Endovenous Laser Ablation (980 nm) of the Small Saphenous Vein in a Series of 147 Limbs with a 3-Year Follow-up

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Abstract   *Aim:* This study aims to demonstrate the treatment outcomes of endovenous laser ablation (EVLA) of incompetent small saphenous veins (SSVs) with a 980-nm diode laser.

Materials and methods: Between 1 June 2003 and 30 June 2006, 128 patients (147 limbs) with varicose veins and reflux in the SSV on duplex ultrasound (US) examination were treated with a 980-nm diode laser under US guidance. EVLA was performed using pulsed mode with a power of 10 W. The pulse duration (1.5—3 s) was chosen to deliver a linear endovenous energy density (LEED) depending on the SSV diameter measured 1.5 cm below the sapheno-popliteal junction (SPJ) with the patient standing. For SSV diameters between 2 and 4.5 mm, the LEED applied was 50 J cm^{-1}. The LEED was 70 J cm^{-1} for 4.5—7 mm, 90 J cm^{-1} for 7—10 mm. Patients were evaluated at 1-week, 1-month, 1-year, 2-year and 3-year follow-up.

Results: The initial technical success rate was 100% in 147 patients. The SSV remained closed in 114 of 117 limbs (97%) after 1 year, all of 61 limbs after 2 years and all of 30 limbs after 3 years. For the three SSVs where re-canalisation was observed, the diameter was greater than 9 mm. Major complications have not been detected and, in particular, there was no deep venous thrombosis (DVT). Ecchymoses were seen in 60% with a median duration of 2 weeks. Temporary paraesthesia (mostly hypoaesthesia) was observed in 40% of treated legs with a median duration of 2 weeks. The maximum duration did not exceed 4 weeks. No skin discolouration, superficial burn, thrombophlebitis or palpable induration was observed.

Conclusion: EVLA of the incompetent SSV with a 980-nm diode laser appears to be an extremely safe technique. After successful treatment, there is a very low rate of re-canalisation of the SSV. Obliteration of the SSV was confirmed at 1-, 2- and 3-year follow-up; this study suggests that this procedure will provide a lasting result.

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Venous valvular incompetence in the lower limb is a common medical condition afflicting 25% of women and 15% of men in the United States and in Europe. Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins. Sapheno-popliteal incompetence and short saphenous reflux, although less common than GSV reflux, may result in symptoms of equal severity. Surgery for the incompetent small saphenous veins (SSV) is more challenging, with more complications and higher recurrence rates, than for the GSV. The potential for damage to the sural nerve with resulting neurological deficit has deterred many vascular surgeons from stripping the SSV routinely.[1,2] Most commonly, the SSV is ligated at the sapheno-popliteal junction (SPJ) only. Recurrence rates of SSV after surgery are about 30—50% at 5 years.[3—5]

Within the past few years, minimally invasive techniques have been developed as alternatives to surgery in an attempt to reduce morbidity and improve recovery time. Endovenous laser ablation (EVLA) is one of the most promising of these new techniques. EVLA is a percutaneous minimally invasive technique where the target vein is cannulated under duplex US guidance and ablated with laser energy. EVLA is an established treatment option for GSV incompetence, with comparable success rates to conventional surgery.[6—8]

Several wavelengths have been used for EVLA — 810, 940, 980, 1064 and 1320 nm,[9—13] with 810, 940 and 980 nm being the most commonly used. At these wavelengths, power is usually set between 10 and 15 W. The energy is administered endovenously, either in a pulsed fashion (pulse duration: 1—3 s with fibre pullback in 3- to 5-mm increments every 2 s) or continuously with a constant pullback of the laser fibre (pullback velocity ranging from 1 to 3 mm s^{-1}). With these parameters, the average linear endovenous energy density (LEED), which is commonly used to report the dose administered to the vein, ranges from 20 J cm^{-1} to 140 J cm^{-1}.[14,15] These doses induce heating of the vein wall, which is necessary to cause collagen contraction and destruction of endothelium. This stimulates vein wall thickening leading to luminal contraction, venous thrombosis and vein fibrosis.[16] Since tumescent anaesthesia is always used, patients feel no pain during EVLA. Tumescent anaesthesia has two functions: it compresses and reduces the diameter of the veins and it acts as protective barrier, minimising the risk of heat-related damage to adjacent tissues.[17,18] Patients generally report discomfort for 5—8 days following EVLA, which is related to the inflammation resulting from successful endovenous ablation (i.e., wall thickening).[19] It is related neither to the presence nor to the degree of ecchymosis nor is it the result of laser damage to perivenous tissue.

The purpose of this study is to report on the effectiveness and safety of EVLA of the SSV in patients from a single centre with medium-term follow-up results.

Patients and Methods

Patients

A clinical history was taken and physical examination, including duplex ultrasound (US)-imaging evaluation of the superficial venous system, was performed in the limbs of patients with varices suspected of arising from the SSV. Study inclusion criteria included varicose veins caused by SPJ incompetence with SSV reflux as demonstrated by duplex US imaging, age of at least 18 years and the ability to return for scheduled follow-up examinations for 12, 24 and 36 months after endovenous laser treatment. Exclusion criteria included impalpable pedal pulses; cardio-vascular disease, inability to ambulate; deep vein thrombosis; general poor health; pregnancy, nursing or plan to become pregnant during the course of participation in the investigation; and extremely tortuous SSVs that would not allow endovenous catheterisation and passage of the laser fibre as identified on pre-treatment venous duplex US mapping. Recurrent SSV after surgical treatment and SSVs with a diameter greater than 10 mm were also excluded. After initial consultation and evaluation, subjects meeting the appropriate criteria were offered surgical treatment and endovenous laser treatment. Nearly all patients chose endovenous laser over surgical ligation and stripping. The patients were treated at the Clinique de Villeneuve d'Ascq, France (private hospital). The study protocol was approved by the local ethics committee. All patients gave written, informed consent before treatment.

Procedure

Duplex US (Aloka 3500, Decines, France) was performed with the patient in the standing position to map sources of venous reflux and then to mark the skin overlying the incompetent portion of the SSV starting at the SPJ. The presence of flow from the deep to superficial venous system in perforating veins was also assessed in the thigh and calf. The SSV diameter was measured in the standing position, 1.5 cm below the SPJ and along the SSV to select the appropriate LEED. In an outpatient procedure room at the hospital, the patient was placed in the prone reverse Trendelenburg's position for treatment of the SSV. Under US imaging, the SSV was cannulated in the mid-to-lower calf using a 21-gauge needle. A 0.035-inch guidewire was passed up to the SPJ under US guidance; a 5-F introducer was placed over the guidewire. A 600-micron optical fibre (Osyfibre: pH-980-15-600-3, Osyris, Villeneuve d'Ascq, France) connected to a 980-nm diode laser (Pharaon, Osyris, Hellemmes, France) was passed through the introducer to the SPJ. Its position was verified by US and by visualisation of the aiming beam through the skin. Duplex control was used to guide injection of 7—8 ml aliquots of 10 ml 1% xylocaïne with epinephrine and 10 ml 1% xylocaïne without epinephrine added to 100 ml of saline. This solution was used for the first 26 patients. For the other 102 patients, to avoid exceeding the safe limits of local anaesthesia, tumescence was achieved with 10 ml 1% xylocaïne with epinephrine diluted in 200 ml of saline. Injections of tumescent anaesthesia were made into the fascial compartment of the SSV at intervals along its length. To reduce the amount of blood inside the vein, patients were in a 15°—20° head-down position.[20]

The treatment was performed as follows: the laser fibre was placed 1—2 cm below the SPJ before treatment commenced. The laser fibre and catheter were slowly withdrawn in 3-mm increments using a graduated scale. Power was set to 10 W and the pulse duration (1.5—3 s) was chosen

to deliver a LEED appropriate to the vein diameter. For SSV diameters between 2 and 4.5 mm, the LEED applied was 50 J cm^{-1}. The LEED was 70 J cm^{-1} for 4.5–7 mm, 90 J cm^{-1} for 7–10 mm. The distal part of the treated vein was monitored by US imaging to prevent skin burns. A total of 39% of the patients in this series underwent concomitant ambulatory phlebectomy. At the end of the procedure, compression was applied with a compression bandage for the first 24 h, and subsequently, a thigh length class 3 medical compression stocking was worn for 3 weeks. Patients were instructed to walk immediately following the procedure and to continue their normal daily activities. All patients received a 5-day course of non-steroidal anti-inflammatory drugs (NSAIDs) (Piroxiam, Feldene®, Pfizer Paris, France).

Follow-up examinations

Patients were evaluated functionally and clinically on day 1 after the procedure and at 1 week, 1 month, 1 year, 2 and 3 years. Patients underwent duplex scanning at 1 year, 2 and 3 years' follow-up to assess the closure rate. Treatment-related side effects and complications, including the presence of ecchymosis, palpable induration, phlebitic reaction and pain, were recorded. The duration of all symptoms was recorded.

Results

A total of 147 patients were seen for SSV treatment between 1 June 2003 and 30 June 30 2006. However, 19 patients were not included into this prospective cohort observational study: one patient due to stage III arterial disease, two patients with cardiac disease contraindicating prolonged Trendelenburg's position, nine patients with an SSV greater than 8 mm in diameter and seven patients were excluded because catheterisation was not possible due to excessive tortuosity of the veins. We included 128 patients (109 female and 19 male; mean age: 49.7 years; range: 21–80 years) who underwent EVLA of incompetent SSV segments with a 980-nm diode laser.

Among those 128 patients, 19 were treated for bilateral SSV reflux. Clinical severity using the Clinical, Etiological, Anatomical and Pathological [CEAP] classification was C2 for 89 limbs, C3 for 36 limbs and C4 for 22 limbs (see details in Table 1). As many as 39% of the patients in this series underwent concomitant ambulatory phlebectomy. Among the 147 SSV segments, the mean SSV diameter, measured in upright position was 5.2 SD 1.5 mm (range 3.0–10.0 mm). The mean length of SSV treated was 18.2 SD 8.3 cm (range 3.5–49.2 cm).

Table 2 reports results with follow-up ranging from 1 year to 3 years. In the 147 limbs, the initial technical success rate was 100%. At day 1 after the procedure and 1-week and 1-month follow-up, all SSVs were closed. The SSVs remained closed in 114 of 117 limbs (97%) after 1 year, in all 61 limbs after 2 years and in all 30 limbs after 3 years. The three failures occurred in large veins (SSV diameter was greater than 9 mm). In these patients, partial ablation of the SSV was observed. Except for those three patients, complete disappearance of the SSV or minimal residual fibrous cord was noted at 1 year in all patients.

Major complications have not been detected; in particular, no deep venous thrombosis (DVT). Similarly, calf DVTs

Table 1 CEAP classification of the 128 patients (147 limbs).

# Patients	CEAP classification				
2	C2	A	EP	AS	Pr 2,3,4
1	C2	A	EP	AS	Pr 3,4
12	C 1,2	A	EP	AS	Pr 4
6	C2	A	EP	AS	Pr 4
4	C 1,2	S	EP	AS	Pr 2,3,4
6	C2	S	EP	AS	Pr 2,3,4
1	C 1,2	S	EP	AS	Pr 3,4
3	C2	S	EP	AS	Pr 3,4
36	C 1,2	S	EP	AS	Pr 4
18	C2	S	EP	AS	Pr 4
1	C 1,2,3	A	EP	AS	Pr 2,3,4
1	C3	A	EP	AS	Pr 2,3,4
1	C3	A	EP	AS	Pr 3,4
4	C 1,2,3	A	EP	AS	Pr 4
1	C1,3	A	EP	AS	Pr 4
2	C 3	A	EP	AS	Pr 4
2	C 2,3	S	EP	AS	Pr 2,3,4
1	C 1,2,3	S	EP	AS	Pr 2,3,4
3	C3	S	EP	AS	Pr 2,3,4
2	C3	S	EP	AS	Pr 3,4
7	C1,3	S	EP	AS	Pr 4
4	C 2,3	S	EP	AS	Pr 4
7	C3	S	EP	AS	Pr 4
1	C 1,2,4a	A	EP	AS	Pr 4
2	C 1,3,4a	S	EP	AS	Pr 2,3,4
1	C 2,3,4 b	S	EP	AS	Pr 2,3,4
1	C 1,4 a	S	EP	AS	Pr 3,4
3	C 1,2,3,4 a	S	EP	AS	Pr 4
4	C 2,4 b	S	EP	AS	Pr 4
7	C 3,4 b	S	EP	AS	Pr 4
1	C 3,4 b	S	EP	AS	Pr 2,3,4
2	C2, 4 b, 5	S	EP	AS	Pr 4

were not observed at day 1 and at any follow-up period. Ecchymoses were seen in 60% with a median duration of 2 weeks. Transient paraesthesia (mostly hypoaesthesia) was observed in 40% of treated legs with a median duration of 2 weeks. The maximum duration did not exceed 4 weeks. At 1-week follow-up, moderate pain was reported in 50% of the patients. Consequently, those patients received analgesics for one more week. No skin discolouration, superficial burn, thrombophlebitis or palpable induration was observed.

The compliance rate for class 3 compression stockings was 100% at 1 week and 70% at 3 weeks. This rate was assessed using a patient questionnaire at the 1-month follow-up appointment. No recurrent varices were seen on clinical examination in the territory of the treated SSV at the 1-, 2- or 3-year follow-up examination. Varicose veins were only seen outside this region arising from other sources than the previously treated SSV.

Discussion

Surgery for SSVs is more challenging, with more complications and higher recurrence rates than for GSVs. EVLA of the GSV has been widely accepted as a treatment for

Table 2 Follow-up recurrence rate and complication rate following EVLA of the SSV with the 980 nm diode laser.

	Follow-up				
	1 Week $n = 147$	1 Month $n = 147$	1 Year $n = 117$	2 Years $n = 61$	3 Years $n = 30$
Occlusion rate	100%	100%	97% (114)	100%	100%
Paraesthesia	40% (58)	0%	0%	0%	0%
Pain (moderate)	50% (73)	0%	0%	0%	0%
Ecchymoses	50% (88)	0%	0%	0%	0%

primary varicose veins, but is less often used in the treatment of SSV reflux. Reluctance of practitioners to use EVLT in the treatment of SSV incompetence may be related to concerns about the proximity of the sural nerve to the vein as well as concerns about popliteal thrombosis. However, as demonstrated by the previous studies, adequate tumescence of the SSV, which theoretically separates the nerve from the vein, can avoid sural nerve injury.[21]

As already proposed by Park et al., EVLA was started from 1 cm to 1.5 cm distal to the SPJ to avoid leaving a long residual SSV stump. Therefore, for almost all patients, EVLA was conducted proximal to the site where the Giacomini vein is drained.

The role of blood during the EVLA should be considered since this may reduce the amount of light transmitted to the vein wall. It is usually recommended to reduce the presence of blood by emptying the vein lumen using leg elevation (Trendelenburg's positioning), peri-saphenous subcutaneous tumescent saline solution infiltration and manual compression. However, larger veins are often only partially compressed by these measures and leg elevation may not be enough to empty the vein. Consequently, higher energy is necessary because some energy is deposited in the luminal blood, creating a thrombus which can re-canalise and cause treatment failure.[15,22]

The correct tumescent anaesthetic technique is essential to ensure that this procedure is safe and painless. A surrounding fascial envelope containing the tumescent solution provides a margin of safety so that heat damage to surrounding structures does not occur.[23]

The experience gained by our group has shown that the energy applied during treatment was the main determinant of success; therefore, LEED remains our choice when comparing energy. Since thermal damage of the inner vein wall (tunica intima) is required to achieve the tissue destruction necessary to lead the vein to permanent occlusion, mathematical modelling of EVLA has confirmed that LEED should be chosen according to the vein diameter,[24,25] which established our policy of adjusting LEED according to the vein diameter.

When compared with other clinical studies, LEED used for EVLA of the SSV appears to be equivalent. When using the 980-nm diode laser, LEED reported by Park and Yim varied between 62 J cm^{-1} and 77 J cm^{-1}.[26] Similarly, in a study performed by another team (Park and Hwang), LEED was adjusted to between 50 J cm^{-1} and 60 J cm^{-1}.[27] Theivacumar et al. delivered a LEED of 66.3 J cm^{-1} (54.2—71.6).[28]

The length of vein treated in our study (18.2 cm SD 8.3 cm) is similar to that treated by Nwaejike (18 cm, range 5—33 cm)[29] and Theivacumar (17 cm, range 12—20 cm).[28] We used a mean total energy (1200 J) comparable to mean

energy reported by Nwaejike: 955 J (range 135—2 800 J). The mean SSV diameter in our study (5.2 mm SD 1.5 mm) is comparable with the average diameter of the SSV in the Elias' series of 50 limbs, which was 5.8 mm.[30]

The clinical outcome of EVLA in the SSV has been reported in a few articles. In Park's series, four of 95 SSVs re-canalised with the recurrence of reflux at 1-month follow-up. Continued closure of the SSV was seen in 89 of 93 limbs (96%) at the 1-month follow-up, all of 87 limbs at the 3-month follow-up, all of 82 limbs at the 6-month follow-up, all of 77 limbs at the 1-year follow-up, all of 71 limbs at the 2-year follow-up and all of 55-limbs at the 3-year follow-up, which were available in the follow-up.[27] We observed similar findings with the three recurrences only occurring in veins greater than 9-mm diameter. Park and Yim also observed re-canalisation of large-diameter SSVs, in most cases greater than 9 mm.[26] Since the energy applied during treatment is the main determinant of success, it seems that LEED was too low in those three cases. This observation is in agreement with Timperman's clinical study. Greater energy delivery improves treatment success of endovenous laser treatment.[22]

The incidence of ecchymoses, pain and paraesthesia was similar to previous studies and major complications were not reported. In our study, all paraesthesia were temporary. In Park's study, only one patient complained of paraesthesia at 6-months follow-up with complete resolution at 1-year follow-up.[27] The ecchymosis rate in our study was 60%. This rate was not reported in other clinical studies involving treatment of the SSV. However, it is similar to the rate reported by Sadick et al. (61.7%) in GSVs.[31] Similarly, it compares favourably with the ecchymosis rate (73.2%) observed by Proebstle et al.[32]

We observed no case of DVT after treatment of the SSV as was found by Park et al.[27] A small number of DVTs have been reported in other series.[21,33]

The principal finding in this study and other similar clinical studies is that EVLA with a 980-nm diode laser system, when performed under tumescent local anaesthesia, is clinically feasible and well tolerated.[26,27] Because the vein is accessed via a 21-gauge needle, this is a minimal procedure, leaving virtually no scar on the patient's skin. Local cutaneous side effects, such as skin burns that have been reported in less than 1% of the EVLA procedures, can be easily avoided by injection of enough tumescent fluid.[4]

EVLA offers many potential advantages over conventional surgery for SSV reflux: the procedure is performed with on-table US imaging, giving safe and reliable identification of the variable anatomy. Significantly, there is no neuro-vascular injury. There is no doubt that in the next decade there will be much debate about the optimal treatment for

SSV reflux. There are few good long-term outcome studies, but those available suggest appreciable recurrence rates within 5 years, typically from 30% to 50%.[3,5] It is likely that the role of surgery will diminish as the endovenous methods such as EVLA become more widely used.

Conclusion

EVLA of the incompetent SSV with a 980-nm diode laser appears to be a safe technique. After successful treatment, there is a very low rate of re-canalisation of the SSV. Since closure is confirmed at 1-, 2- and 3-year follow-up, our study suggests that this procedure will provide a lasting result.

Conflict of Interest/Funding

None.

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