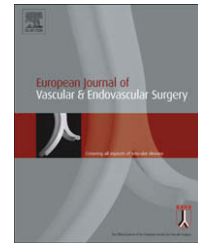




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# Introducing Endovenous Laser Therapy Ablation to a National Health Service Vascular Surgical Unit – The Aberdeen Experience

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## KEYWORDS

Endovenous laser ablation;  
EVLA;  
Varicose veins;  
Learning curve

**Abstract** *Objectives:* To report early clinical outcomes and learning experience following the introduction of endovenous laser ablation (EVLA) to an NHS vascular unit.

*Design:* Prospective observational study.

*Results:* Between February 2006 and January 2008, 631 consecutive patients underwent EVLA to 704 refluxing truncal veins – 579 GSV, 119 SSV and 6 straight segments of anterior accessory GSV. 275/631 (44%) patients had local anaesthesia (LA) plus sedation, 237 (38%) had LA only and 119 (18%) had general anaesthesia. All were treated using the 810 nm diode laser. Adjuvant procedures on-table included foam sclerotherapy 129/704 (18%), multiple stab avulsions 53/704 (8%) and 3 limbs had both. Three-month follow-up with duplex examination is complete in 635/704 limbs (90%). Complete occlusion was noted in 610 veins (96%), 14 (2.2%) were partially occluded and 11 (1.7%) showed no occlusion. 193 (30%) of the 635 limbs seen at follow-up required further treatment for residual varicosities using foam sclerotherapy. There has been one non-fatal pulmonary embolus associated with EVLA and no other complications. *Conclusions:* EVLA is safe and technically effective. It has a defined learning curve requiring new operator skills which can be readily acquired.

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## Introduction

Varicose veins (VV) affect 10–40% of the adult population in the United Kingdom.<sup>1,2</sup> An estimated 60,000 VV procedures are performed each year in the UK, comprising a significant proportion of scheduled vascular surgical workload.<sup>3,4</sup> Currently, due to the continuing pressure on waiting times, there remains considerable debate regarding appropriateness of utilising scarce health care resources to provide the current venous service.<sup>5</sup> Despite this, there is good

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evidence to support improved quality of life when treating uncomplicated venous disease.<sup>6,7</sup>

Endovenous laser ablation (EVLA) for VV in the lower limb is a minimally invasive alternative to conventional surgery, developed by Min et al.<sup>8</sup> Published non-randomised<sup>9–13</sup> and randomised studies have all clearly demonstrated the benefits to patients in the short to medium term, with occlusion rates of the great saphenous vein (GSV) and small saphenous vein (SSV) in excess of 90% at follow-up of between one and nineteen months.<sup>14–18</sup>

In February 2006 our department introduced EVLA as an alternative treatment option for patients with symptomatic varicose veins. Funding for capital (laser) and recurring (disposables) costs was met by our Hospital Trust as part of core Vascular Surgical Services provided. In our proposal it was argued that over time we would be able to release certain resources (e.g. anaesthetic) which could be reallocated to other services within the Hospital Trust elsewhere. A prospective database of consecutive EVLA patients has been maintained. The purpose of this paper is to report our early outcomes following EVLA and present the issues experienced in delivering this service.

## Methods

Aberdeen Royal Infirmary is a tertiary referral centre, a university major teaching hospital with over 1000 beds. All patients referred to the vascular unit with VV were seen initially at an outpatient clinic. Venous duplex scanning was performed if a clinical diagnosis of symptomatic VV (CEAP class 2 or above) requiring treatment was established. Pre-operative venous duplex assessment was performed in the vascular laboratory by our vascular technologists in the initial period while surgeons were being trained in the technique. From May 2006 scans were increasingly performed by the surgeon in the outpatient clinic, until December 2006 when scans were exclusively carried out by surgeons. Two portable duplex scanners were available with a 5 MHz transducer (Micromaxx, Sonosite, Hitchin UK, or Logiq Book, GE Healthcare, Chalfont St. Giles, UK). Reflux was induced with a manual calf squeeze and release and considered significant if it exceeded 1.0 s. Refluxing GSV, SSV or anterior accessory GSV (AAGSV) were assessed for diameter, patency and tortuosity.

Parameters for suitability for EVLA used in our unit include the following: treatable length of at least 10 cm, diameter equal to or greater than 4 mm and BMI <35. Very tortuous veins throughout their length were deemed unsuitable. Presence of thrombus or sclerosis after phlebitis, previous sclerotherapy or surgery, at a level too great to allow passage of the EVLA catheter was also classed as a contraindication.

All patients were offered EVLA routinely if suitable. Standard open surgery was performed in those not suitable for EVLA or if patient requested surgical treatment. Patients with more than one refluxing truncal vein suitable for EVLA could choose to have synchronous or staged procedures.

## EVLA procedure

At first, all procedures were carried out in the daycase operating suite. Initially all procedures were performed

under general anaesthesia and subsequently there was a gradual transition to sedation and finally tumescent saline only. Sedation, if used, consisted of titrated remifentanyl, midazolam or propofol administered by the anaesthetist according to their preference. The EVLA procedure used is standard and has been described in detail elsewhere.<sup>19</sup> Exceptions to this are that the only local anaesthetic used was 0.5–1.0 ml 1% lidocaine infiltrated into the skin at the catheter insertion site in awake patients. In the first four months (65 patients) a very low dilution of lidocaine (less than 0.1%) was used in the tumescent fluid but after Chong's publication<sup>20</sup> we changed to using 0.9% cold saline alone.

All patients were measured for a class 2 full-length compression stocking (Juzo, Dundee, UK) with waist suspender, to be worn for one to two weeks after treatment. The procedures were performed by one of seven different operators. Intra-operative scanning was performed by the vascular technologists until April 2006 and thereafter by the operating surgeon.

The laser (810 nm diode) was operated at either 12 W pulsed mode or 14 W continuous mode (surgeon choice). The aim was to deliver 70–85 J/cm energy, for 12 W the catheter was withdrawn at a rate of 1.4–1.7 mm/s, for 14 W the rate was 1.6–2 mm/s.

During this study period there was no specific policy regarding adjuvant therapy. The operator made the decision whether to include phlebectomies or foam sclerotherapy on-table at the initial treatment or to defer adjuvant treatment to follow-up. In general, if varicosities were very extensive and cannulation had to be made more than a short distance above the site where the tributary branched off the truncal vein, foam and/or phlebectomies were carried out at the time of EVLA.

Patients were encouraged to ambulate as soon as possible after the procedure and were discharged one hour after local anaesthesia or after recovery from sedation or general anaesthesia the same day. A combination of simple analgesia and non-steroidal anti-inflammatory drugs was prescribed prior to discharge for four days. Written after-care was provided and all patients offered review at three months.

At three-month follow-up all patients were assessed by duplex examination. Criteria for successful ablation of the index truncal vein were non-compressibility, absence of colour flow or absence of visible vein. Partial occlusion was defined as visible flow of blood on duplex within a narrowed or sclerotic channel, or ablation of a length of vein less than the length treated with EVLA. Patients with residual varicosities after confirmation of truncal closure received foam sclerotherapy at the discretion of the surgeon or patient's preference.

All procedures and patient demographics were recorded on a datasheet and entered into a prospectively maintained database. Outcome data at scheduled follow-up have been generated based on clinical review, duplex ultrasound examination and the need for additional intervention.

## Results

Between February 2006 and January 2008, 640 consecutive patients were admitted for planned EVLA treatment to 713

refluxing truncal veins. There were 216 men and 424 women with a median age of 51 years (IQR 39–61). By comparison, at the end of this period only 78/718 (11%) of all our symptomatic VV patients underwent traditional open surgery due to patient's choice or unsuitability for EVLA.

This analysis includes four failures of percutaneous cannulation of the GSV in patients with 4 mm diameter veins, two of whom had open surgery on that day and a third re-attended and had successful EVLA. All four occurred in the first seven months of us starting the technique, the last being case number 127/713. Open cannulation was not attempted. A further five failures occurred due to failure to advance the catheter along the vein due to scarring from previous stab avulsions (2), sclerotherapy (1) or phlebitis (2). Overall our rate of failure to gain percutaneous access was 4/713 (0.6%) and failure to advance the catheter proximally was 5/713 (0.7%).

631 patients therefore underwent EVLA to 704 suitable veins. Of these, there were 579 GSV, 119 SSV and 6 straight segments of AAGSV at least 10 cm in length. 563 patients had a single vein treated with EVLA, 63 had two veins treated and five patients had three veins treated at the same sitting. 275/631 (44%) patients had local anaesthesia (LA) plus sedation, 237 (38%) had LA only and 119 (18%) had general anaesthesia. The first 39 patients had general anaesthesia. From May 2006 (case 40) we started to introduce LA with sedation in increasing numbers and from June 2006 (case 65) LA with no sedation. General anaesthesia became uncommon after this date.

491 veins were treated with 12 W in pulsed mode, 184 with 14 W in continuous mode and the rest had a mixture of 12 and 14 W in pulsed and continuous mode, according to surgeon's preference.

181 additional procedures performed on-table at completion of EVLA to varicose tributaries were: foam sclerotherapy 129/704 (18%), phlebectomies 53/704 (8%) and 3 limbs had both. To date, three-month follow-up data are complete in 569/631 (90%) patients with 635/704 (90%) laser treated veins. Complete occlusion was noted in 610 (96.1%) of the treated veins on duplex scanning. Fourteen (2.2%) were partially occluded and eleven (1.7%) had no evidence of occlusion. 193(30%) of the 635 limbs seen at follow-up required further treatment for residual varicosities using foam sclerotherapy (Table 1).

Over time the length of vein treated, volume of tumescent saline injected, operation length and technical outcome are summarised in Table 2 & Fig. 1. The length of GSV treated changed little but SSV length increased. The volume of tumescence used increased and length of operation decreased over time. Operative details regarding the partial and no occlusions are summarised in Table 3. Analysis of gender, body mass index, operating surgeon and age of patient showed similar numbers in the failure groups compared to those with full occlusion. The only difference seen was in the group with no occlusion where the energy delivered was less than in the other two groups.

To date there has been one major complication of EVLA. A 54-year-old female with a body mass index of 34.5 underwent bilateral GSV EVLA with bilateral phlebectomies under general anaesthetic. Cannulation on the second limb was difficult and the procedure lasted 90 minutes. On the

fifth post-operative day she was admitted to the medical department with a pulmonary embolism and required anticoagulation with heparin and warfarin. Review at eight months showed complete occlusion of the GSV with patent deep veins and no residual varicosities. There have been no other major complications of EVLA in our cohort, in particular, no skin burns, pain persisting beyond three weeks, or thermal nerve injury.

## Discussion

EVLA is a safe intervention and in the short term an effective technique for the treatment of incompetence of the GSV, SSV and AAGSV. It has a recognisable safe learning curve but raises several challenging issues.

There is no evidence to our knowledge that surgery for symptomatic but uncomplicated varicose veins in young patients who are expected to mobilise rapidly confers a significant risk of post-operative thromboembolism. It remains our routine practice not to administer prophylaxis against thromboembolism during endovenous surgery. We accept general anaesthesia, body mass index > 30 kg/m<sup>2</sup> and operative time greater than 30 min are considered adverse risk factors.<sup>21</sup> It may be prudent to review one's own practice and consider the issue of prophylaxis when embarking on a new intervention for operating times at least initially may be longer.

It is appreciated that whilst we as clinicians steadily developed the technical skills and progressed along the learning curve in performing EVLA a significant "comfort zone" was provided by GA. The specific skills to be learned included targeted operative duplex scanning, wire/catheter handling and accurate placement of adequate volumes of tumescent fluid. Of these elements duplex scanning was least familiar to the operating surgeons. Initially staff from our Vascular Laboratory provided active duplex scanning support, followed by perioperative training and subsequently pre- and post-operative training in the outpatient setting. It

**Table 1** Frequency of intervention for residual varicose tributaries at three-month follow-up based on original index procedure(s)

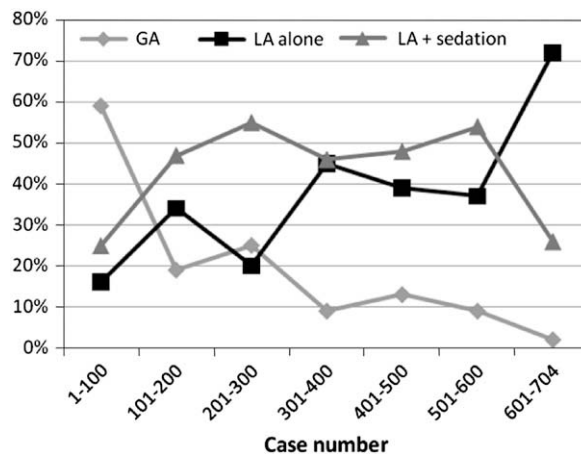
	Additional procedures at 3 months <i>n</i> = 635			
	EVLA alone <i>n</i> = 467	EVLA & foam <i>n</i> = 124	EVLA & avulsions <i>n</i> = 41	EVLA, foam & avulsions <i>n</i> = 3
Initial vein treated				
GSV	384	107	31	3
SSV	79	15	10	0
AAGSV	4	2	0	0
Total	467	124	41	3
Adjuvant foam therapy at 3 months <i>n</i> (%)				
GSV	130 (34%)	32 (30%)	4 (12.9%)	0
SSV	112 (27%)	5 (33%)	0	–
AAGSV	1 (25%)	0	–	–
Total	152 (33%)	37 (30%)	4 (9.8%)	0

GSV = great saphenous vein, SSV = small saphenous vein, AAGSV = anterior accessory GSV.

**Table 2** Changes in operative detail and treatment outcome over study period

	Case number n = 704 veins						
	1-100	101-200	201-300	301-400	401-500	501-600	601-704
GSV length treated (cm)	32 (24-37)	29 (21-37)	31 (22-36)	30 (22-39)	34 (27-42)	32 (27-38)	31 (24-42)
SSV length treated (cm)	15 (10-19)	15 (10-17)	16 (11-20)	20 (11-22)	19 (13-23)	20 (15-27)	20 (15-27)
Volume saline (ml)	90 (60-105)	150 (100-275)	280 (200-380)	300 (250-350)	300 (200-400)	350 (250-400)	350 (250-500)
Procedure length (min)	40 (30-60)	35 (30-40)	35 (30-40)	35 (30-40)	30 (30-40)	30 (30-35)	30 (30-35)
Full occlusion 3 months post-op n = 635 veins	81/84 (96.4%)	82/89 (92.1%)	89/92 (96.7%)	87/89 (97.8%)	89/95 (93.7%)	90/92 (97.8%)	92/94 (97.9%)
No occlusion 3 months post-op n = 635 veins	3/84 (3.6%)	5/89 (5.6%)	0/92	1/89 (1.1%)	0/95	1/92 (1.1%)	1/94 (1.1%)

GSV = great saphenous vein, SSV = small saphenous vein.  
Numbers in first four rows = median (interquartile range).



**Figure 1** Type of anaesthetic provided over time.

was at this point that morphological features of the index truncal vein began to be appreciated in terms of case selection. In addition funds for portable scanning equipment were required.

The EVLA protocol evolved as our experience with the technique increased. We moved towards single vein procedures as the number of GA and LA with sedation cases reduced. This has also been the case with multiple stab avulsions.

From the data presented a departmental experience of approximately 200 procedures was required to achieve satisfactory technical competency. Interestingly after the first 200 procedures despite the operating time remaining constant there was a trend to treat longer lengths (particularly for the SSV), using more tumescent fluid with fewer failures at follow-up (eight in the first 200 versus one in the next 300). It is of interest to consider whether the same high closure rates would have been achieved had the service commenced without anaesthetic assistance. During this period although participating surgeons attended EVLA workshops no surgeon attended a formal Vascular Ultrasound course. As more vascular ultrasound courses become available the number of cases/duration required to achieve competency may change.

Historically, following open superficial venous surgery our patients were either routinely reviewed post-operatively in nurse-led general vascular clinics or sent postal questionnaires and reviewed if necessary. Currently all EVLA patients are provided with clinical review by a surgeon capable of venous duplex scanning and interpretation of post-EVLA changes. Predictably, this has led to increase overall outpatient activity in specific follow-up clinics. Interestingly, 30% of our treated limbs receiving EVLA alone or in combination with adjuvant therapy required further treatment for residual varicosities three months post-operatively. Ideally the most efficient scenario would allow the operator to positively identify and predict the need for adjuvant treatment during the initial procedure. We consider that the need for adjuvant treatment will further decrease as the absolute length of incompetent refluxing truncal vein treated by EVLA increases as reported originally by our colleagues from Leeds.<sup>15</sup> Despite there being no routine policy regarding access point we note and



**Table 3** Operative details of failures

	Duplex result at three months <i>n</i> = 635		
	No occlusion	Partial occlusion	Full occlusion
Number of veins	11 (1.7%)	14 (2.2%)	610 (96.1%)
Median age (IQR) years	58 (50–68)	55 (50–63)	52 (40–63)
No. of veins treated			
GSV	10	11	504
SSV	1	3	100
AAGSV	0	0	6
Length treated in cm median (IQR)			
GSV	33 (20–37)	31 (24–36)	31 (24–38)
SSV	15	10, 20, 20	18 (13–23)
AAGSV	–	–	16 (14–17)
Energy density J/cm median (IQR)			
GSV	72 (66–83)	81 (76–84)	82 (73–86)
SSV	67	84, 85, 89	82 (72–86)

GSV = great saphenous vein, SSV = small saphenous vein, AAGSV = anterior accessory GSV.

accept that the mean treated length of GSV has changed little in this series although the range of lengths has increased slightly. It is debateable whether patients with confirmed occlusion of the truncal vein and only residual branch varicosities do in fact need further therapy.

In conclusion, EVLA is a new technology which is efficacious and can safely be introduced into a vascular surgical service. It has a learning curve requiring new operator skills that can be readily acquired safely. Although EVLA can release certain resources it may also require at least initially, input of additional resource and training. Further investigation is required to identify those patients best served with additional intervention at the time of EVLA. It is likely that with increasing experience and the development of procedure specific packs this procedure could be delivered in an outpatient room with appropriate laser safety precautions. Its effectiveness alongside other non-invasive/surgical venous techniques (in terms of cost-effectiveness) require investigation by multi-centre studies.

## Conflicts of Interest

None.

## Acknowledgements

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