



The treatment of varicose veins

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ABSTRACT

INTRODUCTION Over the past few years, there has been a move to less invasive endoluminal methods in the treatment of lower limb varicose veins combined with a renewed interest in sclerotherapy, with the recent addition of foam sclerotherapy. The development of these new techniques has led many to question some of the more conventional teaching on the treatment of varicose veins. This review examines these new treatments for lower limb varicose veins and the current evidence for their use.

MATERIALS AND METHODS An extensive search of available electronic and paper-based databases was performed to identify studies relevant to the treatment of varicose veins with particular emphasis on those published within the last 10 years. These were analysed by both reviewers independently.

RESULTS There is no single method of treatment appropriate for all cases. Conventional surgery is safe and effective and is still widely practised. Whilst the new treatments may be popular with both surgeons and patients, it is important that they are carefully evaluated not only for their clinical benefits and complications when compared to existing treatments but also for their cost prior to their wider acceptance into clinical practice.

KEYWORDS

Varicose veins – Surgical treatment – Endovenous ablation – Sclerotherapy

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Varicose veins are a common problem and cause disfigurement, disability and impairment in the quality of life (QoL). Over 40,000 operations are performed each year for varicose veins within the NHS in England and Wales. Conservative methods like compression bandaging for ulceration can also be expensive. Varicose veins are, therefore, of significant clinical and economic importance to the health service and also have a major socio-economic impact on society. The advent of endovenous ablation techniques has expanded the surgical options for patients requiring treatment.

Materials and Methods

Relevant studies were identified via the MEDLINE, PREMEDLINE, EMBASE, PubMed, Cochrane Library and Science Citation Index using Boolean search terms from their commencement to 2005. Further studies were obtained from references, reviews, specialty journals, trial registries and the internet and by hand-searching. Abstracts were searched for studies reporting safety, efficacy, technique and outcomes with emphasis on comparative studies and large case series. The authors concentrated on evidence published in the last 10 years to achieve a balance

between comprehensiveness and precision. Non-English articles were excluded unless a translation could be obtained. Conference abstracts and unpublished reports were excluded.

Results

Definitive treatment of varicose veins aimed at abolishing sources of venous reflux and removing long refluxing segments and varicose reservoirs can be achieved by conventional surgery or by endovenous ablation techniques. Transilluminated powered phlebectomy and subfascial endoscopic perforator surgery are less commonly employed.

The main outcome in the selected studies is the abolition of saphenous vein reflux. However, there is wide variation in the reporting of outcomes between studies. Elimination of varicosities, recanalisation after endovenous ablation, recurrence of reflux, re-appearance of varicose veins, symptomatic improvement and re-treatment rates are not reported in all studies. Varicosities evident at follow-up are not clearly differentiated into residual, recurrent or newly incompetent veins. Some studies are affected by significant follow-up loss.

Table 1 Morbidity following varicose vein surgery

- * Bleeding
- * Subcutaneous haematoma along the length of the stripped vein or at avulsion sites
- * Bruising
- * Pain
- * Groin wound problems – haematoma, seroma, cellulitis, infection, abscess, reaction to suture material, wound breakdown, lymphatic leaks and fistulae particularly in recurrent surgery
- * Nerve injury manifesting as numbness, decreased or altered sensation, paraesthesia, dysaesthesia
- * Residual veins
- * Thrombosis in residual varices
- * Telangiectases over avulsion sites
- * Skin discolouration or pigmentation
- * Scarring
- * Recurrence
- * Femoral vein injury during surgery
- * DVT and pulmonary embolism

Conventional surgery

This involves saphenofemoral or saphenopopliteal disconnection, stripping of the great saphenous vein (GSV) and removal of superficial varicosities. This eliminates venous reflux during exercise allowing the calf pump to reduce superficial venous pressure to near-normal levels. GSV stripping is associated with better immediate results and a reduction in the long-term recurrence and risk of re-operation.^{1,2} It is unnecessary to strip the GSV below the knee where the perforators are part of the posterior arch circulation. Moreover, below-knee stripping increases the risk of saphenous nerve injury. QoL improves significantly following surgery.³ The morbidity associated with surgery is summarised in Table 1. Manifestations of nerve injury are common but do not impact on QoL.⁴ More than half the patients will develop some recurrent varicosities by 10 years of surgery.^{2,5} The incidence of duplex-confirmed symptomatic deep vein thrombosis (DVT) is 2.1%. Pulmonary embolism is rare.⁶

Radiofrequency ablation (RFA)

RFA involves the use of high frequency alternating current delivered via a bipolar catheter, placed intraluminally under duplex guidance, to obliterate the vein lumen. The current causes ionic agitation and local heating resulting in

venous spasm and irreversible denaturation of collagen with intimal destruction. This produces a fibrotic luminal seal with minimal thrombus formation.

The procedure is performed under general, regional or tumescent local anaesthesia. The GSV is usually accessed at the knee level by Seldinger technique. Relative contra-indications include a GSV diameter that is < 2 mm (too small to cannulate) in the supine position, tortuous vein or thrombus in the vein. The authors have restricted the use of RFA to veins < 12 mm in their current trial although recent studies have shown that larger veins can be safely and effectively treated.⁷

Randomised, controlled trials and other non-comparative studies have established the safety, efficacy and clinical advantages of RFA. Vein occlusion rate at 1-week following RFA is over 90%.^{8,9} At 2 years, 85–90% of those treated remain occluded^{9,10} and at 4 and 5 years, 85% and 87%, respectively.¹¹ Reflux (or anatomical failure defined as flow in any segment or whole of the treated vein or groin reflux despite completely occluded GSV) is observed in about 10% at 2 years,¹² 12% at 3 years,^{11,15} and 16.2% at 5 years.¹¹ An unoccluded segment of GSV greater than 5 cm poses a risk of recurrence.¹⁵ Catheter pullback speed and body mass index are risk factors for anatomical failure.¹¹ The incidence of recurrent varicose veins is about 12% at 3 years¹⁵ and 21% at 4 years.⁷ By avoiding a groin dissection, RFA provides no stimulus for neovascularisation and may potentially reduce recurrence. This fact has been borne out by some studies¹² but not by others.¹⁰ Some 94–100% of patients had complete symptomatic resolution or a significant improvement.^{7–9,12} Even those with anatomical failure had a 70–80% symptomatic improvement from 6 months to 5 years.¹¹ Over 90% of patients expressed satisfaction with RFA.^{9,14}

The first randomised trial (RFA versus conventional high ligation and stripping of GSV) revealed less postoperative pain, earlier return to activities and shorter sick leave in patients undergoing ablation, with similar complication rates in both groups.¹⁴ It also suggested that RFA could be cost-saving for society particularly in the employed group. A second trial showed significantly better outcomes in terms of time to return to activities and work, postoperative pain and QoL in patients undergoing RFA.^{8,10}

Significant complications of RFA include paraesthesia (0–19%), thermal injury to skin overlying the vein (0–3%), DVT (1%) and pulmonary embolism (< 1%).^{8,9,15} A recent study observed a 16% incidence of DVT following RFA treatment.¹⁶ The authors believe that this is possibly due to commencing ablation too close to the sapheno-femoral junction. Tumescent anaesthesia along with increasing experience may reduce the risk of paraesthesia and skin burns.

Current evidence has shown RFA to be a durable procedure with 5-year outcomes comparable to conventional surgery and significant benefits in terms of postoperative pain, return to activities and work and quality of life. Whether

these benefits outweigh the costs can only be proven by cost-effective analysis on a larger sample of patients.

Endovenous laser treatment (EVLASER)

EVLASER uses laser energy delivered via a 600 µm (400–750 µm) laser fibre to obliterate the vein. Steam bubbles generated from boiling blood in the lumen cause heat injury to the vein wall.¹⁷ Lower wavelengths have a shallower depth of penetration and are better absorbed by blood causing lesser damage to surrounding non-target tissue and better homogeneous heating of the vein.¹⁸ The procedure is usually performed under perivascular tumescent local anaesthesia. The GSV or small saphenous vein (SSV) is cannulated at the ankle or just below the knee either by needle puncture or via a cut down.

Vein closure at the end of follow-up of up to 2 years varies from 90–100%.^{18–20} Re-treatment for recanalisation is seen in less than 10% of cases. Failure of EVLASER or early recanalisation appears to be related to lower laser fluence²¹ and lower doses of energy delivered per length of treated vein.²² A higher body mass index is linked to a greater risk of failure.²³

EVLASER leads to clinical and symptomatic improvement in over 95% of patients.^{24,25} A study of active ulcers showed 83% healed after EVLASER.²⁶ Patient satisfaction is high²⁶ and patients return to normal activities²⁵ almost immediately. No study has reported on long-term QoL changes after EVLASER.

Post-procedure bruising, pain and phlebitis rarely persist beyond 4 weeks. Heat-induced paraesthesia and superficial burns resolved completely with time.²⁴ DVT following EVLASER varies from 0–7.7%.²⁷ Inadvertent creation of an arteriovenous fistula between SSV and superficial sural artery in the popliteal fossa has been reported.²⁸ One death has been reported from mesenteric infarction 6 weeks after EVLASER.¹⁹

Current safety and efficacy data appear to support the use of EVLASER but long-term data are lacking (<<http://www.nice.org.uk/pdf/IPG052guidance.pdf>> last accessed 10 September 2006). No randomised trials comparing EVLASER with other modalities of treatment of saphenous reflux have so far been published.

Sclerotherapy (liquid and foam)

Sclerotherapy is considered the treatment of choice for reticular varicosities and telangiectasia. Until recently, it was considered ineffective for treating varicosities associated with haemodynamically significant reflux and used only to obliterate residual varicosities after surgery or in those not fit for, or not desiring, surgery. Duplex ultrasonography has improved the safety and efficacy of conventional sclerotherapy, allowed a better evaluation of its results, and an understanding of the advantages of using

sclerosant as foam. The superiority of foam over liquid sclerosant has been clearly demonstrated.^{29,50} Recent studies report a high immediate success rate, low cost and acceptable complication rate with foam sclerotherapy.^{29–31} The use of foamed sclerosants for varicose veins was reported as early as 1939.

Foam is a mixture of air or carbon dioxide with liquid sclerosant. Its durability is related to bubble size, tensio-active property of the sclerosant and conditions under which the foam is prepared and maintained.³¹ The smaller the bubble size, the higher the sclerosant concentration in the foam, the lesser its dilution with blood and greater the sclerosant activity. The foam pushes the blood proximally and into the collaterals and ensures a uniform contact of the sclerosant with the endothelium. This is enhanced by venospasm that follows the injection. The potential advantages include better adhesiveness, echovisibility due to mixing with air and hence increased safety, enhancement of sclerosing power and reduction of drug doses and concentration.

The popular methods of foam production include the Tessari, Monfreux, Frullini, and Cabrera techniques.^{31,32} The most common sclerosants are sodium tetradecylsulphate (0.1–3%) and polidocanol (0.5–3%). The dilution of sclerosant to air (1:5 to 1:6) and maximum volume of sclerosant per session (5–30 ml) varies between centres. Following intravenous injection of foam, observation of venous spasm and of a thin white line on the venous wall on duplex ultrasonography are considered predictive of success. Elastic compression stockings are applied for usually 1–2 weeks, although there is no definite evidence that they significantly influence outcome.

Immediate or early closure in medium-to-large veins was achieved in over 85% cases usually requiring more than one sitting.^{31–33} 80–90% of these remained occluded 3 years after foam sclerotherapy.³⁴ High patient satisfaction and significant improvement in symptoms and QoL was noted at a mean follow-up of 2 years after foam sclerotherapy.³⁵

Complications include skin hyperpigmentation and necrosis, phlebitis, transient lymphoedema, allergic reaction, transient scotoma or confusional states. Five cases of DVT following foam sclerotherapy to the SSV have been reported.^{31,35} None of these led to pulmonary embolism.

Foam sclerotherapy is becoming established as a primary method of treating refluxing saphenous veins. Its popularity is related to its relatively low cost, feasibility as an anaesthetic-free, out-patient procedure, minimal post-procedural pain and easy repeatability. However, the correct indications, the best sclerosant and the most effective technique are still unclear. Long-term data on QoL and symptomatic and cosmetic improvement are lacking. The results of a phase III European trial (surgery versus sclerotherapy) and a phase II US study of Varisolve[®] (polidocanol microfoam) are eagerly awaited.

Transilluminated powered phlebectomy (TIPP)

This technique involves an irrigated transilluminator, passed deep to the varicosities, and a powered suction resector, each introduced through a skin incision. On activation, the vein is sucked into the resector under direct vision, morcellated and removed by suction.

TIPP is as effective as conventional phlebectomy in removing varicosities with no significant difference in pain, cosmesis, associated morbidity or patient satisfaction.³⁶⁻³⁸ It requires fewer incisions. Side-effects include bruising, cellulitis, nerve injury, residual veins, haematoma and seroma. One case of DVT has been reported. Current evidence, however, does not appear adequate to support its wide-spread use (<<http://www.nice.org.uk/pdf/ip/IPG037guidance.pdf>> last accessed 10 September 2006). Lack of definite advantages over conventional methods is likely to restrict its wider applicability.

Subfascial endoscopic perforator vein surgery (SEPS)

SEPS is a minimal access option to open surgery in patients with chronic venous insufficiency due to perforator incompetence. It may be performed even with active ulceration although infection is a contra-indication. Deep venous occlusion should be ruled out pre-operatively. Of the various methods available, the authors' practice is to introduce two endoscopic ports in the subfascial plane in the calf away from ulceration. A space-maker balloon creates the initial space, which is then maintained by carbon dioxide. Under direct vision, the incompetent perforators are clipped and divided or dealt with by harmonic scalpel.

Most studies combine SEPS with some form of superficial venous surgery and also suffer from significant follow-up loss. Hence, the clinical and haemodynamic improvements attributable to SEPS are difficult to ascertain. Published evidence indicates good clinical and symptomatic improvement with an ulcer healing rate of over 80%.³⁹⁻⁴¹ At long-term follow-up, ulcer healing and recurrence rates are comparable to open surgery.⁴¹ Limbs with post-thrombotic insufficiency have poorer outcomes.^{40,42} Concomitant abolition of superficial reflux and lack of deep venous obstruction are predictive of ulcer healing.⁴⁰ Multilevel deep venous reflux and ulcer size more than 2 cm are associated with delayed healing.⁴³

SEPS results in significantly fewer wound complications compared to open surgery and a shorter hospital stay. Cutaneous nerve injury and DVT have been reported.⁴¹ The long-term outcome, cost-effectiveness and the subgroup of patients who would benefit most from SEPS are yet to be established (<<http://www.nice.org.uk/pdf/ip/IPG059guidance.pdf>> last accessed 10 September 2006).

Conclusions

There is no single appropriate method for treating the range of manifestations of venous disease. Treating varicose veins

improves QoL and reduces disability and yet, increasingly, this treatment is being denied in the UK National Health Service. Although endovenous venous ablation techniques are becoming popular, there is a clear need for randomised, controlled trials to assess efficacy, cosmesis, satisfaction, QoL and cost-effectiveness.

Reporting the outcome of any new technique must follow a standard format and criteria for patient selection clearly defined. Only then will it be possible to compare different modalities reliably and establish the role of each in the wider context of treatment of the disease.

Declaration of conflict of interest

The authors are currently involved in a randomised controlled trial comparing radiofrequency ablation with conventional surgery for long saphenous vein incompetence.

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