

Endovenous laser treatment for uncomplicated varicose veins

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Abstract

Objective: Endovenous laser ablation (EVLA) of incompetent truncal veins has been proposed as a minimally invasive alternative to conventional surgery for varicose veins. Various strategies have been proposed for successful treatment and this study reviews the evidence for these.

Method: A Medline and 'controlled trials online database' search was performed to identify original articles and randomized controlled trials (RCTs) reporting outcomes for EVLA. Information on patient selection, equipment, technique and outcomes were recorded.

Results: Ninety-eight original studies, including five RCTs, were identified. RCT data indicate short-term outcomes (abolition of reflux, improvement in quality of life [QOL], patient satisfaction) were equivalent to those for surgery. Long-term follow-up is not available. A further RCT showed superior outcomes for ablation commencing at the lowest point of superficial venous reflux rather than at an arbitrary point (fewer residual varicosities, greater improvement in QOL).

Non-randomized series suggest that laser energy of >60 J/cm results in reliable truncal vein occlusion and that longer wavelength lasers may be associated with less post-treatment discomfort.

Conclusion: In the short-term EVLA is a safe and effective treatment for patients with varicose veins. Long-term follow-up is still required.

Keywords: varicose veins; great saphenous vein; small saphenous vein; endovenous laser; EVLA; treatment

Search methods for systematic review

A Medline search was performed using the database 1950-today and the keywords 'endovenous' OR 'varicose AND veins' OR 'vein OR venous, AND insufficiency OR disease OR incompetence OR reflux' AND 'laser'. This yielded 455 articles of which 152 related to endovenous laser therapy of varicose veins. Ninety-eight of these were original studies including five randomized controlled trials (RCTs).

All registers on the controlled trials online database (see www.controlled-trials.com) were searched using the keywords 'endovenous laser'. This yielded 13 studies of which five were duplicates. Two had been published,^{1,2} five are awaiting publication and one is still in progress (expected completion date 2011).

Description of technique

Endovenous laser treatment (EVLTM) was first described by Navarro in 2001³ using an 810 nm diode laser. EVLTM is a trademark referring to a specific 810 nm diode laser and thus the term endovenous laser ablation (EVLA) will be used throughout this document.

Laser is an acronym for 'light amplification by stimulated emission of radiation'. Monochromatic

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(single wavelength) light is emitted from a laser medium (both diodes and Neodymium-doped yttrium aluminium garnet [Nd:YAG] are used for EVLA) and amplified by mirrors.

EVLA involves insertion of a laser fibre into the incompetent truncal vein (usually great [GSV] or small saphenous vein [SSV]) with subsequent thermal ablation of the vein. This should achieve the same effect as saphenofemoral or saphenopopliteal ligation together with stripping of the truncal vein.

Patient selection

Although EVLA was initially used to treat GSV reflux there are several large series describing successful SSV⁴⁻⁷ and anterior saphenous vein ablation.^{8,9} There are also isolated reports of treatment of incompetent perforating veins^{10,11} and varicosities themselves.¹²

Exclusion criteria

Patient factors:

- Unsuitable for local anaesthesia;
- Peripheral arterial disease where both truncal vein ablation and compression bandaging may be inappropriate;
- Pregnancy or breast-feeding.

Anatomical factors:

- Tortuosity;
- Thrombophlebitis.

Most authors exclude patients with deep vein occlusion, and some those with deep vein incompetence (a relative contraindication). Patients with large diameter veins may also be excluded, although Min (personal communication) has treated veins of up to 35 mm diameter. Warfarin therapy, coagulation disorders or other medical comorbidity may also lead to exclusion, although an unpublished series has indicated that EVLA is effective in patients taking warfarin. There is little published evidence to support or refute the other criteria. Further, it is the authors' view that patients with large tributaries arising <10 cm from the truncal/ deep vein junction may not experience an optimal outcome.

Anaesthesia

EVLA is usually performed using tumescent local anaesthesia, which provides analgesia, compresses

the vein thus enhancing contact between the vein wall and laser fibre, and protects surrounding tissues from thermal damage. When tumescent anaesthesia is omitted there is a high incidence of nerve damage (saphenous or sural nerves) and skin burns.¹³ Although reported infrequently, oral or intravenous sedation may be administered and rarely epidural or general anaesthesia is used. The latter prolong recovery and increase procedure costs. There are no studies comparing the risks or benefits of different anaesthetic techniques.

Most authors have used dilute lidocaine for tumescent anaesthesia, which may be neutralized with bicarbonate to reduce pain on injection.^{14,15} Although this can also be achieved by warming the solution to body temperature,¹⁶ this will reduce the protective 'heat-sink' effect of the tumescent anaesthesia. The maximum recommended dose of lidocaine is 3 mg/kg without adrenaline and 7 mg/kg with adrenaline, but doses of 35 mg/kg lidocaine have been safely used for tumescent anaesthesia in plastic surgery.¹⁷ For EVLA around 300 mL per limb at 0.1–0.2% concentration is normally used. In order to avoid the risk of lidocaine toxicity, Chong *et al.* have described the use of cold saline rather than local anaesthetic for tumescence.¹⁸ If lidocaine is used, it is important to be alert for signs of toxicity.

Patient position

For GSV ablation, the patient lies supine with the hip partially flexed and externally rotated. A pillow or small foam wedge placed under the pelvis/lower back on the opposite side is used to turn the patient towards the limb for treatment. For SSV ablation, the patient is positioned in the prone position.

Venous access

The vein for ablation is cannulated percutaneously under ultrasound guidance with the patient in the reverse Trendelenberg position to maximize vein diameter. Thus a tilting table is recommended. Once the fibre is correctly positioned the table is moved to the Trendelenberg position to empty the vein of blood prior to ablation. If percutaneous cannulation proves difficult the vein may be hooked to the skin surface (Oesch phlebectomy hook) via a small stab incision and cannulated under direct vision. This is difficult for the SSV as it lies deep to the fascia in the calf.

The great saphenous vein

The original reports for GSV EVLA described cannulation at the level of the knee joint, mimicking the current practice for limiting stripping of the vein to reduce the risk of saphenous nerve injury. However, when below-knee GSV reflux persists post-ablation, the improvement in symptoms scores is less.¹⁹ Further, a RCT comparing above-knee EVLA alone with above and below-knee EVLA (from the lowest point of reflux) in patients with below-knee GSV incompetence has confirmed a superior symptomatic outcome in the latter with only 17% of patients having residual varicosities requiring delayed sclerotherapy (versus 61% for above-knee ablation).²⁰ This trial also included a third treatment group (who underwent above-knee EVLA with foam sclerotherapy to the below-knee GSV). Although this was not as effective as 'full-length' EVLA, it was superior to above-knee EVLA alone and is recommended for patients with a tortuous below-knee GSV that precludes successful EVLA.

There is one report describing proximal GSV access after percutaneous cannulation of the contralateral groin. This appears to offer little benefit and requires fluoroscopy and enhanced catheter skills.²¹

The small saphenous vein

This is usually accessed in the distal calf, preferably above the distal third (where the sural nerve is closely adherent) to reduce the risk of nerve injury.

Anterior accessory saphenous vein

The anterior saphenous vein may also be suitable for EVLA either alone or in addition to GSV ablation if this is also incompetent. Suitability is limited to those patients who have a relatively straight segment of vein (10 cm or more) between the SFJ and the varicosities. One report describes good outcomes for such patients although additional sclerotherapy or phlebectomies are often required.²²

Positioning the fibre tip

Accurate positioning of the catheter tip (and thus the laser fibre) close to the saphenofemoral (SFJ) or sapheno-popliteal junction (SPJ) but not within the deep vein is vital. The optimal distance from the junction has not been determined, but 1 cm seems appropriate. This can only be achieved with

duplex ultrasound and while there are reports in which the tip of the laser fibre is positioned using the aiming beam,¹³ this is potentially dangerous and cannot be recommended. Some have debated whether the fibre should be positioned proximal or distal to the superficial epigastric vein (which may not be easy to visualize) although there is no evidence to show a benefit in relation to this. Data from Theivacumar *et al.*²³ has shown that a policy of locating the fibre 1 cm distal to the SFJ results in flush GSV/SFJ occlusion with no patent tributaries in 40% of limbs. In the remainder, one or more patent tributaries were visible but all were competent. Persistent non-refluxing GSV tributaries at the SFJ did not appear to have an adverse impact on clinical outcome one year after successful GSV ablation and were not associated with recurrence.

Once positioned, the fibre should be locked to the catheter to prevent movement.

Laser wavelength

Lasers with wavelengths from 808 nm to 1320 nm have been used for EVLA. Wavelength is a determinant of laser penetration and absorption, but there is no evidence that wavelength affects clinical outcome.

The mode of action is not precisely understood. One theory suggests that steam bubbles are formed at the laser tip causing diffuse thermal damage to the vein wall. Thus, a wavelength of 940 nm that would be maximally absorbed by haemoglobin should be optimal.²⁴ Nevertheless, when *in vitro* steam bubble formation using 810, 940 and 980 nm lasers were compared, bubble volume was linearly related to laser energy and unaffected by wavelength.²⁵

Others believe that the combined effects of vein spasm, compression by perivenous tumescent anaesthesia and ablation in the Trendelenberg position results in an 'empty' vein and direct thermal damage to the vein wall. This is supported by several histological studies that show intimal damage combined with discrete full thickness perforations and relatively 'normal' intervening vein.^{9,26,27}

A small double-blinded RCT compared 810 nm and 980 nm lasers for GSV ablation. Occlusion rates were similar in both groups, but there was a trend towards less phlebitis, bruising and pain in the 980 nm group.²⁸ Further, a non-randomized study comparing 940 nm and 1320 nm wavelengths reported significantly less pain, bruising and analgesia use in the longer wavelength group with

no difference in GSV ablation rates.²⁹ The authors postulate that a longer wavelength results in fewer vein perforations because of lower energy absorption by blood.

These studies provide weak evidence for fewer complications with a longer wavelength laser although all seemed equally effective in achieving truncal vein ablation.

Laser dose

Lasers used for EVLA are continuous wave (CW) lasers that emit constant energy. This can be turned on and off to produce short bursts of laser energy. This should not be confused with 'pulsed laser' as this refers to a different and more powerful type of laser. The 'dose' of laser energy delivered can be expressed as joules (J)/cm vein, sometimes called linear endovenous energy density (LEED) or as fluence, which is laser energy delivered for a given surface area (J/cm²). Calculation of fluence requires estimation of the cross-sectional area of the vein, which varies given that the vein diameter changes depending on the point at which it is measured or whether the patient is standing or supine. Further, spasm following catheterization and administration of tumescent anaesthesia affects vein diameter.

In man, a wide range of laser energies have been used, from as little as 16 J/cm (estimated)¹² to 15,240 J per vein (not calculated per cm).¹³ Data from animal models are not particularly helpful in providing useful guidelines other than confirming more extensive transmural vein wall damage with increasing laser dose.³⁰ In one animal model using a 1064 nm laser with a diffusing tip, a minimum laser fluence of 84 J/cm² was recommended.³¹ It is unclear whether this can be extrapolated to a bare-tipped laser fibre employed clinically.³¹

Most clinical studies report doses in the range of 20–95 J/cm. Although there have been no prospective RCT comparing different regimens, a mathematical modelling study advised a LEED of 65 J/cm for a 3 mm vein and 100 J/cm for a 5 mm vein (in continuous mode).³² This is consistent with the findings of a number of observational studies. Thus, a non-randomized study comparing 15 W (24 [12–36] J/cm) and 30 W (63 [33–156] J/cm) power using a 940 nm laser showed that ablation rates were significantly higher in the 30 W group (90% versus 100%; $P < 0.001$). Recanalization at three months was associated with a lower laser dose. Conversely, analgesia use, paraesthesia and hyperpigmentation were more frequent in the

higher energy group. This study also assessed fluence based on supine GSV diameter and recommended a minimum of 20 J/cm².³³

Several other studies have reported a difference in LEED between failed and successful treatments.^{30–32,34,35} Thus, Theivacumar *et al.* advises a minimum LEED of 60 J/cm.³⁷ However, the range of median doses for successes in these studies was wide (24–63 J/cm) and overlapped with the range for failures (20–47 J/cm).^{34–38} A weakness of these reports is that the number of failures was generally small, a fact highlighted by one study with only three failures, which found no difference in LEED between successes and failures. Interestingly, the failures had significantly larger veins suggesting that comparisons of fluence (not calculated) might have been different.³⁹

In a further study, Chang *et al.* used very high laser doses without tumescent anaesthesia which at least, in part, was responsible for the high complication rates (36.5% paraesthesia, 4.5% skin burns).¹³ Nevertheless, there does seem to be an association between laser dose and both successful ablation and the risk of complications. Although the importance of fluence is still being evaluated, it has the theoretical advantage of allowing a more accurate calculation of laser dose for veins of different size. The difficulties in defining this are described above.

Even with relatively high laser doses (95 J/cm) failures may still occur,³⁶ which suggests that laser dose is not the only determinant of success. However, the available data indicates that optimum occlusion rates are achieved with a minimum laser energy of 60 J/cm. Pragmatically, withdrawal of the laser fibre at a rate of 1 cm/5 s using 14 W power allows easy and accurate delivery of 70 J/cm.

Fibre withdrawal

The fibre may be withdrawn in a stepped or continuous fashion and the laser fired continuously or with one-second exposures. Although initial reports described 'stepped' withdrawal, 'continuous' withdrawal now appears to be favoured. This reduces treatment times and perhaps perforation and bruising. One small RCT has failed to confirm the latter.²

Manual compression during treatment

Some authors have advised manual compression of the vein during ablation. However, vein constriction following cannulation and administration of tumescent anaesthesia would suggest that this is unlikely

to be of benefit and might increase the risk of perforation.

Compression following treatment

While all authors advocate compression following treatment, the type (non-stretch bandage, Class I and II stockings) and duration (2–42 days) have neither been standardized nor tested in randomized trials. Review of the literature indicates that two weeks compression is most often advised. Patients should be warned about the need for compression since this may be more restrictive than the treatment itself.

Analgesia

There appears to be wide variation in analgesia requirement following EVLA. While most patients require no pain relief initially (for those that do, paracetamol is usually sufficient), a proportion of patients develop discomfort or pain in relation to the ablated vein 4–5 days post-treatment. Although this is often termed phlebitis, it is likely to be the result of thermal injury to the vein. If troublesome, a non-steroidal anti-inflammatory drug (NSAID) should be prescribed until the pain resolves. Anecdotal evidence suggests that a short course of an NSAID (diclofenac 50 mg t.d.s. for 3 days) commencing on the day of treatment may ameliorate this.

Adjunctive procedures

Since EVLA only treats junctional and truncal vein incompetence, a variety of adjunctive procedures have been described with EVLA. These include both saphenofemoral and perforator ligation. The former is unnecessary²³ and the latter can justifiably be performed either surgically or by a minimally invasive technique (laser, radiofrequency, foam sclerotherapy) at a later date if reflux persists.

The issue of whether to perform concomitant phlebectomies or sclerotherapy (foam or liquid) in conjunction with EVLA has attracted considerable debate. The alternative of delayed sclerotherapy (or local anaesthetic phlebectomies) seems to be a more sensible approach. Protagonists of the former suggest that patients prefer to complete their treatment in a single visit. Conversely, Theivacumar *et al.*²⁰ have shown that when EVLA is commenced at or below the lowest point of truncal vein reflux, only 17% of patients with GSV reflux and 11% with SSV incompetence⁶ have residual varicosities requiring treatment after EVLA alone. Thus,

with concomitant therapy many patients undergo unnecessary treatment that may require additional resources and increase the cost of the procedure. Further the patient is at risk of avoidable pigmentation following sclerotherapy or scarring after phlebectomies for veins that do not require treatment.

Treatment of bilateral varicose veins

There have been no RCT comparing bilateral with sequential unilateral treatment. A non-randomized comparison of unilateral and bilateral procedures found that bilateral procedures were well-tolerated with no evidence of lidocaine toxicity (doses <4.5 mg/kg).⁴⁰

Since the catheter and laser fibre are the main cost of EVLA, there are obvious advantages to bilateral therapy. The potential influence of provider payment for individual treatment episodes within the NHS will not be discussed here.

Thromboprophylaxis

Although the incidence of DVT and pulmonary embolus following EVLA appears very low, some authors advocate up to one week of low-molecular weight heparin following treatment to reduce the risk of thromboembolic complications. There is no good evidence to support or refute this strategy.

The evidence for EVLA

Evidence for symptom improvement

Disease-specific health-related quality-of-life

Despite the plethora of series describing outcomes for EVLA, few have used validated outcome measures to assess changes in patients' symptoms. However, five studies which used the Aberdeen Varicose Vein Questionnaire (AVVQ: validated disease-specific quality-of-life [QOL] measure) to assess this have shown an improvement following truncal vein ablation.

Two RCT (240 legs in total)^{1,2} and one non-randomized trial (132 legs)⁴¹ have shown similar improvements in AVVQ at three months following GSV EVLA or surgery, but none was powered for equivalence. In two of these studies concomitant phlebectomies were performed.^{1,41} Although Mekako *et al.*⁴¹ showed lower (better) AVVQ after EVLA, this group had lower initial scores than the surgical patients.

Another series (68 legs) has shown a significant improvement ($P < 0.001$) in AVVQ scores three

months after SSV EVLA,⁶ while a further report indicates that a significant improvement in AVVQ was maintained at one year.²³

A further RCT comparing saphenofemoral ligation combined with EVLA or stripping reported similar findings using the CIVIQ measure four weeks after treatment.⁴² Although the study protocol included longer follow-up this has not been published.

Generic health-related QoL

Generic health-related QoL (which is less sensitive to change) has also been assessed following EVLA using the Short Form 36 (SF36) questionnaire. Mekako *et al.* in a non-randomized comparison of EVLA with phlebectomies versus surgery found a reduction in QoL in the surgical group one week following treatment (for the domains of physical role, physical functioning, social functioning and bodily pain), which was not seen in the EVLA group. By three months there was an improvement in QoL for both groups with no difference between them.⁴¹

Similar results are reported by Rasmussen *et al.*¹ (RCT comparing EVLA with phlebectomies and surgery) using SF36. In particular, increased bodily pain was evident in the surgical group at 12 days. Again QoL improved in both groups by three months.

Darwood *et al.* found a reduction in QoL one week following treatment, which then improved to better than baseline following EVLA or surgery, no significant difference was seen between groups (unpublished data).

These studies suggest that surgery may be associated with a larger 'dip' in QoL following treatment, but long-term outcomes are the same.

Evidence that EVLA abolishes varicosities and improves cosmesis

There is no validated measure to assess the cosmetic outcome of varicose vein treatments. While some authors report the proportion of patients with residual or recurrent varicosities, it is not always clear how, when or by whom this has been assessed. Since adjunctive procedures are often used with EVLA, the assessment is not of EVLA alone but of a 'package of care', which varies between institutions.

Three studies have used a patient-completed visual analogue score (which may be subject to positive skew) indicating satisfaction with cosmesis after EVLA.^{2,41,43} One of these studies, an RCT of

EVLA versus surgery,² showed equally high levels of satisfaction (>90%) for both groups.

The AVVQ score also includes the extent of visible varicose veins within the composite score, but does not provide specific information about cosmesis alone.

Evidence that EVLA is cost-effective

There is no good data regarding the cost-effectiveness of EVLA.

For health-care providers, there are initial set-up costs including purchase of the laser power source (in the region of £20,000 [€22,200, US\$29,500]). It might also be necessary to purchase an ultrasound machine although spare capacity on existing equipment may be available in many institutions. In addition, disposables are required for each procedure (around £275 [€305, US\$405] at current prices). Balanced against this is the reduced cost associated with undertaking treatment in a suitable 'outpatient' setting rather than an operating theatre. Staffing costs are also lower compared with surgery since fewer nurses and no anaesthetist or recovery room staff are required. Conversely, a vascular technologist or ultrasonographer may be required by clinicians who do not possess the relevant ultrasound skills.

It is also likely that EVLA is associated with lower indirect costs with little or no requirement for community nursing services and patients may return to work and normal activities more quickly than after conventional surgery.

Although one RCT against surgery suggested that EVLA was more costly, the conclusion was flawed by using government re-imburement fees rather than precise costs. In addition, operating theatre time was not measured but assumed to be equal in both groups.¹ A formal cost comparison of EVLA and surgery is required.

Hazards of EVLA

Lasers pose potential hazards to both user and recipient. The diode laser used for EVLA is a class 4 laser and eye protection is advised during use. Laser safety precautions also require that mirrors and windows are covered to prevent inadvertent reflection or diffusion of the laser beam and that doors are locked to prevent entry of unprotected personnel (see Standards to deliver service – Safety below).

Complications of EVLA

Phlebitis

Post-treatment discomfort or tenderness over the treated vein is usually termed phlebitis with symptoms maximal 5–7 days after treatment. Estimates of frequency range from 0% to 33% of patients.²⁸ Although not proven it appears more common with higher laser doses perhaps, reflecting thermal injury rather than a true phlebitis. Routine prescription of a NSAID for three to five days post-EVLA may lessen the associated pain and inflammation.

The literature includes one report of a severe diffuse phlegmonous thrombophlebitis following EVLA in a patient with a leg ulcer (covered during treatment). Failure to respond to intravenous antibiotics necessitated surgical drainage. The authors concluded that antibiotic prophylaxis should be considered in ulcer patients undergoing EVLA.⁴⁴

Bruising

The incidence of bruising varies hugely between series (11–100%)^{1,44} and depends on both its definition and the follow-up protocol. Some bruising seems common in the majority of patients secondary to either administration of tumescent anaesthesia or vein wall perforation by the laser.

Cutaneous nerve injury

The highest incidence of nerve injury was reported by Chang *et al.*¹³ who used very high laser energies and no tumescent anaesthesia. Thirty-six and a half percent of patients suffered temporary paraesthesia and 2.4% permanent numbness. Most authors report a much lower incidence (1–10%) of these complications with the majority being temporary.

The variation in incidence may depend on the vein treated (GSV or SSV) and the site of treatment. Thus, below-knee GSV or distal SSV ablation are more likely to be associated with this complication. Although laser dose and the timing of assessment may also influence the perceived frequency of this complication, the adequacy of tumescence is perhaps the most important. Provided the latter is adequate the perivenous temperature fails to reach the level at which nerve injury is likely to occur.⁵⁹

Deep vein thrombosis

The incidence of DVT following EVLA is difficult to establish. Many studies, including those with rigorous

early duplex follow-up,^{8,33,46} report no thromboembolic complications. Conversely, several authors report extension of thrombus into the CFV (or popliteal vein) from the ablated truncal vein.^{36,46,47,49} There is no consensus on how this should be managed and advice varies from simple observation to various durations of heparin or warfarin therapy or even insertion of an IVC filter. In all cases, the thrombi resolved by three months without sequelae.^{5,49} There are also two reports of pulmonary emboli occurring three to four days following EVLA; there was no evidence of DVT in either patient.^{50,51}

Risk factors for DVT are unclear although adjunctive procedures (phlebectomies), which prolong treatment and particularly the use of general or spinal anaesthesia (preventing immediate mobilization) may be important. The role of DVT prophylaxis, the duration of compression, the proximity of laser fibre to the deep veins and laser dose have not been elucidated. Nevertheless, the incidence of DVT appears low.

Hyperpigmentation

Hyperpigmentation in the line of the ablated vein occurs in up to 12% patients,¹⁰ although most authors report a much lower incidence.^{2,33,38,45} It tends to improve with time.

Arteriovenous fistula

There is one report of a symptomatic arteriovenous fistula developing between the SSV and a branch of the popliteal artery (treated by coil embolization) following EVLA of the short saphenous vein.⁵² The authors of this paper have also had a similar case in which the fistula closed spontaneously by three months. Whether these were secondary to laser ablation or trauma during administration of tumescent anaesthesia is unknown.

Thread vein formation

Two papers describe single patients developing thread vein formation following EVLA.^{8,53} This can also occur following conventional varicose vein surgery, but the mechanism for their development is unclear.

Skin burns

Excluding the study by Chang *et al.*¹³ in which no tumescent anaesthesia was used, only nine cases

of burns have been reported; two occurred when no local anaesthetic was used and two during treatment of tributaries. This emphasizes the importance of careful local anaesthetic infiltration, especially when treating highly superficial veins.

Technical

One broken catheter has been reported following EVLA,⁴⁶ the authors postulate that the laser fibre was pulled back inside the catheter resulting in thermal damage. This complication can be avoided by ensuring that the fibre is locked to the catheter before withdrawal (standard manufacturer's instructions).

Results of EVLA versus surgery

Non-randomized studies

There have been several large case series describing outcomes for EVLA. Most report GSV ablation rates of over 90%,^{23,45,50,54} with associated improvement in symptoms as described above.

Randomized controlled trials

Five trials have compared EVLA with conventional varicose vein surgery although the package of treatment with respect to EVLA has varied. These are summarized in Table 1.

De Medeiros and Luccas⁵⁵ assessed EVLA against GSV stripping (to the ankle) in a single-blinded (patient blind) study of 20 patients with bilateral saphenofemoral incompetence. All patients underwent saphenofemoral ligation (SFL), ligation of perforators and phlebectomies, with EVLA to the right leg and conventional stripping to the left under spinal or epidural anaesthesia. Less bruising and swelling was observed following EVLA. Although satisfaction was high after both treatments, 70% patients preferred EVLA. Successful abolition of SFJ and GSV reflux was observed in 19 of 20 legs treated with EVLA.

Rasmussen *et al.*¹ compared EVLA with surgery in an unblinded study of 137 patients with GSV incompetence. Both procedures were performed under tumescent local anaesthesia with sedation and both had concomitant phlebectomies. There was a similar improvement in QoL (Aberdeen Vein Score, SF36 and venous clinical severity score [VCSS] at 3 months), and return to normal activity (7 days) in both groups. Less bruising occurred

Table 1 Summary of outcomes for randomized trials of surgery vs. endovenous laser ablation (EVLA)

	De Medeiros ⁵⁵	Ying <i>et al.</i> ^{56,*}	Rasmussen <i>et al.</i> ¹	Kalteis <i>et al.</i> ⁴²	Darwood <i>et al.</i> ²
Number of limbs (surgery versus EVLA)	20 vs. 20 [†]	80 patients	68 versus 69	48 versus 47	35 versus 79 (1:2 randomization)
Anaesthesia for EVLA	Regional		Tumescent LA Sedation	General or regional	Tumescent LA
Surgical treatment	SFL, GSV stripping, phlebectomies		SFL, GSV stripping, phlebectomies	SFL, GSV stripping, phlebectomies	SFL, GSV stripping, phlebectomies
Additional therapy for EVLA patients	SFL and phlebectomies		Concomitant phlebectomies	SFJ ligation and phlebectomies	Delayed sclerotherapy (6 weeks)
Outcome measures	Bruising, abolition of reflux, pain	Pain, blood loss, hospital stay	Bruising QoL Normal activity (NA) Abolition of reflux Pain	Bruising QoL Normal activity (NA) Abolition of reflux Pain Patient satisfaction	QoL Normal activity (NA) Abolition of reflux Pain Patient satisfaction
Results	EVLA: less bruising Patients preferred EVLA EVLA: 95% ablation Pain: equivalent	All reduced by EVLA	EVLA: less bruising Equivalent ↑QOL NA: Equivalent Ablation: 96% versus 94% [‡] Pain: less with EVLA	EVLA: less bruising Equivalent ↑QOL EVLA: delayed NA Ablation: 100% both Pain: equivalent Cosmesis: equivalent 16 weeks	Equivalent ↑QOL NA: earlier with EVLA Ablation: 88% versus 94% [‡] Pain: equivalent Satisfaction: equivalent Three months (limited 12 month data)
Duration of follow-up	60 days		Six months	16 weeks	Three months (limited 12 month data)

SFL, saphenofemoral ligation; GSV, great saphenous vein

*Limited data (abstract only)

[†]20 patients: bilateral varicose veins

[‡]Ablation rates: surgery versus EVLA

after EVLA but procedural costs were said to be higher (see above). Again abolition of superficial venous reflux was achieved in 66 out of 68 patients following surgery (two incompletely stripped) and all patients in the EVLA group, but three demonstrated recanalization within six months.

Kalteis *et al.*⁴² compared EVLA with surgery in a non-blinded study of 95 patients with GSV incompetence. Procedures were performed using general or regional anaesthesia with SFL and phlebectomies. The primary endpoints were the size of haematoma at one week (measured) and the CIVIQ (disease-specific QoL) score at four weeks. Bruising was significantly less following EVLA while improvement in QoL was similar in both groups. Successful GSV ablation was noted in all patients at 16 weeks with equivalent outcomes for cosmesis. Interestingly, although post-treatment pain scores were comparable in both groups during the first week, return to work was delayed (20 days versus 14 days) in the EVLA group. Since EVLA was performed without tumescent anaesthesia it is tempting to suggest that this reflects greater medium term discomfort due to thermal soft tissue injury in these patients.

Darwood *et al.*² recruited 103 patients with GSV incompetence in a three-arm study: EVLA with stepwise withdrawal (LA), EVLA with continuous withdrawal (LA) or surgery (GA). Patients undergoing EVLA received delayed sclerotherapy (6 weeks) for persisting varicosities. The principal outcome measures of improvement in QoL and abolition of GSV reflux (EVLA 94%; surgery 88%) were similar in each group, but recovery time was shorter in the EVLA groups. Patient satisfaction with the results of treatment was similar in all groups (>90%). Since this study was performed, the same authors have shown that a higher laser dose and commencing ablation from the lowest point of reflux improve the results for EVLA.

Ying *et al.*⁵⁶ compared EVLA with surgery in 80 patients and found less pain, blood loss and shorter hospitalization in the EVLA group (abstract only available).

Summary of RCTs

These randomized studies suggest that abolition of GSV reflux, improvements in QoL, patient satisfaction and cosmesis are similar for surgery and EVLA. Three studies also show that post-treatment discomfort was no different for either technique.^{2,42,55} Although this may be surprising it is likely to reflect GSV and adjacent soft tissue inflammation ('phlebitis') following the thermal injury inflicted by EVLA.

Although pain levels appear similar for surgery and EVLA return to normal activity or work is variously reported as occurring earlier after EVLA,² at the same time following either modality¹ or delayed after laser therapy.⁴²

It is evident from these trials that there is no consensus as to the optimum treatment protocol for EVLA. Given the results reported by Rasmussen *et al.*¹ and Darwood *et al.*² it seems that concomitant SFL is unnecessary, thus allowing EVLA to be performed without general or regional anaesthesia in an outpatient or office setting.

The question of adjuvant treatment for the varicosities has not been answered by these studies. Only Darwood *et al.*² used delayed sclerotherapy for persisting varicose veins after EVLA. As discussed earlier provided that truncal vein ablation is commenced at the lowest point of reflux, only a minority of patients require additional treatment thus supporting a policy of delayed sclerotherapy over synchronous phlebectomies for EVLA.

Long-term follow-up and the risk of recurrent varicose veins

Case series of EVLA with one to three year duplex follow-up have reported truncal vein ablation rates of 93–99%,^{4,23,48,54,57} with most recanalizations appearing within the first year.

Critics of EVLA have suggested that the technique results in thrombotic truncal vein occlusion and that medium to long-term recurrence rates are likely to be high. However, a study which undertook serial duplex ultrasound during the first year after surgery has shown that the GSV was no longer visible in 95% of limbs one year after treatment.²³ This confirms permanent irreversible ablation in the majority of patients. A further study by Thievacumar *et al.* has shown that neovascularization at the SFJ was evident in 1% of EVLA patients at 12 months compared with 18% in a matched control group undergoing conventional surgery.⁵⁸ These data suggest that long-term recurrence rates should be low and potentially better than those for surgery.

Training needs

EVLA is currently performed by professionals of different specialties (surgery, dermatology, radiology) depending on local expertise. Ideally, the person performing EVLA should also assess the patient following referral to confirm that treatment is indicated. They should be experienced in assessing

patients with venous disease and understand (although not necessarily perform) the benefits and risks of different treatment modalities.

Training for EVLA includes developing ultrasound skills (unless the assistance of a trained ultrasonographer is sought), knowledge about laser safety issues and training in the EVLA technique. Further, the clinician performing EVLA should be able to undertake follow-up, provide any further treatment that may be required and manage complications. Currently, there is no standard training programme for EVLA in the UK and most practitioners learn via an informal mentoring programme.

Standards to deliver service

Safety

New guidance was issued in April of this year on the safe use of lasers by the MHRA (DB 2008(03)) and can be accessed via their website (see www.mhra.gov.uk). This covers training of personnel, protective equipment and safety precautions.

Setting

EVLA does not require an operating theatre and may be performed in an outpatient setting. However, the room must meet laser safety recommendations and the procedure should be performed using appropriate aseptic techniques for intravenous cannulation. In addition, a tilting table is required and equipment for resuscitation should be available.

Training

There is currently no formalized training for EVLA.

Patient pathway

Assessment for treatment: patients should be assessed clinically and with duplex ultrasound prior to treatment to determine:

- (1) Is treatment indicated? (See NICE guidelines www.nice.org Referral Advice: A guide to appropriate referral from general to specialist services. *National Institute for Clinical Excellence* 2001. ISBN 1-84257-144-3);
- (2) What is the most appropriate treatment?

Patient should complete informed consent. The procedure is usually performed as a day case under local anaesthesia. Arrangements for follow-up should be made (NICE guidance, see www.nice.org IPG052). A helpline or contact number may be useful should the patient experience problems.

Technique

It is difficult to prescribe a specific technique for EVLA since the literature describes considerable variation with a poor evidence base. There is little evidence to recommend a specific laser wavelength. Most current laser sources use a diode laser with a wavelength of 810–940 nm, which reflects the absorption spectrum of haemoglobin. Although a range of laser energy has been used there is reasonable evidence to suggest that ≥ 70 J/cm will successfully ablate the GSV and SSV. There is also evidence from one RCT that commencing ablation at the lowest point of reflux will lead to maximum shrinkage/disappearance of varicose tributaries. This is particularly relevant when a policy of delayed sclerotherapy or local anaesthetic phlebectomies is adopted for persistent varicosities. Nevertheless, a proportion of practitioners prefer to undertake concomitant phlebectomies at the time of EVLA on the basis that this completes treatment at a single visit.

It is strongly recommended that duplex ultrasound is used to confirm the position of the laser fibre prior to treatment rather than relying on visualization of the aiming beam. In addition, despite a lack of Level 1 evidence, tumescent anaesthesia appears important in preventing complications.

New developments in laser technology are currently being assessed. In particular, a 1470 nm diode laser (absorption wavelength of water) has recently become available with the putative advantages of being effective at much lower energy levels, not requiring tumescent anaesthesia, and causing only minimal post-EVLA discomfort. This requires further evaluation.

Clinical governance and audit

Suitable mechanisms should be in place for clinical governance and audit. In addition to the information recorded for all invasive procedures/surgery, power and energy delivery should be recorded together with follow-up data on occlusion rates and adverse events. Adverse incidents relating to laser use should be reported to the MHRA.

Conflict of interest

The authors hereby declare no conflict of interests.

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