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Endovenous laser ablation of varicose veins in an office-based facility: a three-year review

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1. Purpose

Endovenous laser ablation (EVLA) to treat varicose veins is becoming increasingly more popular as an alternative to surgical ligation and stripping in the last decade (1, 2). Recent systematic reviews and meta-analysis of studies comparing traditional surgery with endovenous techniques have shown that EVLA is actually safer and more effective in the short to medium term (3, 4) Longer-term data of EVLA outcomes with Doppler ultrasound (DUS) proven vein occlusion rates of 97% at 3 and 4 years have been reported (5, 6).

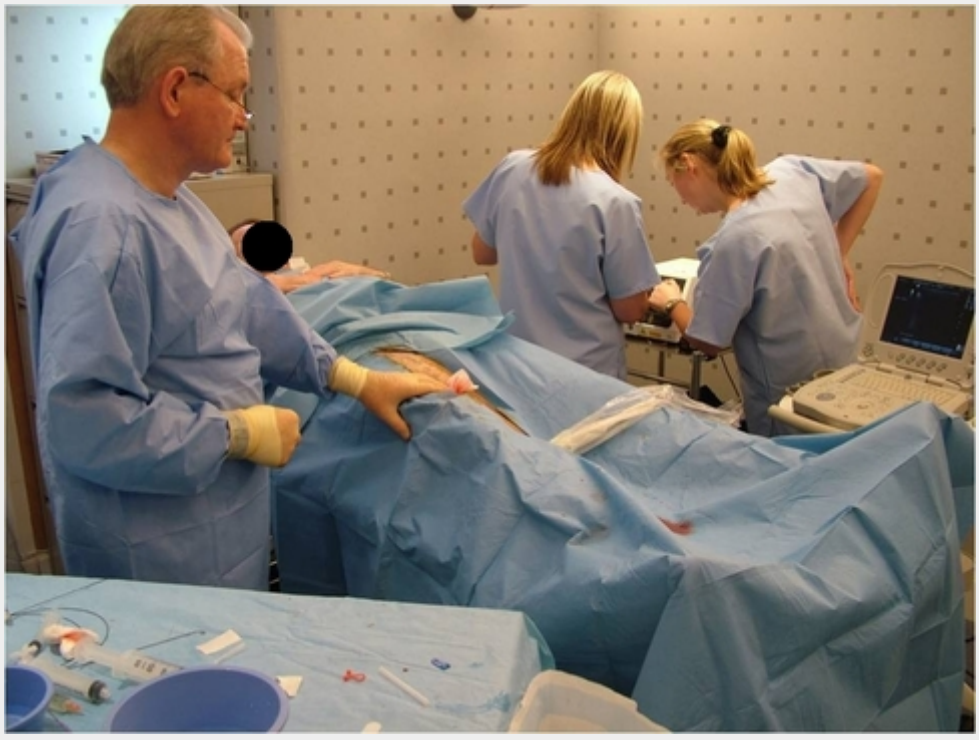
One major advantage of EVLA over surgery is the ability to perform this endovenous procedure under local anaesthetic in a clinic room (7)The technique is safe and cost-effective and is now the established routine practice for treatment of venous disease in North America (8, 9). This clinical series analyses the safety and effectiveness of EVLA practiced in a dedicated vein clinic within a modified consulting room by an interventional radiologist.

2. Materials/Methods

For a three year period from January 2007 116 patients were seen and assessed with clinical examination and DUS and were deemed suitable for EVLA to treat primary and recurrent varicose veins. Venous disease severity was measured using the Venous Clinical Severity Score (VCSS) and each limb was classified according to the CEAP classification (10). Pre- and post-EVLA VCSS was recorded and analysed using the large-sample standard error of difference between means method.

The procedure was performed in a modified consulting office which complies with laser safety regulations (Fig. 1) Initial DUS with the patient standing identified the lowest level of incompetence within the target vein with a relatively straight course, in order that a guidewire and sheath can be passed to the sapheno-femoral (SFJ) or sapheno-popliteal (SPJ) junction. The tip of a graduated 5French sheath is then identified near the SFJ/SPJ and prior to insertion of the laser fibre ultrasound (US) guided tumescent anaesthesia is applied along the perivenous track within the saphenous compartment. Approximately 8 - 10ml /cm of dilute lidocaine solution (20ml 2% lidocaine with adrenaline in 440ml normal saline) is given by infusion pump from puncture site to junction. Then the laser fibre is inserted and locked within the sheath and placed using US guidance 1.5cm from the vein junction. We use an 810nm diode laser (Biolitec, Germany) set at 14 Watt in continuous mode with a pullback rate of 10mm every 5 seconds. This delivers an energy of approximately 70 -80J/cm. Following ablation the leg is wrapped in a cohesive bandage for 7 days and a Class 2 compression stocking is worn for 2 weeks. Review with DUS is done at one, three and six months routinely. Any adjuvant therapy, usually ultrasound-guided foam sclerotherapy (UGFS) is performed at 4 -6 weeks post-EVLA, but in some recurrent cases with neovascularization foam sclerosant is injected via the sheath prior to EVLA.

Fig. 1; Modified consulting room used for EVLA procedure. Tilting couch, procedure trolley, ultrasound machine and laser generator.



Picture 1

3. Results

Table 1: Materials; Patient demographics and disease distribution

Number of patients	116	Female 91 (78.4%)	Male 25 (21.6%)
Age, years (range)	50.6y (27-79)		
Number of limbs	159	Unilateral 73 (63%)	Bilateral 43 (37%)
Primary disease	83 (71.6%)		
Recurrent disease	33 (28.4%)		

A total of 116 patients had 159 limbs treated with EVLA (Table 1) There were 91 (78.4%) females with mean age overall of 50.6 years. In all, 43 (37%) procedures were bilateral and 33 (28.4%) were done for surgical recurrence. Clinically over three-quarters had grade C_2 and C_3 disease (Table 2). The pre-treatment VCSS mean was 4.7; range 2 - 16 (standard deviation 1.77). A total of 170 vein segments were treated in various combinations, and all patients were treated in a single session (Tables 3 & 4)

Table 2: Clinical presentation at first assessment prior to EVLA

CLINICAL FEATURES	Number (%); n=159	CEAP Classification
Active ulcer	1	C6, Ep, As, Pr
Healed ulcer	5 (3%)	C5, Ep, As, Pr
Phlebitis / cellulitis	8 (5%)	C4b, Ep, As, Pr
Skin changes	22 (14%)	C4a, Ep, As, Pr
Oedema	32 (20%)	C3, Ep, As, Pr
All other varicose veins	91 (57%)	C2, Ep, As, Pr
Venous clinical severity score	Mean 4.7 (2 - 16)	

Table 3: Anatomical distribution of incompetent vein segments treated with EVLA

VEIN SEGMENTS	
Great saphenous vein	117 (69%)
Small saphenous vein	33 (19%)
Anterior accessory saphenous vein	20 (12%)
TOTAL	170

Table 4: Combinations of incompetent vein segments treated by EVLA

VEIN SEGMENTS TREATED	Number (segments)	Bilateral (cases)
Great saphenous vein alone	48 (48)	
Great saphenous veins, bilateral	24 (48)	24
Great saphenous vein + AASV	7 (14)	
Great + Small saphenous vein	14 (28)	
Small saphenous veoin alone	9 (9)	
Small saphenous vein bilateral	4 (8)	4
Small saphenous vein + AASV	2 (4)	
AASV alone	5 (5)	
AASV bilateral	3 (6)	3
Bilateral combinations, other		12
TOTAL	170 segments	43

The mean maximum diameter of vein, measured while standing, was 10.3mm (range 6 - 22mm) and mean length treated was 31cm (range 8 - 70cm). Mean laser energy delivered was 85J/cm (range 53 - 123 J/cm) (Table 5). Adjuvant treatment was performed in over 80% of patients, with about one-third receiving UGFS at the EVLA session (Table 6).

Table 5: Target vein characteristics and laser energy delivered

	Mean (range)
Max. diameter of vein treated (mm)	10.3mm (6 - 22mm)
Length of vein treated (cm)	31cm (8 - 70cm)
Laser energy delivered (J/cm)	85 J/cm (53 - 123 J/cm)

Table 6: Adjuvant treatments in association with EVLA

ADJUVANT TREATMENT	Number (%) n = 159 limbs
UGFS via sheath pre-EVLA	26 (16.4%) [3 bilateral]
UGFS of tributaries post-EVLA	26 (16.4%)
UGFS of tributaries subsequently	73 (46%)
Ambulatory phlebectomy, same session	3 (1.9%)
TOTAL	128 (80.5%)

All procedures, including bilateral cases, were well tolerated, but there were 4 (3.4%)technical failuresof access due to vein spasm requiring two surgical cut-downs and two procedure re-calls. There were 29 (25%)minor complications, all of which were self-limiting. There were no cases of deep vein thrombosis or prolonged paraesthesia (Table 7).

Table 7: Complications of EVLA at time of procedure and follow-up

COMPLICATION	Number of episodes (%) n= 116
Technical failure; failed access due to spasm	4 (3.4%)(2 cutdown; 2 repeated)
Bruising; self-limiting	12 (10.3%)
Numbness at exit site (temporary)	2 (1.7%)
Phlebitis requiring treatment	4 (3.4%)
"Trapped blood" requiring aspiration	3 (2.6%)
Prolonged pigmentation	3 (2.6%)
Optical effects of foam sclerotherapy, n=49	3 (6%)
Pain for more than 2 weeks	1
Vasovagal episode	1

Follow-up with DUS ranged from one month to 25 months, with a mean of 6.4 months (Table 8)There was no evidence of any recanalized EVLA-treated truncal veins. The VCSS was scored following additional sclerotherapy to tributary veins in most cases (80%). The mean VCSS at follow-up was 0.18; range 0 - 2; standard deviation 0.52, and standard error of difference of means pre- and post-EVLA was 0.147, with a P value of P<<0.001

Table 8: Venous Clinical Severity Scores (VCSS) pre- and post-EVLA at follow-up (S.D. = standard deviation)

FOLLOW-UP	Mean 6.4 months (range 1 - 25 months)
Doppler ultrasound recurrence	0 (n = 152 limbs)
VCSS pre-EVLA (n = 159 limbs)	4.7 (2 - 16)S.D.= 1.774
VCSS post-EVLA at follow-up (n = 152 limbs)	0.18 (0 - 2) S.D. = 0.52
Difference of two means (probability)	p <<0.001

4. Conclusion

Office-based endovenous treatment of chronic venous disorders have proven benefits for patients, providing dedicated care in a cost-effective environment (8, 9). This study demonstrates that EVLA can be performed in a modified consulting room with excellent outcomes. The introduction of an

endovenous service to hospital practice in the United Kingdom can result in a dramatic shift from venous surgery using general anaesthesia (11). There has been a well recognised learning-curve for vascular surgeons performing ultrasound-guided access and anaesthesia techniques (11, 12). Few articles exist describing EVLA performed by interventional radiologists (IR's) (13), but even in this present series there were four failed accesses due to vein spasm, unrelated to experience.

Some have estimated that only 60 - 73% of patients are suitable for endovenous treatment (14, 15), but these authors excluded many cases where an experienced IR would have managed to manipulate a guidewire and catheter. No case of primary incompetence that presented in this series was unsuitable for EVLA and most recurrent disease will respond to at least a short length of EVLA combined with UGFS, with excellent results. Outcomes for recurrent disease were just as good as primary disease success, confirming recent reports (16).

Interventional radiologists now have an excellent opportunity to incorporate endovenous therapy into their practice (13). They already have all the necesary ultrasound and catheter skills and most know the anatomy and pathology of venous disease. I would therefore encourage more IR's to collaborate with their vascular surgical colleagues who could benefit from their experience.

There is now a sufficient body of evidence to argue that endovenous techniques have become the new gold standard for treatment of varicose veins (17). That does not mean however that we should forget our responsibility to report our results for these new therapies that continue to evolve. The recent reporting standards for endovenous ablation should help promote further venous research (10).

5. Reference

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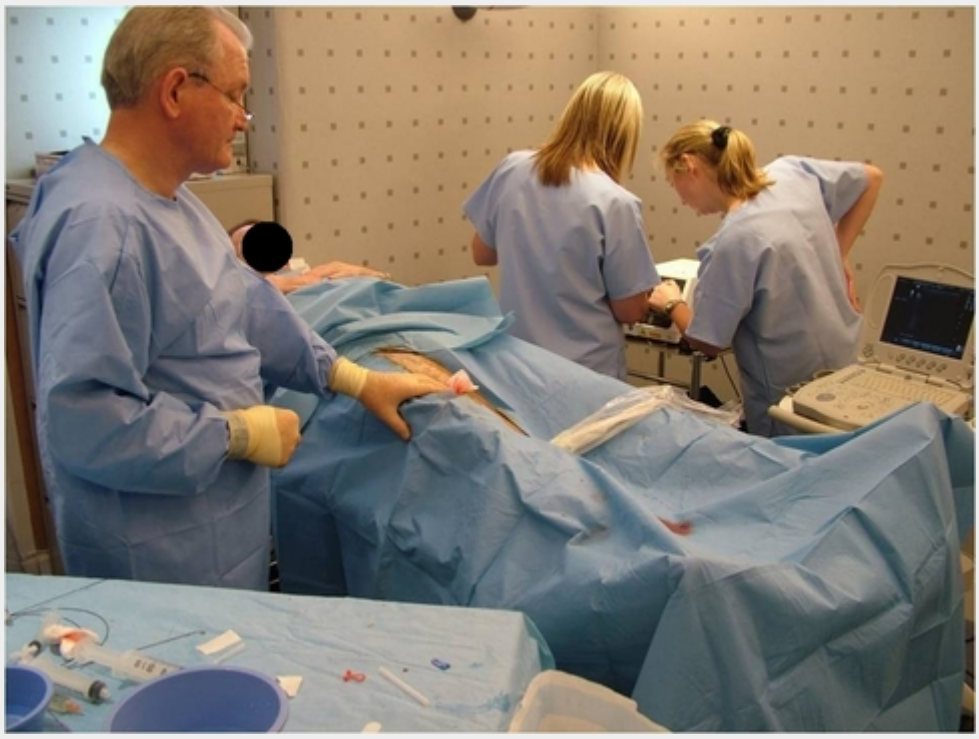
6. Mediafiles

Fig. 1; Modified consulting room used for EVLA procedure. Tilting couch, procedure trolley, ultrasound machine and laser generator.



Picture 1