Randomised Trial of Pre-operative Colour Duplex Marking in Primary Varicose Vein Surgery: Outcome is Not Improved

J. J. Smith*, L. Brown, R. M. Greenhalgh and A. H. Davies

Department of Vascular Surgery, Imperial College of Science, Technology and Medicine, Charing Cross Hospital, London, U.K.

Objective: the ability of colour duplex to accurately locate incompetent venous sites has been widely published; its value in pre-operative marking in simple primary varicose vein surgery is evaluated in this study.

Design of study: prospective randomised controlled trial.

Setting: regional vascular service, hospital patients.

Subjects: consecutive patients (149) undergoing primary varicose vein surgery where the only difference was one group of patients received duplex marking prior to surgery. Six weeks and 12 months post-operatively all patients had a colour duplex scan to determine the accuracy of surgery and the presence of residual/recurrent varicose veins and completed the Aberdeen, SF-36, and EuroQol quality of life questionnaires.

Interventions: varicose vein surgery.

Main outcome measures: Duplex evidence of venous incompetence, quality of life measures using the SF-36 and Aberdeen Varicose Veins Questionnaire.

Results: pre-operative marking of primary varicose veins by skilled duplex ultrasonography does not improve the accuracy or recurrence rate following surgery. Quality of life improved significantly following surgery in both groups, however there was no difference in this improvement between the groups.

Conclusion: the trial has not demonstrated any additional benefit of pre-operative colour duplex marking over that of clinical and hand held Doppler marking in terms of satisfactory varicose vein surgery performance at 6 weeks or 12 months in patients with primary varicose veins of the long saphenous system. Its role in the short saphenous system is less clear.

Introduction

Varicose veins are one of the commonest of all surgical problems with a prevalence of 25% in women and 15% in men. As a consequence operative rates are also high. Around 60,000 operations were performed for varicose veins in the United Kingdom alone in 1997. Thirty years ago Lofgren stated “Recurrence of varicose veins continues to be a problem of great magnitude to the patient and physician alike”. It was also stated that the recurrence rate of the time (20–26%) had not changed much over the preceding 10 years despite surgical advances. The situation is still the same today in terms of recurrence of varicose veins; a recent review of the subject has found that the recurrence rate of varicose veins is 21% over a 10-year period. With such a high demand for a procedure that has a 1 in 5 recurrence rate, ways of improving the outcome of surgery need to be found. Furthermore, recurrence of varicose veins has led to successful claims of negligence.

Over the years different techniques have been tried to reduce recurrence rates in varicose vein surgery. In the last few years PTFE patches have been used to cover the ligated saphenofemoral junction in “re-recurrent” veins to try and prevent recurrence occurring again. Even such physical barriers as this have a recurrence rate of 12% attributed to failure of the patch. A different group using reflected pectineus fascia to cover the junction obtained similar results.

Good surgery depends on a correct pre-operative assessment of patients. It has been repeatedly shown how poor clinical examination is for diagnosing reflux in varicose veins and even hand held Doppler has it limitations with sensitivity of the investigation reported at 73% in the groin and 77% in the popliteal fossa. To improve the results of surgery, we need to use the most accurate method of pre-operative assessment. The ability of colour duplex to accurately locate incompetent venous sites has been widely published, and as such duplex has become established as a method of pre-operative assessment of varicose veins.

* Please address all correspondence to: J. J. Smith, Department of Vascular Surgery, Charing Cross Hospital, Fulham Palace Road, London W6 8RF, U.K.
Few would doubt the ability of colour duplex to accurately diagnose and locate the sites of incompetent connections between the deep and superficial venous systems of the leg\textsuperscript{18–21} and there are some who consider mandatory\textsuperscript{12,16} and necessary to plan the surgical approach.\textsuperscript{22} In order to reduce recurrence rates further still some surgeons are also using colour duplex to mark these incompetent connecting sites immediately prior to surgery. However, is it necessary or beneficial prior to simple primary varicose vein surgery? Colour duplex is expensive and time consuming, and if the accuracy of surgery and recurrence rates are not significantly improved upon over the use of simpler technology such as Doppler then in today’s financial climate it cannot be justified.

The aim of this study was therefore to determine if the addition of colour duplex marking of the sites of deep to superficial incompetence improves the outcome of varicose vein surgery in terms of more accurate surgery, reduced recurrence rates and improved quality of life. The final variable was chosen, as it is the only objective way to measure the impact of an event on a patient’s life.

**Methods and Patient Series**

Approval was sought and obtained from the ethical committee of the Regional Authority to conduct the study. All patients were given printed information sheets prior to entry into the study, which constituted part of their informed consent for participation.

A prospective consecutive cohort of 152 patients with primary varicose veins without venous ulceration was randomised into one of two groups (Fig. 1) over a 14-month period. Randomisation was performed using a sealed envelope system provided from an independent unit; The Department of Health Sciences, University of York on the day before operation. Those patients in group one (the “duplex group”) underwent clinical assessment, hand held Doppler examination, plus the patient has pre-operative colour duplex marking of the sites of deep to superficial incompetence on the day of surgery. For those patients in group two (the “non-duplex group”) the only difference in assessment was that the patients did not have a colour duplex marking scan on the day of surgery. Patients with bilateral disease had both limbs randomised to the same arm of the trial.

Patients were taken from the waiting list for varicose vein surgery and interviewed prior to entry with a full explanation of the study. Prior to commencing the trial it had been standard practice for patients to have a diagnostic duplex scan in the outpatient department before consultation with the clinician. The surgical approach was then planned on the basis of the clinical, Doppler and duplex findings in the outpatient department at first visit. After randomisation using the sealed envelope system the duplex scans were removed from the notes of all patients (approximately 90% of participants) in the clinical group by an independent observer prior to being seen by a surgeon. An experienced vascular technologist performed all of the colour duplex scans with the patient standing with their weight taken mainly on the opposite foot. The vascular technologists had been previously audited for intra-observer and inter-observer error as part of the Small Aneurysm 23 and Four Layer Bandaging studies. Reflux for this purpose was defined as reverse flow seen by colour change for greater than one second following calf pressure augmentation of flow. An Acuson 2000 scanner with a 7.5 MHz linear array probe was used for all venous scans. An Imex continuous wave Doppler with an 8MHz probe was used for hand held Doppler analysis.

The operative procedure was planned in the outpatient department based on all of the information available to the surgeon at the time. All patients underwent elective surgery under general anaesthetic performed by senior vascular higher surgical trainees, lecturers or consultants at the Regional Vascular Centre. Operative procedures on the long saphenous system involved flush sapheno-femoral transfixion with division of surrounding branches and removal of the long saphenous vein to just below the knee if incompetent. Operative procedures on the short saphenous system involved flush sapheno-popliteal transfixion and removal of a section of the short saphenous vein. The removal of branch varicosities was performed via tiny stab incisions and the use of the Oesch phlebectomy hooks or a Kocherised Mosquito clip. These branch varicosities were marked by the operating surgeon with the patient standing immediately prior to surgery in both groups. Follow up was scheduled at 6 weeks and one year following surgery at which point all patients were assessed clinically and by colour duplex scan.

All patients completed quality of life questionnaire booklets containing the Aberdeen Questionnaire, the SF-36 and the EuroQol, prior to surgery and again at 6 weeks and 12 months. These questionnaires were used to determine if there was any difference in quality of life between the patients randomised to “duplex” or “non-duplex”.

Results are analysed by numbers of limbs and procedures performed in order to compare any difference.
made by pre-operative duplex marking. Post-operatively a “recurrence” was defined as reflux at the site of previous surgery. This was then further classified into “inadequate surgery” (persistence of reflux on the 6 week duplex scan), “neovascularisation” (presence of new areas of reflux seen on the 12 month duplex scan in an area where complete obliteration of reflux was seen on the 6 week scan) or “progression of disease” (new sites of reflux in areas previously proven competent on duplex). Incompetent long saphenous vein correction was declared as adequate if the vein was not visible in the upper two-thirds of the thigh on the 6 week duplex scan or if the remaining vein was competent. Statistical analysis was performed using Chi-squared tests with continuity correction or Fishers Exact Test where appropriate using SPSS (Statistical Package for the Social Sciences).

Power calculations were performed prior to the start of the trial. Assuming one wants to improve “recurrence rates” from 20% to 5% and assuming a 5% significance level then one needs 78 limbs per group.

Results

Of the 152 patients entered into the study, 149 had an operative intervention. The discrepancy is accounted for as follows; one could not be traced in the hospital PAS (Patient Administration System) and two had their admission for surgery suspended (not otherwise specified). Figure 1 describes details of attendance for follow-up duplex scans and operative procedures performed in the two groups.

Long saphenous system

The sapheno-femoral junction
One hundred and twenty-five patients (189 limbs) underwent high saphenous ligation and stripping of the long saphenous vein with or without multiple distal avulsions of branch varicosities from hereon known as long saphenous procedures. Bilateral procedures were performed in 51% of patients. In this
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at six weeks and the number rose to 14 at 12 months. Of the 10 at 6 weeks, four were in the duplex arm and six were in the non-duplex arm of the study ($p=0.26$, Fisher’s exact test). Of the 14 at 12 months six were in the duplex arm and eight in the clinical arm ($p=0.17$, Fisher’s exact test). This gives a “recurrence” rate of 27% due to inadequate surgery, a recurrence rate of 10.8% due to neovascularisation and an overall rate of 37.8%.

**Perforator veins and branch varicosities**

The results described include both long and short saphenous procedures and those patients undergoing avulsions alone. Incompetent perforator veins were present in 135 limbs prior to surgery. In six of 135 limbs these incompetent perforators were still present at 6 weeks of which one was in the duplex group and five in the non-duplex group ($p=0.11$, Fisher’s exact test). By 12 months a further 19 new incompetent perforators (in different position on the limb) were present that were not seen at the 6 week scan. Fifteen of these were in the non-duplex group and four in the duplex group ($p=0.012$). This gives a “recurrence” rate of 3% due to inadequate surgery.

As for branch varicosities all except those in two limbs (both in the duplex group) were removed at 6 weeks and none “re-appeared” by 12 months. However, 17 limbs showed “progression of disease” (eight in duplex and nine in non-duplex) by the development of new branch varicosities by the time of the 12-month duplex scan ($p=1.0$).

**Quality of life**

Improvement in quality of life was seen following surgery for both groups at 6 weeks and 12 months using both the Aberdeen Questionnaire and the SF-36 ($p>0.05$) and has been reported elsewhere.²⁰

**Short saphenous system**

Thirty patients underwent ligation of the saphenopopliteal junction and removal of a segment of the short saphenous vein with/without multiple distal avulsions as necessary hereon known as short saphenous system procedures. Seven of these procedures were bilateral and therefore a total of 37 short saphenous procedures were performed. Twenty-five of the procedures were combined with a long saphenous system procedure. Of the 37 short saphenous system procedures 22 limbs were randomised to pre-operative duplex marking and 15 to non-duplex marking.

Of the 37 short saphenous procedures, 10 had evidence of continuing reflux into a short saphenous vein
Fig. 3. Post-operative quality of life differences (Aberdeen Questionnaire) – Long Saphenous System.

Fig. 4. Short saphenous quality of life differences – pre- and post-operative (Aberdeen Questionnaire).

compared to 15.85, \( p = 0.034 \) independent sample \( t \)-test), however this difference was not sustained by the time of the 12-month follow-up (Fig. 3).

There was no difference between the two groups at six weeks \((p > 0.38\) all domains) or 12 months \((p > 0.15\) all domains) using the SF-36 as the quality of life measure. Furthermore, no significant difference was seen with question 2 of the SF-36, (health transition item, \( p > 0.47 \)) at six weeks or 12 months.

The short saphenous system

Prior to surgery there were significant differences in health between the duplex and non-duplex group using the Aberdeen Questionnaire \((p = 0.02 – \text{Fig. 4})\), the SF-36 \((p = 0.09\) in the domain of “Physical Functioning”) and the EuroQol \((p = 0.03\)). Quality of life improved within the groups as a result of having the operation at 6 weeks and 12 months but there still continued to be a differences using the different questionnaires between the groups at both 6 weeks \((p = 0.015, \text{Aberdeen Questionnaire})\) and at 12 months \((p = 0.031\) domain of “Bodily Pain” [SF-36] Fig. 5, \( p = 0.5\) [EuroQol]).

Discussion

Attention to detail in any branch of surgery will certainly affect results and this is very true in varicose vein surgery. Recurrence of varicose veins is periodically blamed on surgical trainees inadequately performing the operations.\(^{24}\) Equally there are reports that trainees do as well as consultants. Appropriately supervised, basic surgical trainees can achieve very good results\(^{25}\) therefore showing that with correct supervised training all surgical trainees can achieve good results.

Inappropriate assessment of varicose veins in the pre-operative phase will lead to inappropriate surgery and increased recurrence rates. It has been suggested that failure to get a duplex scan prior to surgery would result in the wrong operation being performed in up to a quarter of cases.\(^{16,26}\) Colour duplex was introduced in the mid 1980s and as stated in the introduction many consider duplex to be mandatory in varicose vein assessment in order to perform the correct procedure and reduce recurrence rates.\(^{12,16,27–29}\) It was also stated in the introduction that recurrence rates have
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changed little over the last several decades. Despite the use of duplex scanning this is still the case today. Three recent papers have reported on recurrence rates after varicose vein surgery all of which have been performed in the “duplex era” and still show that recurrence rates remain at around 20%. Two of the papers were published in 1998 and reported recurrence rates of 18% 30 and 38.7%,31 and one paper in 1999 reporting a rate of 13.6%.

The above represents only three recent papers, with a mean recurrence rate of 23%. One could conclude that the introduction of duplex has done little to improve recurrence rates. This of course is not true, recurrence of varicose veins is a multifactorial problem and the arguments about whom or what is to blame will continue to rage as they have done so in the past. Is recurrence due to trainees,24,25 neovascularisation and/or neoreflux,33,34 or progression of disease? The answer is probably all of these in various combinations. With the introduction of structured training programs and closer supervision of basic and higher surgical trainees there should be a reduction in the number of inadequate procedures performed. Until the biology of neovascularisation is fully understood this will not be able to preventable; the same can be said for progression of disease. At the moment the area to target is inadequate surgery. Some units are pre-operatively marking the position of incompetent junctions as described in this paper with colour duplex. This paper does not attempt to refute the value of duplex diagnosis and planning but seeks to find out if duplex marking can improve the results of surgery. Other studies have also reported that following surgery for primary varicose veins new sites of reflux can be found as early as 6 weeks following surgery, some of which resolves at one year.35 In the study described above this effect is also seen. One can assume that reflux at 6 weeks in the saphenofemoral junction is due to inadequate surgery, which gives a “recurrence” rate of 1% due to inadequate surgery. One can also assume that reflux in veins at the sapheno-femoral junction seen at 12 months and not at 6 weeks is due to neovascularisation if on the 6-week scan there are no veins present in this area, and hence the recurrence rate due to neovascularisation is 8.5% for the sapheno-femoral junction. As for the long saphenous vein, it is to be presumed that they were certainly left behind in 11 of these limbs and of the remaining six; they were probably residual and became more easily detected at 12 months. This gives a “recurrence” rate of 9% all due to inadequate surgery. As far as the saphenous vein in the distal thigh is concerned, one can surmise that greater effort must be made to remove the saphenous vein to the knee level. There are still some centres that practise long saphenous vein preservation despite the fact that a residual long saphenous vein has been shown to increase recurrence rates.13 The recurrence rate in the long saphenous group in this series (9%) may increase over the next 10 years. For this reason these patients are being followed up over a longer time period.

As far as the short saphenous system is concerned, the “recurrence” rate at six weeks (inadequate surgery) was 27%, which confirms that the anatomy is difficult in the area of the popliteal fossa. The deep fascia must be opened and the short saphenous vein has to be followed to the popliteal vein and divided flush and also relevant medial and lateral branches divided and ligated. This has clearly not been done adequately in some of these patients. There were relatively more cases of inadequate surgery in the non-duplex group compared to the duplex group, as the numbers in the former were smaller. This difference however was not significant (p = 0.17). Clearly a much larger study needs to be performed looking specifically at popliteal fossa varicose vein surgery with far more numbers than was in this series in order to get a definitive answer as has been obtained with the long saphenous system above.

The number of “new” incompetent perforators that appeared in new places (not previously seen or operated on) between the 6-week and 12-month duplex is likely to represent “progression of the disease” and should not be taken to mean recurrence as none reappeared at a site of previous surgery. No explanation can be offered as to why the number of new incompetent perforators increased more in the non-duplex group (p = 0.012) and one has to assume this is a result of chance as this represents “new” disease, and there were no differences between the groups for long or short saphenous system incompetence.

The quality of life studies have shown that the patients in the “long saphenous surgery” group were comparable in their randomisation to duplex or non-duplex by having no differences in the pr-operative health status measured with the Aberdeen Questionnaire or the SF-36. At six weeks the duplex group appeared to be doing better in terms of quality of life (Aberdeen Questionnaire) but there was no significant difference at 12 months. Duplex marking therefore confers no benefit in terms of quality of life improvement in the long saphenous system.

However, in patients with short saphenous system problems there were significant differences in their health status. This was completely unintentional as the randomisation was done by a sealed envelope system. Patients in the non-duplex group had significantly worse quality of life pre-operatively and at
6 weeks using the Aberdeen Questionnaire. At 12 months quality of life was still worse in this group, however this was not significant. Similar differences were seen with the SF-36. Less of a difference was seen at six weeks and 12 months; however, the non-duplex group still had worse health. It is difficult to be certain why these patients had a worse quality of life, but as has been said before the numbers in this group are very small and should be interpreted with caution. Furthermore, 70% of the patients in this group also had a simultaneous operation on their long saphenous system (all single side except for one patient), which may also account for some of the differences. Removing these patients from the analysis would make the numbers far too small for analysis and there was no difference anyway in health status between those patients in the “long saphenous” group or those in the “short saphenous” group measured with any instrument at any of the three time points.

Even though some patients had recurrent/residual varicose veins only three further operations were required for persistent varicose veins in the study group. All of the operations were limited to further avulsions only and all were due to cosmetic reasons.

Varicose vein surgery should not only be a targeted procedure based on accurate pre-operative assessment but also targeted to symptoms. The Edinburgh Vein Study has shown that lower leg “venous symptoms” poorly correlate with the presence or severity of trunk varices and that reflux may be present without symptoms.36–38 Patients with symptomatic varicose veins should also have quality of life assessment done prior to surgery to examine the impact of the disease on their lives, as symptoms per se are a poor predictor of severity.20

Colour duplex scanning for varicose vein surgery does have significant cost implications,39 it is therefore important to minimise these costs whilst still maintaining the very high standards we expect from varicose vein surgery.

**Conclusion**

Pre-operative duplex marking of the sites of deep to superficial incompetence confers no additional benefit in terms of outcome in primary varicose vein surgery for long saphenous system varicose veins. The position is less clear for the short saphenous system and will be answered by a larger study specifically looking at this area.

**References**

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