Randomized clinical trial

Randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins

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Background: **Endovenous laser ablation (EVLA) is a popular minimally invasive treatment for varicose veins. Surgical treatment, featuring junctional ligation and inversion stripping, has shown excellent clinical and cost effectiveness. The clinical effectiveness of both treatments was compared within a randomized trial.**

Methods: **Some 280 patients were randomized equally into groups receiving either surgery or EVLA. Participants had primary, symptomatic, unilateral venous insufficiency, with isolated saphenofemoral junction incompetence, leading to reflux into the great saphenous vein. Outcomes included: quality of life (QoL), Venous Clinical Severity Score (VCSS), pain scores and time taken to return to normal function. Owing to the nature of the procedures, blinding was not possible.**

Results: **Both groups had significant improvements in VCSS after treatment ($P < 0{\cdot}001$), which resulted in improved disease-specific QoL (Aberdeen Varicose Vein Questionnaire, $P < 0{\cdot}001$) and quality-adjusted life year (QALY) gain ($P < 0{\cdot}001$). The pain and disability following surgery impaired normal function, with a significant decline in five of eight Short Form 36 (SF-36®) domains ($P < 0{\cdot}001$ to $P = 0{\cdot}029$). Periprocedural QoL was relatively preserved following EVLA, leading to a significant difference between the two treatments in pain scores ($P < 0{\cdot}001$), six of eight SF-36® domains ($P = 0{\cdot}004$ to $P = 0{\cdot}049$) and QALYs ($P = 0{\cdot}003$). As a result, surgical patients took longer to return to work and normal activity (14 *versus* 4 days; $P < 0{\cdot}001$). Complications were rare.**

Conclusion: **EVLA was as effective as surgery for varicose veins, but had a less negative impact on early postintervention QoL. Registration number: NCT00759434 (http://www.clinicaltrials.gov).**

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Introduction

Varicose veins are a common problem[1] and, aside from cosmetic concerns, cause significant impairment in health-related quality of life (QoL)[2–4]. Symptoms include aching, discomfort, pruritus and muscle cramps. A proportion of patients develop the complications of chronic venous insufficiency, potentially progressing to ulceration.

The relatively new, minimally invasive endothermal ablative techniques are gaining in popularity. At the time this trial was initiated, endovenous laser ablation (EVLA) had become the front runner in the endovenous revolution[5]. However, conventional surgery remains the most common treatment for varicose veins in the UK[6,7], and is widely considered to be the gold standard. It results in significant QoL improvement, and is cost effective; it has a calculated incremental cost-effectiveness ratio of £1936 per quality-adjusted life year (QALY) compared with conservative treatment[8].

The key questions, therefore, are whether EVLA is more or less effective than surgery in the management of varicose veins and, additionally, whether there are any benefits beyond those of surgery. The primary aim

of the treatment of varicose veins is to improve QoL; this must be regarded as the most significant outcome measure, and as such was the key focus of the present analysis.

Methods

This non-blinded randomized controlled trial (Hull Endovenous Laser Project 1; HELP-1) was approved by the local research ethics committee, and the institutional Research and Development Department. Patients presenting to a single tertiary referral vascular surgical department with primary symptomatic varicose veins from September 2004 to March 2009 were assessed for suitability for trial participation.

The inclusion criteria were: primary, symptomatic, unilateral varicose veins, with isolated saphenofemoral junction (SFJ) incompetence, leading to reflux into the great saphenous vein (GSV). Incompetence was defined as reflux of at least 1 s on spectral Doppler analysis. In addition, both surgeon and patient had to occupy a position of equipoise regarding the merits of either procedure. Exclusion criteria were: previous treatment for ipsilateral varicose veins, deep venous incompetence or obstruction, age less than 18 years, pregnancy, impalpable foot pulses and inability to give informed consent to trial participation.

The power calculation was based on Short Form 36 (UK SF-36® V1; Medical Outcomes Trust, Waltham, Massachusetts, USA) domains. Up to 120 patients per group were required to detect a medium (5–10-point) difference in physical domains between two groups, with a power of 80 per cent and a significance of 5 per cent[9]. Assuming that the differences in the pilot study were reproduced[10], the target recruitment was 140 per group, allowing for dropout.

Patients were seen in a dedicated one-stop venous clinic, where they were assessed and underwent detailed duplex ultrasonography to establish eligibility. If eligible, and after providing written informed consent, patients were randomized equally into two groups by means of sealed, opaque envelopes, receiving either surgery or EVLA. Patients selected their own envelope in the clinic under the supervision of a research nurse.

Interventions

All surgical procedures were performed under general anaesthesia in either a day-case or dedicated vascular surgical theatre. Patients received a single dose of preoperative antibiotics[11]. Flush SFJ ligation was followed by ligation of all tributaries back to the second branch, and inversion stripping of the GSV to the knee. The cribiform fascia, superficial fascia and skin were closed following infiltration of 0·5 per cent levobupivacaine into the wounds.

All EVLA procedures were performed under local tumescent anaesthesia in a dedicated procedure room within the outpatient department. Patients were marked before the procedure guided by duplex ultrasonography. The GSV was cannulated percutaneously with the patient in reverse Trendelenburg. The initial aim was to cannulate the perigenicular GSV, but the technique evolved during the trial, and latterly cannulation was performed at the lowest point of demonstrable reflux. A 5-Fr catheter was introduced into the vein using the Seldinger technique, and its tip accurately positioned at the SFJ under ultrasound guidance, aiming for a flush occlusion. The patient was then put in the Trendelenburg position, and perivenous tumescent anaesthetic was infiltrated around the GSV. The constituents were 20 ml 2 per cent lidocaine with 1 : 200 000 adrenaline and 20 ml 0·5 per cent levobupivacaine in 1 litre 0·9 per cent saline. Total local anaesthetic did not exceed the recommended maximum safe dose per patient. A sterile bare-tipped 600-nm laser fibre was introduced via the catheter for laser ablation of the GSV. Endovenous laser energy was delivered using an 810-nm diode laser generator (Diomed/Angiodynamics, Cambridge, UK) set at a continuous power delivery of 14 W. No antibiotics were used in this group.

In both groups, surface varicosities and incompetent perforators were marked before the procedure in the dependent position and concomitant phlebectomies were performed via stab incisions made over varicose tributaries, which were avulsed using a Kocherized mosquito clip or vein hook. Perforating veins were divided and ligated through a 1·5-cm incision, which was then closed with a subcuticular monofilament suture. Stab incisions were closed with Steri-strips™ (3M, St Paul, Minnesota, USA), and cotton wool, gauze and elastic compression dressings applied. These were later replaced by a thigh-length T.E.D.™ antiembolism stocking (Tyco Healthcare, Gosport, UK), which patients were advised to wear for a total of 6 weeks. All patients were discharged with diclofenac 50 mg to be taken regularly three times daily for 1 week and paracetamol 1g four times daily for breakthrough pain.

All patients were seen immediately before and after the procedure by the same research nurse, who provided identical instructions in both groups: to elevate the leg while at rest; mobilize as much as possible; return to work

as soon as feeling able to do so; and avoid driving, returning only when able to perform an emergency manoeuvre safely. A 24-h contact number was also given for advice or help. Patients were assessed at 1 week, 6 weeks, 3 months and 1 year in a dedicated clinic.

Outcomes

The primary outcome measure was generic QoL assessed using the UK SF-36® V1, which uses 36 items to derive eight domains, each scored from 0 (worst possible) to 100 (best possible). The domain profile includes: physical function, role limitation due to physical disability (role – physical), bodily pain, general health, vitality, social function, role limitation due to emotional problems (role – emotional) and mental health. In addition, the results can be transformed into a single utility index (SF-6D) representing the QALY[12,13]. These values were derived from the standard gamble technique; this is accepted as the optimal method for QALY derivation, as patient utility is ascertained under the conditions of choice and uncertainty[14–16].

Secondary outcomes

Generic QoL was also assessed using the EuroQol 5D instrument (EQ-5D™; EuroQol Group, Rotterdam, The Netherlands). Responses to the five domain questions were transformed using the UK time trade-off tariffs into a global single index scale[17]. In this case, preference values were derived under the conditions of choice with certainty. As with SF-6D, these scores are used to calculate QALY weights. The value of 1 is ascribed to normal 'full health' and 0 to death. SF-6D runs from 0·3 to 1·0, and EQ-5D™ from −0·6 to 1·0. SF-36® and EQ-5D™ have both undergone extensive testing of validity and reliability, including in the context of venous treatment[8,18–26].

The Aberdeen Varicose Vein Questionnaire (AVVQ) was also completed. This instrument records the specific impact of venous disease on QoL and is scored from 0 (no impact of varicose veins on QoL) to a theoretical maximum of 100. Scores rarely exceed 35 in patients with primary, symptomatic, uncomplicated varicose veins. This has been shown to be reliable, valid and responsive[21,23,26]. All QoL instruments were completed independently by the patients themselves.

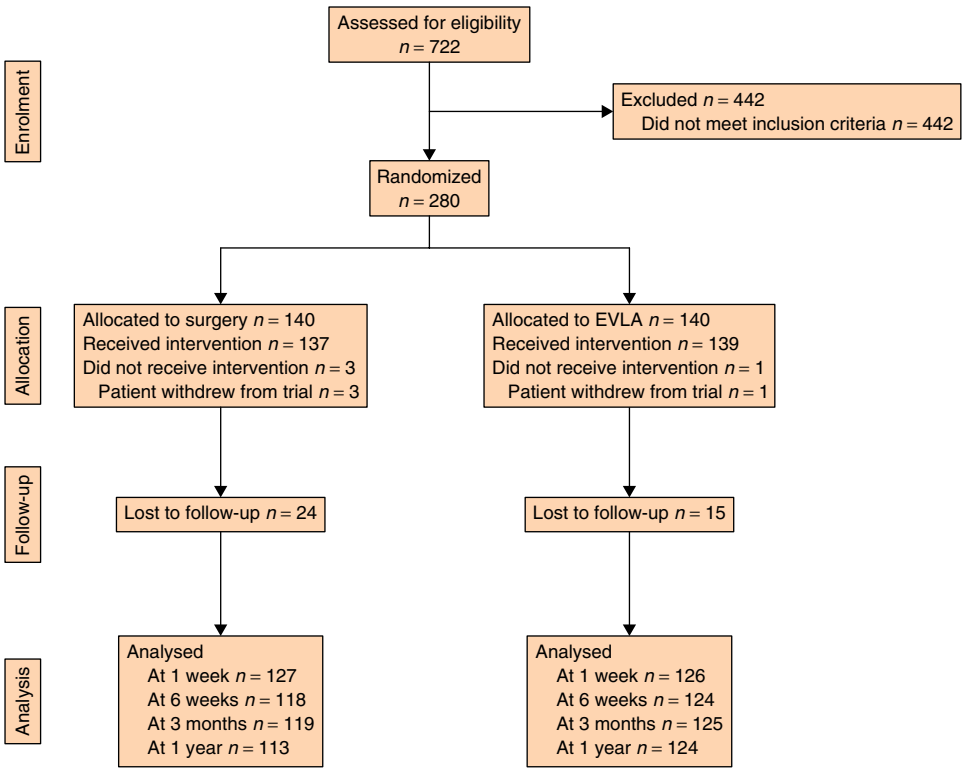

Fig. 1 CONSORT chart showing the flow of patients through the trial of surgery (saphenofemoral junction ligation and inversion stripping) *versus* endovenous laser ablation (EVLA)

In addition to QoL measurement, objective assessment of the severity of venous disease was performed by a research nurse using the clinical grade of the Clinical Etiologic Anatomic Pathophysiologic (CEAP) system[27,28] (from C0 representing no disease, to C6 indicative of active venous ulceration), and also the Venous Clinical Severity Score (VCSS; 0 represents no significant venous disease and 30 is the maximum score). The VCSS has been shown to be a valid, sensitive and responsive measure of the severity of varicose veins[29,30].

Postprocedure pain scores were recorded in a patient diary daily for the first week using an unmarked 10-cm visual analogue scale (0, no pain; 10, worst imaginable pain), alongside the requirement for supplementary analgesia, and the time to return to normal activity and work. Patients also recorded their satisfaction with the cosmetic outcome and the intervention overall at 3 months and 1 year. These were again both marked on a 10-cm unmarked visual analogue scale (0, completely unsatisfied; 10, completely satisfied).

Statistical analysis

All data were recorded in a dedicated database (Microsoft® Access; Microsoft, Redmond, Washington, USA). Continuous data were first tested for normality. Normally distributed data were presented as mean(s.d.), and hypothesis significance testing was performed with paired and unpaired *t* tests. If the data were not normally distributed, median (interquartile range) values were presented, with analysis using the Mann–Whitney *U* test for unrelated samples and Wilcoxon signed rank test for paired data. Friedman test was used to analyse multiple related samples across the study interval. Categorical data were analysed by means of χ^2 test or, if necessary, Fisher's exact test. The incidence and timing of those lost to follow-up was

Table 1 Baseline comparison of the groups

	Surgery ($n = 137$)	EVLA ($n = 139$)	P‡
Age (years)*	49(13)	49(14)	0·632§
Women	90 (65·7)	85 (61·2)	0·433
Left leg	74 (54·0)	73 (52·5)	0·803
Smoking status			0·805
Ex-smoker	37 of 130 (28·5)	35 of 132 (26·5)	
Current smoker	30 of 130 (23·1)	35 of 132 (26·5)	
Employed	85 (62·0)	93 (66·9)	0·399
Antiplatelets/anticoagulants	12 (8·8)	9 (6·5)	0·474
Height (m)*	1·7(0·1)	1·7(0·1)	0·391§
Body mass index (kg/m^2)*	26·0(4·3)	26·6(5·0)	0·290§
GSV diameter (mm)*			
Groin	8·2(2·7)	8·7(2·8)	0·092§
Knee	6·7(2·0)	6·7(1·8)	0·874§
VCSS†	4 (3–5)	4 (3–5)	0·919¶
CEAP clinical grade			0·824
C2	96 (70·1)	95 of 138 (68·8)	
C3–C6	41 (29·9)	43 of 138 (31·2)	
AVVQ†	13·7 (9·9–18·2)	12·6 (9·6–17·2)	0·177¶
SF-36® domain profile†			
Physical function	90 (80–100)	90 (75–100)	0·644¶
Role – physical	100 (75–100)	100 (50–100)	0·170¶
Bodily pain	74 (52–100)	74 (52–100)	0·609¶
General health	77 (67–87)	77 (62–92)	0·377¶
Vitality	70 (53–80)	70 (55–80)	0·616¶
Social function	100 (75–100)	100 (75–100)	0·242¶
Role – emotional	100	100	0·553¶
Mental health	80 (68–90)	84 (68–92)	0·027¶
EQ-5D™†	0·841 (0·796–1·000)	0·848 (0·796–1·000)	0·954¶
SF-6D†	0·795 (0·717–0·847)	0·804 (0·744–0·856)	0·172¶

Values in parentheses are percentages unless indicated otherwise; values are *mean(s.d.) and †median (interquartile range). EVLA, endovenous laser ablation; GSV, great saphenous vein; VCSS, Venous Clinical Severity Score; CEAP, Clinical Etiologic Anatomic Pathophysiologic; AVVQ, Aberdeen Varicose Vein Questionnaire; SF-36®, UK Short Form 36 V1; EQ-5D™, EuroQol 5D; SF-6D, single index utility score derived from SF-36®. ‡χ^2 test, except §*t* test and ¶Mann–Whitney *U* test.

subjected to Kaplan–Meier analysis, with intergroup log rank significance testing.

Analysis was by the principle of intention to treat. All data were collected during the dedicated clinic follow-up. Statistical analysis was done using SPSS® version 16.0 (SPSS, Chicago, Illinois, USA).

Results

A total of 280 patients were randomized, as intended (*Fig. 1*). Baseline variables were comparable in the two groups (*Table 1*). There was a statistically significant difference in the mental health domain of SF-36®, but this was not of sufficient magnitude to be regarded as clinically significant[9,31–33]. There was no difference between the groups in terms of the numbers lost or the length of successful follow-up ($P = 0{\cdot}081$).

Interventions

In the surgery group the mean length of GSV stripped was 33(11) cm. In the EVLA group the mean energy density was 95(15) J/cm. EVLA took longer (mean 67(16) *versus* 61(14) min; $P = 0{\cdot}002$). All EVLA procedures were performed on outpatients, whereas unsuitability for day-case general anaesthesia necessitated inpatient treatment in 21·2 per cent (29 of 137) of the surgery group ($P < 0{\cdot}001$).

Complications were relatively rare in both groups, but sensory disturbance, haematoma and infection rates were significantly higher after surgery (*Table 2*). The surgery group took longer to return to normal activities (median 14 (7–25) *versus* 3 (1–10) days; $P < 0{\cdot}001$) and, in employed individuals, to return to work (14 (13–28) *versus* 4 (2–14) days; $P < 0{\cdot}001$).

Table 2 Postoperative complications

	Surgery ($n = 133$)	EVLA ($n = 137$)	P*
Sensory disturbance	13 (9·8)	4 (2·9)	0·020†
Haematoma	11 (8·3)	1 (0·7)	0·003†
Infection	8 (6·0)	2 (1·5)	0·048†
Phlebitis	6 (4·5)	4 (2·9)	0·536
Persistent pain	5 (3·8)	1 (0·7)	0·116
Pigmentation	1 (0·8)	4 (2·9)	0·371
Anaesthetic complication	3 (2·3)	0 (0)	0·118
Persistent bruising	2 (1·5)	1 (0·7)	0·618
Allergy	1 (0·8)	0 (0)	0·493
Thromboembolism	0 (0)	0 (0)	–

Values in parentheses are percentages. EVLA, endovenous laser ablation. *Fisher's exact test, except †χ^2 test.

Clinical classification

Both groups experienced a similar significant decrease (improvement) in VCSS values over the study period, from a median of 4 (3–5) to 1 (0–1) by 3 months ($P < 0{\cdot}001$). This was maintained up to 1 year. There was no difference between groups at any time.

Generic quality-of-life profile

After 1 week, the surgical group demonstrated significant deterioration in five of the eight SF-36® domains: physical function ($P < 0{\cdot}001$), role – physical ($P < 0{\cdot}001$), bodily pain ($P < 0{\cdot}001$), social function ($P = 0{\cdot}001$) and role – emotional ($P = 0{\cdot}029$) (*Table 3; Fig. S1a–b*, supporting information). EVLA caused significant deterioration in only two domains: physical function ($P = 0{\cdot}018$) and role – physical ($P < 0{\cdot}001$); preoperative scores in the domains of bodily pain, social function and role – emotional were preserved.

After this initial deterioration, both treatments resulted in significant overall improvements in five of the eight domains (surgery: physical function, $P < 0{\cdot}001$; role – physical, $P = 0{\cdot}040$; bodily pain, $P < 0{\cdot}001$; general health, $P = 0{\cdot}001$; vitality, $P = 0{\cdot}003$. EVLA: physical function, $P < 0{\cdot}001$; role – physical, $P = 0{\cdot}001$; bodily pain, $P < 0{\cdot}001$; general health, $P = 0{\cdot}030$; vitality, $P < 0{\cdot}001$).

The relative preservation of QoL in the EVLA group after 1 week resulted in significantly higher (better) scores in six of the eight domains than those observed after surgery: physical function ($P = 0{\cdot}012$), role – physical ($P = 0{\cdot}005$), bodily pain ($P = 0{\cdot}031$), vitality ($P = 0{\cdot}049$), social function ($P = 0{\cdot}004$) and role – emotional ($P = 0{\cdot}027$). From 4 weeks onwards there were no differences between the groups.

Disease-specific quality of life

Both groups had the same significant increase (worsening) in AVVQ scores after 1 week ($P < 0{\cdot}001$) (*Table 3; Fig. S2*, supporting information). This in turn was followed by a decrease (improvement) in AVVQ scores over the rest of the study ($P < 0{\cdot}001$). There was no significant difference in AVVQ scores between the groups at any time point.

Index utility scores – quality-adjusted life years

Both groups described a significant decrease (worsening) of EQ-5D™ scores after 1 week (surgery, $P = 0{\cdot}003$; EVLA, $P = 0{\cdot}024$) (*Table 3; Fig. S3a*, supporting information). Again, following this, there was an increase (improvement)

in scores over the rest of the study ($P < 0{\cdot}001$), with no significant difference between the groups at any time.

In contrast, deterioration in SF-6D scores was only evident in the surgery group at 1 week ($P < 0{\cdot}001$); scores were preserved in the EVLA group, with no difference from baseline ($P = 0{\cdot}141$) (*Table 3; Fig. S3b*, supporting information). As with EQ-5D™, both groups reported significant improvements overall ($P < 0{\cdot}001$). The lack of deterioration from preoperative health status at 1 week in the EVLA group resulted in significantly higher (better) scores compared with those in patients who had surgery ($P = 0{\cdot}003$).

All of the observed longitudinal and cross-sectional changes in QoL scores reaching statistical significance in this trial were independently accepted as being clinically significant and meaningful[9,31–35].

Reported pain and analgesia use

The early postoperative differences in QoL were echoed in the domain-specific pain scores. Patients who had EVLA reported less pain than those in the surgery group from day 1 ($P = 0{\cdot}004$ to $P < 0{\cdot}001$) (*Fig. 2*), which resulted in a higher proportion of patients in surgery group requiring supplementary analgesia over the same interval ($P = 0{\cdot}012$ to $P = 0{\cdot}001$) (*Fig. S4*, supporting information).

Patient satisfaction

Patients in the EVLA group reported slightly higher satisfaction with the cosmetic outcome of the procedure at 1 year ($P = 0{\cdot}034$), but there was no significant difference in satisfaction with the overall outcome (*Fig. S5*, supporting information).

Table 3 Changes in health-related quality of life after treatment

	Time after procedure (weeks)	Surgery	EVLA
SF-36® domain profile			
Physical function	0	90 (80–100)	90 (75–100)
	1	80 (65–90)	88 (70–95)
	52	95 (80–100)	95 (85–100)
Role – physical	0	100 (75–100)	100 (50–100)
	1	50 (0–100)	100 (25–100)
	52	100	100
Bodily pain	0	74 (52–100)	74 (52–100)
	1	62 (41–74)	74 (54–84)
	52	94 (72–100)	100 (72–100)
General health	0	77 (67–87)	77 (62–92)
	1	82 (72–92)	81 (67–92)
	52	82 (72–92)	82 (67–92)
Vitality	0	70 (53–80)	70 (55–80)
	1	65 (55–80)	70 (60–80)
	52	75 (65–85)	75 (60–85)
Social function	0	100 (75–100)	100 (75–100)
	1	75 (63–100)	100 (75–100)
	52	100 (75–100)	100 (88–100)
Role – emotional	0	100	100
	1	100 (67–100)	100
	52	100	100
Mental health	0	80 (68–90)	84 (68–92)
	1	84 (68–92)	88 (76–92)
	52	88 (76–92)	88 (74–92)
AVVQ	0	13·7 (9·9–18·2)	12·6 (9·6–17·2)
	1	16·5 (12·2–22·7)	16·6 (12·4–21·1)
	52	2·0 (0–5·3)	2·0 (0–5·3)
EQ-5D™	0	0·841 (0·796–1·000)	0·848 (0·796–1·000)
	1	0·801 (0·691–0·895)	0·796 (0·760–1·000)
	52	1·000 (0·841–1·000)	1·000 (0·877–1·000)
SF-6D	0	0·795 (0·717–0·847)	0·804 (0·744–0·856)
	1	0·759 (0·672–0·830)	0·796 (0·735–0·838)
	52	0·835 (0·777–0·878)	0·843 (0·773–0·876)

Values are median (interquartile range). EVLA, endovenous laser ablation; AVVQ, Aberdeen Varicose Vein Questionnaire; SF-36®, UK Short Form 36 V1; EQ-5D, EuroQol 5D; SF-6D, single index utility score derived from SF-36®.

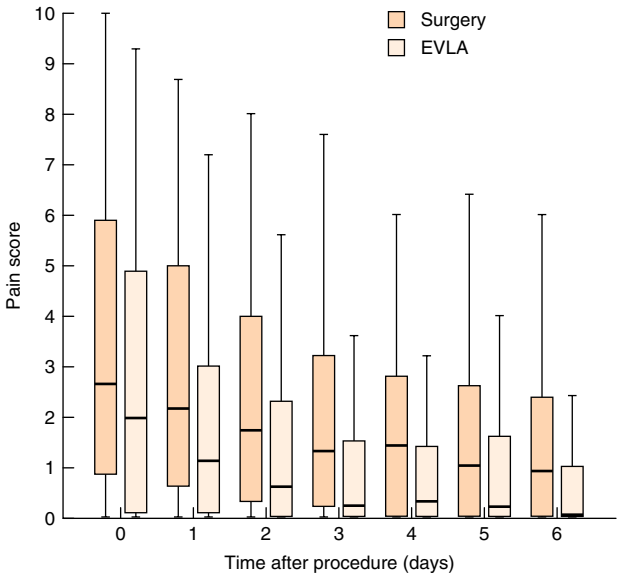

Fig. 2 Pain after surgery or endovenous laser ablation (EVLA) reported on a visual analogue scale from 0 to 10. Median (line within box), interquartile range (i.q.r.) (box), and range of data with 1·5 × i.q.r. below the first quartile and above the third quartile (error bars) are shown

Discussion

This trial was powered to allow an in-depth analysis of health-related QoL after varicose vein treatment. Previous studies have centred on technical and safety outcomes, and have shown new endothermal ablative techniques in particular to be safe[36] and result in better duplex-derived outcomes than conventional surgery[37]. The hope is that recurrence rates will be reduced in the long term, although a clear understanding of the impact of the milder degrees of recurrent veins on QoL has yet to be ascertained. Until now, there has been little hard evidence to show that EVLA, or the other technologies, demonstrates measurable QoL benefits over conventional surgery.

What has been shown clearly is that successful treatment of venous insufficiency results in significant QoL improvements[8]. Minimally invasive techniques have been demonstrated to result in less postprocedure pain than surgery[10,38–41], and allow an earlier return to work and normal activities[38,39,41,42], although this has not been a unanimous finding[40,43].

The present trial confirmed that both surgery and EVLA are highly efficacious. Both resulted in significant improvements in the objective severity of venous disease, with lower VCSS values after treatment. This caused a decrease in AVVQ scores, signifying a reduction in the impact of venous disease on QoL, which in turn had a positive effect on generic QoL. Primarily the physical, rather than emotional and psychological, attributes of health were improved, enhancing overall QoL, as evidenced by QALY gains.

Any invasive procedure will have some negative short-term impact on QoL, but this was minimized in the group receiving EVLA. The surgery group had a significant deterioration in early QoL, whereas QoL was relatively preserved following EVLA. Patients who had EVLA had less disruption of their activities of daily living, and returned to normal quicker. The time taken to return to work is known to be influenced by multiple factors[44,45]. However, the groups in this study were well matched at baseline, and efforts were made to give the same advice regarding the expected convalescence. Thus the difference of 10 days reported here is likely to be real.

In common with most trials of different techniques for the treatment of varicose veins, neither the patients nor the assessors could be blinded to the technique used. The risk of observer bias was reduced, however, as the majority of outcomes reported (including the primary outcome) were reported independently by the patient. Those observed by an assessor were registered using objective, validated instruments. Another feature in common with other trials is that a number of patients were lost to follow-up. This did not have a critical effect on the power of the trial.

In designing this trial, the aim was to produce a study that gave clarity in the outcome and interpretation, while being a true reflection of clinical practice in the UK. QoL data are subject to significant degrees of unsystematic variation, leading to problems with statistical interpretation. Therefore, it was felt important to minimize variation and allow meaningful differences to be uncovered. A criticism of this study is that patients in the surgery arm underwent conventional inversion stripping under general anaesthesia. This reflects the predominant practice in the UK. There are newer techniques such as cryostripping, or even the use of tumescent anaesthesia for surgical stripping, but there is little convincing evidence to date that these will improve short-term outcomes following surgery[39,40,46].

Another area of controversy is the treatment of branch varicosities after EVLA. Concomitant ambulatory phlebectomy and incompetent perforator ligation result in a low requirement for subsequent procedures, and can enhance QoL[47]. Patients receiving sequential treatment, if required, did not experience the same rapid improvement in VCSS or AVVQ scores. There was no difference in clinical efficacy between the two treatments studied

here, as evidenced by the same VCSS and AVVQ improvement in the EVLA and surgery groups. This might not have been the case without the present treatment protocol.

It has been noted previously that EQ-5D™ is a relatively insensitive instrument, particularly when used in situations such as the present study[8,19,48]. Yet it has been chosen as the index health instrument of choice for National Institute for Health and Clinical Excellence evaluations[49] and routine collection of patient-reported outcome measures in the UK[50]. In the present study, SF-6D was more sensitive, demonstrating an intergroup difference at 1 week.

Patient satisfaction is known to be low following venous surgery[32] and it is reassuring to see such high rates following either treatment. There is a trend that fewer patients are being referred for treatment of varicose veins in the UK[6]. The data from this and other studies[2–4,8] suggest that treatment results in significant, durable improvement in QoL.

The immediate postoperative benefits of minimally invasive intervention with EVLA warrant the adoption of this technology as a standard treatment for varicose veins.

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Supporting information

Additional supporting information may be found in the online version of this article:

Fig. S1 Short Form 36 domain-specific outcomes after surgery or endovenous laser ablation for varicose veins: **a** physical function, **b** role – physical, **c** bodily pain, **d** general health, **e** vitality, **f** social function, **g** role – emotional and **h** mental health (Word document)

Fig. S2 Aberdeen Varicose Vein Questionnaire scores after surgery or endovenous laser ablation for varicose veins (Word document)

Fig. S3 Single index utility scores **a** Euroqol 5D (EQ-5D™) and **b** Short Form 6D (SF-6D) after surgery or endovenous laser ablation for varicose veins (Word document)

Fig. S4 Proportion of patients requiring supplementary analgesia after surgery or endovenous laser ablation for varicose veins (Word document)

Fig. S5 Patient satisfaction, measured on a visual analogue scale from 0 to 10, after surgery or endovenous laser ablation for varicose veins (Word document)

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