



Varicose veins and their treatment

By

Professor Andrew Bradbury, BSc MB ChB MBA MD FRCSEd
Professor of Vascular Surgery and Consultant Vascular and Endovascular Surgeon
Director: Midland Vein Centres, PO Box 13581, Solihull, B91 9GD
Appointments/enquiries: 07858-430-403

Introduction

The circulation is similar to the central heating system in your house. The:

- § **Heart** is the pump that sends the blood around the body (the house!)
- § **Arteries** are the pipes that carry the blood away from the heart to the organs & tissues (the radiators!)
- § **Veins** are the pipes that collect blood from the organs & tissues (radiators) and take it back to the heart (the pump)

For blood to return to the heart from the feet it must travel up the leg veins against gravity. This is made possible by the:

- § **Muscle pump:** when the muscles of the leg (especially those in the calf) contract when you walk, the veins that run through and between them get squeezed and the blood that is in those veins is squirted back up the leg
- § **Valves:** these sit inside the veins and look like the flippers in a pin-ball machine. They prevent the blood that has been squeezed up the leg from falling back down again under the influence of gravity when the leg muscles relax

If the muscles are weak and/or the valves stop working then, as the result of gravity, blood travels down, instead of up, the leg veins. This, so-called, venous 'incompetence' or 'reflux' causes the pressure inside the veins to increase. This, in turn, stretches the vein wall, causing it to become dilated and twisted, so forming 'varicose veins' (VV).

There are two sets of veins in the leg; the:

- § **Superficial veins:** lie directly under the skin and can be visible; these veins form VV and can also become inflamed (known as phlebitis)
- § **Deep veins:** lie in the middle of the leg and cannot be seen; these veins can get filled with blood clot to form a deep vein thrombosis (DVT). If a piece of this blood clot breaks off, it can travel to the lungs to form a so-called pulmonary embolus (PE), which can be serious and even fatal

Why have your varicose veins (VV) treated?

VV affect up to a third of the adult population and increase with age. Patients seek treatment for VV for three main reasons:

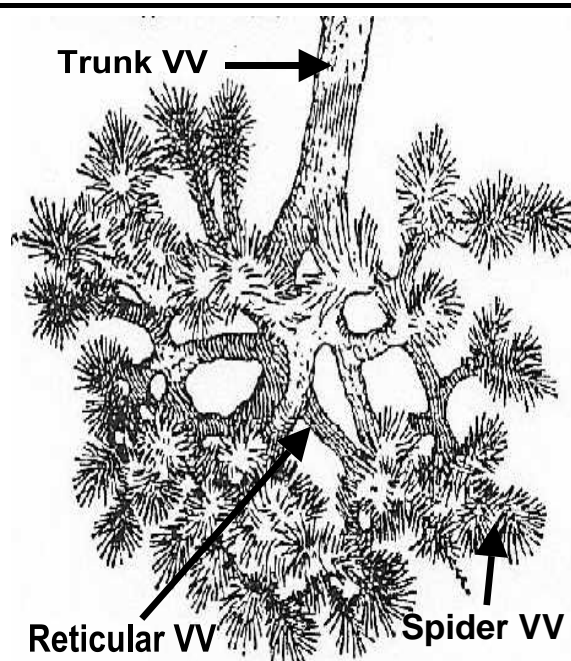
- § Dissatisfaction with the appearance of the leg
- § Symptoms such as pain, heaviness and itching
- § Concern about possible complications such as DVT, varicose eczema and ulceration

Types of varicose veins (VV)

There are three main types of VV and it is not unusual for all three to be present in the same patient. It is sometimes helpful to think of VV in the leg as an "upside-down" tree:

- § **Trunk** varicose veins: these are formed from the main superficial veins and their largest branches. They lie under the skin, are lumpy and usually more than 4mm across (*the trunk of the tree and the main branches*)
- § **Reticular** veins: these are formed from smaller branches, lie inside the deeper layers of the skin, are less lumpy and are usually less than 4mm across (*the smaller branches of the tree*)
- § **Spider** veins (or thread veins, or telangectasia): are formed by the very smallest branches, lie in the upper layers of the skin and are usually less than 1-2mm across (*the twigs at the end of the small branches!*)

Reticular and spider veins rarely cause symptoms and are usually treated for cosmetic reasons



Treatment options for VV

We offer four types of treatment for VV:

- Surgery
- Liquid sclerotherapy
- Foam sclerotherapy
- Radiofrequency ablation (VNUS Closure Fast)

Which treatment, or combination of treatments, is best for each individual depends upon the patient's:

- VV (type, size, and extent)
- General health and previous treatment for VV
- Preferences following a full and frank discussion of the pros & cons, risks & benefits of each treatment

Surgery for trunk VV

In my practice, VV surgery is usually reserved for very extensive, lumpy, 'trunk' VV affecting both legs. Surgery works by removing the VV from under the skin and usually involves a general anaesthetic (although it can be done under epidural or spinal anaesthesia) and an overnight stay in hospital to recuperate (although some VV surgery can be done as a 'day-case'). The great majority of patients sail through their surgery without difficulty and are usually pleasantly surprised by how straightforward it is. However, as with all operations, even in the best of surgical hands, VV surgery can potentially be associated with a number of unwanted side-effects and complications of which you should be aware:

- § **Pain:** While, of course, every attempt is made to minimise post-operative pain there is always a degree of discomfort afterwards. This usually responds to simple analgesia such as paracetamol and codeine or ibuprofen (Nurofen)
- § **Bruising:** The leg is usually quite bruised after VV surgery and this is unavoidable. The bruising usually settles down over 4-6 weeks but can persist for a few months. Bruising can give way to some pigmentation (brown discolouration) of the skin where the veins used to be. This usually disappears over a few months but can, unusually, be permanent
- § **Wound infection:** As wounds heal they normally appear red and can be quite itchy. However, if one or more of the wounds becomes very red, starts getting more painful, or begins to discharge any 'mucky' fluid then that suggests they may have become infected and that you may require antibiotics. In my practice, the risk of this happening is about 1-2%. Wound infection, if severe (rare), may lead to increased scarring
- § **Use of antibiotics to reduce wound infection:** Although, there is no incontrovertible evidence that it reduces the risks of wound infection, I, along with many other surgeons, routinely prescribe antibiotics at the time of VV surgery.
- § **Wound scarring:** While, of course, every effort is made to make the wounds as small and as neat as possible, some degree of scarring is inevitable after any operation. In most patients the scars fade and become almost invisible over 6-12 months. However, some people with certain skin types do not heal as well as others and, rarely, such patients can form scars that are permanently lumpy and discoloured (brown/pink). In my own practice over the last 15 years I have only seen this in a handful of patients. Such scars can sometimes be treated with injections or very effectively masked using special camouflage make-up
- § **Numbness/tingling:** Small patches of tingling and numbness, particularly around the wounds, can develop in up to 20% of patients. Once reassured that it is common and nothing to be concerned about, patients are not usually troubled and it normally settles over a few weeks and months. Rarely (I have never seen it in my own practice), the numbness can be permanent, painful and troublesome
- § **Bleeding:** Sometimes, especially during the first post-operative week, there may be a spot of bleeding from your leg, especially if you knock it or towel it particularly vigorously after showering. The bleeding is usually very minimal and will stop if you elevate the leg, press on it and rest up for a couple of hours. Essentially, you can deal with it as you would a cut finger. Serious bleeding after VV surgery is rare (I have never seen in my own practice)
- § **Deep vein thrombosis (DVT):** Many patients are concerned and ask specifically about the risks of DVT after VV surgery and, indeed, there is continuing debate within the profession regarding the magnitude of those risks and how to minimise them. The best study (van Rij AM. Chai J. Hill GB. Christie RA. Incidence of deep vein thrombosis after varicose vein surgery. British Journal of Surgery. December 2004 Volume 91(12):1582-5, - *paper available on the web-site*) comes from New Zealand where 377 patients were scanned 2-4 weeks, 6 and 12 months after VV surgery. Patients were instructed to contact a physician if symptoms consistent with DVT occurred before the scheduled follow-up appointment. DVT was detected in 20 (5.3 per cent) patients. Only 8 patients had symptoms and no patient developed symptoms consistent with pulmonary embolus (PE). Eighteen of the 20 DVTs were confined to the calf veins. Half of the DVTs had resolved without any residual damage to the deep veins at 1 year. The authors of this paper concluded that incidence of DVT following VV surgery was higher than previously thought, but that most of these DVTs had minimal short or long-term clinical significance. In my own practice I have never seen a DVT after straightforward VV surgery
- § **Pulmonary embolus (PE):** If a DVT develops after VV surgery then, as described above, there is a risk that a piece of that clot might break off and travel to the lung causing a PE, which could be serious even potentially fatal. In my own practice I have never seen a PE (or had a death from any cause) after VV surgery
- § **Stopping the oral contraceptive pill (OCP) or hormone replacement therapy (HRT):** Both the OCP and HRT contain the female sex hormone oestrogen and it is well recognised that this hormone increases the stickiness of the blood; and so the risks of blood clots, including DVT. Some surgeons ask their patients to stop their OCP/HRT 6 weeks before VV surgery and to recommence 6 weeks after their operation. The problem with that approach is that patients face a real risk of (presumably unwanted) pregnancy and a return of menopausal symptoms. In addition, there is no evidence that for the majority of patients this approach meaningfully reduces the risks of DVT/PE after

VV surgery. For these reasons, I, along with many other surgeons, do not routinely recommend discontinuation of OCP/HRT

§ Use of heparin to reduce the risk of DVT/PE: Although there is no incontrovertible evidence that it reduces the risks of DVT/PE, I, along with many other surgeons, often prescribe heparin (which thins the blood) at the time of surgery

§ Residual veins: It is not always possible to remove every single VV at the time of surgery. If necessary, these residual veins can be 'tidied up' with injections after a few weeks (so limiting the number of scars on the leg)

§ Recurrence of VV: The term recurrent VV is, strictly speaking, inaccurate as VV removed at surgery cannot recur. However, patients prone to VV can grow *new* VV and the risk of this happening is reported in the surgical literature at around 20% at 5 years. In my own practice, the numbers of patients that I have operated on and who have then come back requiring further VV surgery in the same leg has been very small. However, about a third of the patients that are referred to me have had one or more previous VV operations elsewhere by other surgeons. In most cases I am able to treat these new VV by means of duplex ultrasound guided foam sclerotherapy (UGFS) which offers very significant advantages over 'redo' VV surgery (please see over)

Liquid sclerotherapy for small reticular and spider VV

This is the preferred treatment for the small ('reticular veins') and very small ('spider or thread veins') superficial VV that actually lie within the skin (as opposed to 'trunk' VV that lie under the skin) and so cannot be surgically removed. Liquid sclerotherapy is performed with the patient lying on a couch in the consulting room and involves injecting a detergent-like material (the 'sclerosant') into the VV so that they empty of blood and shrivel up. Many patients have 'trunk' and 'reticular' and 'spider' veins. If the latter two are treated by sclerotherapy without first dealing with the 'trunk' veins the long-term results are often disappointing. So, many patients first undergo surgery (or UGFS) for the big veins under the skin and then liquid sclerotherapy for the small veins in the skin. These different treatments should be seen as complementing each other; working together to get the best overall results. Liquid sclerotherapy requires no anaesthetic or stay in hospital and is generally very safe. However, even in the best of surgical hands, there are a number of unwanted side-effects and complications of which you should be aware:

§ Allergic reactions to the sclerosant: The literature reports a risk of 'anaphylactic shock' of about 1 in 10,000 patients. In my own practice, I have never seen a severe allergic reaction but if you have any allergies (especially after any previous injection treatments for VV) please do let me know

§ Bruising and redness at the injection sites: This occurs in almost all patients and the leg nearly always looks worse for a while before it begins to look better. The bruising may be associated with firmness and tenderness of the treated vein but in the great majority of patients this settles down over a few weeks and months. Unusually, it may be necessary to release a small bruise through the skin with a small needle. Use of the prescribed hosiery after each treatment session will reduce the risk and degree of bruising

§ Pigmentation: About 30% of patients undergoing sclerotherapy notice some discolouration of the skin, usually light brown streaks, after treatment. In virtually all patients this will fade but, in some cases, the pigmentation can take several months to disappear. Unusually, pigmentation can be permanent

§ Ulceration at the injection site: I have never seen this in my own practice but it is reported in the literature. These ulcers can be quite painful but usually heal spontaneously in a few weeks, sometimes leaving a scar

§ Pain: Sclerotherapy involves undergoing a moderate number of injections (average 20-25) at each session. However, the special needles I use are extremely small and sharp so that any discomfort is minimised. The treated area may be uncomfortable and the treated veins tender to touch afterwards. In most cases, this settles after a few days and responds well to paracetamol or non-steroidal analgesics, such as ibuprofen (Nurofen). In my own practice, I have observed that very few patients need to take pain-killers after liquid sclerotherapy

§ Deep vein thrombosis: This is extremely rare - probably affecting less than 1 in 5,000 patients (I have never seen it).

§ Recurrence: Liquid sclerotherapy is not a cure for reticular and spider (thread) veins, it simply holds them at bay. There is around a 20% chance that you will develop new VV in the future, which may require further sclerotherapy treatment. It is perhaps useful to draw an analogy between repeated sessions of sclerotherapy over the years to keep your legs looking as good as possible and repeated visits to your dentist to keep your teeth healthy and your smile pearly!

Sclerotherapy works by causing mild inflammation within the VV so that they empty of blood, shrivel up and become less visible and uncomfortable. The final result can take several months to achieve and the treated area often looks worse (red and blotchy) immediately after treatment before it begins to look better. The response to sclerotherapy varies between different patients. So, it is sensible to treat one (usually the worst) area first to see how you react. If you are happy with the result then other areas can be treated at later sessions. How many sessions are required depends on how severe and widespread your veins are. However, typically, 3-5 sessions are required to treat one 'average' leg of reticular and spider (thread) veins. If both legs are affected then, of course, more treatments will be required. As a rule of thumb, each session will be able to deal with an area roughly 2-3 times the size of the palm of your hand. About 20% of patients develop more VV over the next 5 years and regular 'tidy-up' treatment sessions are often sought by patients to keep the veins under control (again, like check-ups, scale and polish at the dentist). In my experience, around 90% of patients are very pleased with the cosmetic results of liquid sclerotherapy, 10% are fairly pleased and a small minority of patients are disappointed. It is important to understand that liquid sclerotherapy can never get rid of all the veins in your leg; nor, realistically, can it make your legs look as they did when you were a teenager

Ultrasound guided foam sclerotherapy (UGFS) for large reticular and trunk VV

(Please note that patients considering UGFS should read this information sheet in conjunction with the Guidance for Patients issued by NICE (National Institute for Health and Clinical Excellence) (http://www.nice.org.uk/page.aspx?o=IP_244) which is available on the web-site).

UGFS is a variation of liquid sclerotherapy that can be used instead of surgery to treat 'trunk' VV, provided that they are not too large or extensive (having said that we have successfully treated very large VV in patients who did not wish to or could not have surgery and/or anaesthesia). Foam sclerotherapy is performed as an out-patient procedure; takes about 30-45 minutes; and is performed under local anaesthetic (similar to that used by dentists for fillings) with the patient lying on a couch. Once the anaesthetic has taken effect (a few seconds), using the ultrasound scanner as a guide, very small plastic tubes are placed through the area of numbed skin into the VV. This is usually either the 'long saphenous vein' on the inside of the thigh or the 'short saphenous vein' on the back of the calf and their main branches. The number of tubes required varies with the size and extent of the VV but 3-6 would be typical. Once the tubes are in position, the leg being treated is raised in the air to empty the veins of as much blood as possible. The foam is freshly prepared and injected into the VV via the plastic tubes. Once the foam enters the VV it is milked along the VV by massaging your leg. Because the foam is full of bubbles it can be seen very clearly on the ultrasound scan. This allows us to see where the foam is and to make sure all the VV are full. The injection causes no pain in the leg, although sometimes some 'bubbling' sensations can be felt. Typically we inject 8-12 ml of foam at each treatment session. I know that some foam may enter the deep veins although, by pressing gently on the VV at key sites and moving your foot between injections this can be kept to a minimum. In about 85% of patients, only one foam treatment session is required; about 15% of patients require two sessions and 1-2% require three sessions. The larger and more extensive, the more likely it is that more than one session will be required.

We have been doing UGFS since January 2002 and at the time of writing have treated almost 1500 legs of VV in this manner. This is one of the largest experiences in the UK and the great majority of patients undergo their treatment without complication and are very pleased with the outcome (and that they have avoided surgery). However, there are a number of unwanted potential side-effects and complications of which you should be aware:

- § **Bruising:** There is usually none or very little but if there is it nearly always disappears in a few weeks.
- § **Pigmentation:** About 20-30% of patients, especially those with large VV near to the skin surface, can develop streaks of brown pigmentation over where the VV used to be. This usually fades over a few months and in most patients is gone by 6-12 months; however, it can be permanent
- § **Lumpiness:** It is normal, especially in patients with large VV, to be able to still feel some lumpiness beneath the skin. Depending on the size of VV this disappears over a few months and in most patients is gone by 6-12 months; however, some lumpiness can be permanent. Aspiration of lumpy veins about 4 weeks after treatment can hasten this process.
- § **Allergy:** I have observed one case of mild allergy; serious allergy (anaphylaxis) has not been observed or reported
- § **Inadvertent intra-arterial injection:** I have never seen this but a few cases have been reported in the literature
- § **Thrombophlebitis:** In patients with large and especially lumpy VV, a painful red lump over the site of one or more of these veins may develop following treatment. This is called 'superficial thrombophlebitis' and can be treated with anti-inflammatory medication (e.g. ibuprofen gel and/or tablets) of, if especially problematic, by inserting a needle into the lump under local anaesthetic and removing small amount of trapped blood (aspiration). In my practice, I have observed the need to do this in about 1 in 5 patients. After such treatment, the thrombophlebitis usually settles down over the next couple of weeks
- § **Deep vein thrombosis:** As with surgery, foam sclerotherapy is associated with a small risk of DVT. At the time of writing I have treated almost 1500 legs of VV with foam sclerotherapy and, to date have seen DVTs in three patients. So, I estimate the risk of DVT to be about 0.2% (1 in 500). The literature reports a similar level of risk. Although DVT is very unlikely, if your leg swells and/or becomes painful after treatment you should contact me immediately for advice and a consultation. If a DVT has formed you will probably require treatment with heparin (injections daily for 3-4 days) and then warfarin (tablet daily for 3-6 months). As with surgery, I do not routinely ask patients to stop the OCP/HRT
- § **Pulmonary embolus (PE):** As with surgery, if a DVT were to develop after foam sclerotherapy, there is potential risk that a piece of the clot could break off and travel to the lung causing a PE, which could be serious even potentially fatal. We have seen one minor PE after UGFS.
- § **Ulcers (cutaneous necrosis):** I have not seen this in my practice but it is reported in the literature
- § **Stroke:** I have not seen this in my practice but one case with full recovery has been reported in the literature. The cause was never clearly established but this patient was subsequently found to have a large "hole in the heart" which may have allowed some of the foam to travel to the brain
- § **Epileptic fit:** I have not seen this in my practice but one case with full recovery has been reported in the literature
- § **Transient confusion:** I have not seen this in my practice but a few cases have been reported
- § **Heart attack:** I have not seen this in my practice but one case in a 70-year old occurring 30 minutes after treatment has been reported in the literature
- § **Transient visual disturbance:** This has been reported after foam and liquid sclerotherapy but seems commoner with the former (the literature suggests the risk is around 1%) and, possibly, in patients who get regular migraines. To date, I have observed it in 5 patients and in all cases it resolved spontaneously within 30 minutes. The cause is unknown. The longest visual disturbance ever reported was 2 hours; permanent 'blindness' has never been reported
- § **Headache:** This is reported in up to 4% of patients; I have not observed this in more than a handful of patients
- § **Coughing, chest tightness and heaviness, metallic taste in the mouth, panic attacks:** These have all been reported but I have not seen them in my own practice

Would you like more information? If so, foam sclerotherapy has recently been reviewed by the Health Services Research Unit at the University of Aberdeen. Their full report, as well as a (much more digestible) summary of their findings (published in the British Journal of Surgery 2007 94:925-36), are available on the MVC web-site. NICE also have information and guidance on their web-site (http://www.nice.org.uk/page.redirect?o=IP_244)

Ultrasound guided foam sclerotherapy or surgery for trunk VV – what are the pros and cons?

IWe have been performing UGFS since January 2002 and at the time of writing have treated almost 1500 legs of VV. Our experience has led me to believe that in properly trained and experienced hands the results of UGFS in correctly selected patients are as good as (and in many cases much better than) those of surgery. However, there are some potential pros and cons to foam sclerotherapy when compared to standard surgery.

<p>Potential advantages of UGFS?</p> <ul style="list-style-type: none"> · Out-patient procedure · No general anaesthetic · No cuts so no risk of wound infection or scarring · No risk of nerve damage · Virtually painless · Much less bruising · Much earlier return to work and other normal activities · No shaving required; a major bonus for the men! · About half the cost of surgery 	<p>Potential disadvantages of UGFS?</p> <ul style="list-style-type: none"> · It usually takes longer to achieve the final result because only one leg is treated at a time, you may require more than one treatment per leg and the veins can feel lumpy for several months afterwards (but this can also occur after surgery) · In order to keep the treated VV empty of blood while they seal off, it is necessary to wear compression for several weeks after each treatment (please see below) · The skin over the treated VV can turn brown. This can take a few months (sometimes up to year) to disappear and may, unusually, be permanent (but this can also occur after surgery) · Thread (spider) veins may develop where the foam has been injected (but this can also occur around the wounds after surgery) · The majority (80-90%), but not all, VV are suitable for UGFS
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Pre-treatment preparation for liquid and foam sclerotherapy

1. On the day of treatment wash your leg with ordinary soap but please do not apply any lotions, creams or perfumes
2. Do not shave your legs (men); unless you want to (the ladies)
3. Please wear loose trousers and soft, flat-soled shoes (e.g. training shoes would be ideal)
4. Please note that we will have to gain access to the whole of your leg and often the groin area; patients (ladies especially) may want to bear that in mind when choosing underwear
5. Please ask someone to come with you and take you home afterwards
6. Please take your usual medication on the day of treatment. You may also eat and drink normally before your treatment.

Post-treatment care liquid and foam sclerotherapy

1. Compression is absolutely vital for a safe and successful outcome. Following foam and liquid sclerotherapy I apply a bandage and a compression stocking to the leg. The bandage can usually be removed after 5 days (for foam) or 2 days (for liquid) but the stocking should be worn for another 3 weeks
2. Please go for a brisk 15 minute walk immediately after your treatment
3. Thereafter, please walk about for at least 5-10 minutes each and every hour (that you are awake) for the first 24 hours (5-10 minutes is a minimum, there is no upper limit to the amount of walking you can do).
4. Try to avoid prolonged standing, kneeling, squatting, bending and avoid vigorous exercise (e.g. jogging, gym work-out, racquet sports etc.) for 4 weeks after treatment
5. Try to avoid flying (especially long haul) for 4-6 weeks afterwards
6. Washing – this is the trickiest bit – a compromise between personal hygiene, protecting the skin over the treated areas, and maintaining compression:
 - a. Try to avoid getting the treated areas wet whilst bandaged after treatment; the easiest solution is to strip wash at the sink
 - b. After the bandage and the stocking have been removed and you have refitted your spare stocking you can then shower/bath (with the stocking on) and refit the first (washed) dry stocking afterwards. Try to avoid very hot water as it will increase the blood flow to your skin and may increase bruising and reduce the effectiveness of the treatment
7. Driving:
 - a. Left leg: you can drive (if you can and you want to) the next day
 - b. Right leg: **You may drive once you feel able to do an emergency stop.** In practice, you may find this difficult while you have the bandage on; if in doubt, avoid driving until you are just in a stocking
 - c. Insurance companies have differing policies with regard to driving after surgical and other medical procedures; if in doubt, you are advised to check your cover with them
 - d. If you are on a long car (whether driving or a passenger) or train journey during the first month after treatment please stop the car every hour and walk around (up and down the train) for a minimum of 5-10 minutes
8. Long-term compression may improve the results of treatment and reduce the risks of developing new VV. You might want to consider purchasing some light-weight compression hosiery for long-term use

Which sclerosants do I use for liquid sclerotherapy?

I use two sclerosants for sclerotherapy:

1. Sodium Tetradecyl Sulphate (STS) is purchased as Fibrovein from STD Pharmaceuticals (<http://www.stdpharm.co.uk>). STS has a UK license for the treatment of VV as a liquid but not as a foam; so I am using a licensed drug "off label"
2. Polidocanol (PD) is purchased as Sclerovein from STD Pharmaceuticals who import it from the manufacturers, Resinag, Switzerland. PD does not have a UK license

Why are you telling me this, what does this mean for me, and should I be worried? The short answer is: I am legally obliged to tell you, not very much and, no, you should not worry. For the long answer please read on.....

Why are medicines licensed? In the UK, most medicines go through strict checks to make sure that they are safe and effective. When the medicine passes all the required checks, a product license is granted which means that the medicine can be used in the treatment of specific medical conditions. Pharmaceutical manufacturers must apply to the official government agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), for a product license (aka Marketing Authority) if they want to market and sell their medicines in the UK. The MHRA only agrees to issue a product license for a medicine if it has been proven to work for the illnesses it was developed for, does not have too many side effects or risks and has been made to a high standard.

What is an unlicensed or off-label medicine? Medicines are usually only licensed for conditions that have been investigated in clinical trials. However, some illnesses may not have been studied in this way, but still need to be treated. In these situations, doctors and pharmacists are fully entitled to use their medical experience and specialist knowledge to recommend the use of unlicensed or off-label medicines. They may choose to use:

- a licensed medicine for a purpose, dose or route that is not covered by the licence – 'off-label' use (the case with STS)
- a medicine that is currently undergoing clinical trials but does not yet have a licence
- a medicine that used to be licensed in the UK but is no longer available
- a medicine that is only available from abroad and needs to be imported (the case with PD)
- a medicine that needs to be specially made because it is not readily available from a manufacturer

Why am I wanting to use a medicine off-label (STS) and an unlicensed medicine (PD) for the treatment of VV?

Like many, many other surgeons in the UK, Europe, North America, and around the world, I believe that in some circumstances:

- patients will get a better result with STS if I use it as a foam rather than a liquid
- PD provides better results and can be more pleasant for the patients (less pain and inflammation) than STS

Should I be worried about the use of unlicensed or off-label medicines? No, because I am only using these drugs in this way because, like many other surgeons around the world, I believe that the benefits far outweigh any risks

Key points:

1. The fact that a drug is not licensed does not necessarily mean it has been shown or is considered to be unsafe or ineffective (it means the manufacturer has never applied for license; often because of the costs involved)
2. Many drugs (including many of those used for babies and children) are used in the UK outside their licensed indications
3. If a practitioner uses a non-licensed drug or a drug outside its license indications ("off-label") then they must tell the patient that is the case and the practitioner (not the manufacturer) is liable for any adverse outcome

If you require any further information this is available on the MVC website

Radio-frequency ablation (RFA) for trunk VV using the VNUS Closure Fast procedure

(Patients considering RFA should read this information sheet in conjunction with the Guidance for Patients issued by NICE (National Institute for Health and Clinical Excellence) at <http://www.nice.org.uk/Guidance/IPG8?PublicInfo/pdf/English>)

How does this technique work and how is it done?

VNUS Closure Fast is used to treat trunk VV (the trunk of the tree is depicted on page 1 of this information sheet) and works by heating the vein from the inside using electricity. This shrinks the trunk vein down causing it to block off. The main advantage of this technique is that, like foam sclerotherapy, it avoids traditional surgical stripping and a cut in the groin and is associated with less pain, bruising and a quicker return to normal activities. Depending on the size and extent of the VVs, and patient preference, it can be performed either under local or general anaesthesia, either as a day-case or as an overnight stay in hospital. Similar to foam sclerotherapy, the ultrasound scanner is used to place a small plastic tube into the trunk vein usually around the level of the knee. A fine wire (catheter) with the heating element at the end of it is then passed through this tube and up the main trunk vein to the level of the groin. Local anaesthetic is then placed around the trunk vein to keep it away from the skin to insulate the body against the heat generated inside the vein by the catheter tip. The catheter is slowly withdrawn from the vein while the energy is delivered to the vein wall. This takes less than 10 minutes, at the end of which the main trunk vein is blocked off. The catheter is then removed from the leg. If required, the branches of the tree can then be treated by pulling them out through small cuts in the leg(s) (phlebectomies), or by foam or liquid sclerotherapy, either at the same time or at a later date. As with foam sclerotherapy, after the procedure a bandage and a stocking will be applied to your leg (please see above). As with foam sclerotherapy, most patients will return to normal activities within a few days.

Are there any risks?

As discussed above, all treatments for VV carry some risk and even in the best of hands there are a number of unwanted potential side-effects and complications that may be associated with the VNUS Closure Fast of which you should be aware:

Bruising and pigmentation: As with foam there may be some bruising and pigmentation of the skin over the treated veins. This is much less than with surgery and nearly always disappears over a few weeks or months. Very rarely, as with foam and surgery, some staining of the skin can be permanent

Thrombophlebitis: In patients with large VV, a painful red lump (called 'superficial thrombophlebitis') may very rarely develop over the site of one or more of the lumpy veins following treatment. This can be treated with anti-inflammatory medication (e.g. ibuprofen gel and/or tablets) and the lumpiness will usually settle over a couple of weeks.

Deep vein thrombosis (DVT): The risk of deep vein thrombosis after VNUS Closure FAST is low; probably less than 1%. The risk is less than with surgery but possibly higher than with foam. Although DVT is very unlikely, if your leg swells and/or becomes painful after treatment you should contact us immediately for advice and a consultation. If a DVT has formed, you will probably require treatment with heparin (injections daily for 3-4 days) and then warfarin (tablet daily for 3-6 months). As with surgery, we do not routinely ask patients to stop taking the oral contraceptive pill or HRT.

Pulmonary embolus (PE): If a DVT were to develop there is the potential risk that a piece of the clot could break off and travel to the lung causing a PE, which could be serious or even potentially fatal.

Infection: As with any invasive procedure, however minimal, there is a very small risk of infection occurring at the site where the catheter is inserted through the skin.

Skin burns: There is a very small risk of burns to the skin overlying the veins during treatment. This can easily be avoided by ensuring that enough local anaesthetic is injected along the track of the vein to be treated.

Abnormal sensation/numbness: Occasionally patients have described an abnormal sensation in the leg in the region where the vein has been treated. This should improve/disappear within a few days.

Should I have foam sclerotherapy or VNUS Closure Fast for my trunk VV?

- Each treatment has its pros and cons and there are a number of factors that will influence our advice as to which treatment will suit you best; the final decision will, of course, also depend upon your own personal preferences based on the information we have provided to you

Potential advantages of VNUS over foam	Potential disadvantages of VNUS over foam
<ul style="list-style-type: none"> • If your VVs are very large and close to the skin they may be less lumpy afterwards. There may also be a lower chance of skin pigmentation. • Compression may not be required for quite as long • It may be possible to treat both legs at the same time • Some insurance companies may not pay for foam 	<ul style="list-style-type: none"> • Has to be performed in hospital as a day case procedure or overnight stay, rather than as an outpatient in clinic. • May require a general anaesthetic • Very small risk of skin burns • Small incision required in the leg to introduce the catheter so small risk of infection • VNUS only blocks off the trunk of the tree so most patients require a further treatment for the large and small branches (either at the same time or at a later date)

How do I prepare for VNUS Closure FAST?

This is very similar to foam sclerotherapy: Do not shave your legs (men); unless you want to (the ladies); please wear loose trousers and soft, roomy flat-soled shoes; please ask someone to come with you and take you home afterwards; please take your usual medication on the day of treatment; **if you are having your treatment under general anaesthetic, you should eat nothing for 6 hours before and drink only clear fluids up to 2 hours before the treatment.**

What happens after VNUS Closure FAST?

This is very similar to what happens after foam sclerotherapy

- The bandage and stocking should be worn for 48 hours to reduce bruising and the risk of DVT (during this time you will need to keep the leg dry). They can then be taken off and replaced with the second clean stocking provided which should be worn day and night for two weeks (you can now bathe/shower with the stocking on).
- Any paper stitches that were required will usually drop off on their own accord during the first week.
- Most patients get little or no pain; if you do, then take whatever you might take for a headache (e.g., ibuprofen, paracetamol) will usually be sufficient.
- As with all treatments for VV it is important to stay mobile afterwards; we recommend a minimum of 5 minutes brisk walking every hour that you are awake for the first week.
- The treated vein can sometimes be felt under the skin, like a thick cord. It may feel a little tight at first if you are exercising or stretching but it softens up quite quickly and within a few weeks disappears altogether.
- You will usually be reviewed in the out-patient clinic in 4 weeks. At that time any remaining VV can be 'tidied up' with either foam or liquid sclerotherapy.
- We recommend no flying or vigorous or contact sports for 4 weeks after treatment (e.g. rugby, squash, running)
- Driving is best avoided for at least 48 hours while the anaesthetic works its way out of your system. Some people feel ready to drive after 48 hours, some take a little longer depending on the extent and length of your operation.

Costs, payment terms and conditions

Understandably, the great majority of patients want the likely costs of their treatment to be set out clearly and 'up front' so that there are no unpleasant surprises when it comes to settling their accounts. These costs depend primarily on whether patients are self-funding or covered by private health insurance.

Self funding patients

- **Consultation:** The fee for your initial consultation (including a full colour duplex ultrasound scan of the deep and superficial veins of both legs) will be **£299** payable in full by personal cheque/cash prior to or at your consultation
- **VV surgery & VNUS:** The total costs (surgical plus anaesthetic fees and hospital charges) of VV surgery are in line with those recommended by the major insurers and range between c. **£2000** for one leg to c. **£4,000** for two legs depending on the complexity of the surgery. You will be provided with an estimate following your consultation and a full professional fee schedule can be found at <http://www.groupamahealthcare.co.uk/YourHealth/Schedule.html>. We may be able to offer you a fixed price, all-inclusive package in conjunction with the Spire Parkway hospital in Solihull (<http://www.spirehealthcare.com/>) or another partner private hospital. Payment in full of all fees and charges will be required by the hospital prior to admission
- **Foam sclerotherapy:** The fixed, all-inclusive, price for foam sclerotherapy is **£975** per leg regardless of how many treatment sessions are required; this fee also includes all aftercare for the first 6 months. This is payable in full by personal cheque/cash at the time of treatment
- **Liquid microsclerotherapy:** The charge is **£195** per session plus a one-off charge of **£45** for two stockings. This is payable in full by personal cheque/cash at the time of treatment
- **Additional stockings:** These will be charged at **£25** per stocking
- **Overseas patients:** Patients will be asked to settle their fees in full prior to treatment in British Sterling either as cash or as a bank transfer. Account details can be provided on request

Insured patients

Please bring your full insurance details with you including the policy and, where appropriate, the authorisation number. May I also politely recommend that you make yourself fully aware of any limitations and conditions that apply to your policy so that any reimbursement shortfall does not come as an unpleasant and unexpected shock.

- Consultation and duplex ultrasound scan: I will invoice your insurance company for your consultation and duplex ultrasound scan in accordance with their schedule of fees (these are normally based on 'BUPA rates', widely regarded as the 'industry standard')
- Foam sclerotherapy: The fixed, all-inclusive, price for foam sclerotherapy is **£975** per leg regardless of how many treatment sessions are required; this fee also includes all aftercare for the first 6 months
- Liquid microsclerotherapy: The charge is **£195** per session. There is also a one-off charge of **£45** for two stockings
- Additional stockings: these will be charged at **£25** per stocking
- VV surgery & VNUS: My fees are in line with those recommended by the major insurance companies; a full fee schedule can be provided on request and is also available at <http://www.groupamahealthcare.co.uk/YourHealth/Schedule.html>
- Shortfall: In the event of an insurance re-imburement shortfall in respect of your consultation, duplex scan or treatment fees, you will be asked to kindly settle the difference by personal cheque/cash within 30 days

Non-attendance and cancellation

Failure to attend your appointment without giving reasonable notice (24 hours) may result in a cancellation charge of **£150** being levied; this is also payable by personal cheque/cash within 30 days

Please note we cannot accept credit or debit card payments

Cheques should be made payable to "**Professor Andrew Bradbury**" and either sent to **Midland Vein Centres, PO Box 13581, Solihull, B91 9GD** or brought with you to your treatment session. Patients wishing to pay by cash can pay when they attend for their treatment session. Receipts will, of course, be provided

Summary

The aim of this document is to present as full and frank a picture as possible of what can be achieved by means of VV surgery, liquid and foam sclerotherapy and radio-frequency ablation; what it entails, the risks and the benefits, and the costs involved. It is intentionally detailed and comprehensive because experience tells me that is what patients want and expect. Having said that, of course, no such document can ever cover every eventuality and I will be only too pleased to answer any further questions that you may have and provide whatever further information you require in order to enable you to make a fully informed decision regarding your VV and their treatment.

Website:

www.midlandveincentres.co.uk

E-mail:

info@midlandveincentres.co.uk

Appointments:

07858 430403