Neovascularisation is not an innocent bystander in recurrence after great saphenous vein surgery

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ABSTRACT

INTRODUCTION This study sought to establish the causes of failure of great saphenous vein surgery among patients in whom there was confidence that accurate saphenofemoral ligation had been carried and the great saphenous vein had been stripped at least to knee level.

METHODS This was an observational study of 100 limbs (66 patients) operated on by a single surgeon 5–22 years previously (mean: 12 years). The index operation was primary in 54 limbs and for recurrence in 46 limbs. Thirty-two patients were studied having been re-referred for recurrence while 34 were recalled for review. All were examined clinically and with duplex ultrasonography, and all completed questionnaires (Aberdeen varicose vein questionnaire [AVVQ] and EQ-5D-3L). In order to measure the extent of visible recurrence, a scoring system similar to that in the venous clinical severity score was used but with a range of 0–8.

RESULTS There were visible varicosities in 77 of the 100 limbs. Duplex ultrasonography showed that recurrent saphenofemoral incompetence (SFI) was present in 27% of the limbs. This was judged to result from neovascularisation and was the most common source of reflux. AVVQ scores for the 27 limbs with recurrent SFI (median: 34, interquartile range [IQR]: 20–42) were higher than for the 73 with no recurrent SFI (median: 17, IQR: 11–29), which was a significant difference (Mann–Whitney U test, $p < 0.01$). Analysing clinical scores with chi-squared tests indicated fewer visible varicosities in limbs without recurrent SFI than in those with recurrent SFI ($p < 0.01$).

CONCLUSIONS Neovascularisation remains poorly understood but it cannot be considered an innocent bystander.

KEYWORDS

Great saphenous vein – Varicose vein surgery – Recurrent varicose veins

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The difficulties of establishing a reliable estimate of the rate of recurrence after great saphenous vein (GSV) surgery are well known. The main problems are the chronicity of the disease, requiring a long follow-up period, and the lack of uniformly acceptable and reliable measures of recurrence.

In 1975 Rivlin reported in his personal series a recurrence rate after 5–10 years of only 6% for GSV surgery¹ but by present standards, this would be regarded as unduly optimistic. Rates between 7% and 62% are quoted by Jeanerret and Karatolios.² The estimate of 62% provided by Winterborn *et al* (83 limbs after 11 years)³ may be the most reliable, coming from a controlled trial, but entrants were restricted to CEAP (Clinical, Etiological, Anatomical and Pathophysiological) clinical categories 2–3 so with categories 4–6 excluded, even this figure is biased favorably.

In 1993 Bradbury *et al* pointed to the high incidence of inadequate groin surgery and unstripped GSVs in patients with recurrent varicose veins.⁴ It has long been an interest of the senior author (CRR) to understand why varicose veins should recur when he knew with near certainty that

saphenofemoral ligation had been performed correctly and the GSV stripped at least to the knee. The importance of neovascularisation, which is the development of newly formed venous channels draining into the femoral vein in the region of the previously ligated saphenofemoral junction (SFJ), has been established by many authors.^{5–8} On the other hand, Egan *et al* saw neovascularisation as an ‘innocent bystander’⁹ (ie a finding on duplex imaging that was incidental to the real cause of recurrence).

Endovenous therapies almost eliminate neovascularisation,¹⁰ besides having many other advantages, but conventional surgery is still widely practised and controlled trials have yet to show superiority for endovenous methods in terms of recurrence.^{11–15}

The present study relates to the long-term follow-up of 100 limbs (66 patients), operated on 5–22 years earlier (mean: 12 years) by a single vascular surgeon, looking for the cause of recurrence when it was known, as far as possible, that the SFJ had been ligated accurately and the GSV stripped. These objectives were never confirmed by postoperative duplex imaging, which in any case was

unavailable for earlier patients. Fifty-four limbs had primary operation and forty-six limbs were operated on for GSV recurrence. The weakness of the study is that the clinical and duplex assessment of outcome was carried out by the operating surgeon. In order to counter any suggestion of bias, it is pointed out that the reported recurrence rate is higher than any referred to above.

Methods

Sixty-six patients (50 female, 16 male; mean age: 63 years, range: 36–94 years) were examined with one hundred limbs available for study. A large database collected prospectively between 1985 and 2011 was used to invite patients to reattend for examination (34 patients, 50 limbs) while the remainder had been referred back to the outpatient department because of recurrence (32 patients, 50 limbs). Only those patients who had been operated on in the past by the senior author (CRRC) were studied but sometimes the new referral was initiated because of varicosities on the contralateral, previously untreated limb. Patients were only included if they had had previous GSV surgery, either primarily or to deal with recurrence in that territory. Concurrent small saphenous vein surgery was not a cause for exclusion.

All patients were operated on five or more years before review. The surgical technique was fairly constant over the period of study and was based on accurate flush ligation of the GSV on the femoral vein, exposing the latter on medial and lateral sides as well as about 1cm above and below the junction to check all superficial tributaries were divided. The GSV, if present, was always stripped with the intention that stripping should extend to below the knee.

From 1989, attention was paid to careful closure of the cribriform fascia over the SFJ. We endeavoured to remove all preoperatively marked varicosities by stab phlebectomies. All sutures were absorbable. A routine single dose heparin injection at the time of operation was introduced in 1989 and from 1991, more attention was paid to dividing tributaries beyond their secondary branches in the hope of reducing reconnections to the SFJ. The approach in recurrent cases varied somewhat over time but the end result was always the same as for primary cases. From 1999, for re-explorations, a small piece of polypropylene mesh (approximately 2cm x 1cm) was sewn as a barrier over the religated SFJ. From 2003, we paid more attention to the anterior accessory saphenous vein,¹⁴ stripping it as far down the thigh as possible with an Oesch Pin stripper.¹⁵

The overall response rate to invitations for review was 27% (34/124). The 34 patients (50 limbs) who responded are referred to as the 'recall' group. The letter to the patients explained the nature of our investigation. They were asked to complete the Aberdeen varicose vein questionnaire (AVVQ)¹⁶ and the EQ-5D-3L questionnaire,¹⁷ sign a consent form and telephone for an appointment. For the AVVQ, the score ranges from 0 (no problems) to a possible maximum of 100 and can be used for an individual limb as well as for the patient. The five domains of the EQ-5D-3L (mobility, self-care, usual activities, pain/discomfort and

anxiety/depression) each have three categories and the EQ VAS score is a visual analogue scale score between 100 (perfect health) and 0 (death).¹⁷

Thirty-two patients (50 limbs) were included as a result of referral to the outpatient department during 2007–2011 because of recurrent varicose veins. They were seen and examined in a single visit clinic but if there was insufficient time for detailed analysis, they returned at a more suitable time. They provided consent and completed questionnaires. These patients did not necessarily have a poor result. Some were referred because of symptoms on the previously untreated limb but we took the opportunity to examine the previously treated limb.

Clinical examination included measurement of body mass index (BMI) and $\geq 30\text{kg/m}^2$ was regarded as obese. Careful examination of the lower limbs was made with note of the CEAP clinical class and use of a clinical scoring system that we had validated previously (unpublished) before the venous clinical severity score (VCSS)¹⁸ was introduced. It is similar but uses a range of 0–8 rather than 0–3 in the VCSS. Each limb is subdivided into four regions, above and below knee on anterior and posterior aspects. Each area is scored 0 (no varices), 1 (single varix) or 2 (two or more varices), making a maximum limb score of 8. Flares, reticular veins and the condition of the skin are excluded from consideration. Those patients with longest follow-up were treated before the introduction of CEAP scoring but their clinical classification could be inferred from the notes.

All duplex imaging was performed by CRRC but on occasion reference could be made to earlier imaging carried out by accredited ultrasonographers. Patients were examined in the standing position using manual calf compression and the Valsalva manoeuvre. Two instruments were used: a Fukuda UF-750XT (Tokyo, Japan) with a 6–9MHz linear array transducer and a SonoSite Titan® (Bothell, WA, US) with a 5–10MHz linear array transducer. Attention was directed to all areas in the greater and small saphenous territories and other sources of recurrence but less attention was directed to calf perforating veins in view of the continuing uncertainty about their significance when incompetent.¹⁹ Assessment of deep venous incompetence (DVI) was based on insonation of the popliteal and superficial femoral veins. Reflux persisting for more than one second was recorded as positive.

Where we refer to the 'index' operation, this is to the most recent operation, whether it was a primary GSV operation or an operation to deal with recurrence in the GSV territory, provided we performed the primary operation. The index operation may have been primary on one side and for recurrence on the other. Follow-up duration relates to the limb rather than the patient as limbs may have been operated on at different times. Statistical analysis (StatsDirect, Altrincham, UK) was by non-parametric methods and chi-squared analysis. The latter was used for categorical data (clinical scores 0–8, CEAP classes 0–6 and categories in the five domains of the EQ-5D-3L). A p -value of <0.05 was regarded as statistically significant.

Approval for the study was obtained from the Brighton West Research Ethics Committee (ref: 06/Q1911/64).

Table 1 Patients studied

Source	n	Female/male	Mean age at review
Recalled	34	27/7	65 (range: 41–82)
Referred	32	23/9	61 (range: 36–94)
Total	66	50/16	63 (range: 36–94)

Results

Table 1 shows the age and sex of the 66 patients. Table 2 shows the status of the 100 limbs studied according to whether the index operation was for primary or recurrent disease and whether the patient was referred to the outpatient department or recalled for review. There were no statistically significant differences in the follow-up intervals between primary and 'redo' operations or between recalled and referred patients. However, the recalled and referred patients were different in that there were more patients operated on for recurrence in the recalled group than in the referred group. The latter contained more patients referred to clinic because of failure of the primary operation (Table 2) and these referred patients had significantly higher AVVQ scores than recalled patients ($p<0.05$). Table 3 shows the various sources of incompetence in all 100 limbs. There was often more than one defect in a single limb.

At review, 73 limbs had no recurrent SFI on duplex examination whereas recurrent SFI was present in 27 limbs. The differing AVVQ scores and clinical scores are shown in Figures 1 and 2. The two factors that appear to be linked with a poor prognosis are DVI found on imaging at review and obesity. The effects of DVI and obesity on AVVQ scores were statistically significant (Fig 3) but there was no corresponding significant effect on the clinical scores for visible varicosities. Note that limbs with DVI in CEAP classes 4–6 may not exhibit visible varicosities (Table 3) but there was correlation between AVVQ scores and clinical scores for all 100 limbs (Spearman's rho = 0.23, 95% confidence interval [CI]: 0.04–0.41, $p<0.05$).

Among the 16 limbs with DVI, 11 exhibited recurrent SFI (69%) whereas in the absence of DVI, only 19% of limbs (16/84) had recurrent SFI (Fisher's exact test, $p<0.001$).

Among obese patients (BMI $\geq 30\text{kg/m}^2$), the incidence of recurrent SFI was 56% (14/25 limbs) but it was only 17% (13/75) for those with a BMI of $<30\text{kg/m}^2$ (Fisher's exact test, $p<0.001$).

There was no evidence to show any benefit from inserting polypropylene mesh in redo groin operations, with 3/20 instances (15%) of recurrent SFI for mesh compared with 6/26 instances (23%) where no mesh was used (Fisher's exact test, $p=0.5$). Any suggestion of a possible benefit has to be set against an average follow-up interval of only 95 months after mesh insertion compared with 171 months for the group with no mesh so more recurrences could be anticipated in the mesh group over time.

In 23 of the 100 limbs, there were no visible varicose veins (clinical score zero) after a median of 12 years but the result was only perfect in 8 of these as the other 15 did have reflux on duplex imaging with 6 of these being CEAP 4–6; two limbs showing no varices were ulcerated at review (Table 3). Overall, there were eight ulcerated limbs before the index operation and eight at review. All limbs had been healed at some stage. On the more positive side, 46% of all limbs had clinical scores between 0 and 2, meaning only up to two visible varicosities.

Before the index operation, 82 of the 100 limbs were classified as CEAP 2–3 and 18 were CEAP 4–6. Table 4 shows that the proportion of limbs classified as CEAP 4–6 increased with time in all groups but more so in those limbs shown to have recurrent SFI at review. (Just 13 patients moved from CEAP 2 to CEAP 0/1 and none of these had recurrent SFI.) In other words, poor outcome is predictable at presentation on clinical signs alone.

Analysis of data from the EQ-5D-3L questionnaires did not show consistent trends in the five domains for recurrent SFI, CEAP class, DVI or obesity but numbers were small within subgroups, there being three categories in each of the five domains. There was a significant negative correlation between the AVVQ score and the EQ VAS measure of overall health (Spearman's rho = -0.28, 95% CI: -0.45–-0.09, $p<0.05$). Note that this is a negative correlation: high AVVQ scores represent poor results while high EQ VAS scores equate to good overall health.

Of the 46 limbs assessed after redo groin surgery, five were 'own recurrences' after primary operation by CRRC

Table 2 Limbs studied

	n	Primary	Recurrent	p-value
Recalled	50	15	35	<0.0001*
Referred	50	39	11	
Total	100	54	46	
Median follow-up duration (months)	148 (IQR: 97–166)	148 (IQR: 102–180)	150 (IQR: 96–161)	0.5**

IQR = interquartile range

*Significant difference in proportions of primary and recurrent operations (Yates' chi-squared test) between patients recalled for review and those referred to the outpatient department with the likelihood of a bias as referred patients are more likely to be symptomatic.

**No difference in follow-up intervals for primary and recurrent operations (Mann-Whitney U test).

while the other 41 limbs had had the primary operation by other surgeons, often in other institutions. In all these five redo limbs, no stump of residual GSV was found and neo-vascularisation was judged to be the cause of recurrent SFI. All five were reoperated on 7–8 years after primary surgery and at reassessment, 7–13 years after redo surgery, none showed further duplex recurrence at the SFJ. In three earlier patients, mesh had not been inserted; in two later

instances mesh had been inserted. Either way, reasonable durability was demonstrated.

Discussion

We set out to establish the main causes of recurrence after GSV surgery, aiming to study 100 limbs. We found that neo-vascularisation is the most common source of recurrent reflux and is linked to poor results as measured by AVVQ scores and clinical scores.

Defects of the study

Aspects of the work are open to criticism. A surgeon is likely to be biased assessing his own work but we have tried to record every defect and with 77% of limbs showing visible varices, this is higher than the 62% reported in Winterborn *et al*'s series of 132 limbs, which only included patients in CEAP classes 2–3.³ The exclusion of limbs in CEAP classes 4–6 would be expected to introduce a favourable bias.

Duplex imaging was not performed by an accredited ultrasonographer. It was carried out by the surgeon (CRRC), who only took up imaging, after instruction, from 2006 in order to practise endovenous treatments. From then on, carrying out around ten venous scans per week, he was reasonably proficient and on occasion was able to have findings checked by accredited sonographers. Having all the imaging performed by an accredited person would have required more travel for patients to another hospital and a separate visit for clinical examination. The response

Table 3 Sources of incompetence in 100 limbs

Source of reflux	n	Comment
Recurrent SFI	27	Connecting vessel diameter: 2–9mm
Short saphenous system	23	Presumed progression of disease
Anterior accessory saphenous vein	17	Possibly eliminated by Pin strip at initial operation?
Deep venous incompetence	16	Reflux >1 sec at popliteal level
Cross-groin tributaries	14	Serial imaging suggests recurrent SFI develops
Midhigh perforators	12	GSV had been stripped in all 12 limbs
Unstripped GSV below knee	11	Residual GSV not filled from elsewhere
Unstripped GSV in thigh	7	Failures occur, possible duplicated GSVs
Incompetent calf perforators	6	Not always sought, underestimated
Pudendal veins	5	
Gastrocnemius veins	4	
Giacomini veins	3	
Vein in GSV strip track	3	Apparent new vein formed along GSV strip track
Total defects in 100 limbs	147	
Note also:		
Varices present, no source	16	Reflux in tributaries only, no source identified
No varices but reflux on duplex imaging	15	Includes 6 in CEAP classes 4–6 (4 of whom had deep venous incompetence)
No varices, no reflux on duplex imaging	8	Ideal but uncommon result

SFI = saphenofemoral incompetence; GSV = great saphenous vein; CEAP = Clinical, Etiological, Anatomical and Pathophysiological

Table 4 CEAP (Clinical, Etiological, Anatomical and Pathophysiological) status and the influence of recurrent saphenofemoral incompetence (SFI)

Category	Number of limbs	Limbs in CEAP 4–6	Limbs in CEAP 0–3
All limbs: preoperative	100	18 (18%)	82 (82%): CEAP 2–3
All limbs: postoperative	100	26 (26%)	74 (74%): CEAP 0–3
Limbs with no recurrent SFI:			
Preoperative status	73	7 (10%)	66 (90%): CEAP 2–3*
Status at review	73	13 (18%)	60 (82%): CEAP 0–3**
Limbs with recurrent SFI:			
Preoperative status	27	11 (41%)	16 (59%): CEAP 2*
Status at review	27	13 (48%)	14 (52%): CEAP 2**

*Fisher's exact test, $p < 0.001$; **Fisher's exact test, $p < 0.01$

rate to letters asking patients to come for review was low at 27%. It is always difficult recalling patients many years after varicose vein surgery; some will have moved and the eldest may have died. We did not try telephone consultations, which are of very limited value. The best compromise was to combine the duplex and clinical assessments. In future, more surgeons are likely to carry out their own imaging.^{20,21}

After operation, patients were seen once at a week but were generally not seen again until called for review years later or referred back to clinic. In the interval between the index operation and reassessment, five patients had between them ten sessions of sclerotherapy or phlebectomies, which could have affected their AVVQ and clinical scores but not the incidence of SFI.

Duplex imaging was never performed postoperatively to verify SFJ ligation or stripping of the GSV from the thigh. It was not available at all for the earliest patients and preoperative duplex imaging was not routine for all cases until 2000. We believe all SFJ ligations were done correctly but point out a failure of complete removal of the GSV from the thigh in 7% of limbs (Table 3).

Our duplex findings (Table 3) are in line with those in the respected REVAS (recurrent varices after surgery) study.²² This provides some credence to the findings of an unaccredited ultrasonographer. Nevertheless, the incidence of reflux is likely to be higher in the REVAS study as their

patients were referred for clinical recurrence whereas many of ours were asymptomatic. It is also worth noting that there is great variation in reports based on the findings of accredited ultrasonographers (for example, the incidence of DVI ranges from 10%²³ to 63%²⁴).

A sample larger than 100 limbs would be desirable but this was the number we set out to examine and we felt it provided a fair representation of the practice over 25 years. There was an imbalance between primary and redo cases in the 'recalled' and 'clinic' groups (Table 2) but this would not have affected our conclusions regarding neovascularisation.

Significance of neovascularisation

Although neovascularisation remains poorly understood, many authors have demonstrated its frequency among patients with recurrent varicose veins, a frequency that increases with time.⁷ The reported range of incidence is extraordinarily wide from 1.5%²⁵ to 62%⁵ and there is lack of agreement about the effect of barrier techniques. Randomised controlled trials have reported both positively²⁶ and negatively²⁷ on the ability of a polytetrafluoroethylene patch to block neovascularisation. More recently, the importance of neovascularisation has been challenged by Egan *et al*, who reported that it only occurred in 8% of 500 patients with recurrence.⁹ However, they reported a high incidence of GSV stump incompetence (38%) with a persisting incompetent GSV in 44% of thighs. They therefore concluded that neovascularisation was not the real criminal but rather an 'innocent bystander'. We suggest they reached this conclusion because of the defects of the primary surgery, neovascularisation being overshadowed by incompletely ligated junctions and unstripped GSVs.

Recurrent reflux via neovascular connections is seldom the sole source of reflux. In our series, this was true for only 1 limb among 27. More often it fills the anterior accessory vein (10 limbs) or partners DVI (11 limbs). From our findings, neovascularisation appears to be linked to both DVI and obesity. The link with DVI has been reported before,²⁸ as has the link between recurrence and obesity.⁸ We suggest that certain individuals are more prone to recurrence so that even when the original surgery is performed correctly, owing to adverse factors such as DVI and obesity (doubtless compounded in some by inherited factors), the system becomes leakier. Neovascularisation would seem to us more of a 'guilty accomplice' than an 'innocent bystander'. Neovascularisation may become irrelevant if endothermal methods replace conventional surgery as the 'gold standard'.²⁹

National guidance

In 2014 the National Institute for Health and Care Excellence published guidelines for patients with symptomatic varicose veins; conventional surgery was relegated to third place after endothermal ablation, by laser or radiofrequency, with ultrasound guided foam sclerotherapy in second place.³⁰ Conventional surgery is inferior on the grounds of morbidity and longer recovery but, as the most recent National Health Service Hospital Episode Statistics show, conventional surgery still accounts for more than a third of

procedures.³¹ This is likely to diminish further but open surgery will probably not disappear and will continue in other countries, nor will it necessarily prove inferior in terms of recurrence.^{11–15}

Conclusions

It is perhaps depressing that our recurrence rate is the highest reported but this is a comprehensive and honest account recording even minor recurrences. Indeed, it has been our practice for years to inform patients at the outset that their varicosities will return with time as it is better that patients have expectations that are realistic rather than inflated.

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