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Chapter 10

Innovations in varicose vein treatment

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Introduction.

New treatments for varicose veins must be compared with the current gold standard of surgery. Most varicose veins arise from incompetence of the long saphenous vein (LSV). Conventional surgery is defined as high ligation of the LSV and tributaries at the saphenofemoral junction via a 2-3 cm incision in the groin. This is accompanied by Perforation-INvagination (PIN) stripping of the LSV to the knee. The remaining varicosities are avulsed using a hook via small (2mm) incisions. Any novel treatment must be at least as good as conventional surgery and must demonstrate clear advantages if it is to be universally accepted.

Conventional Surgery.

The results of surgery are good and patients are generally satisfied. Surgery is associated with an improvement in quality of life in most patients[1]. However, there is a significant rate of minor complications. Rates of morbidity vary from series to series. In one of the largest, 17% of patients suffered minor complications[2]. Stripping and hook phlebectomy both cause transient bruising which can be reduced by bandaging. Some patients will develop painful subcutaneous haematomas which resolve more slowly. The groin incision can become infected and rarely patients may develop a lymphatic leak. In patients with extensive varicosities avulsions may be time consuming, tedious and will involve multiple incisions. There may also be residual veins which are missed.

The most common cause of litigation following surgery for varicose veins is for nerve injury[3]. Injuries to the saphenous nerve can be caused by stripping of the LSV, resulting in an area of numbness above the medial malleolus. Although most patients tolerate this well a very small number develop a poorly understood chronic dysaesthetic pain syndrome called saphenous neuritis[4]. The rate of nerve injury can be reduced to 7% by stripping to just below the knee rather than to the ankle[5]. Avulsion phlebectomy can also cause nerve injury[4].

Thromboembolism is an unusual but serious complication. The rate of clinically detectable DVT is low at 0.15-0.5%[2,6]. Prospective scanning for DVT reveals calf vein thrombus in 5% but the majority of these resolve spontaneously[7].

Long term there is known to be a rate of recurrence following surgery for varicose veins. At 11 years 62% percent have developed recurrent veins despite surgery by a consultant[8]. The majority of recurrences are due to neovascularisation rather than technical failure[9]. A treatment that avoided the development of recurrent veins would be highly desirable.

The rate of morbidity following varicose vein surgery varies considerably between different series and trials. This is partly caused by real differences in technique and partly by differences in assessment. It is certainly true that pre-operative counseling of patients so that they have realistic expectations of surgery will reduce dissatisfaction. In addition avoidance of delegation of surgery to inadequately trained juniors will also improve outcomes. Outcomes such as paraesthesia, cosmesis and pain are subjective and the method of measuring this data will influence the result. It is also important to note that symptoms experienced by the patient may correlate poorly with visible varicose veins[10].

High quality, randomized, controlled trials, blinded as far as possible, are therefore essential in order to compare any new treatment with surgery.

Novel therapies for varicose veins have been developed with the aim of avoiding the morbidity of specific parts of the procedure. Various methods have been developed to ablate the LSV and thus avoid the groin incision and complications of stripping of the LSV. These include radiofrequency ablation, laser and foam sclerotherapy. They do not avoid the morbidity of hook phlebectomy which is usually performed concurrently.

Radiofrequency Ablation.

Both radiofrequency ablation (RFA) and endovenous laser therapy (EVLT) work by causing thermal injury to the LSV. In the case of RFA a heating catheter is passed under colour flow Doppler control up to the saphenofemoral junction. The most commonly used is the VNUS Closure® system (VNUS Medical Technologies, San Jose, California, US). Once satisfactorily positioned the catheter is heated by radiofrequency alternating current. The vein wall temperature is monitored and held at 85°C via a feedback mechanism. Heating causes contraction of collagen fibres in the vessel wall, intimal damage, luminal thrombosis and thus ablation of the vessel. The catheter is withdrawn slowly (3 cm per minute) to the level of the knee. This procedure may be carried out under general or local anaesthesia. Phlebectomy can be carried out at the same time through stab incisions.

Two randomized controlled trials of surgery against RFA have been carried out[11,13]. These both found that there was a quicker return to normal activity, to work and initially less pain in patients undergoing RFA compared with surgery. Morbidity of the groin incision and potential for infection are avoided. Rautio et al analysed costs to demonstrate that savings from reduced sick days more than compensated for the cost of equipment and sonographer[13]. No attempt was made to blind patients in either trial. Three of 17 patients in Rautio's study randomized to surgery refused operation, suggesting that surgery had perhaps been presented in an unfavourable light.

It should be noted that in the EVOLVeS trial there were higher rates of paraesthesia in the RFA patients (15.9% at 3 weeks compared with 5.6% for surgery). This was not statistically significant and was not discussed by the authors[11]. For RFA to be successful it involves administering enough thermal injury to obliterate the LSV and this seems to be sufficient to cause some nerve damage. It may also cause skin burns. In fact ablation of the LSV by diathermy current has been used in the past but was abandoned due to excessive skin burns and nerve damage[14]. The bipolar current of RFA causes fewer complications but it is not known exactly how much less.

Although there were no skin burns in the EVOLVeS trial there were three out of 13 (23%) cases in the other study. The results of several case series and the VNUS registry may help to quantify rates of complications[15-21]. Rates of paraesthesia vary from 0 to 20.5%, and skin burns vary from 0 to 20% (Table 1).

Several series with lower levels of skinburns and paraesthesia employ tumescent anaesthesia. This technique involves surrounding the LSV with approximately 100-200ml of a dilute (0.2%) solution of lignocaine. This potentially insulates the heated vein from surrounding structures. It has also been noted that the rate of paraesthesia is lower if the LSV is ablated to the knee rather than the ankle[20]. Unfortunately no series or trial clearly states how paraesthesia was defined and measured. In addition reporting of side effects to the registry may be incomplete. There is therefore no clear evidence that RFA gives lower rates of nerve injury than surgery.

There are concerns that RFA may be involved with higher rates of venous thrombosis because of propagation of thrombus from the LSV into the common femoral vein. The exact rate of clinically significant thromboembolism is unknown. In one study prospective duplex scanning of the saphenofemoral junction (SFJ) in the first two weeks following the procedure revealed a tongue of thrombus extending into the common femoral vein in 11 of 66 patients[15]. A further patient developed calf vein thrombus. The natural history of the femoral vein thrombus and therefore its significance is not known. The rate of duplex-detected DVT following RFA varies between series from 1% to 16% (Table1). The rate of clinically detectable DVT is lower. Trials that have been carried out are underpowered to assess this endpoint in comparison to surgery. Newer randomized studies are needed which use early duplex scanning as a measure of DVT. However, the rate of DVT following RFA seems to be at least as high as surgery. The need for early duplex monitoring for thrombus in the common femoral vein has important cost and resource implications.

Rates of technical success in occluding the LSV vary from 100% to 88%. High ligation and stripping can be assumed to have a technical success rate of near 100%. Occlusion of the LSV following endovascular treatments has been assessed using duplex scanning. However, it is not known what constitutes a successful treatment of the LSV. Following endovascular treatment there is often a stump of LSV adjacent to the femoral which is patent and drains the inferior epigastric vein. In their series of patients followed up over three years Nicolini et al found that a partially occluded LSV was insignificant in terms of developing new symptoms provided that the patent segment was less than 5 cm in length[21]. It is suggested that persistence of this segment may prevent development of venous hypertension in the perineum and so reduce the stimulus to neovascularisation. Nicolini found that 60 of 68 patients (88%) had a completely or partially occluded LSV at three years.

Quoted technical success rates do not include patients who are excluded because of tortuosity of the LSV. In most series a proportion of patients are unable to undergo endovascular treatment because the LSV is too tortuous to pass a RFA or laser catheter.

There is no long term trial follow up beyond two years to compare the rates of clinical recurrent veins between conventional surgery and RFA. Several studies have performed duplex scanning of the saphenofemoral junction at 2 years. Two of these have found no evidence of neovascularisation [22,23]. It has been speculated that by avoiding surgery induced inflammation neovascularisation be prevented. However, a study using duplex scanning optimized for increased sensitivity for small vessel networks compared the appearances of patients who had undergone RFA alone with those who had undergone RFA with surgical ligation of the SFJ [24]. It was found that the prevalence of small vessel networks and recanalization of the LSV was significantly more common after RFA alone without ligation of the LSV. This suggests that surgery does not cause neovascularisation. It seems likely that recurrence would be at least as frequent as following conventional surgery.

Endovenous Laser Therapy.

EVLT has been used as another method to ablate the LSV. This is achieved by insertion of a laser catheter into the LSV usually at the knee. Duplex scanning is used to position the catheter just distal to the SFJ. Laser energy is then used to ablate the vein. A variety of different wavelengths, different energies and both pulsed and continuous light have been used. The mechanism of occlusion is controversial, but excised treated veins show loss of the intima and contraction of the wall. It is thought that a longer duration of exposure causes microperforations of the vein which may make the ablation more effective.

As EVLT ablates the vein by delivering energy in the same way as RFA it is likely to cause damage to surrounding structures in the same way[25]. Unlike RFA energy is delivered at a predetermined rate without a feedback control mechanism. In a series of 244 legs treated with a 1064nm laser skin burns were noted in 4.8% and paraesthesias in 36.5% [26]. However other series have reported better outcomes. For example Min et al treated over 500 limbs with an 810nm laser and reported no paraesthesia or skin burns [27]. They did however note bruising in 24%, tightness over the LSV in 90% and phlebitis in 5%. They explain the better results by the use of a large volume of tumescent anaesthesia. The shorter wavelength may cause better energy transfer to the vein wall.

There is no randomized controlled trial which compares EVLT with surgery. It is therefore not clear what significance should be attached to the high rates of bruising and tightness along the LSV. Results of published studies are summarised in Table 2.

DVT is a potential danger of EVLT. In a single study of 39 patients who underwent early postoperative duplex scanning three were found to have thrombus extending into the common femoral vein [32]. These patients all underwent EVLT under general or epidural anaesthesia with concomitant stab avulsions. This may have prolonged the period of immobility compared with EVLT alone with only tumescent anaesthesia. However, most surgeons would probably wish to perform avulsion phlebectomy at the same time thereby completing treatment at one sitting. This necessitates general or regional anaesthesia. The rate of clinical DVT following EVLT is low with only one other event reported in approximately 900 patients and no reported pulmonary emboli [32]. As with RFA the exact rate of clinically significant thromboembolism is unknown. Early duplex scanning for extension of thrombus into the common femoral vein is necessary.

Technical success rates of EVLT in occluding the LSV vary from 90.4% to 100%. Min et al achieved 93.4% occlusion at 24 months [27]. Once again these rates exclude patients with tortuous veins unsuitable for the procedure. There are no studies with long term follow up beyond two years.

Foam Sclerotherapy.

Sclerotherapy was previously widely used for non operative treatment of varicose veins. Hobbs compared sclerotherapy with surgery in 1974. He concluded that sclerotherapy was very effective for varicosities secondary to incompetent perforators below the knees [33]. Surgery was more effective if either the saphenofemoral or saphenopopliteal junctions were incompetent.

Ligation of the saphenofemoral junction has been combined with injection to avoid the morbidity of stripping the LSV. However, stripping gives better cosmetic results and fewer recurrences [34]. More recently foam sclerotherapy (FS) agents have been developed. These offer the advantage that the sclerosant stays closer to the site of injection. There is also the theoretical advantage of less dilution by blood allowing the sclerosant to reach the endothelium in higher concentration. Foam is easy to visualise with duplex scanning and this allows for accurate placement in larger veins.

The great advantage of duplex-guided FS overl the other new therapies described is that it is the most easy to perform on an awake patient as an 'office' procedure. It is also cheaper than RFA or EVLT. Several sessions may be necessary to complete treatment and the procedure may not be acceptable for needlephobic patients.

Duplex-guided FS gives better results in occluding the LSV than liquid sclerotherapy. In a non-randomised series Yamaki et al achieved complete occlusion of the LSV in 67.6% with foam compared with 17.5% with liquid [35]. A prospective randomized study comparing six treatments in 800 patients (foam sclerotherapy, liquid sclerotherapy, high dose liquid sclerotherapy, multiple ligations, stab avulsions and ligation with sclerotherapy) found that at five years surgery gave the lowest recurrence rates at 34% [36]. Foam sclerotherapy compared favourably at 44%. Interestingly at 10 years the recurrence rates were similar in all groups.

There have been no other randomized trials of FS. There are several published series (Table 3). The morbidity of FS is relatively low. The main complications are visual disturbances (usually transient scotomas) occuring up to 2.6% of the time and phlebitis up 4.5%. Paraesthesia seems to be less frequent than with other treatments. However, this has not been clearly demonstrated with prospective neurological examination.

Deep vein thrombosis occurs with a frequency of up to 1.1%. Guex et al report a considerably lower figure of 0.008% for clinical DVT [41]. This may be an underestimate due to underreporting in a multicentre study. The true figure lies somewhere between the two and therefore may or may not be superior to surgery.

Rates of initial technical success in obliterating the LSV lie between 88 and 97%. There is little information on long term occlusion. The VEDICO trial demonstrated that foam sclerotherapy had rates of recurrence that were slightly worse than surgery [36].

Other Treatments for LSV Incompetence.

All the above treatments and conventional surgery seek to treat the incompetent LSV by destruction. A number of surgical techniques have been developed to attempt to restore competence at the SFJ. This has been attempted by transposition of a valvuloplasty, valvuloplasty with vavle transposition and insertion of an artificial valve formed from small bowel mucosa on nitinol stent. Valve transposition is technically difficult and its indications are unclear[42]. In certain patients who have incompetence mainly due to dilatation of the vein valvuloplasty can be performed with an external valve support (EVS) [43]. The ingenious formation of artificial valves has been demonstrated to work well in sheep[44]. With advances in tissue engineering such techniques will surely improve. Although it is a long way from being applicable to the typical patient with LSV varicosities it may be that restoration of a competent LSV may be the solution to the long term problem of recurrence.

Powered Phlebectomy.

All the previous interventions deal with the incompetent LSV. They still require avulsions for the varicosities. Transilluminated, powered phlebectomy is a newer method of removing varicosities. This involves the use of a light source which is inserted into subcutaneous fat via a 1cm incision. This demonstrates the position of varicosities in a darkened theatre. A phlebectomy device is inserted through another 1cm incision. This consists of a tube containing a covered, rotating blade which also provides suction. This is able to remove veins from a 5cm diameter area [45]. The most frequently used powered phlebectomy unit is the TriVex system (Smith and Nephew Inc., MA, USA).

The theoretical advantages of this technology are that it may reduce morbidity by allowing a smaller number of 1cm incisions rather than many 2-3mm hook phlebectomy incisions. It could thus reduce amount of bruising, chance of infection and improve the cosmetic result. A randomized controlled trial of TriVex versus conventional surgery showed that there was no reduction in bruising or pain or improvement in cosmetic result with TriVex [46]. There was a significant reduction in procedure time in a group of patients with extensive varicosities. It has been shown to be a safe procedure; however, it seems that the small speed advantage in some patients probably does not justify the $30,000 cost of the equipment.

Conclusions.

New techniques have been developed as an alternative to stripping and ligation for the incompetent long saphenous vein. RFA, EVLT and FS remove some of the morbidity of conventional surgery, particularly that of the groin incision. RFA has been shown to give less postoperative pain and a quicker return to work. With both RFA and EVLT rates of nerve injury are comparable to surgery. FS probably causes less, if any, nerve injury. There is probably a trade off between adequacy of treatment of the LSV and morbidity. Surgery has the highest technical success rate at the cost of a groin incision. RFA and EVLT avoid the incision but not paraesthesia or DVT. FS has the least morbidity but the lower rates of LSV occlusion and may require several sessions. There are concerns regarding high rates of duplex-detected DVT following RFA and EVLT. Long term rates of recurrence are not known but are likely to be at least as high as surgery. All these techniques require the use of colour flow Doppler during the procedure. Early postoperative scanning to exclude femoral vein thrombus is also necessary. This is not freely available and surgeons require training in its use. In addition to imaging, both RFA and EVLT require the purchase of equipment and catheters. Surgery requires little special equipment all of which is reusable and cheap. Use of these novel treatments is unlikely to become widespread because of these constraints.

There is a lack of quality, randomized controlled trial data to properly evaluate these treatments. The proponents argue that benefits of minimally invasive treatments are self evident. Due to the prevalence of varicose veins the sale of equipment for their treatment is potentially highly lucrative. A cynic would also suggest that phlebologists in private practice may have little interest in subjecting their special technique to scrutiny. This is a shame because if benefits of endovascular treatment are real, then better trial data would bring pressure to make it more widely available.

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Study	Numbers	Technique	Skinburns	Phlebitis	Paraesthesia	DVT	Obliteration LSV	Long term occlusion
Randomised controlled trials								
EVOLVeS[11,12] Multicentre 2004	44 RFA	GA 27%	0%	4.5%	15.9%	0	90.5%	86%
	36 Surgery	GA 53%		5.6%	5.6%	0	100%	
Rautio et al[13] Multicentre 2002	15 RFA	GA	20%		16%	0	100%	
	13 Surgery	GA			20%	0	100%	
Case series								
Hingorani[15] New York 2004	66 patients	GA 44% Regional 36% LA 11%	nr	nr	nr	16%	96%	
Weiss[16] Johns Hopkins 2002	120 patients 140 limbs	LA Tumescent	0%	0%	0%	0%	98%	90% 19/21 24 months
			Bruising and tenderness <1%					
Goldman[17] San Diego 2002	50 limbs	nr	0%	0%	0%		90%	
			Bruising 28/54 erythema 5/54 fibrous cord 8/54					
Sybrandy[18] Rotterdam 2002	26 patients 26 limbs	Spinal	3.8%		20%	0 *LMW Heparin*	88%	
Chandler[19] Multicentre 2000	272 patients 301 limbs	nr	3%		20.5%	1.1% 1 PE		
Merchant[20] Multicentre 2002	286 patients 319 limbs	GA/LA Tumescent in some	nr	2.1%	15%	1% 1 PE		
Nicolini[21] Multicentre 2005	294 patients 330 limbs	GA/LA Tumescent in some	nr	nr	nr	nr		88% 60/68 24 months

Table 1: Summary of studies of radiofrequency ablation (RFA).
GA – general anaesthetic, LA – local anaesthetic, nr – not recorded

Study	Numbers	Technique	Skinburns	Paraesthesia	Phlebitis	DVT	Obliteration LSV	Long term occlusion
Min et al[27] Cornell 2003	423	810 nm laser 14W cont 3mm/s Tumescent	0% Bruising 24% Tightness 90%	0%	5%	0%	98%	93.4% at 24 months
Proebstal et al[28] Mainz 2002	26 patients 36 limbs	940nm laser 15W 1s pulse 2 off Tumescent	0% Bruising/Induration 100% Hyperpigmentation 3%	0%	6%	0% *LMW Heparin*	97%	90.4% at 12 months
Chang et al[26] Taiwan 2002	244 limbs	1064nm laser 10-15w 10s pulse GA	4.8%	36.5%	1.6%	0%		96.8% at 28 months
Perkowski[29] Phoenix 2004	165 patients 203 limbs	940nm laser Tumescent		0%		0%	97%	
Navarro[30] New York 2001	40 patients 33 limbs	810nm laser	0% Mild pigmentation	0%	0%		100%	
Timperman[31] Indiana, US 2004	111patients 87 limbs	810-940nm				0.9%		77.5% at mean 29.5 months
Mozes[32] Mayo Clinic 2004	56 patients 41 limbs	810nm laser 17w GA/spinal with tumescent	nr	nr	nr	7.7%	nr	nr

Table 2: Summary of studies of endovenous laser therapy (EVLT).
GA – general anaesthetic
nr – not recorded.

Study	Numbers	Technique	Visual disturbance	Phlebitis	Paraesthesia	DVT	Obliteration LSV	Long term occlusion
Barrett et al[37] Aukland NZ 2004	100 limbs	Tessari microfoam 3% STD	0%	0%	0%	0	97%	nr
Cavezzi et al[38] Trieste, Italy 2002	177 patients	Tessari microfoam 0.2-3% STD	0.6%	4.5%	0%	1.1%	91%	67% at approx 6 months
Tessari et al[39] Trieste, Italy 2001	77 patients	Tessari microfoam 1-3%STD	2.6%	1.3%	0%	0%		nr
			Hyperpigmentation and small areas of skin necrosis in patients with small varicosities.					
Frullini et al[40] Trieste, Italy 2002	453 patients	Tessari 196 patients	0.5%	3.6%	0%	1%	93.3%Tessari	nr
		Monfreux 257 patients	1.2%	1.9%	0%	0.4%	88.1%Monfreux	
Guex[41] Multicentre 2005	12173 sclerotherapy sessions	5434 liquid 6395 foam 344 both	0.16% total 0.3% foam			Single femoral vein thrombosis	90%	nr

Table 3: Summary of studies of foam sclerotherapy (FS)
STD – sodium tetradecyl sulphate
nr – not recorded
Tessari method – foam is produced using two disposable syringes and a three-way tap.
Monfreux method – foam is produced in a glass syringe with the tip closed by a sterile plug and tension on the piston.