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Randomized clinical trial of VNUS® ClosureFAST™ radiofrequency ablation *versus* laser for varicose veins

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Background: **Endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are both associated with excellent technical, clinical and patient-reported outcomes for the treatment of varicose veins. The aim of this study was to compare the techniques in a randomized clinical trial.**

Methods: **Consecutive patients with primary great saphenous vein reflux were randomized to EVLA (980 nm) or RFA (VNUS® ClosureFAST™) at a single centre. The primary outcome measure was postprocedural pain after 3 days. Secondary outcome measures were quality of life at 6 weeks, determined by the Aberdeen Varicose Vein Questionnaire (AVVQ) and Short Form 12 (SF-12®), and clinical improvement assessed by the Venous Clinical Severity Score (VCSS). Analyses were performed on the basis of intention to treat using multivariable linear regression.**

Results: **Some 131 patients were randomized to EVLA (64 patients) or RFA (67). Mean(s.d.) pain scores over 3 days were 26·4(22·1) mm for RFA and 36·8(22·5) mm for EVLA ($P = 0·010$). Over 10 days, mean(s.d.) pain scores were 22·0(19·8) mm *versus* 34·3(21·1) mm for RFA and EVLA respectively ($P = 0·001$). The mean(s.d.) number of analgesic tablets used was lower for RFA than for EVLA over 3 days (8·8(9·5) *versus* 14·2(10·7); $P = 0·003$) and 10 days (20·4(22·6) *versus* 35·9(29·4) respectively; $P = 0·001$). Changes in AVVQ, SF-12® and VCSS scores at 6 weeks were similar in the two groups: AVVQ ($P = 0·887$), VCSS ($P = 0·993$), SF-12® physical component score ($P = 0·276$) and mental component score ($P = 0·449$).**

Conclusion: **RFA using VNUS® ClosureFAST™ was associated with less postprocedural pain than EVLA. However, clinical and quality-of-life improvements were similar after 6 weeks for the two treatments. Registration number: ISRCTN66818013 (http://www.controlled-trials.com).**

Based on an abstract presented to the Annual Meeting of the Vascular Society of Great Britain and Ireland, Liverpool, UK, November 2009, that was awarded the Venous Forum Prize and published as *Br J Surg* 2010; **97**(Suppl 1): 13

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Introduction

In the past decade the introduction of minimally invasive endovenous ablation therapy has revolutionized the treatment of varicose veins. In 2001, endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) were approved for use by the National Institute for Health and Clinical Excellence in the UK. Since then surveys and venous registries have shown that their use has been increasing steadily[1–5]. Perceived advantages over traditional surgery include fewer complications, minimal postprocedural pain[6–8] and faster recovery times[9,10]. Theoretically, the reduced incidence of neovascularization in the groin may also result in lower recurrence rates in years to come[11]. The majority of patients with primary varicose veins have great saphenous vein (GSV) incompetence that is amenable to endovenous thermal ablation[12]. With evidence to suggest that patients are concerned about recovery times and recurrence rates[13], the appeal of endovenous interventions is understandable.

A wide range of endovenous laser wavelengths and fibres are now available, although the 980-nm wavelength and bare fibre are used most widely in the UK at present[4]. The most popular RFA system is the VNUS® ClosureFAST™

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(VNUS Medical Technologies, San Jose, California, USA) segmental ablation catheter, which has superseded earlier continuous-withdrawal catheters. Although a number of studies have compared RFA or EVLA with traditional superficial venous surgery[8–9,14], studies comparing EVLA with RFA are scarce and findings have been inconclusive[15–17]. To date, only one small randomized trial comparing VNUS® ClosureFAST™ and EVLA has been published[18]. The aim of the present study was to compare early outcomes following EVLA 980 nm and segmental RFA in a randomized study.

Methods

Consecutive adults presenting to one vascular specialist were screened for suitability for the trial. All patients underwent colour duplex ultrasonography (Philips iU22, Andover, Massachusetts, USA) and patients over 18 years of age with primary GSV incompetence were invited to participate. All scans were performed by an accredited vascular scientist and reflux was defined as retrograde flow of more than 0·5 s after calf compression. Patients with current deep vein thrombosis (DVT), significant arterial disease (ankle : brachial pressure index below 0·8) or who were unsuitable for general anaesthesia were excluded.

Treatment allocation

Consenting patients were randomized to either VNUS® ClosureFAST™ (RFA) or 980-nm laser (EVLA) using a bare fibre, using an internet randomization service[19]. In patients with bilateral GSV incompetence, the leg that was more symptomatic according to the patient was randomized and the same treatment was performed on both legs. All patients were blinded to treatment allocation; however, for practical reasons, assessors were not blinded. Ethical approval for the study was granted by Charing Cross Research Ethics Committee (reference 08/H0711/19) and the trial was registered with Current Controlled Trials (ISRCTN66818013).

Interventions

All interventions were carried out under general anaesthesia in an operating theatre by one of three surgeons experienced in both techniques. For both techniques, the GSV was cannulated at, or as near as possible to, the most distal point of venous reflux, and the catheter tip was positioned 2 cm from the saphenofemoral junction under ultrasonographic guidance. Standard tumescent local anaesthesia (50 ml 1 per cent lidocaine with 1 : 200 000 adrenaline (epinephrine) in 1000 ml normal saline) was infiltrated along the length of the vein under ultrasonographic guidance. In patients treated with segmental RFA, the first segment was treated with two RFA cycles according to the manufacturer's instructions, and the remainder of the vein was treated with one RFA cycle per 7-cm segment. Extrinsic pressure was applied over the vein during treatment cycles. In patients who had EVLA, the laser was continually withdrawn with the aim of delivering energy greater than 60 J/cm to the vein wall, with a power setting of 11 W. Patients with additional small saphenous or anterior thigh vein incompetence were treated with the allocated treatment modality at the same sitting. Patients with varicosities were treated with concomitant phlebectomies using a standard technique with an Oesch hook and all phlebectomy sites were sutured with 6/0 polypropylene. Tumescent anaesthesia was not used for phlebectomy incisions.

In all patients the patency of the deep veins was checked by the operating surgeon using duplex ultrasonography in the operating theatre immediately after the procedure. After treatment, a crepe bandage was applied for at least 2 h, and was replaced with a thromboembolic deterrent (TED) stocking before discharge. Patients were instructed to wear the TED stocking continuously for 1 week. On induction of anaesthesia, all patients received thromboprophylaxis consisting of 5000 units subcutaneous unfractionated heparin sodium and prophylactic antibiotics: amoxicillin 1 g and flucloxacillin 1 g. All patients were discharged with a supply of paracetamol (1 g up to four times a day) and ibuprofen (400 mg up to three times a day) and instructed to take them only if required. All patients were also provided with a written information sheet advising them to mobilize as much as possible after the procedure, and to return to work and normal activities as soon as they felt able.

Outcomes assessed and follow-up protocol

All patients were asked to complete the Aberdeen Varicose Vein Questionnaire (AVVQ), a validated disease-specific quality-of-life questionnaire for varicose veins[20,21], and the Short Form 12 (SF-12®; Medical Outcomes Trust, Waltham, Massachusetts, USA) to assess generic quality of life before the procedure, and the Clinical Etiologic Anatomic Pathophysiologic (CEAP) class and Venous Clinical Severity Score (VCSS) were recorded by a clinician. Patients were assessed at 10 days and 6 weeks. Patients were given a diary card with a 100-mm visual analogue scale to record postprocedural pain each day for 10 days. They were also asked to record any analgesic drugs taken, and the time taken to return to normal activities and

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work, if applicable. The primary outcome measure was mean postprocedural pain over the first 3 days. Patients were invited to attend follow-up after 6 weeks, when quality of life was assessed using the AVVQ and SF-12®. The VCSS was also assessed and any complications at 1 and 6 weeks were recorded. Assessment of vein occlusion rates 6 months after the intervention will be undertaken and reported separately. Duplex imaging was not otherwise performed unless a patient presented with symptoms suspicious of DVT.

Sample size calculation

Power calculation was based on the primary outcome measure of postprocedural pain after 3 days using data from a published departmental cohort study and the published literature[6,9,22,23]. The calculation was based on detection of a 20-mm difference in pain scores over the first 3 days with a standard deviation of pain score of 20 mm. To attain 90 per cent power at the 5 per cent significance level, a minimum target sample size of 47 legs per group was required. This number allowed for 10 per cent non-compliance in the randomized group and 20 per cent dropout at 6 weeks.

Statistical analysis

All analyses were performed according to a predefined analysis plan using Stata® software version 10.0 (StataCorp, College Station, Texas, USA) on the basis of intention to treat. As the trial was relatively small, Student's t and χ^2 tests were used to compare baseline characteristics between groups in order to check whether any differences had occurred by chance. The distribution of continuous

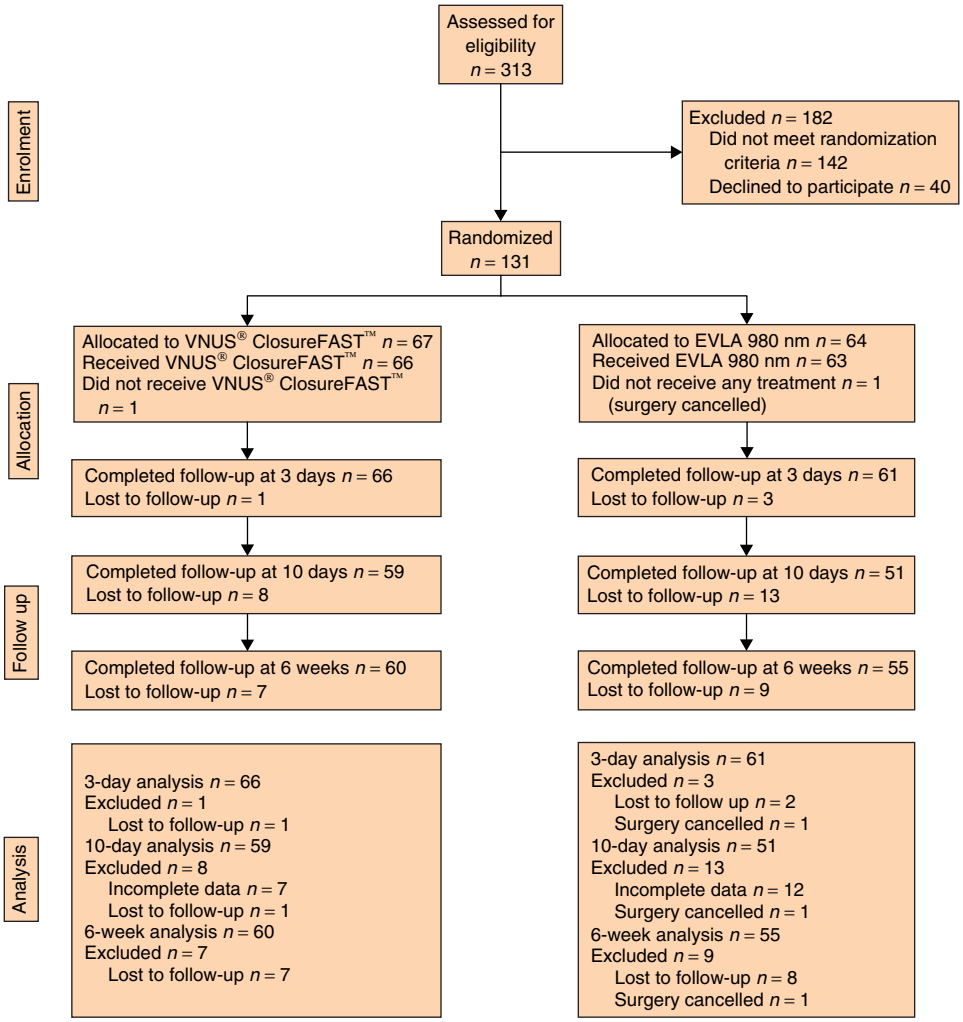

Fig. 1 CONSORT diagram for the trial

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Table 1 Comparison of baseline patient characteristics in a trial comparing two treatments for varicose veins

	RFA ($n = 67$)	EVLA ($n = 64$)	*P*
Sex ratio (F : M)	47 : 20	42 : 22	0·579‡
Age (years)*	49(15)	48(16)	0·540†
Body mass index (kg/m^2)			0·334‡
< 30	61 (91)	61 (95)	
≥ 30	6 (9)	3 (5)	
VCSS*	5·1(2·1)	4·7(2·1)	0·278†
AVVQ*	20·6(9·4)	19·2(9·5)	0·412†
CEAP class			0·467‡
C1–C2	23 (34)	26 (41)	
C3–C4	39 (58)	36 (56)	
C5–C6	5 (7)	2 (3)	
Deep vein disease			0·178‡
Yes	13 (19)	7 (11)	
No	54 (81)	57 (89)	
Pattern of disease			0·727‡
GSV	54 (81)	50 (78)	
GSV and small saphenous vein	13 (19)	14 (22)	
Unilateral or bilateral disease			0·433‡
Unilateral	31 (46)	34 (53)	
Bilateral	36 (54)	30 (47)	
Procedural parameters			
Length ablated (cm)*	49(16)	46(14)	0·177†
Total no. of phlebectomies above or below knee*	6·2(4·0)	6·2(3·6)	0·945†

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). RFA, radiofrequency ablation; EVLA, endovenous laser ablation; VCSS, Venous Clinical Severity Score; AVVQ, Aberdeen Varicose Vein Questionnaire; CEAP, Clinical Etiologic Anatomic Pathophysiologic; GSV, great saphenous vein. †Student's *t* test; ‡χ^2 test.

variables was checked using normal plots, with transformation of any skewed variables. Postprocedural pain scores were analysed using linear regression with two levels of adjustment. Primary adjustment was made for age, sex, body mass index, clinical disease severity, number of truncal veins ablated on the trial leg, total length of vein ablated on the trial leg and number of phlebectomies on the trial leg as primary adjustment. Secondary adjustment was made for all co-variables in the primary analysis as well as for the use of analgesia.

Secondary outcomes including quality of life and clinical improvements were analysed using analysis of co-variance (ANCOVA), which adjusted changes in outcome for baseline values. In addition, primary adjustment was made using the same variables as those used for the pain score analysis, and also for presence of bilateral disease and presence of deep venous incompetence.

Results

Over 12 months from July 2008 to July 2009, 313 patients were screened for inclusion in the study. A total of 171 met the eligibility criteria and were invited to participate; 131 patients consented to randomization. Of the 40 patients who declined inclusion, six expressed a preference for a particular treatment (RFA, 2; EVLA, 4). Some 128 patients were treated within 24 h of randomization; overall, patients were treated a median of 0 (range 0–48) days after randomization. One operation was cancelled owing to problems with theatre equipment, and therefore 130 patients were treated as part of this study (*Fig. 1*). One patient who was randomized to RFA received EVLA, owing to non-availability of RFA equipment. For patients treated with EVLA, the mean(s.d.) energy density delivered to the GSV was 71·71(12·98) J/cm.

The patients included 89 women and 42 men with a mean(s.d) age of 49(16) years. Baseline characteristics were comparable between the randomized groups (*Table 1*).

Primary outcome measure: pain scores

Diary cards were available for 127 patients; postprocedural pain scores after EVLA (61 patients) and RFA (66) are shown in *Fig. 2*. Two patients included in the analysis did not require concomitant phlebectomy, although analyses were adjusted for the number of phlebectomy incisions. Patients receiving RFA reported less pain over the first 3 days, with a mean(s.d.) pain score of 26·4(22·1) for RFA and 36·8(22·5) for EVLA (primary adjusted difference $= -10{\cdot}2$; $P = 0{\cdot}012$) (*Table 2*).

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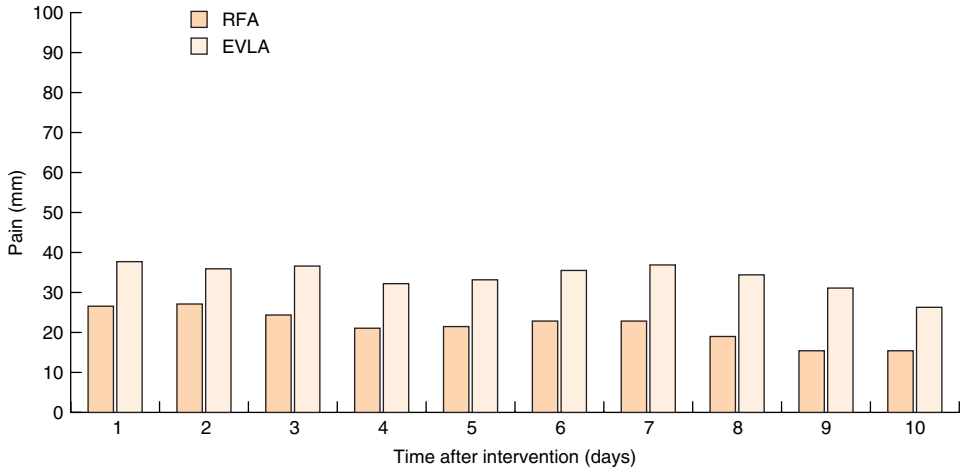

Fig. 2 Daily visual analogue pain scores after endovenous treatment for varicose veins with radiofrequency ablation (RFA) or endovenous laser ablation (EVLA)

Table 2 Linear regression analysis of pain scores after radiofrequency or endovenous laser ablation treatment for varicose veins

	RFA ($n = 66$)	EVLA ($n = 61$)	Crude unadjusted difference*	*P*	Primary adjusted difference*†	*P*	Secondary adjusted difference*‡	*P*
Mean(s.d.) pain score								
First 3 days	26·4(22·1)	36·8(22·5)	−10·4 (−18·2, −2·6)	0·010	−10·2 (−18·1, −2·3)	0·012	−6·4 (−14·3, 1·6)	0·115
First 10 days	22·0(19·8)	34·3(21·1)	−12·3 (−19·5, −5·1)	0·001	−12·8 (−20·2, −5·5)	0·001	−6·3 (−13·3, 0·7)	0·079

*Values in parentheses are 95 per cent confidence intervals. †Primary adjustment for age, sex, body mass index of 30 kg/m^2 or above, Venous Clinical Severity Score in the randomized leg (as a measure of varicose vein disease severity), pattern of disease (great saphenous vein (GSV) *versus* GSV and small saphenous vein), length of vein ablated, number of phlebectomies (above or below knee). ‡Secondary adjustment: adjusted primary model for use of analgesia. RFA, radiofrequency ablation; EVLA, endovenous laser ablation.

Postprocedural pain and analgesia use

Patients in the RFA group also reported less pain over the first 10 days, with mean(s.d.) scores of 22·0(19·8) for RFA and 34·3(21·1) for EVLA (primary adjusted difference = −12·8; $P = 0·001$) (*Table 2*). Patients in the RFA group took fewer analgesic tablets than those in the EVLA group: mean(s.d.) over 3 days 8·8(9·5) tablets after RFA *versus* 14·2(10·7) tablets after EVLA ($P = 0·003$) and over 10 days 20·4(22·6) *versus* 35·9(29·4) tablets respectively ($P = 0·001$) (*Fig. 3*). When pain scores were adjusted for the number of analgesic tablets taken, differences between the groups were reduced and of only borderline significance (*Table 2*).

Secondary outcome measures

Quality of life and Venous Clinical Severity Score

Quality of life was assessed a median of 48 (interquartile range 43–54) days after intervention; data were available for 115 patients (RFA, 60; EVLA, 55). Improvements in quality of life were seen in both groups, although there were no significant differences between the two groups in AVVQ, VCSS or SF-12® in either the physical component or mental component score (*Table 3*).

Return to normal activities and work

Data regarding return to normal activities were available for 62 patients after RFA and for 50 after EVLA. The majority of patients returned to normal activities within 3 days: EVLA, 25 (50 per cent) of 50 patients; RFA, 37 (60 per cent) of 62. About three-quarters of patients resumed normal activities within 7 days: EVLA, 37 (74 per cent) of 50; RFA, 48 (77 per cent) of 62. Regarding return to work, data were available for 41 patients in the RFA and 34 in the EVLA group. Results were similar, with 15 (37 per cent) and 14 (41 per cent) patients returning to work within 3 days, and 29 (71 per cent) and 24 (71 per cent) returning to work within 7 days in RFA and EVLA groups respectively.

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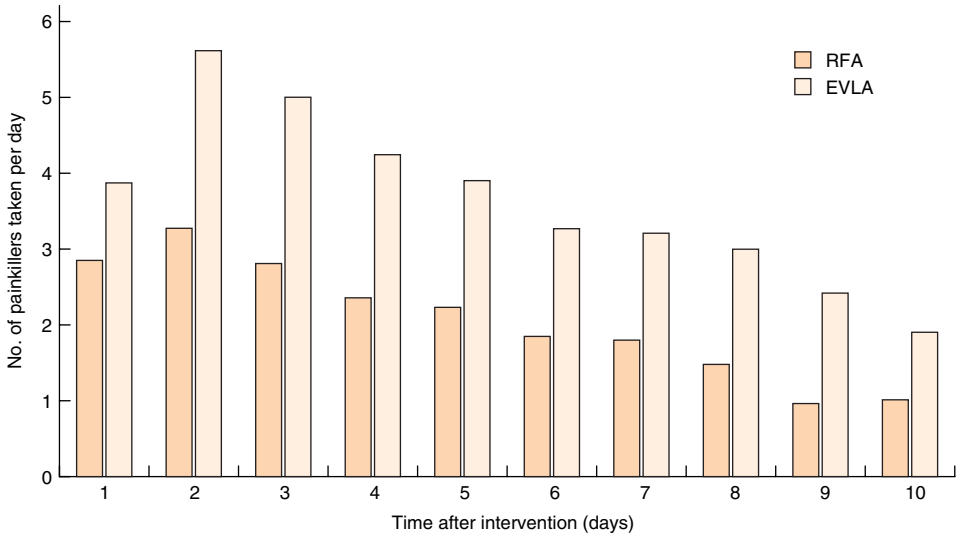

Fig. 3 Number of analgesic tablets used each day after endovenous treatment for varicose veins with radiofrequency ablation (RFA) or endovenous laser ablation (EVLA)

Table 3 Analysis of co-variance for secondary outcomes after radiofrequency or endovenous laser ablation for varicose veins

	RFA ($n = 60$)	EVLA group ($n = 55$)	Crude difference*†	*P*	Adjusted difference*‡	*P*
AVVQ						
Baseline	20·6(9·4)	18·9(9·8)	−0·3 (−3·1, 2·6)	0·854	0·2 (−2·8, 3·2)	0·887
6 weeks	10·9(9·2)	10·8(8·9)	—		—	
VCSS						
Baseline	5·1(2·1)	4·7(2·1)	−0·1 (−0·7, 0·5)	0·777	0·0 (−0·6, 0·6)	0·993
6 weeks	1·7(1·7)	1·5(1·8)	—		—	
SF-12® PCS						
Baseline	48·9(9·5)	48·1(10·1)	−2·6 (−0·6, 0·5)	0·101	−1·8 (−5·2, 1·5)	0·276
6 weeks	50·7(8·7)	53·1(7·3)	—		—	
SF-12® MCS						
Baseline	47·1(11·0)	48·0(13·1)	−0·7 (−4·4, 3·0)	0·704	−1·5 (−5·4, 2·4)	0·449
6 weeks	50·4(9·5)	51·3(9·9)	—		—	

Values are mean(s.d.) unless indicated otherwise; *values in parentheses are 95 per cent confidence intervals. †Adjusted for baseline value. ‡Adjusted for baseline value as well as age, sex, body mass index of 30 kg/m^2 or above, Venous Clinical Severity Score (VCSS) in the randomized leg (as a measure of severity of varicose vein disease), pattern of disease (great saphenous vein (GSV) *versus* GSV and small saphenous vein), length of vein ablated, number of phlebectomies (above or below knee), presence of deep vein disease and unilateral *versus* bilateral disease. RFA, radiofrequency ablation; EVLA, endovenous laser ablation; AVVQ, Aberdeen Varicose Vein Questionnaire, SF-12®, Short Form 12; PCS, physical component score; MCS, mental component score.

Complications

During the study, two major complications were observed. One patient randomized to RFA suffered a pulmonary embolus 2 weeks after intervention (the patient was treated with warfarin, although no evidence of DVT or clot extension in the leg veins was found on duplex imaging). One patient in the EVLA group developed a lymphatic leak from the cannulation site, and lymphoscintigraphy confirmed increased lymphatic collateral flow consistent with trauma at the site.

Table 4 Reported complications after radiofrequency or endovenous laser ablation

	RFA ($n = 67$)	EVLA ($n = 64$)
Wound infection	4 (6)	2 (3)
Haematoma	0 (0)	2 (3)
Thrombophlebitis	5 (7)	3 (5)
Paraesthesia	8 (12)	5 (8)
Staining to skin	6 (9)	2 (3)
Seroma	2 (3)	1 (2)
Pulmonary embolus	1 (1)	0 (0)

Values in parentheses are percentages.

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Minor complications included wound infection (4·6 per cent), haematoma (1·5 per cent), thrombophlebitis (6·1 per cent), saphenous nerve paraesthesia (9·9 per cent) and skin staining (6·1 per cent) (*Table 4*). Two patients in the EVLA group reported an increase in spider veins and, despite the intention to perform procedures as a day case, four patients (3·1 per cent) required overnight admission after the procedure because of nausea (RFA, 1; EVLA, 1), hypotension secondary to general anaesthesia (RFA, 1) or pain requiring opioid analgesia (RFA, 1).

Discussion

This study demonstrated that VNUS® ClosureFAST™ resulted in significantly less pain than 980-nm EVLA for varicose veins. However, reported pain and analgesia use was very variable in both groups and, interestingly, reductions in pain did not translate into faster recovery times. At 6 weeks there was no significant difference in clinical disease severity or quality-of-life scores, and the degree of improvement in the AVVQ and VCSS was similar to that reported in other randomized trials[9,24,25]. The results of the present study support the findings of other studies that have shown less postprocedural pain after RFA[16,18], but failed to show differences in outcomes after 1 month[18]. Discrepancies between studies may be explained by variations in procedure technique and follow-up times. In contrast to the RECOVERY trial[18], minor complications including paraesthesia, thrombophlebitis and skin infections were not more prevalent in the EVLA group at any time point. One patient in the RFA group had a pulmonary embolus 10 days after the procedure. This was diagnosed and treated at a different hospital and no DVT was found in the leg veins on duplex imaging. The cause of this pulmonary embolus remains unknown; the patient had no known risk factors for thromboembolic disease at the time of surgery and remained on warfarin.

One possible explanation for the reduced pain scores following RFA may be that the controlled heating and segmental ablation technique of VNUS® ClosureFAST™ reduces the number of vein wall perforations and the extravasation of blood into the tissues[26,27]; this has been shown to occur after use of the 980-nm laser in animal models[26] and in humans[28].

Recent research has suggested a rapid increase in the popularity of endovenous thermal ablation and this trend appears likely to continue[1–3,5]. Patients seeking superficial venous interventions are frequently concerned about postprocedural discomfort, recovery times and recurrence[13]. It is therefore important to provide sufficient information about all the available procedures, so that patients and physicians can reach evidence-based decisions about treatment options.

This study was sufficiently powered to evaluate postprocedural pain and both procedures were performed under identical conditions. The authors decided not to evaluate postprocedural bruising owing to difficulties in accurate quantification, and because previous studies have shown that it does not necessarily correlate with postprocedural pain[29] or time taken to resume normal activities[6]. Patients were blinded to treatment allocation, significantly reducing the potential for bias and allowing a direct comparison of the outcomes of the two procedures. Although the assessors were not blinded, the primary outcomes were patient reported and therefore unlikely to have been affected by the assessors. Patients also underwent concomitant phlebectomies if necessary, with the aim of completing all treatment in a single visit. This approach has been shown to be preferable for many patients[13], associated with improvements in clinical and quality-of-life outcomes and a reduced need for further procedures[30].

Limitations of the study included the fact that all procedures were performed under general anaesthesia, so that an assessment of the adequacy of the tumescence during the procedure was not possible. However, the technique of tumescent anaesthesia infiltration under ultrasonographic guidance was standardized for both procedures. Elsewhere, a significant proportion of endovenous thermal ablation procedures are performed as outpatient procedures[5], and even performing concomitant phlebectomy is feasible as an office-based procedure[31]. However, this may be difficult in patients with bilateral disease or those with large numbers of varicosities. As the aim was to complete all treatments in one sitting, patients were therefore offered general anaesthesia. Moreover, the groups in this randomized study were well matched in terms of disease pattern, and analyses were adjusted for numerous variables including number of phlebectomies performed to ensure that detected differences were truly due to the ablation technique.

To date, the majority of studies have provided data supporting the short-term efficacy of EVLA and RFA, and long-term data are scarce. EVLA would appear to have better occlusion rates, of around 95 per cent, in comparison with 80 per cent for the early RFA catheters at 5 years[32]. However, results from VNUS® ClosureFAST™ appear promising[22] and may be superior to the original RFA in the longer term. Long-term studies of venous occlusion and recurrence are clearly required to support the durability of endovenous thermal ablation procedures.

Both this study and the smaller RECOVERY trial[18] support the premise that VNUS® ClosureFAST™ is less

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painful than 980-nm EVLA. However, to reduce the post-procedural discomfort associated with EVLA, newer radial fibres, longer wavelengths and jacketed laser fibres have been developed. These newer techniques have been shown to be associated with low postintervention pain scores[33–36] and are likely to replace the 980-nm bare-tip laser fibre. Data from randomized trials supporting the use of these newer devices are awaited.

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Commentary

Randomized clinical trial of VNUS® ClosureFAST™ radiofrequency ablation *versus* laser for varicose veins (*Br J Surg* 2010; 97: 810–818)

This was a well constructed prospective randomized trial comparing the early outcomes of radiofrequency ablation and endovenous laser ablation of the great saphenous vein. The primary outcome measure of postprocedural pain was clearly stated and the study was adequately powered with additional numbers built in for non-compliance and dropout. The findings were similar to those of the RECOVERY trial[1]. Both studies showed that radiofrequency ablation using the VNUS® ClosureFAST™ technique caused less postoperative pain as determined by a visual analogue scale. The additional comparison of analgesic use strengthens the results; however, pain is subjective and the study would have been improved by comparing some objective features such as bruising, and by ensuring that clinicians performing the follow-up were blinded. Unlike the RECOVERY study, which compared quality of life at 2, 7, 14 and 30 days, quality of life in this study was reassessed only at 6 weeks postprocedure, and showed no difference between the groups. Unfortunately, a considerable proportion (12 per cent) of the patients were lost to follow-up at 6 weeks and, although this was built into the power calculation, one has to consider why these patients did not attend.

All patients undergoing treatment for varicose veins should receive information and advice regarding analgesia requirements and return to normal activity. Although there is no evidence that changing patient information alters patients' choices, it is important to standardize the information given to patients in a study of this kind in order to remove bias[2].

This study suggests that radiofrequency ablation using the VNUS® ClosureFAST™ technique is better for patients in the short term. The longer-term clinical results are awaited eagerly.

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