

Varicose Veins

the risks of minimally invasive techniques

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■ The NHS treats about 35,000 patients per year for varicose veins and about another 10,000 are treated in private hospitals. This is a commonly undertaken operation but varicose vein treatments are amongst the most common giving rise to medical negligence litigation in general and vascular surgery.

In recent years several new methods have come into use which require surgeons to use a new range of skills and equipment to cure varicose veins. These offer less invasive treatments but surgeons are often less familiar with new techniques and this may also give rise to complications of treatment.

Each type of treatment carries risks specific to that treatment as well as some problems which are common to all treatments.

Varicose vein surgery

Surgery for varicose veins has been undertaken for more than 2,000 years although current 'vein stripping' techniques have only been in use since the beginning of the 20th century. Varicose veins lie close to other important structures including arteries, veins and nerves. Surgery performed in a substandard way may cause damage to these structures including ligation or stripping of the main artery or vein to the leg or damage to a major motor nerve leading to disabling paralysis of the limb. Such events affect only a very small proportion of operations but are very likely to give rise to a claim for damages. Cutaneous nerves providing sensation to the skin run close to many varicose veins and commonly suffer damage during varicose vein surgery leading to some loss of normal sensation in the skin in up to 20% of patients. Fortunately most of these cases improve with time and a more limited number of patients experience long term numbness of the skin.

Following varicose vein surgery bruising of the leg is invariable and more severe haemorrhage may also arise. Wound infections are fairly common and scars may persist in the leg, especially if incisions to remove varicose veins are made in a substandard manner. Less commonly, deep vein thrombosis may complicate any treatment for varicose veins. Appropriate precautions should be taken to minimise the risk of these complications, especially the prevention of post-operative deep vein thrombosis.

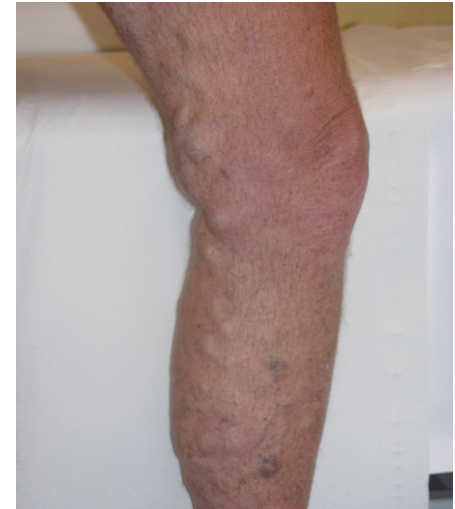
Patients may find that the outcome of their treatment is disappointing. Perhaps they had been given unreasonable expectations of the outcome of treatment or the surgeon may have undertaken surgery which would not be likely to improve the appearance of the limb. Such claims may be more difficult to pursue. I have provided advice in cases where a poor cosmetic result has been shown to be due to a substandard technique and a favourable settlement has been obtained for the claimant.

Modern varicose vein treatments

In the last decade or two several new ways of curing varicose veins have been introduced. These use a number of different strategies to destroy the veins but without removing them from the leg. Veins obliterated by these treatments are reabsorbed by the body in the months following treatment. In general the more modern methods are associated with far less post-operative discomfort and a more rapid return to normal activities and are to be welcomed. However, during the 'learning curve' for new methods of treatment a number of unintended consequences may arise. In addition, the new methods of treatment have complications specific to the technique.

The new methods of treatment include the use of skills with which many surgeons used to conventional surgical methods are unfamiliar. Minimally invasive methods necessitate ultrasound guided treatment which is not a standard surgical skill and requires significant amounts of training to gain basic competence. Care must be taken during treatment since heating or injecting the wrong section of vein can lead to ineffective treatment or cause unintended damage to nearby structures. Many veins have nearby nerves which may be damaged by thermal ablation of the associated vein. Patients should be aware of the range of complications that may arise after the new types of treatment.

The thermal ablation techniques are the most widely used of the minimally invasive treatments. A catheter is passed along the vein to be treated and used to heat the vein by either electrical or laser energy. Another method heats the vein using small puffs of steam introduced via the catheter. All of these methods require the treated vein to be surrounded by a substantial volume of



dilute local anaesthetic solution to prevent pain which would otherwise result from heating the vein. Temperatures involved range from about 120°C with electrical heating to 800°C with some laser systems. The solution also insulates the surrounding structures such as nerves and the skin, preventing these from being damaged during heating of the vein.

One of the hazards of thermal ablation is that if heat is applied to the wrong thing then it too may be damaged. Great care must be taken to avoid heating the skin and skin burns are a recognised, though infrequent, complication of this treatment. Sensory nerves running adjacent to the vein may also be damaged leading to regions of paraesthesia and numbness. Thermal ablation techniques have been in use for more than 12 years and so the benefits and possible adverse events which may be encountered are well known.

During ultrasound guided foam sclerotherapy, a foamed sclerosant, is injected into the veins to be treated under ultrasound guidance. This method is a modern version of injection treatments originally described more than 165 years ago. Creating foam from drugs which have been used to inject veins for decades, multiplies the efficacy of treatment by about 20-fold. Long term eradication of varicose veins has been shown following this treatment. Ultrasound imaging is required to place the treatment in precisely the right location. Experienced practitioners can readily identify veins which require injection and guide a needle to the correct place. A very small number of instances of inadvertent intra-arterial injection has been reported. If a major artery is injected with foam severe damage to the leg results which may necessitate amputation of part of the limb.

More common adverse events include the



TABLE 1

Complications of varicose vein treatment. This table includes the more important complications of treatment but is not intended to be exhaustive.

Treatment	Examples	Common Complications	Serious Complications
Varicose vein surgery	<ul style="list-style-type: none"> Stripping operations Phlebectomy, hook phlebectomy, removal of varices 	<ul style="list-style-type: none"> Post-operative bruising and pain Wound infection Lymphatic problems: lymph leak, lymphocele Sensory nerve injury Scars Poor cosmetic outcome Recurrence or persistence of varicose veins Thrombophlebitis Complications arising from general anaesthesia 	<ul style="list-style-type: none"> Damage to motor nerves Damage to main artery or vein, eg femoral artery, femoral vein Deep vein thrombosis Lymphatic injury resulting in lymphoedema
Thermal ablation techniques	<ul style="list-style-type: none"> Endovenous laser ablation, endovenous radiofrequency ablation, steam ablation 	<ul style="list-style-type: none"> Post-operative bruising and pain (much less than following varicose vein stripping procedures) Sensory nerve injury Thrombophlebitis Poor cosmetic outcome Induration over track of treated vein Recurrence or persistence of varicose veins 	<ul style="list-style-type: none"> Skin burns Deep vein thrombosis Fracture of catheter/laser fibre leading to retention of part of the catheter system in the patient's leg (rare)
Foam sclerotherapy	<ul style="list-style-type: none"> Foam sclerotherapy of saphenous trunks, saphenous tributaries and of varicose veins 	<ul style="list-style-type: none"> Post-operative bruising and lumps (much less than following varicose vein surgery) Transient chest symptoms and/or visual disturbance Thrombophlebitis Poor cosmetic outcome Recurrence or persistence of varicose veins Induration over track of treated vein Persistent skin pigmentation – lasting many months. 	<ul style="list-style-type: none"> Deep vein thrombosis Severe allergy to sclerosant drugs (rare)
ClariVein™	<ul style="list-style-type: none"> Mechanically assisted sclerotherapy 	<ul style="list-style-type: none"> Not fully established 	
Sapheon™	<ul style="list-style-type: none"> Endovenous glue occlusion of saphenous trunks 	<ul style="list-style-type: none"> Not fully established 	

retention of excess thrombus within the treated vein leading to lumps and bruising in the legs. These sometimes become very tender due to the development of thrombophlebitis (inflammation of the vein). Skin pigmentation may arise over treated veins, sometimes taking many months to resolve. Immediately following injection inflammatory factors are released from the treated veins and travel by the blood to the lungs. This may lead to tightness of the chest or coughing in a few cases. In patients with migraine, containing circulation of the inflammatory factors may lead to visual disturbance, experienced by migraine patients early in the onset of an attack. Both of these problems resolve within 10-30 minutes in most cases.

A more recent technique is ClariVein™ in which a catheter, equipped with a rotating wire powered by an electric motor, is passed along the vein. As the rotating wire is withdrawn it causes damage to the lining of the vein. At the same time a sclerosant is injected via the catheter into the vein to complete the treatment. The outcome of this technique is probably fairly similar to that which may be obtained by ultrasound guided foam sclerotherapy. This is a fairly new method and detailed long-term studies have not yet been reported.

A further technique which remains in the early stages of evaluation is Sapheon™ which comprises a catheter system used to deliver cyano-acrylate glue into the saphenous vein. This obliterates the vein by sticking the walls of the vein together. Only limited data of efficacy

and hazards of this technique has so far been published and so complete understanding of its safety and efficacy is yet to be established.

Table 1 summarises the complications of varicose vein treatments in common use. All treatments might incur the remote risk of post-operative death (<1 in 100,000) but surgeons would not normally mention this to patients since it might unnecessarily raise concerns about the treatment. This complication has been omitted from the table.

Patients should be warned of the possibility of the complications that I have mentioned in this table before undergoing treatment, as part of good clinical practice. Claims arising from post-operative complications in the 'common complications' column can probably be defended under these circumstances. In the 'serious complications' column, the problems of damage to major arteries, veins and motor nerves (following surgical treatment) should never happen and claims arising from these problems may be difficult to defend. Similar arguments probably apply to skin burns following endovenous thermal ablation methods.

Post-operative deep vein thrombosis

Deep vein thrombosis may occur following any treatment for varicose veins. This is more likely to occur in some patients than in others so selective use of preventive measures is considered appropriate. Patients with a previous history or family history of venous thromboembolism or thrombophlebitis, the elderly, those with severe venous disease (e.g. leg ulcers) or very

large varicose veins are most at risk. Most treatments for varicose veins include the use of compression stockings or bandages and these may be sufficient in patients assessed as being at low risk. For those at moderate or high risk of DVT additional measures should be taken, most commonly the injection of low-dose low molecular weight heparin. Manufacturers of these drugs recommend a 7-10 day course of treatment following surgery but it is common practice to use only a single dose on the day of treatment in view of the reluctance of patients to inject themselves following discharge from hospital. However, an observational study found no evidence that this strategy reduced the risk of DVT following varicose vein surgery. In the event of a DVT occurring under such circumstances it could be argued that the DVT would have been avoided had the clinicians complied with the manufacturer's recommendations.

In general, the outcome of minimally invasive treatments is excellent in skilled hands. The hazards of these treatments are probably fewer than those of conventional varicose vein surgery. Certainly the post-operative course is less uncomfortable for the patient and a more rapid recovery from treatment can be expected. □

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