

First results with a new 1470-nm diode laser for endovenous ablation of incompetent saphenous veins

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Abstract

Introduction: Most of the published EVLA data concern 810, 940, 980 nm diode lasers and 1064 or 1320 nm Nd:Yag laser systems. Major side effects are postoperative pain and bruising. The aim of this study was to show the outcome one year after EVLA of incompetent saphenous veins with a 1470 nm Diode laser (Ceralas E, biolitec).

Patients and method: Between December 2006 and February 2007, 134 saphenous veins (108 GSV, 26 SSV) in 117 legs of 100 consecutive patients were treated by EVLA for GSV and SSV incompetence. All patients were examined clinically and with duplex by an experienced phlebologist prior to intervention, and at the follow-up visits for complications, occlusion, flow and reflux in the treated vein segment. The clinical evaluation included clinical CEAP and the presence of recurrent varicose veins. Patient satisfaction was assessed by a 0 to 4 scale.

Results: After a mean follow-up period of 184 days (SD 27) 127 treated veins (102 GSV, 25 SSV) of 111 limbs in 94 patients and after 329 days (SD 14) 105 treated veins (94 GSV, 21 SSV) of 105 limbs in 83 patients were reinvestigated. Six patients were lost to follow up after six months and an additional 11 patients after one year. Up to one year follow-up all treated veins remained occluded. At six months, one new insufficient anterior accessory saphenous vein (AASV) and after 12 months, three new insufficient AASV occurred. After one year 45 patients were very satisfied with the method, 34 were satisfied, three were fairly and one was not satisfied. The mean of all answers was 0.5 (SD 0.5). In three cases phlebitic reactions after 10 days, but no severe complications such as deep vein thrombosis occurred.

After six months in 9.5% of the legs paresthesia was present in the treated area which reduced to 7.6% after one year. Intake of painkillers was mean 6.7 tablets (SD 3.5). When we compared GSV legs treated with LEED below or above 100 J/cm, the paresthesia rate was significantly lower in the first group with 2.3% compared to 15.5 % in the higher LEED group. The differences for number of days with analgesic intake and for the paraesthetic area were significant.

Discussion: In this prospective follow-up study with 100 consecutive patients and 134 treated saphenous veins a high occlusion rate of 100% could be demonstrated one year after treatment. However, with LEED > 100 J/cm in this study, the incidence of paresthesia rose significantly. Therefore it seems adequate to stay below 100 J/cm in the future as the occlusion rate was the same below and above 100 J/cm.

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Conclusion: EVLA of GSV and SSV with a 1470 nm diode laser is a minimally invasive, safe and efficient therapy option with a high success rate.

Keywords: EVLA; 1470 nm; great saphenous vein; diode laser; endovenous

Introduction

Chronic venous diseases are among the most common diseases in the western world.^{1,2} These result in ongoing symptoms such as a feeling of heaviness, tendency to swelling and pain in the legs, as well as in skin changes and even venous leg ulcers. In the Bonn Vein Study, we were able to show that the prevalence of varicose veins in the general population is 19.8% in men and 25.8% in women.³ In recent years, minimally invasive procedures like radiofrequency ablation (RFA), endovenous laser ablation (EVLA) and foam sclerotherapy have enriched the range of therapy.^{4–8} Most of the published EVLA data concern 810-, 940-, 980-nm diode and 1064- or 1320-nm Nd:Yag laser systems. In most publications, the success rate after various follow-up observation times is 90–100%.^{9–13} Major side-effects are post-operative pain and bruising. Results after EVLA with 1320 nm showed good occlusion rates, and less bruising and less pain. Higher wavelengths, more specific for water than for blood might be useful.^{14–17} It is discussed whether these systems produce more direct damage to the venous wall and not indirectly by steam bubbles as demonstrated with the diode lasers of 810–980 nm.¹⁸ In this study occlusion rate and clinical outcome one year after EVLA of incompetent saphenous veins with a new 1470-nm diode laser (Ceralas E, biolitec) was systematically assessed with a standardized protocol, which included both duplex ultrasound assessment and clinical features. This was an investigator-initiated study without industrial support.

Patients and methods

Between December 2006 and February 2007, 117 legs in 100 consecutive patients attending the Health Center 4, Center of Phlebology in Riga, Latvia, where treated by EVLA for great saphenous vein (GSV) and small saphenous vein (SSV) incompetence. In some patients, GSV and SSV were treated in the same leg in the same session. This resulted in the treatment of 134 saphenous veins (108 GSV, 26 SSV). All patients agreed to be included in a follow-up study and for their data to be evaluated in accordance with the Declaration of Helsinki. We obtained permission from the ethics committee. Patient characteristics are presented in Table 1.

All patients were examined clinically and with duplex by an experienced phlebologist, who was a member of the surgical equip prior to intervention, and at the follow-up visits for complications, occlusion, flow and reflux in the treated vein segments.

Duplex was performed in upright position. Flow was defined as being antegrade and could be triggered by manual compression of the leg. Reflux was defined as retrograde flow of >0.5 s duration after a Valsalva manoeuvre concerning the proximal part of the vein or manual compression and decompression of the distal vein if more distal parts were involved. The entire treated vein and for diameter measurement, the sites 3 cm and 20 cm (SSV) or 25 cm (GSV) distally to the junction were assessed. Even a slight marginal flow or reflux with a largely closed vein was assessed as pathological. The entire deep venous system was checked for signs of deep venous thrombosis.

The clinical evaluation included preoperative clinical classification according to the clinical, aetiological, anatomical and pathological classification (CEAP)^{7–9} and the presence of recurrent varicose veins in the follow-up period. Recurrent varicose veins were defined as every subcutaneous varicosity of more

Table 1 Patient and treatment characteristics

| Variable | Value |
|---|---------------------------|
| Patients | 100 |
| Legs | 117 |
| Veins | 134 |
| GSV | 108 |
| SSV | 26 |
| Side of the limb treated | Left 59, right 58 |
| Gender | 82 women, 18 men |
| Age (years), mean (range, SD) | 45 (17–77, 12.6) |
| CEAP classification per limb, n (%) | |
| C2 | 117 (100) |
| C3 | 62 (53) |
| C4 | 26 (22) |
| C6 | 2 (2) |
| Ep | 115 (98) |
| Es | 2 (2) |
| As | 117 (100) |
| Ad | 2 (2) |
| TLA (mL) per limb, mean (range, SD) | 732 (200–1700, 296) |
| OP time (min) (ELT + phlebectomies), mean (range, SD) | 43 min/leg, (20–95, 14.6) |
| LEED (J/cm vein) | |
| GSV, mean (range, SD) | 107 (62.2–162.6, 22) |
| SSV, mean (range, SD) | 129 (83.5–238.2, 31.9) |
| Follow-up (days), mean (range, SD) | 333 (311–364, 14.1) |

than 3 mm in diameter in the treatment area, which occurred after the initial treatment. Patient satisfaction was assessed by a scale ranging from 0–4. 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) and '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 sonographic guidance (Micro-Maxx, SonoSite, Inc.) using tumescent local anaesthesia with 0.05% lidocain. The vein was punctured at the most distal point with valve insufficiency with an 18-gauge needle. A guide wire was placed below the saphenofemoral or saphenopopliteal junction and an angiography catheter was forwarded over the guide wire in Seldinger technique. The guide wire was replaced by a 600 μ m laser fibre. The tip of the laser fibre was positioned under duplex guidance 1–2 cm distal to the junction. The tumescent local anaesthesia was then applied perivenously under duplex guidance.

Laser treatment was carried out in a continuous mode with a power of 15 W. Eccentric compression with cotton wool rolls on the treated vein and 23–32 mmHg compression stocking were applied for 24 hours. On the following day, a 23–32 mmHg compression stocking was recommended for one month. In addition, all patients were given a thromboembolism prophylaxis with low-molecular weight heparin for seven days. The patients were mobilized immediately after the intervention. Additional varices were treated by phlebectomies in the same session in 97.4% of cases. The NSAID Mesulid, 100 mg twice daily, was prescribed for five days to be taken in the case of postoperative pain.

Postinterventional checkups took place one and 10 (T1 and T10) days after intervention for immediate results and complications, and thereafter at one, six and 12 months.

Statistics

For statistical evaluation of data, we used Fisher's *t*-test.

Results

Follow-up data

After a mean follow-up period of 186 days (SD 27.0), 127 treated veins (102 GSV, 25 SSV) of 111 limbs in 94 patients were reinvestigated. After a mean follow-up period of 333 days (SD 14.1), the

last follow-up visit of the remaining 105 treated veins (94 GSV, 21 SSV) of 105 limbs in 83 patients was performed. Six patients were lost to follow-up after six months and additional 11 patients after one year (Table 2).

Linear endovenous energy density

We used an average linear endovenous energy density (LEED) for the GSV of 107 J/cm vein with a minimum of 62.2 J/cm and a maximum of 162.6 J/cm (SD 22). For the SSV, the average LEED was 129 J/cm vein with a minimum of 83.5 J/cm and a maximum of 238.2 J/cm (SD 31.9).

Occlusion and reflux

In all cases, reflux was initially completely eliminated with EVLA. Up to one year follow-up, all treated veins remained occluded and no new reflux in the treated segments occurred.

Recurrent varicose veins

Six months after the initial treatment, one new insufficient anterior accessory saphenous vein (AASV) and after 12 months, three new insufficient AASV occurred.

Compression treatment

Compression stockings were worn for a mean of 55 days (SD 45). The shortest period was 20 days, the longest 182 days.

Subjective assessment of treatment by patients

After six months, 46 patients were very satisfied with the method, 39 were satisfied, seven were fairly satisfied and two were not satisfied. The mean of all answers was 0.6 (SD 0.6) on the scale from 0–4. After one year, 45 patients were very satisfied with the method, 34 were satisfied, three were

Table 2 Patients, limbs and veins controlled at follow-up

| Variable | Day 0 | Day one | Day 10 | One month | Six months | One year |
|----------------------------|-------|---------|--------|-----------|------------|----------|
| Patients | 100 | 100 | 100 | 100 | 94 | 83 |
| Patients lost to follow-up | – | 0 | 0 | 0 | 6 | 17 |
| Limbs lost to follow-up | – | 0 | 0 | 0 | 6 | 18 |
| Limbs at risk | 117 | 117 | 117 | 117 | 111 | 99 |
| Veins at risk | 134 | 134 | 134 | 134 | 127 | 105 |
| Treated GSV | 108 | 108 | 108 | 108 | 102 | 94 |
| Treated SSV | 26 | 26 | 26 | 26 | 25 | 21 |

fairly satisfied and one was not. The mean of all answers was 0.5 (SD 0.5).

In response to the question: 'Would you choose endovenous laser therapy again?' after six months 52 patients said that they definitely would, 33 said probably yes, six did not know, one answered that he probably would not and two definitely would not choose EVLA again. After one year, 48 patients answered definitely, 25 said probably yes, nine did not know and one would probably not choose EVLA again.

Return to daily activities

The patients returned to daily activities after an average of 1.7 days (SD 1.3).

Complications and side-effects

Severe complications such as deep venous thrombosis (DVT), pulmonary embolism, skin burns, motor nerve lesions or the formation of arteriovenous fistula did not occur in any of the 117 legs treated. In three cases phlebitic reactions occurred in the region of the treated vein after 10 days (2.2%).

After six months, in 9.5% of the legs paraesthesia was present in the treated area but this reduced to 7.6% after one year. After six months, the paraesthetic area measured between 1.5 cm² and 96 cm² with a mean of 6.2 cm² (SD 18.8).

Pain

Intake of painkillers ranged between 0 (1 patient) and 21 (1 patient) tablets with a mean of 6.7 tablets (SD 3.5). Despite this, pain in the area of treatment developed in 33 patients and lasted between one and 14 days with a mean of 2.5 days (SD 4.2).

LEED and pain

When we compared GSV legs treated with LEED below or above 100 J/cm, the paraesthesia rate was significantly lower in the first group with 2.3% compared with 15.5% in the higher LEED group (Table 3). The differences between the two groups for number of days with analgesic intake and for the paraesthetic area were significant ($P < 0.05$). Because of the smaller number of treated veins, these differences were not calculated for the SSV.

Discussion

In the available literature, high success rates after EVLA was reported.^{14,20–23} The laser systems with 1320 nm and 1470 nm wavelengths have their main absorption in water.¹⁴ It was discussed that they have a more specific, direct effect on the venous wall. With the 1320 nm Nd:Yag system, a high effec-

Table 3 Comparison between GSV legs treated below and above 100 J/cm LEED (SD = standard deviation, ns = not significant, LEED = linear endovenous energy density)

| Variable | LEED < 100 J/cm mean, range (SD) | LEED > 100 J/cm 123.2, 100.9– 162.5 (15.9) | Significance |
|--|--|--|--------------|
| Treated GSV, n | 44 | 58 | – |
| Pain days | 2,4, (4.2) | 2,6, (4.3) | ns |
| Analgesics days | 6,7, (3) | 6,9, (3.2) | <0,05 |
| Paresthetic area (cm ²) | 0,4, (2.3) | 9,6, (2.6) | 0,015 |
| Paresthesia in region of treated GSV, n (%) | 1 (2,3%) | 9 (15.5%) | – |
| To start again daily activi- ties, days | 1,9, (2.4) | 1,7, (1.9) | ns |
| Patients' satisfaction | 0,8, (0.7) | 0,5, (0.3) | 0,05 |
| Patients' readiness to repeat EVLA | 0,7, (0.9) | 0,5, (0.7) | ns |

tivity, and less post-treatment pain and bruising have been reported.^{15–17} No published data concerning the 1470 nm laser was available up to now.

In this prospective follow-up study with 100 consecutive patients and 134 treated saphenous veins, an occlusion rate of 100% could be demonstrated one year after treatment. This was reached with a high mean LEED of more than 100 J/cm vein. Our patients did not experience any serious complications, such as DVT, pulmonary embolism or skin burns. In the literature, the average rate of DVT after EVLA of saphenous veins is <1%.²³ However, individual cases of asymptomatic in-grown thrombi at the level of the junction have been reported.^{22,24} Even after stripping, asymptomatic DVT was detected in up to 5.3% of cases.²⁵ In contrast to most centres, our patients were given low molecular weight heparin prophylaxis for seven days. Three cases of phlebitic reaction occurred within 10 days. The paraesthesia rate of 9.5% after six months reduced to 7.6% after one year. In the literature, similar rates were reported for the 810–980 nm lasers.²³ Phlebectomies were performed in the majority of cases as well in the thigh as in the calf. This may have influenced postoperative pain, bruising and paraesthesia.

The reported recurrence rates after EVLA depend on the LEED used and on concomitant treatment of non-saphenous varices.^{26,27} Min¹⁰ was able to show that the recurrence rate after two years was <10%. Proebstle *et al.*²⁸ showed that after EVLA with low energy density, worse results and more relapses could be expected than with higher energy doses.

The recurrence rate of 5–10 years after stripping operation is in the double-digit percentage range.²⁹ With the high LEED of above 100 J/cm used in this study with the 1470 nm laser, no recurrent reflux or recanalization occurred within one year of follow-up. However, with higher LEED the incidence of paraesthesia also rose significantly. Therefore, it seems adequate to stay below 100 J/cm in the future as the occlusion rate was the same in both groups.

Reflux in the treated vein is not the only criterion that is critical to clinical success. New varicose veins only developed in three legs within one year. Patient satisfaction was very high. Traditional stripping surgery does not produce better results.²⁸ In a recent study one year after saphenofemoral ligation and stripping, complete strip-track revascularization reached 6%.³⁰

EVLA of GSV and SSV with a 1470 nm diode laser is a minimally invasive, safe and efficient treatment option with a high success rate after one year follow up.

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