (63%)
Probably yes		11 (23%)	13 (33%)
Did not know		1 (2%)	1 (2%)
Probably not			1 (2%)

EVLA, endovenous laser ablation; CEAP, clinical, aetiological, anatomical and pathological elements; GSV, great saphenous veins

Table 3 Pain, ecchymoses and return to daily activities after EVLA with the radial fibre

Variables	Outcome
Postoperative pain	
Patients without pain after the procedure *n* (%)	21 (44%)
Pain score at day one, mean (SD)	0.9 (0.8)
Pain score at days 2–10, mean (SD)	0.6 (0.6)
Pain score days at 11–30, mean (SD)	0.5 (0.6)
Days with pain, (SD)	2.5 (3.8)
Patients without analgesics after the procedure, *n* (%)	24 (50%)
Analgesics	
Analgesic tablets (*n*) at day one, mean (SD)	0.5 (0.8)
Analgesic tablets (*n*) from day two to day 10, mean (SD)	1.3 (2.7)
Analgesic tablets (*n*) from day 11 to day 30, mean (SD)	0.5 (2.1)
Analgesic tablets (*n*) total, mean (SD)	2.3 (4.2)
Days with analgesics (*n*), mean (SD)	2.1 (3.8)
Return to daily activities (days), mean (SD)	1.6 (1.1)
Ecchymoses	
Postoperative ecchymoses in a track of treated GSV	
Limbs with no ecchymoses at day one, *n* (%)	35 (80%)
Limbs with no ecchymoses at day 10, *n* (%)	38 (80%)
Limbs with no ecchymoses at day 30, *n* (%)	47 (100%)

EVLA, endovenous laser ablation; GSV, great saphenous veins

At six months, 25 patients definitely and 13 patients probably would chose EVLA again. One patient was uncertain and one patient probably would not choose EVLA again.

Return to daily activities: The patients returned to daily activities after an average of 1.6 days (SD 1.1).

Complications and side-effects: No severe complications such as deep venous thrombosis, pulmonary embolism, skin burns, motor nerve lesions or the formation of arterio-venous fistula occurred in any of the 50 treated legs. In four patients, local paresthesia occurred in the region of EVLA at 30 days with average paresthesia area of 47 cm^2. After six months, paresthesia disappeared in one patient. In the other patients, the paresthesia area reduced to 24 cm^2.

Pain: Forty-four percent of patients did not have any pain after the treatment and 50% did not take analgesic tablets at any time after the procedure. Twenty-seven patients developed moderate postoperative pain with a mean value of 0.6 (SD 0.6) between days two and 10. The patients took a mean of 2.3 analgesic tablets (SD 4.2) at a mean of 2.1 days (SD 3.8).

Ecchymoses: Postoperative ecchymoses in the track of the treated GSV was rare. In 80% of the limbs, no ecchymoses was observed at any time after the treatment.

Discussion

EVLA is an effective method to treat insufficient saphenous veins.[1–6] Occlusion rates were demonstrated to reach about 95%.[1] However, moderate postoperative pain and bruising are frequent findings.[2,6] In earlier studies the majority of treated patients showed these findings.[6] Most studies used 810, 940 or 980 nm diode lasers and a bare fibre.[1–5] These wavelengths have a high absorption rate in blood.[10] Laser systems with higher wavelengths, like 1320 and 1470 nm, under duplex guidance, with a higher absorption in water show less pain after the procedure and less bruising.[7–9] Bare fibres emit the laser beam in a straightforward manner out of the tip. This leads to a higher rate of penetrations of the venous wall.[6] A newly-developed fibre (radial fibre, Biolitec) is emitting the laser energy 360° radially around the tip directly into the venous wall. By this it is thought to have a more homogeneous effect on the venous wall with less penetration which could lead to less pain and bruising. Sroka could demonstrate in *ex vivo* experiments with a cow's foot that the fluence rate is dramatically reduced below the ablation threshold with the radial fibre, thus no perforation could be observed during experiments. The induced tissue alterations were circumferential and homogeneous. Shrinkage of the vessel due to thickening, loss of flexibility and change in colour as a sign of effective treatment could be observed throughout the complete vessels.[11]

In this study using a 1470 nm diode laser and a radial fibre EVLA showed a very high occlusion rate after six months. Energy density was relatively high (LEED 90.8 J/cm, EFE 35.5 J/cm^2). Bruising was a rare finding and pain was less frequent compared with studies using a bare fibre and lower wavelength. Eighty percent of the patients in this study developed no bruising at any time and 44% had no postoperative pain. In earlier studies using a lower wavelength and bare fibres, the majority of the patients developed ecchymoses or bruising and moderate postoperative pain for a few days.[12] Our study shows a combined outcome of a high wavelength (1470 nm) and a radial fibre. To show the effect of the radial fibre alone, a prospective comparative randomized study should be carried out. It could be discussed if the concomitant phlebectomies which were carried out in all our patients for additional tributary treatment were responsible for pain and bruising but only the events in the track of the treated GSV were counted in this trial. It is also questionable if all of our patients needed prophylactic dosage of LMWH postoperatively. This may also influence bruising. In former EVLA studies, an LEED of more than 60 J/cm was proposed to sufficiently occlude GSV.[13,14] Based on these results lower energy densities should be studied in further

trials. The results for occlusion rate, pain and ecchymoses are comparable to those using a radiofrequency ablation (RFA) system (ClosureFAST).[15] In the RECOVERY study, 66.7% of the patients treated with RFA showed no ecchymosis after 48 hours compared with 80% in our study and the pain score on a 10-point scale reached 0.7 compared with 0.6 on a five-point scale between days two and 10.[15]

Conclusions

EVLA of GSV with a radially emitting laser fibre using a 1470 nm diode laser is a safe and efficient treatment option.

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