Original article

Late follow-up of a randomized trial of routine duplex imaging before varicose vein surgery

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Background: Routine preoperative duplex examination led to an improvement in results 2 years after surgery for primary varicose veins. The aim of the present study was to evaluate the impact of preoperative duplex imaging after 7 years, in relation to other risk factors for varicose vein recurrence.

Methods: Patients with primary varicose veins were randomized to operation with (group 1), or without (group 2) preoperative duplex imaging. The same patients were invited to attend follow-up with interview, clinical examination and duplex imaging. Quality of life (QoL) was measured with the Short Form 36 questionnaire.

Results: Some 293 patients (343 legs) were included initially; after 7 years 227 were interviewed, or their records reviewed: 114 in group 1 and 113 in group 2. One hundred and ninety-four legs (95 in group 1 and 99 in group 2) were examined clinically and with duplex imaging. Incompetence was seen at the saphenofemoral junction and/or saphenopopliteal junction in 14 per cent of legs in group 1 and 46 per cent in group 2 ($P < 0{\cdot}001$). QoL was similar in both groups. After a mean follow-up of 7 years (and including patients who underwent surgery after the review), 15 legs in group 1 needed reoperation and 38 in group 2 ($P = 0{\cdot}001$).

Conclusion: Routine preoperative duplex imaging improved the results of surgery for primary varicose veins for at least 7 years. Registration number: NCT01195623 (http://www.clinicaltrials.gov).

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Introduction

Recurrence rates after treatment for varicose veins remain high[1–3]. One reason is inadequate surgery owing to inadequate preoperative investigation[4]. The use of duplex ultrasound imaging before surgery has increased[5,6]. Duplex imaging is time-consuming and costly, and so in some hospitals it is restricted to patients with recurrent varicose veins or severe skin change. Furthermore, a previous study showed no clear benefit of routine duplex imaging in the treatment of uncomplicated varicose veins[7]. Other causes of recurrent veins are neovascularization (new vessel formation) and progression of disease[5,8]. With the advent of endovenous methods it has even been suggested that surgery in the groin itself induces recurrence through neovascularization.

The authors reported previously that the rate of recurrence and reoperation 2 years after varicose vein surgery was lower with preoperative duplex examination than without[4]. A major reason was that incompetence in the great saphenous vein (GSV) or small saphenous vein (SSV) was often missed in the group without preoperative duplex imaging. However, if neovascularization and progression of disease are major contributors to the rate of recurrence, 2 years of follow-up may be too short.

The aim of this study was to evaluate the impact of preoperative duplex imaging before primary varicose vein surgery on recurrence rates after substantially longer follow-up.

Methods

Patients referred to Capio St Göran's Hospital, Stockholm, Sweden, with primary uncomplicated varicose veins were randomized to surgery with (group 1), or without (group 2) preoperative duplex imaging. The study protocol,

including data collection and statistical analysis, has been described in detail previously[4]. The trial was approved by the Ethics Committee at the Karolinska University Hospital, Stockholm, Sweden.

In the study, participants were encouraged to examine and treat patients according to their usual clinical practice, to make the study as pragmatic as possible. Preoperative evaluation with hand-held Doppler was therefore variable; diagnosis was often confined to inspection and palpation.

The patients participating in the earlier study were invited to attend follow-up. Those who accepted were interviewed by telephone, and scheduled for clinical and duplex examination. The clinical examinations were done by one of three surgeons. Skin changes were graded according to the Clinical Etiologic Anatomic Pathophysiologic (CEAP) clinical class[9]. Generic quality of life (QoL) was measured using the Short Form 36 (SF-36® Standard Swedish Version 1.0; QualityMetric; Lincoln, Rhode Island, USA) questionnaire[10,11].

Patients with skin change, oedema or recurrent veins significantly affecting QoL were offered further surgery after the follow-up. Some had already presented on their own initiative. Duplex findings alone in the present study were not considered an indication for redo surgery.

Duplex examination

The duplex examinations were performed by an experienced vascular technician at the Department of Clinical Physiology, Capio St Göran's Hospital[8]. Duplex results and videos were reviewed further by two consultants in clinical physiology.

Analysis of duplex data focused on the saphenofemoral junction (SFJ) and the saphenopopliteal junction (SPJ). Patients in both groups had previously been examined using duplex imaging 2 months after the original operation, which served as a baseline for comparison with the findings at 2 years and the present follow-up. Veins present after 2 months were defined as residual varicose veins, and further subdivided as technical failure if present in a location addressed by surgery, or as tactical failure if not. Recurrent veins only identified later were defined as progression of disease. If follow-up duplex imaging showed a varicose vein in a SFJ or SPJ that was obliterated at postoperative duplex examination, it was classed as neovascularization[12,13]. The classification of recurrent varices after surgery (REVAS) could not be used, as the study started before the guidelines were published[14].

Statistical analysis

The results were analysed by intention to treat. χ^2 test and Fisher's exact test were used for comparison of proportions, and the Mann–Whitney *U* test for comparison of SF-36® scores between groups. Changes in SF-36® scores over time were analysed with the Kruskal–Wallis test. Statistical significance was accepted at $P < 0{\cdot}050$. Statistica version 9.1 (StatSoft Scandinavia, Uppsala, Sweden) was used for statistical analysis.

Results

In all, 293 patients (343 legs) had varicose vein surgery in the original study: 166 legs in group 1 and 177 in group 2. Baseline patient characteristics were similar and have been described in detail previously[4]. Some 221 patients were contacted by telephone for an interview: 113 (123 legs) in group 1 and 108 (126 legs) in group 2. Medical records were available for a further six patients who had recent reoperation: one (1 leg) in group 1 and five (8 legs) in group 2. Information was thus available for 124 legs in group 1 and 134 in group 2.

A total of 175 patients (198 legs) attended for clinical examination: 86 (96 legs) in group 1 and 89 (102 legs) in group 2 ($P = 0{\cdot}969$). The mean(s.d.) follow-up after primary surgery was 7·4(1·0) years. The male : female ratio was 25 : 61 in group 1 and 25 : 64 in group 2 ($P = 0{\cdot}886$), and the mean(s.d.) age was 56·3(10·6) and 52·6(12·9) years respectively.

Sixty patients (20·5 per cent) from the original study were lost to follow-up, 33 in group 1 and 27 in group 2. Reasons included: declining the offer of further participation (51), dementia (1) and death (8; 5 in group 1 and 3 in group 2).

Duplex results

Some 172 patients (194 legs) had duplex imaging after a mean of 7·4 years: 85 (95 legs) in group 1 and 87 (99 legs) in group 2. Incompetence was seen in the SFJ and/or SPJ in 14 per cent of legs in group 1 and in 46 per cent in group 2 (*Table 1*). These numbers included legs that had been reoperated on, as the analysis was by intention to treat.

Quality of life

When questioned specifically about the treated leg, comparing its current condition with that before surgery, it was considered better in 107 legs in group 1 and in 98 in group 2, and unchanged or worse in 16 and 28 legs respectively ($P = 0{\cdot}057$).

Table 1 Duplex imaging results 7 years after varicose vein surgery

	Preoperative duplex	No preoperative duplex	*P*†
Legs examined	95	99	
SFJ reflux	11	38	< 0·001
SPJ reflux	2	9	0·036
SFJ and/or SPJ reflux*	13 (14)	46 (46)	< 0·001

Values in parentheses are percentages. SFJ, saphenofemoral junction; SPJ, saphenopopliteal junction. *One leg had combined reflux. †χ^2 test.

Eighty-five patients in group 1 and 89 in group 2 completed the SF-36® questionnaire. There was no significant difference in any variable between group 1 and 2 after 7 years. When changes in SF-36® score over time were analysed for the whole study population, the only score that improved significantly after 2 years compared with preoperative values was that for bodily pain[11]. This difference was still significant after 7 years ($P = 0·034$), although the bodily pain score was lower than after 2 years.

Clinical results

In the 7 years before follow-up a number of patients requested, and underwent, reoperation for recurrent veins: seven legs (5·6 per cent) in group 1 and 26 (19·4 per cent) in group 2 ($P < 0·001$). After follow-up, more patients required reoperation, giving a total of 15 legs (12·1 per cent) in group 1 and 38 (28·4 per cent) in group 2 that had been reoperated on or scheduled for reoperation ($P = 0·001$).

None of the patients in the study developed a venous ulcer during follow-up. Hyperpigmentation or eczema (C4a) was found in three legs in group 1 and nine in group 2 ($P = 0·172$). There was no difference in CEAP clinical classes between the two groups.

Risk factors for recurrence

The number of legs affected and the rate of each specified type of recurrence for the whole study cohort are detailed below. Reoperation rates in the SFJ for each specified type of recurrence in the two study groups are shown in *Table 2*, which included only patients who had complete duplex data at 2 months and 7 years.

Residual varicose veins owing to inadequate preoperative investigation (tactical failure)

Some 124 legs that did not have initial SFJ ligation were examined by duplex imaging at 2 months after surgery: 35 (28·2 per cent) had incompetence in the SFJ. The corresponding values for the SPJ were 13 (4·1 per cent) of 315 legs.

Table 2 Number of reoperations for each type of recurrence at the saphenofemoral junction

	Preoperative duplex		No preoperative duplex	
	Legs at follow-up	Legs reoperated	Legs at follow-up	Legs reoperated
Tactical failure	2	1	28	15
Technical failure	1	0	4	2
Progression of disease	3	1	12	3
Neovascularization	11	0	12	1

Only patients who had complete data at both 2 months and 7 years were included.

Residual varicose veins owing to inadequate surgery (technical failure)

Nine (4·5 per cent) of 202 legs that had surgery at the SFJ still had SFJ incompetence at 2 months after operation, indicative of inadequate surgery. Only 13 had SPJ ligation, and none of these had incompetence at the SPJ after surgery.

Progression of disease

There were 75 legs without surgery at the SFJ, and no incompetence in the SFJ after 2 months. Of these, 15 (20·0 per cent) developed reflux in the SFJ after 7 years. The corresponding values for the SPJ were four (1·6 per cent) of 253 legs.

Neovascularization

A total of 163 legs showed no reflux in the SFJ 2 months after surgery; of these, 23 (14·1 per cent) had incompetence at the SFJ at 7 year follow-up. In the SPJ, four (36·4 per cent) of 11 legs developed incompetence.

Reoperation in relation to type of recurrence

The rate of redo surgery varied according to the nature of the recurrence (*Table 2*). The most common form of recurrence was tactical failure, which also most often led to redo surgery. Technical failure was less common, but often necessitated reoperation. Recurrence owing to progression of disease was considered an indication for a new operation in a quarter of the patients. Neovascularization was frequent, but seldom resulted in a further surgical procedure. The proportion of legs that had reoperation for tactical or technical failure at the SFJ and/or SPJ was significantly higher than that for neovascularization (21 of 47 *versus* 1 of 25; $P < 0·001$).

Discussion

This analysis showed that the addition of routine preoperative duplex imaging continued to offer an advantage for at least 7 years after surgery for uncomplicated varicose veins. It also showed that patients who developed new incompetent veins in the operated areas (neovascularization) rarely needed a reoperation, in contrast to patients with residual veins.

The preoperative duplex examination enables a surgeon to tailor the operation to the individual patient, thereby improving the final result. It facilitates planning for surgeons less experienced in venous surgery. This is important, as most patients are treated in a similar setting: a surgical department with a mixture of vascular and general surgeons, and surgeons in training. The rate of hand-held Doppler device use was not known and may have influenced the results, although its value has been questioned[15]. The study was designed to be pragmatic, and even now many Swedish surgeons plan varicose vein surgery using inspection, palpation and clinical tests only.

The majority of the patients were satisfied with the result of their varicose vein surgery and not interested in reoperation, even though many of them had visible recurrent veins. Patients with symptomatic recurrence were offered reoperation. At primary surgery the number of operations on the GSV and SSV was significantly higher in group 1, but not all of the residual incompetent GSVs and SSVs in group 2 needed a reoperation during follow-up. This illustrates the complex relationship between symptoms and the extent of varicose veins.

The SF-36® did not detect any difference in QoL between the groups despite the lower recurrence rate after preoperative duplex imaging. The result may have been different with the use of a disease-specific questionnaire, but this was not available when the study started. The only SF-36® score that significantly improved over time was that for bodily pain, although the improvement declined between 2 and 7 years. Whether this was due to recurrent veins is speculation; a disease-specific questionnaire may have answered this question.

One aim of varicose vein surgery is to prevent venous skin changes[16,17]. Patients with a history of venous ulcer were excluded from this study. Although the study was too small for definite conclusions to be drawn, no patient developed a venous ulcer during follow-up. Skin change attributable to venous hypertension was graded according to the CEAP classification, which was difficult. Some patients classed as C4 were downgraded when seen by another doctor as their eczema could have been of dermatological origin[18].

A major problem with varicose vein treatment is the high recurrence rate[1]. Progression of disease makes a larger contribution with time, and thus the reduced early recurrence rate observed 2 years after routine preoperative duplex imaging might lessen with time. However, the duplex group still had significantly lower recurrence and reoperation rates after 7 years.

Progression of disease was seen more often in the SFJ than in the no-duplex group. A possible explanation may be that some patients with minor incompetence in the GSV regained competence in the SFJ temporarily after reducing the total varicose vein volume at surgery. Had they been examined with duplex before surgery, the GSV would have been removed.

A controversial topic in varicose vein treatment is the importance of neovascularization, which has been described as either the principal cause of recurrence or an innocent bystander[6,19]. The prevailing definition is the presence of tortuous new veins in a previously obliterated area such as the SFJ or SPJ[20]. The term was used in the present study when veins with reflux were seen at follow-up in the SFJ or SPJ if postoperative duplex imaging had shown obliteration after surgery. These veins might not be new, but remnant tributary veins that have dilated with time, so-called neoreflux[21]. Within 7 years neovascularization did not cause recurrence with symptoms that required reoperation. This is interesting because one reason for recommending the new endovenous methods is the avoidance of neovascularization caused by surgical trauma in the groin. In the Curriculum of the American Venous Forum it is stated that 'identifying and dividing tributaries to the saphenofemoral junction can lead to neovascularization and hence to recurrence of varicosities'[22]. A recent Danish study, however, showed no significant difference in recurrence rate or QoL between endovenous laser ablation and surgery[23]. Other studies have reported similar findings: more neovascularization after surgery, but not more recurrences of clinical importance[24].

Routine preoperative duplex imaging continued to provide improved results 7 years after surgery for primary varicose veins. Routine surgery had good long-term durability in terms of QoL, in spite of a large number of visible recurrences, presumably as most were asymptomatic. In the present study neovascularization in the SFJ or SPJ seldom caused recurrence of clinical significance.

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