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VENous INtervention VEIN Project



VENous INtervention (VEIN) Project

Venous Forum of The Royal Society of Medicine

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Introduction:

Varicose veins affect up to 25% of the adult population in the United Kingdom. Their management comprises a significant proportion of the workload of most vascular specialists. In the last decade a variety of new treatments have become available, yet there remains controversy

about how and when to employ them. The VEIN Project was conceived to define how services should be provided for patients with symptomatic, uncomplicated varicose veins, and the way the interventions should be delivered. Standardisation of facilities and methods is expected to produce optimal results from all the interventions.

The VEIN Project is a collection of six evidence-based articles concerning interventions for uncomplicated varicose veins, and the methods currently available. This summary document uses these papers to define the various interventions and standards for their use. It is envisaged that the project documents will be used by healthcare professionals, commissioning groups, and even patients to influence the provision of varicose vein treatment in their hospitals. Readers of this summary document are strongly encouraged to refer to the complete articles which are published in a supplement of the journal *Phlebology* 2009.

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Bachoo P. Interventions for uncomplicated varicose veins. *Phlebology* 2009; 24 suppl 1: 3-12.

Palfreyman S. A systematic review of compression hosiery for uncomplicated varicose veins. *Phlebology* 2009; 24 suppl 1: 13-33.

Perkins J. Standard varicose vein surgery. *Phlebology* 2009; 24 suppl 1: 34-41.

Gohel M, Davies AH. Radiofrequency ablation for uncomplicated varicose veins. *Phlebology* 2009; 24 suppl 1: 42-49.

Darwood R, Gough M. Endovenous laser treatment for uncomplicated varicose veins. *Phlebology* 2009; 24 suppl 1: 50-61.

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1. Components of a venous service

1.1 Assessment. Every patient referred with uncomplicated varicose veins should undergo a formal assessment that includes: history (including severity of symptoms), clinical examination and investigation. Assessment should include examination with hand-held Doppler (HHD) by a clinician trained in the technique, and who can interpret the findings. There is some evidence that duplex imaging should be a routine part of the investigation of every patient with varicose veins, particularly if they are to undergo intervention. It is necessary as part of both selection and control during foam sclerotherapy, laser and radiofrequency ablation. Preoperative duplex has been shown in a randomised trial to improve the outcome from standard varicose vein surgery. Where clinicians choose to employ the investigation selectively before standard surgery, the following are specific indications for preoperative duplex imaging: recurrent varicose veins, reflux in the popliteal fossa on HHD (all small saphenous varicose veins) and past history of deep vein thrombosis (DVT).

1.2 Facilities. The major change in the delivery of venous intervention in the last decade has been the move away from treatment under general anaesthesia in a sterile operating theatre to ambulant outpatient treatment. For optimal delivery this requires a dedicated venous intervention room, which may be situated in outpatients. The area should be easily cleaned, and stocked with all the equipment needed for the

interventions. A tilting treatment couch capable of Trendelenburg and reverse Trendelenburg positions is necessary for foam sclerotherapy and endovenous thermal ablation techniques. The room should be large enough for the laser or radiofrequency generator, the infusion pump, duplex machine, disposables, sclerotherapy equipment, drugs and dressings. It will need to accommodate the operator and up to two assistants. It needs to be well illuminated and ventilated, but have the capacity to dim the light (blinds or dimmer switch) to see the duplex monitor screen easily. Separate secure patient and staff changing facilities also need to be close by. For laser therapy it is mandatory that the facilities are inspected and signed off by the institution's laser safety officers (usually part of the Medical Physics / Radiation Safety Department of a Hospital).

1.3 Training Standard varicose vein surgery is currently a core activity taught to all vascular surgical specialists during their training, and monitored through logbooks, training review and RITAs. Established consultants should consider adding their procedures to a database such as the Venous Registry (www/host.e-dendrite.com/CSP/IVF/Frontpages/ivrfont.csp) to monitor outcome and performance. For trained vascular specialists who wish to develop a new service such as endovenous laser ablation therapy (EVLT), radiofrequency ablation (RFA) or foam sclerotherapy (FS), training and mentoring are essential. This should comprise training in the theoretical aspects of the technique, the equipment required and the technique itself. All of the new methods require

duplex ultrasound imaging skills, and duplex-guided venous cannulation, which should be learned before undertaking any new intervention. This process should be agreed with the relevant hospital authorities, and documented by the individuals. Only when all these components have been achieved and competence has been demonstrated should the vascular specialist undertake the procedure independently.

1.4 Documentation. The indications for any venous intervention should be documented clearly in the medical notes. Consent to the treatment should be taken by a member of the team trained to take consent and written information sheets should be given to each patient before the intervention. For each technique there should be an accurate record of the operator, site(s) of cannulation, energy used (Joules), length of treated

segment (cm), settings of the laser / RFA generator, or dose and type of sclerosant. A record should also be kept of the efficacy of the technique and any complications. All procedures should only be undertaken according to current guidance at the time from the National Institute of Health and Clinical Excellence (NICE).

1.5 Vascular specialists should only offer treatments that they are trained and able to deliver, but they should be able to inform patients about the available range of alternative treatments. Most current specialists will offer an alternative to standard surgery. Patients who choose an intervention that is not available at their referral hospital should have the opportunity to transfer to a centre where it is available. Information sheets describing the risks and benefits of the available treatments should be available to patients before they decide what to have done.

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2. Indications for intervention

2.1 There exist evidence-based treatments for patients with complications from their varicose veins such as leg ulceration and thrombophlebitis. This document specifically examines the potential advantage of treating patients with symptomatic, uncomplicated varicose veins.

2.2 Varicose veins are associated with a negative effect on the physical domains of quality of life measurement. A large prospective cohort collaborative study involving 5,688 subjects over 5 years, concluded that the reduction in quality of life (both generic and disease-specific) was directly linked to the severity of the varicose veins. This has been confirmed in a number of other studies.

2.3 In the REACTIV trial (Michaels et al, 2006), which compared surgery or conservative treatment for symptomatic, uncomplicated varicose veins, 57% of patients randomised to conservative treatment expressed unhappiness and over half sought surgical intervention. Patients who had surgery for their veins had a marked improvement in quality of life; the cost per quality adjusted life year (QALY) was £1864, well below the acceptable threshold of £30,000 for treatments within the National Health Service.

2.4 In the same study, liquid sclerotherapy was lower cost, but also produced lower QALY gains. Liquid sclerotherapy has a higher recurrence rate than surgery (Belcaro et al, 2003; Einarrson et al, 1993; and Rutges and Kitslaar, 1994).

2.5 New thermal ablation techniques for treating varicose veins all show a consistent improvement in disease-specific quality of life after intervention. Compared to standard surgery, the trials suggest a reduction in pain and earlier return to normal activity.

3. Compression Hosiery

3.1 There are five different systems applied to the categorisation of compression stockings. United Kingdom (UK) hospitals use the European Standard, whereas community pharmacists use the UK Standard. As such, a patient wearing Class II stockings using the UK Standard will have a pressure range of approximately 18-24 mm of mercury compared to 23-32 mm of mercury for the Class II prescribed according to the European Standard. Clinicians must be aware of the different systems, and be sure that their patients are prescribed the appropriate strength; patients with uncomplicated varicose veins usually need Class II UK Standard hosiery.

3.2 Skin necrosis can occur with badly fitting stockings. The risk increases in patients with impaired blood supply and/or impaired sensation, especially diabetics. Rolling down of the stockings can effectively cause a tourniquet on the leg. In the absence of easily palpable foot pulses, ankle brachial pressure index (ABPI) should be measured to exclude arterial disease before compression hosiery is prescribed. In general, compression hosiery should not be prescribed when the ABPI is less than 0.9.

3.3 Compression hosiery can improve symptoms in patients with uncomplicated varicose veins. Of 23 clinical studies included in the systematic review (Palfreyman, 2009), only three were randomised trials. Hosiery improved pain and discomfort compared to no stockings, but only while the stockings were actually worn; there was no long-term benefit.

3.4 A combination of exercise and compression stockings can improve symptoms more than stockings alone. Compliance with compression hosiery is often poor. In one study there was a 39% withdrawal rate (Chant et al, 1989). Raju et al 2007 in a large cohort study of 3,144 patients reported that only 37% had full, or even partial compliance.

3.5 There remains controversy over the value of compression hosiery during pregnancy. Two randomised studies explored the value of Class I compression tights, but concluded they were not suitable. It was also noticed,

however, that there was no difference between Class I and Class II stockings. Both European Class I and II stockings were shown to improve leg symptoms compared with controls by Cochlan et al, 2001. Wearing stockings during pregnancy does not affect the progression of varicose veins (Thaler et al, 2001).

3.6 There is no evidence to suggest that long leg stockings have any advantage over below knee length hosiery, either for symptom control or treatment. Nor is there any evidence that wearing compression stockings prevents progression of varicose veins or recurrence after treatment.

3.7 Compliance remains a fundamental issue, and vascular teams should include an individual (usually a specialist nurse) with responsibility for optimising the use of compression hosiery: providing advice and support to patients and general practice, keeping updated with industry advances and stocking aids.

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4. Standard Varicose Vein Surgery

4.1 Conventional surgery remains the most common form of varicose vein intervention in the NHS. All new techniques must be assessed against this previously gold standard.

4.2 In the NHS, surgery for varicose veins is limited to those with significant symptoms and/or complications (NICE guidance, 2001). Surgical intervention for uncomplicated varicose veins improves quality of life and symptom relief compared to conservative treatment (Michaels et al, 2006). Indeed, many patients get long term satisfaction after 10 years, associated with relief or improved symptoms (Campbell et al, 2003).

4.3 Although there is evidence that routine duplex imaging can improve the accuracy of varicose vein surgery, it is still acceptable that surgery is planned on the basis of HHD alone in selected patients (experienced surgeon, typical great saphenous veins).

4.4 The single evidence based component of standard surgery is routine stripping of the great saphenous vein (GSV) to knee level. There is no obvious advantage to any particular brand of stripping device, but inversion stripping appears to cause the least associated trauma (Durkin et al, 1999). Stripping can reduce recurrence and reoperation rates. Other suggested practice techniques are: clear dissection of the saphenofemoral junction (SFJ); division of all tributaries at the SFJ, closure of the cribriform fascia, the use of a thigh tourniquet to minimise bleeding. Routine

use of a barrier (prosthetic patch) at the SFJ is not yet supported by controlled trials for either primary or recurrent veins.

4.5 Due to the variable anatomy at the saphenopopliteal junction (SPJ), pre-operative duplex imaging is advised, with marking of the junction an option. This allows for accurate placement of the skin incision, but has not been shown to improve the clinical outcome. The results of small saphenous varicose vein surgery are not as good as GSV surgery, with higher rates of persistent reflux in up to 25% (Rashid et al, 2002, van Rij et al, 2003). It is not clear whether flush SPJ ligation and/or stripping can optimise the outcome for SSV surgery, though more surgeons now routinely expose the SPJ than in 2004 (10% vs. 67%) (Winterborn et al, 2004, Campbell 2007). There is early evidence that stripping the SSV to mid calf can improve the haemodynamic result, and does not appear to increase the rate of sural nerve damage.

4.6 The additional value of perforating vein surgery for primary varicose veins has not been demonstrated convincingly. Traditional open operation was associated with significant wound problems. Sub-facial endoscopic perforator surgery (SEPS) reduced the rate of wound complications and was associated with fewer incompetent perforator veins at 1 year, but had no effect on recurrence or quality of life (Kianiford et al, 2007).

4.7 Multi stab phlebectomies causes less postoperative bruising and pain than transluminated-powered phlebectomy (TIPP). (Chetter et al, 2006).

4.8 Serious complications are few after varicose vein surgery. Injury to the saphenous nerve injury occurs after 7% of procedures, but does not usually affect quality of life (Holme, 1990). Major nerve injuries such as sural nerve and common peroneal nerve damage resulting in foot drop are rare (2-4% Atkin et al, 2007). All patients undergoing varicose vein surgery should be counselled about these potential complications as part of the consent process.

4.9 DVT is also rare after varicose vein surgery; the rate of pulmonary embolus is approximately 0.6% (Critchley et al, 1997). There remains controversy about whether all patients undergoing varicose vein surgery require thromboprophylaxis.

The majority of vascular surgeons in a postal questionnaire did not give routine prophylaxis ten years ago (Lees et al, 1999). However, the failure to perform a risk assessment and provide prophylaxis in high risk patients is potentially negligent (Scurr and Scurr, 2007). All patients undergoing varicose vein surgery should have a risk assessment, and thromboprophylaxis is mandatory in high risk patients (see NICE Guidelines CG46 – www.nice.org.uk). It is justified to exclude thromboprophylaxis in young, fit patients undergoing varicose vein surgery that lasts for less than 1h.

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5. Radiofrequency Ablation

5.1 Radiofrequency ablation (RFA) for the treatment of superficial venous reflux was introduced in 1998, and has evolved significantly. RFA uses a bipolar endovenous catheter that generates temperatures of 85-120°C at the vein wall. This is controlled locally by inbuilt feedback using vein wall impedance.

5.2 The method was originally designed as a continuous pull back technique (VNUS Closure™, VNUS Medical Technologies, San Jose, California, USA). However in 2006, VNUS introduced the Closure Fast™ technique allowing 7 cm segments to be treated in 20 seconds. Another RFA device (the Olympus Celon RFITT™, (Olympus Medical Systems, Hamburg, Germany) is also available.

5.3 Tumescence local anaesthesia is common to both RFA and endovenous laser ablation (EVLA). Surrounding the vein to be treated with fluid reduces the risk that healthy tissues will suffer thermal damage. Some authors use normal saline alone, others use Hartman's solution in combination with local anaesthetic to give additional anaesthesia/analgesia. Dilute epinephrine may be added to reduce local bleeding. General anaesthesia is only required if multiple phlebectomies are done at the same time.

5.4 The vein to be treated is cannulated under duplex ultrasound control; accurate positioning is essential. The RFA probe should be sited 2cm below to the refluxing junction (SFJ or SPJ). After the treatment, Class I or II graduated compression stockings are employed for 1-2 weeks, although there is no

consensus on the ideal regimen. Delayed sclerotherapy or phlebectomies may be used to deal with residual veins after the truncal veins have been treated with RFA.

5.5 The main reported complications following RFA include skin burns, nerve damage and deep vein thrombosis, although all these are rare. Patients also need to be counselled about the possibility of residual, or recurrent veins (since long term outcome data are lacking).

5.6 A systematic review (Gohel and Davies, 2009) identified 23 published reports comprising 3 randomised studies, 2 meta-analyses and 15 prospective observational studies. Only one study involved the VNUS ClosureFast™ system. Initial vein occlusion rates were 89% at 3 months, reducing to 80% after 5 years (van den Boss et al, 2008). In a prospective international registry (Merchant and Pichot, 2005) suggested late occlusion rates of 87.2% at 5 years.

5.7 The newer VNUS ClosureFast™ system was reported to have an occlusion rate of 99.6% within 2 years in a single prospective series (Proebstle et al, 2008).

5.8 Quality of life appears to be improved after both RFA and EVLA, with no significant difference between the two in the medium term in comparative studies. RFA is suitable for the office outpatient environment with subsequent reduction in costs. Both techniques also enable a more rapid return to work than standard surgery.

5.9 There is a learning curve to the RFA technique. There is no substitute

for appropriate training, mentorship and continued audit to ensure that complication rates are kept to the minimum. Operators should be familiar with the equipment used, particularly the energy generator and the RFA catheters. They must also be competent to use duplex ultrasound imaging for monitoring the RFA process.

5.10 Although a rate of DVT as high as 16% was reported in one study (Hingorani et al, 2004), the overall DVT rate is usually less than 1% (Merchant et al, 2005). For this reason thromboprophylaxis is not required in patients having RFA under

local anaesthetic, unless they are in a high risk category. Similarly phlebitis (2.9%) and skin burn (1.2%) occur occasionally, though the majority were reported before the use of tumescence became routine

5.11 As with the other new endovenous techniques, the intervention should only be undertaken according to current NICE guidelines. It is important to collect outcome data including occlusion and complication rates. Medium and long term outcome data are also important to ensure that late recurrence is a rare event.

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6. Endovenous Laser Ablation

6.1 Endovenous laser ablation (EVLA) involves insertion of a laser fibre into the incompetent truncal vein (usually great or small saphenous vein) with subsequent thermal ablation of the vein. Laser is an acronym for "light amplification by stimulated emission of radiation".

Monochromatic light is emitted from a laser medium (both diodes and Nd:YAG are used for EVLA) and amplified by mirrors. 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.

6.2 Although EVLA was initially used to treat great saphenous vein (GSV) reflux there are several large series describing successful small saphenous vein and anterior saphenous vein ablation. There are also isolated reports of treatment of incompetent perforating veins and varicosities themselves. Generally, the vein needs to be straight to allow the passage of the laser fibre, though more tortuous veins can be treated by experienced practitioners.

6.3 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. Techniques for anaesthesia are similar for EVLA and RFA.

6.4 The vein for ablation is cannulated percutaneously under ultrasound guidance with the patient in the reverse

Trendelenberg position to maximise 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 before ablation. EVLA does not require an operating theatre and may be performed in an outpatient setting.

6.5 A randomised controlled trial 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 from below-knee EVLA, with only 17% of patients having residual varicosities requiring delayed sclerotherapy (versus 61% for above-knee ablation).

6.6 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). Optimum occlusion rates are achieved with a minimum laser energy of 60J/cm. Withdrawal of the laser fibre at a rate of 1cm/5 seconds using 14W power allows easy and accurate delivery of 70J/cm. The fibre may be withdrawn in a stepped or continuous fashion and the laser fired continuously or with 1 second exposures. Continuous withdrawal now appears to be favoured. This reduces treatment times and perhaps perforation and bruising.

6.7 Randomised controlled trials suggest that abolition of GSV reflux, improvements in quality of life, patient satisfaction and cosmesis are similar for surgery and EVLA. Three studies also show that post-

treatment discomfort was no different for either technique. Case series of EVLA with 1-3 year duplex follow-up have reported truncal vein ablation rates of 93-99%, with most recanalisations appearing within the first year.

6.8 Five studies which have used the Aberdeen Varicose Vein Symptom Questionnaire have shown an improvement in quality of life following truncal vein ablation. There are no good data regarding the cost-effectiveness of EVLA. Three studies have used a patient-completed visual analogue score (which may be subject to positive skew) indicating satisfaction with cosmetic outcome after EVLA.

6.9 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 0-33% of patients. This appears more common with higher laser doses perhaps reflecting thermal injury rather than a true phlebitis. Routine prescription of non-steroidal analgesia for 3-5 days post-EVLA may lessen the pain and inflammation. Some bruising seems common in the majority of patients secondary to either administration of tumescent anaesthesia or vein wall perforation by the laser. The incidence of cutaneous nerve injury is between 1-10% with the majority being temporary. The incidence of DVT is low. Other rare

complications include hyperpigmentation, arteriovenous fistula and thread vein formation, and skin burns.

6.10 The clinician undertaking EVLA should assess the patient following referral to confirm that treatment is indicated. They should be experienced in assessing patients with venous disease and understand 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. The clinician performing EVLA should be able undertake follow-up, provide any further treatment that may be required and manage complications.

6.11 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 (www.mhra.gov.uk). The procedure should be undertaken in accordance with NICE guidelines, and after local agreement with the hospital Trust. 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.

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7. Sclerotherapy

7.1 Liquid sclerotherapy has been available for use for almost 50 years. Initially popular, controlled trials suggested it was associated with high recurrence rates: up to 50% had residual saphenofemoral reflux after treatment of truncal veins. Since the introduction of ultrasound-guided foam sclerotherapy (FS) by Cabrera in 1995 there has been renewed interest in sclerotherapy. Many case series have described good early results with FS, but few have included follow-up beyond three years.

7.2 Foam sclerotherapy is a new discipline that involved skills that most current vascular specialists did not acquire during training. It involves diagnostic imaging using duplex (though this may be done by a trained vascular scientist), ultrasound-guided venous cannulation, and use of ultrasound imaging during foam injection. The two latter parts of the method require training before FS is undertaken. Ultrasound cannulation can be practised in part using a phantom. Training should be guided as discussed in section 1.3 and competence must be achieved in all the components of FS before independent practice.

7.3 Foam sclerotherapy should be conducted under local anaesthesia since there is a high risk of DVT when foam is introduced under general anaesthesia. All patients should receive a full explanation of the risks and benefits of the procedure and a relevant information sheet.

7.4 The foam is usually prepared with the Tessari technique: a ratio of one part sclerosant to four parts gas (usually air).

A 5 micron filter placed between the air and sclerosant syringes can improve the quality of the foam. Currently acceptable sclerosants include: Sodium Tetra Decyl Sulphate STD, Fibro-vein, STD Pharmaceuticals, Hereford, UK) or Polidocanol 0.5-3% (Sclero vein™, ResinAG, Zurich, Switzerland). A range of concentrations of sclerosant should be available for use. Absolute contraindications to FS include previous severe allergy and occluded deep veins, but caution should be exercised in any patient with previous DVT. A resuscitation box should be available containing rescue drugs and equipment for the treatment of anaphylaxis.

7.5 All cannulae (venflon or butterfly needles) should be sited in the vein before foam is introduced. At all times it is vital that the tip of the cannula remains within the vein lumen; regular flushing with normal saline will ensure this. Between 2 and 6 cannulae are needed to treat one leg.

7.6 The leg should be elevated to empty the veins before foam injection. Repeated ankle dorsiflexion just after injection should minimise the risk of calf vein thrombosis. A maximum of 12ml foam is usually employed during one session (though this may be increased if carbon dioxide is used as the vehicle gas).

7.7 Compression following sclerotherapy is variable. Some simply suggest using compression stockings, others suggest a short stretch bandage secured with wide adhesive tape under a Class II stocking for 7-14 days. There is no evidence that there is yet an optimal regimen. Early ambulation and return to work are

encouraged. Patients are advised not to drive for 30min after foam treatment, to ensure that they do not develop visual symptoms whilst at the wheel of a car.

7.8 Most patients develop thrombophlebitis in the successfully treated vein. If this is excessive, it may be aspirated under local anaesthetic during follow-up, when liquidised. Other management includes continued compression and anti-inflammatory analgesia. Deep vein thrombosis is very uncommon after FS (<2%), but should be excluded by duplex imaging if suspected. Established DVT should be managed with anticoagulation according to local protocols.

7.9 The major potential complication is a neurological event, such as a stroke. This has only occasionally been reported

in the literature. Visual disturbance occurs in approximately 2% after FS and resolves in approximately 30 minutes. It is most frequent in those who suffer migraines and can recur with repeat injection. This phenomenon remains under investigation. Migraine is not currently a contra-indication to FS. Other symptoms that are seen include a tight feeling in the chest and coughing. Patients should be warned about all these potential side effects during the consent process.

7.10 The late results of foam are unknown and await detailed follow-up studies, as suggested by NICE. Occlusion of truncal veins occurs in about 75-85% of patients after 6 to 12 months. Residual skin pigmentation and lumps can take up to a year to resolve.

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(main references taken from original articles) For full list of references, consult Phlebology 2009 supplement I

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Venous Forum

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