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Economising Vein-graft Surveillance Programs

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Objectives: *To investigate the effectiveness of two alternative vein-graft surveillance strategies. In the first strategy surveillance was restricted to patients with a possible higher risk of significant stenosis development, i.e. those with a moderate stenosis identified early after the operation. In the second strategy the effects of reducing the number of duplex tests per patient was examined.*

Patients and Methods: *In a prospective study in three vascular surgical departments 300 patients (300 femoropopliteal or distal grafts) underwent duplex surveillance during the first year after the operation. The duplex-derived PSV-ratio was considered to represent the degree of stenosis. Arteriographic confirmation of suspected stenoses was routinely obtained, and patients without a suspected graft stenosis underwent a consented arteriogram during the first postoperative year. The decision to perform a graft revision was taken on the basis of an arteriographic stenosis of at least 70% diameter reduction. In the first strategy graft categories were defined on the basis of the first postoperative duplex examination: grafts with a PSV-ratio <1.5, grafts with a PSV-ratio <1.5–2.0, grafts with a PSV-ratio of 2.0–2.5, grafts with PSV-ratios 2.5–3.0, and grafts with PSV-ratios >3.0. The primary patency rate at 12 months was compared for these categories. In the second alternative strategy the number of examinations and the percentage of event causing* de novo *stenoses were analysed per surveillance interval.*

Results: *The presence of moderate abnormalities at the initial duplex scan did not identify patients with a high risk of an event, as initial PSV-ratios of 1.5–2.0 and 2.0–2.5 (early mild-moderate lesions) had comparable 12-month primary patencies to patients with a PSV-ratio <1.5 (completely normal grafts): (63%, 73%, and 71%, respectively). The interval incidence of event causing* de novo *stenoses was 8% of the total number of duplex tests performed at 3 months, and 8% at 6 months after the operation. In patients who had no previous intervention for stenosis and had a normal bypass during the first 6 months postoperatively, a sharp drop in this incidence was seen at 9 and 12 months, with event causing* de novo *stenoses observed in only 2% and 1% of all duplex tests.*

Conclusions: *All patients should be included in a surveillance program, as the presence of a normal vein graft at the first duplex examination does not rule out the subsequent development of graft stenosis. The duration of the surveillance period may be restricted to the first 6 months after operation in patients who have a normal bypass during that time period, as only few stenoses will be missed by this policy.*

Key Words: Infrainguinal vein bypass; Vein-graft stenosis; Non-invasive assessment; Graft surveillance.

Introduction

Intrinsic vein-graft stenosis is a major threat to infrainguinal bypasses. In approximately 30% of all vein grafts, stenotic lesions will develop, due to intima hyperplasia, remodelling or fibrosis.[1–3] Vein-graft surveillance has been shown to be an effective method of identifying stenotic lesions, thus allowing repair of these defects before graft thrombosis occurs. However, the necessity for repetitive duplex testing during a longer period of time makes considerable demands on patients and vascular laboratories. Better utilisation of resources may be obtained by restricting surveillance testing to patients at high risk of developing graft stenosis. Several patient factors, operative technical and vein-graft related factors have been identified as being associated with an increased risk of stenosis development or graft occlusion.[4,5] Recently it has been suggested that most stenotic lesions are the result of progression of residual vein-graft lesions or platelet deposits already present at the time of operation. In this view it might be possible that patients with grafts that have a high risk of developing significant lesions during follow-up can be identified by the first postoperative duplex scanning soon after the bypass procedure.[6–8]

The large majority of graft lesions develop within the first 12 months, and many authors agree, therefore,

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that surveillance may be discontinued at that time.[4,9] Others have stressed that serial examinations cannot be dispensed after 1 year and graft surveillance should be continued for longer periods, if not for the duration of the patient's life.[10–13] An alternative way of reducing expenses and workload involved with stenosis detection may be to limit the duration of the surveillance period and thus the number of examinations.

In this study the effectiveness of these two strategies targeted to a reduction of duplex surveillance testing was investigated. The first strategy attempted to reduce the number of patients for continued surveillance by identifying grafts with a higher risk of significant stenosis, indicated by the presence of early duplex abnormalities. In the second strategy, the effect of reducing the duration of the surveillance program in the overall patient group, with regard to the number of graft stenoses that would be missed, was examined.

Patients and Methods

From June 1993 to September 1995, 346 patients underwent infrainguinal bypass grafting and enrolled in a prospective follow-up study that involved a carefully monitored surveillance program. This study was a combined effort of three vascular surgical departments: the University Hospital Maastricht, Sint Antonius Hospital Nieuwegein, and Catharina Hospital Eindhoven. All centres had a well-equipped and staffed clinical vascular laboratory.

The preoperative workup consisted of a preoperative angiogram. Duplex assessment of the greater saphenous vein was performed if there was doubt about its suitability. A variety of operative techniques was used to perform the bypass procedures. *In situ* saphenous vein grafts was the preferred method if there was a suitable ipsilateral saphenous vein available. Ectopic veins were used, either in a reversed or in a non-reversed fashion depending on the vein taper and the optimal size match between vein graft, inflow and recipient arteries. Small or fibrotic segments were replaced by a segment of arm vein or contralateral greater saphenous vein. All operations were performed by vascular surgeons, vascular fellows, or by residents in their last term of surgical training supervised by a vascular surgeon. Postoperative anticoagulation with dicoumarol or acenocoumarol was instituted postoperatively in all patients who had no contraindications to use.

After discharge a surveillance program, which consisted of serial colour-flow duplex examinations, and ankle blood pressure measurements, commenced. The examinations were performed at 6 weeks, 3 months, 6 months, 9 months, and 12 months after the operation. Thereafter ankle blood pressure measurements were performed every 6 months. To assess the optimal duration of graft surveillance, a regularly measured PSV-ratio was used as an indicator of "significant graft stenosis" (PSV-ratio ≥ 2.5). An "event causing stenosis" was present if a stenosis required a revision. All revised lesions had a diameter reduction greater than 70% on angiography. Moreover, stenoses that had caused a graft occlusion before a revision was undertaken, were defined as "event causing stenoses". A stenosis was classified a "*de novo* stenosis" if the previous PSV-ratio was <2.0, and a "progressive stenosis" if it was ≥ 2.0 at a previous visit and increased by 1.0 or more. If the graft was revised during follow-up the surveillance schedule was resumed as for newly implanted grafts. The duplex equipment used was: Acuson 128 XP/10 (Catharina Hospital), Hewlett Packard Sonos 1000 (University Hospital Maastricht), and Hewlett Packard Sonos 2000 (Sint Antonius Hospital Nieuwegein). In all three centres a 7.5 MHz transducer was applied unless the graft was deep, when a 5.0 MHz transducer was used. All examinations were performed by qualified technologists. The vein graft was examined from the groin down its entire length to below the distal anastomosis, including the first centimetres of the recipient run-off artery. The same surveillance protocol was used in the three participating institutions. Adherence to the protocol was verified by a visiting data-manager and a study nurse. Vascular laboratory meetings were organised regularly to ascertain uniform duplex scanning techniques and recording of parameters. Intraoperative or predischarge duplex entire graft scanning was infrequently performed during the study. Therefore these data were not included in the analysis. Early duplex scanning was defined as the first complete graft examination, which was at 4–6 weeks postoperatively.

When surveillance examinations revealed one of the following criteria for an abnormality of the graft, its inflow or run-off, a digital subtraction angiography was performed: recurrent claudication or rest pain, an interval decrease of the ankle brachial index >0.15, a peak systolic velocity ratio (PSV-ratio) >2.0, a peak systolic velocity at the mid-thigh graft <45 cm/s, and end-diastolic velocity >20 cm/s. A PTA or an open surgical procedure was only performed if the angiogram confirmed the presence of a stenotic lesion with a $\geq 70\%$ diameter reduction.

Definitions and data analysis

A primary event was defined as revision of a stenotic but patent graft, or graft occlusion. Primary graft

failure was used as the study endpoint for a patient. The efficacy of initial surveillance measurements as predictor for the development of severe graft stenosis was represented by the primary patency. For all patients the occurrence of primary events and the time interval between the event and the initial duplex scanning was recorded. Kaplan–Meier curves were used with grafts categorised according to the PSV-ratio at the first surveillance visit. Receiver operating characteristic (ROC) curves were used to assess the sensitivity and specificity of the initial PSV-ratio for predicting primary graft failure in the first year. The analysis was performed using SPSS 7.0 for Windows statistical software.

Results

Patient series

Three hundred patients entered the prospective surveillance program, while 46 patients with infrainguinal vein grafts operated on in the same period were not considered for analysis, because of death of the patient, a reversible graft failure within 30 days after graft implantation, or no return for follow-up visits. There were 179 (60%) men and 121 (40%) women, with a mean age of 70 years (33–99). Operative indications for lower limb revascularisation consisted of critical ischaemia in 216 (72%) grafts, disabling claudication in 78 (26%) and popliteal aneurysm in six (2%) grafts. The site of the proximal anastomosis was the common femoral artery in 57%, the superficial femoral artery in 25% and other sites in 18%. Two hundred and sixty-seven (89%) grafts consisted of a single greater saphenous vein segment, while composite grafts of multiple vein segments were used in 54 (18%). Of the latter, 13 (4%) had arm-vein segments used. Other graft characteristics and preoperative risk factors are summarised in Table 1. Most (74%) of the initial duplex examinations were performed within 6 weeks after the operation, and 94% were performed within 3 months after graft implantation.

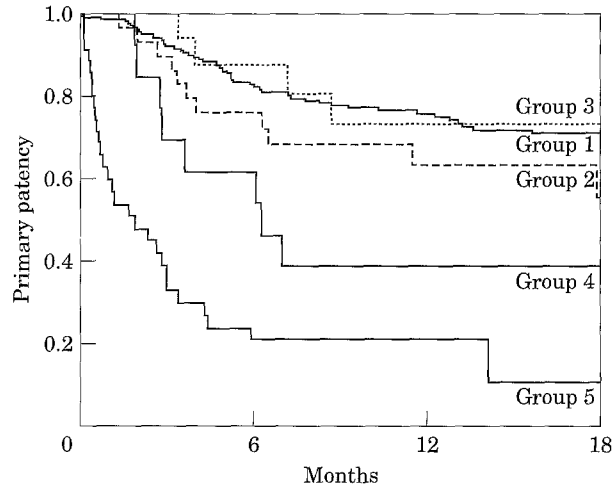
Initial duplex examination

Kaplan–Meier curves of the primary patency were constructed for patient groups with an initial PSV-ratio <1.5 (group 1), 1.5–2.0 (group 2), 2.0–2.5 (group 3), 2.5–3.0 (group 4), and >3.0 (group 5) (Fig. 1). Patients with "early lesions" groups 2 and 3 did not show a

Table 1. Risk factors and graft characteristics in 300 infrainguinal vein grafts.

Variables	Number of grafts (%)
Presenting symptoms	
Critical limb ischaemia	216 (72)
Claudication	78 (26)
Aneurysm	6 (2)
Associated disease and risk factors	
Diabetes mellitus	117 (39)
Hypertension	94 (31)
History of smoking	210 (70)
History of other vascular disease	152 (51)
Preoperative data	
ABI[1] <0.60	223 (78)[2]
SVS/ISCVS[3] run-off score >2.0	178 (59)
Graft	
Previous ipsilateral infrainguinal reconstruction	83 (28)
Other than *in situ* graft	172 (57)
Crural distal anastomosis	150 (50)
Minimal graft diameter <3.5 mm	38 (13)

[1] = ABI, ankle-brachial blood pressure index; [2] = incompressible vessels in 15 patients; [3] = Society for Vascular Surgery/International Society for Cardiovascular Surgery.



Grafts at risk.

Initial PSV ratio	0 months	6 months	12 months	18 months
≤ 1.5 (Group 1)	203	149	95	65
1.5–2.0 (Group 2)	30	20	11	7
2.0–2.5 (Group 3)	18	13	7	5
2.5–3.0 (Group 4)	14	8	3	3
> 3.0 (Group 5)	35	7	3	1

Fig. 1. Primary patency rates represented by Kaplan–Meier curves of patient groups according to the initial PSV-ratio: group 1 (PSV-ratio <1.5), group 2 (PSV-ratio 1.5–2.0), group 3 (PSV-ratio 2.0–2.5), group 4 (PSV-ratio 2.5–3.0), and group 5 (PSV-ratio >3.0). On the abscissa T = 0 represents the time of the initial duplex examination.

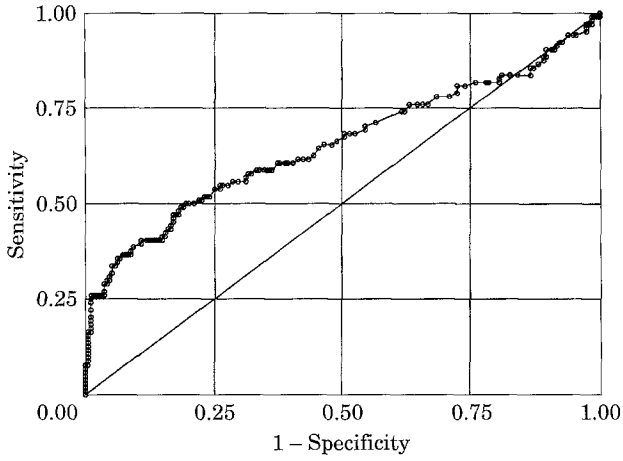


Fig. 2. Receiver operating characteristic (ROC) curves of the peak systolic velocity (PSV-ratio) and its correlation with primary events in the first year.

different course of their primary patency than patients with "normal grafts" (group 1) (primary patencies at 12 months of 63%, 73%, and 71%, respectively). The primary patency of groups 4 and 5 at 12 months was 38% and 21%, respectively. Group 4 differed from groups 1 to 3 (p, respectively, <0.001, 0.07, 0.01), and group 5 differed from groups 1 to 3 (p, all <0.001).

The clinical applicability of the initial PSV-ratio to discriminate grafts with a high and a low probability of encountering a primary event during the first year was further assessed by a ROC-analysis, represented in Fig. 2. There was no distinct threshold value for this separation, as the best combination of sensitivity and specificity was still rather low (54% and 75%, respectively). The secondary 12-month patency for groups with a PSV-ratio ≥3.0 and <3.0 was 80% and 92%, respectively ($p=0.01$).

Duration of surveillance period

For all grafts in this study (including grafts that were enrolled again after their first or second revision) the time of onset of "significant stenosis" (PSV-ratio ≥2.5), and of "event causing *de novo* stenosis" (revision or occlusion) is represented in Table 2. Of all performed surveillance examinations the interval rates of significant *de novo* stenosis were 17%, 14%, and 10% at 6 weeks, 3 months, and 6 months. At the ninth and 12th month interval the incidence was considerably lower, 5% and 5%, respectively. Event causing *de novo* stenosis occurred at the sixth week, third month and sixth month interval in 8%, 8%, and 8%. At the ninth and 12th month interval this type of stenosis occurred in 4% and 7% of the grafts. Of the total of 111 event causing stenosis that occurred during the first year, 100 were associated with a revision and 11 with an occlusion.

In a second analysis of a similar nature, grafts that underwent a revision were excluded after this primary event. In this assessment, in which second and third graft revisions were not considered, the interval rate of significant *de novo* stenosis at 9 and 12 months was 4% and 3%, respectively, and significant *progressive* stenoses were observed in 2% and 5%, respectively. The interval rate of event causing *de novo* stenosis at the ninth and 12th month interval was 2% and 1%, respectively (Table 3). Of the total of 82 event causing stenoses that were observed in the first year, 75 were associated with a revision and seven with an occlusion. The sharp drop in the interval incidence of event causing *de novo* stenoses in previously unrevised grafts after 6 months is shown in Fig. 3. During the first year, of all event causing *de novo* stenoses, 84% had occurred within 6 months.

Discussion

The usefulness of duplex scanning for follow-up of infrainguinal vein grafts has long been recognised, and several comparative studies have demonstrated that duplex scanning is superior to standard follow-up methods for detecting graft stenosis.[2,14–17] Some individual grafts are at greater risk of failure than others. Factors that were reported to be associated with this higher risk include: critical limb ischaemia, diabetes, poor crural run-off, previous arterial reconstruction, composite or spliced vein grafts, non-*in situ* technique, and minimal graft diameter.[4,5,10,16] In the present study the risk of severe graft stenosis requiring intervention was significantly increased in grafts that had a PSV-ratio (≥2.5) at the initial duplex examination. It is likely that the development of stenoses in many patients begins at the time of surgery, and if progression is rapid, these lesions are associated with a high failure rate.

It has been suggested that the first duplex scanning is best performed at the completion of the operation or before discharge. Unrepaired early duplex abnormalities required later correction in 32–52%.[5–8,18] It is assumed that residual and minor defects in vein grafts may serve as a nidus for severe graft stenoses to develop later after implantation. It was hypothesised that if early postoperative duplex findings permitted distinction of grafts into low- and high-risk groups, a more rational surveillance protocol may be instituted. Mills and coworkers found that 45% of lesions detected

Table 2. Stenoses occurring in all grafts surveyed, including grafts that were enrolled again after a first and a second revision.

All grafts		6 weeks	3 months	6 months	9 months	12 months
Number surveyed grafts		244	244	238	221	210
Significant graft stenosis[1]	Total	41	57	50	40	35
	De novo[2]	41	34	23	11	10
	Progressive[3]	–	23	27	29	25
Event causing stenosis[5]	Total	20	31	32	12	16
	De novo[2]	20	20	19	8	15
	Progressive	–	11	13	4	1
	Recurrent stenosis[4]	–	4	5	6	9
Event causing *de novo* stenosis/ number grafts (%)		8	8	8	4	7

[1]=Significant stenosis: PSV-ratio ≥2.5; [2]=*de novo* stenosis: previous PSV-ratio <2.0; [3]= progressive stenosis: previous PSV-ratio ≥2.0 and increase of PSV-ratio ≥1.0; [4]=recurrent stenosis: revised graft with secondary event causing stenosis; [5]=event causing stenosis: graft with revision or occlusion.

Table 3. Stenoses occurring in surveyed grafts with follow-up ending after a first revision.

Previously unrevised grafts		6 weeks	3 months	6 months	9 months	12 months
Number surveyed grafts		244	244	203	169	152
Significant graft stenosis[1]	Total	41	50	39	24	18
	De novo[2]	41	31	18	6	5
	Progressive sten.[3]	–	9	12	4	7
	Stable sten.[4]	–	10	9	14	6
Event causing stenosis[5]	Total	20	26	23	6	7
	De novo	20	19	15	4	2
	Progressive	–	7	8	2	5
Event causing *de novo* stenosis/ number grafts (%)		8	8	7	2	1

[1]=Significant stenosis: PSV-ratio ≥2.5; [2]=*de novo* stenosis: previous PSV-ratio <2.0; [3]= progressive stenosis: previous PSV-ratio ≥2.0 and increase of PSV-ratio ≥1.0; [4]=stable stenosis: previous PSV-ratio >2.0 and increase of PSV-ratio <1.0; [5]=event causing stenosis: graft with revision or occlusion.

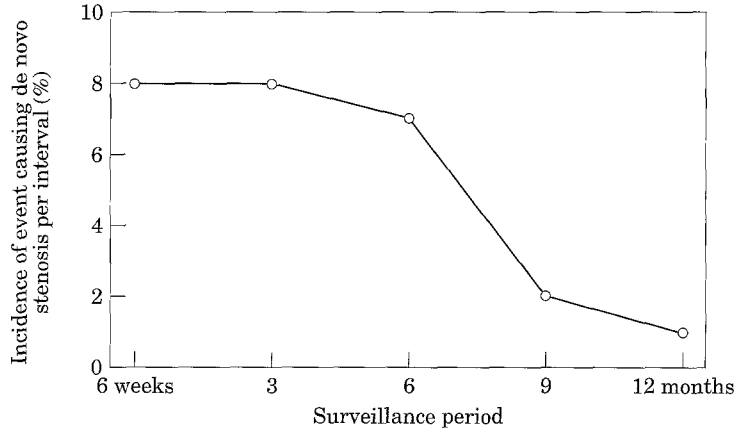


Fig. 3. The incidence of event causing *de novo* stenoses per surveillance interval in previously unrevised grafts during the first postoperative year.

by intraoperative duplex scanning progressed to high-grade stenoses, which either required revision or occluded before an intervention was performed. In their study 23% of lesions remained stable, and 32% regressed.[6] These authors, as well as others, suggested that an early separation of grafts into high-risk and

low-risk groups was possible, allowing them to focus all surveillance attention to the higher risk group, while subjecting the other grafts to a less intensive or no-surveillance policy.[6,8] The outcome of the present prospective study supports the observation of these earlier studies, though not necessarily their conclusions. As expected, we found that early severe lesions (PSV-ratio ≥ 2.5) quite often required a revision. Grafts with "early mild to moderate lesions" represented by initial PSV-ratios between 1.5 and 2.5 follow a similar course with regard to primary patency as grafts in patients with completely normal PSV-ratios (<1.5). In addition, it appears that patients with normal grafts by no means avoid later trouble, as the primary patency at 12 months was 71%. Therefore, excluding initially normal grafts from further surveillance would have resulted in a less effective surveillance protocol. These observations are supported by other studies, in which it was found that normal early duplex findings did not equate with the long-term absence of graft-threatening lesions.[19,20] Consequently, all grafts need to be followed from an early stage. At present we perform a full predischarge duplex scan in all patients. Whether this will improve on the information obtained by a 6-week scan as the initial examination requires further evaluation. It is known that approximately one-third of early identified stenoses regress,[6] negating the usefulness of their detection in the first post-operative week. The favourable overall outcome of revising identified severely stenotic lesions, which has been reported in many previous studies,[2,7,17,19] was confirmed in the present study. The secondary patency rate in the category with PSV-ratios ≥ 3.0 was 80%, which may be considered a satisfactory result.

Taylor *et al.* were among the first to propose a rationalised surveillance program by limiting the duration.[9] In their study all stenoses were detected in the first year after operation and none occurred after this time. It was recognised that grafts will continue to fail in subsequent years, but this was at an annual rate of only 2–3%, which did not justify the cost involved with continuing surveillance of all grafts. At the present time many authors agree that routine graft surveillance is not indicated after 12 months of follow-up.[4,9,21] However, Erickson *et al.* maintain an opposite view.[13] They observed that, of 236 grafts that developed surveillance abnormalities, 21 had their initial defect more than 2 years after the initial bypass procedure. However, in this series stenoses in the vein itself developed after a median follow-up period of 6–8.5 months, whereas inflow and run-off lesions developed after a median follow-up of 15 and 29 months, respectively. This difference in the time of onset of lesions in the vein conduit and in the arteries was explained by the different nature of the lesions, with slower progressing atherosclerosis being the dominant factor in the inflow and run-off segments.

It has been suggested that grafting technique makes a difference to the time of onset of stenoses. In a series exclusively consisting of *in situ* bypasses, only two of 117 grafts needed a revision after 6 months of follow-up.[22] Unfortunately, not many series will exclusively consist of *in situ* bypasses, as this type of bypass requires a greater saphenous vein with a good calibre throughout its entire length. We found that grafts with treated stenoses are at increased risk of developing a recurrent stenosis or a second stenosis at another location. After revision a venous bypass should be followed by regular duplex examination for at least another 6 months, as a recurrence can be expected in about one out of four grafts.[9,23,24] However, the majority of grafts do not require an intervention within 6 months after operation, and if there is no evidence of a stenosis and the maximum PSV-ratio is less than 2.0, intensive surveillance can be safely stopped, which was the crucial observation in the present study. Only 2% of surveilled patients without previous revision at 9 months and in 1% at 12 months developed an event causing *de novo* stenosis. Moreover, it has been reported that *de novo* lesions that develop after 6 months tend to be stable, and infrequently require revision.[25,26]

In conclusion, the typical time course of vein-graft failure and intervention appeared to be related to the onset and progression of graft lesions. Our current protocol after discharge includes examinations at 6 weeks, 3 months and 6 months. Thereafter, in the absence of previous revisions or duplex abnormalities, discretionary clinical examinations may be scheduled annually.

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