Vein graft surveillance: Is graft revision without angiography justified and what criteria should be used?

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Purpose: The objective of this study was to assess the accuracy of color-flow duplex surveillance parameters to detect infrainguinal vein graft stenoses and to investigate whether graft revision without angiography is justified.
Methods: In a prospective study in which three centers participated, the data of graft surveillance in 300 patients were analyzed. For the evaluation of surveillance criteria all patients underwent a digital subtraction angiography if a graft stenosis was suspected. To create a control group, in patients with normal grafts a consented digital subtraction angiography was performed also. From these data the accuracy of seven duplex and three ankle blood pressure-derived variables was assessed. The relation between various surveillance criteria and continued graft patency was determined with life table analysis with the transient state method.
Results: The mean follow-up period was 20 months (range, 1 to 40 months). At univariate and multivariate analysis the peak systolic velocity (PSV) ratio provided the best correlation with angiographic stenoses ≥70% (PSV ratio cutoff 3.0: sensitivity 80%, specificity 84%). This finding did not differ between the participating centers. With life table methods it was demonstrated that the best combination of efficacy (limitation of the number of unnecessary revisions), safety (minimal number of correctable lesions missed), and reduction of angiograms was obtained by a two-parameter surveillance algorithm. This algorithm included a PSV ratio <2.5 to delineate patients in whom a conservative approach without angiography or revision was appropriate, a PSV ratio ≥4.0 to indicate patients in whom vein graft revision without angiography could be scheduled, and a group with PSV ratios between 2.5 and 4.0 in whom angiography was to be performed to determine clinical management on the basis of the stenosis severity. This algorithm had a positive predictive value of 93% and a negative predictive value of 89%. In addition, it resulted in a reduction of the number of angiograms of 49% compared with a policy of angiographies in all patients with a PSV ratio ≥2.5.
Conclusions: The best criterion to identify a failing graft is the PSV ratio. With a two-parameter algorithm for vein graft surveillance, the incidence of unnecessary revisions and of missed high-grade lesions was acceptably low, whereas the number of angiograms was reduced by one half. (J Vasc Surg 1998;27:399-413.)

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

Variables	*No. of grafts (%)*	
Presenting symptoms		
Tissue loss from G or U	109	(36)
Rest pain	107	(36)
Claudication	78	(26)
Aneurysm	6	(2)
Associated disease and risk factors		
Female sex	121	(40)
Diabetes mellitus	117	(39)
Hypertension	94	(31)
History of smoking	210	(70)
History of other vascular disease	152	(51)
Preoperative data ABI		
ABI <0.60	223	(78)*
SVS / ISCVS runoff score >2.0	178	(59)
Graft		
Previous ipsilateral infrainguinal reconstruction	83	(28)
Other than in situ graft	172	(57)
Proximal anastomosis below common femoral artery	111	(37)
Proximal anastomosis below superficial femoral artery	30	(12)
Crural distal anastomosis	150	(50)
Venovenous anastomosis	54	(18)
Minimal graft diameter <3.5 mm	38	(13)

G, gangrene; *U*, ulceration; *SVS/ISCVS*, Society for Vascular Surgery / International Society for Cardiovascular Surgery.
*Incompressible vessels in 15 patients.

Autogenous vein grafts provide the best conduit for bypass management of femoropopliteal and femorocrural occlusive disease. However, bypass longevity is threatened by the development of stenosis either from intimal hyperplasia or from fibrous stricture development in 20% to 30%.[1-3] Frequent noninvasive examinations followed by elective revision of failing but nonoccluded grafts has become a valued strategy that is believed to salvage conduits and limbs.[4-7]

Angiography allows the demonstration of significant vein graft stenoses, and in fact this method was used in the first comprehensive study reporting on the phenomenon of graft stenosis by Szilagyi et al.[1] in 1973. The presence of a significant angiographic stenosis is a reliable predictor of graft failure unless the lesion is repaired.[8-10] There is no consensus about which of the noninvasive methods or parameters as applied during follow-up has the best correlation with angiographically critical graft stenoses, nor is there agreement on what outcomes of surveillance measurements are reliable indicators of expected graft failure or obvious need for intervention.

Replacing angiographic evaluation of vein graft stenosis by duplex scanning would be advantageous.[11] Graft occlusions may occur within the interval between the surveillance visit and the confirmative angiography.[9] Avoiding arteriograms during follow-up would not only result in less delay of the revisional procedure, it also would reduce the overall cost of graft surveillance programs. This approach assumes that surveillance examinations have a high positive predictive value (PPV) and negative predictive value (NPV) to avoid unnecessary interventions and to avoid missing a large proportion of patients with failing grafts.

In this report the results are presented of a prospective cohort study with strictly standardized surveillance techniques, digital subtraction angiography (DSA) in a series of patients with infrainguinal venous bypasses, and a fixed protocol with regard to interventions for documented severe lesions in the graft or the adjacent arterial segments. The objectives of this study were (1) to assess the accuracy of different surveillance parameters in comparison with angiography as a gold standard and (2) to examine correlations of parameters with the fate of the graft during follow-up. For the first analysis a comparison is made on the basis of DSA performed in this series, whereas in the second analysis the patients entering the follow-up period constitute the statistical unit. In addition, the threshold level for the angiographic degree of stenosis to distinguish grafts with a high and a low risk of failure was validated.

PATIENTS AND METHODS

Patients of three institutions following the same surveillance protocol were included in a prospective cohort surveillance study. Three hundred patients with autologous vein bypass grafts of the infrainguinal arteries were studied. Patients entered the study if they had undergone open bypass grafting before discharge from the hospital. Only one graft per patient was included in this study. The three participating institutions were Catharina Hospital, Eindhoven (177 grafts), Sint Antonius Hospital, Nieuwegein (62 grafts), and University Hospital, Maastricht (61 grafts). Forty-six patients with vein grafts who underwent surgery in the same period were not considered for analysis because of death of the patient (11), irreversible graft occlusion (17), amputation with open bypass within 30 days after the operation (8), or no return for surveillance visits (10). The operations were performed between June 1993 and September 1995, and the follow-up of this study ended in September 1996. Of the 300 patients 179 (60%) were men, and 121 (40%) were women (Table I). The mean age was 70 years (range, 33 to 93 years). Diabetes mellitus (type 1 or 2) was pre-

sent in 117 (39%) patients. Critical ischemia was the indication for the bypass procedure in 216 (72%). A total of 83 (28%) procedures were redo operations, that is, new grafts, because a previous attempt of revascularization of the popliteal or crural arteries in the same limb had been performed. The distal anastomosis was at the level of the popliteal artery or tibioperoneal trunk in 150 (50%) and at a crural artery in 150 (50%). The runoff score as determined on the basis of preoperative angiograms[12] indicated an impaired runoff (score >2.0) in 178 (59%) of the patients.

A variety of techniques were used to perform the bypass procedures. In situ saphenous vein grafts were used when the ipsilateral saphenous vein was available and suitable for use. Ectopic veins were either reversed or nonreversed, depending on the vein taper and the optimal size match between vein grafts and inflow and recipient arteries. Small distal or fibrotic segments were replaced by a segment of arm vein or greater saphenous vein. The procedures were performed by staff surgeons in the three institutions or by vascular fellows assisted by the surgeon. Postoperative anticoagulation with coumarin (Dicoumarol or Acenocoumarin) was instituted after surgery in all patients without contraindications for its use.

In the three participating institutions the same graft surveillance protocol was used. The adherence to the protocol was accomplished by frequent visits of a data manager and a study nurse, who performed the data collection. Vascular laboratory meetings were organized regularly to ascertain a uniform duplex scanning and measurement technique and for recording of parameters. The surveillance examinations were performed by a group of nine vascular laboratory technicians.

Surveillance protocol. Before discharge from the hospital graft patency was confirmed by a graft velocity measurement at the mid-thigh level of the bypass. For the study, however, only the outcomes of entire bypass duplex scannings during follow-up were used in addition with ankle pressure measurements at rest and during reactive hyperemia (RH). Surveillance visits were routinely performed at 6 weeks, 3 months, 6 months, 9 months, and 12 months. In grafts without abnormalities subsequent follow-up examinations consisted of ankle blood pressure measurements at rest and during RH at 18, 24, and 30 months after the operation. The rationale for restricting duplex examinations to the first postoperative year has been well documented in the literature.[4]

An intraarterial DSA (Catharina Hospital and Sint Antonius Hospital) or an intravenous DSA (University Hospital Maastricht) was performed if one of the following criteria for a failing graft were present: recurrent claudication or rest pain, interval decrease of the ankle/brachial blood pressure index (ABI) >0.15, a peak systolic velocity ratio (PSV ratio) >2.0, a peak systolic velocity at the mid-thigh section (for a length of at least 7 cm) of the graft (PSV graft) <45 cm/sec, and an end-diastolic velocity >20 cm/sec. If the intravenous study had insufficient resolution, a subsequent intraarterial DSA was performed. Accurate assessment of the angiographic diameter ratio of stenotic and normal graft sites was facilitated by multiple projections and by magnified views. If at DSA examination a stenosis of 70% diameter reduction (DR) or greater was observed either in the graft, the anastomoses, or the adjacent artery segments, a revisional procedure, either a percutaneous transluminal angioplasty or an open surgical procedure, was planned. In fact, this angiographic criterium was the sole determinant for the decision for intervention. After the lesion was repaired, surveillance was continued until 1 year after the revision. In case of a stenosis with a DR of 50% to 70%, no intervention was undertaken, but subsequent surveillance duplex examinations were performed at reduced intervals. If no further increase of the PSV ratio occurred, a conservative approach was adopted, and the surveillance schedule resumed at routine intervals. Bypasses with less than 50% DR were considered normal grafts.

Patients without evidence of graft stenosis at surveillance examination underwent a DSA after their consent was obtained. These control DSA studies were made either 6 months or 1 year after the operation, a choice that was determined by randomization.

Surveillance examination. Systolic ankle blood pressure (ABP) measurements were performed with the patient lying supine with a 15-cm wide blood pressure cuff, and the average of two measurements was recorded. The highest of the right and left systolic brachial blood pressure was used to determine the ABI. ABP during reactive hyperemia was measured after suprasystolic thigh cuff inflation during a 3-minute period.

The color-flow duplex equipment that was used consisted of an Acuson 128 XP/10 in the Catharina Hospital, a Hewlett Packard Sonos 1000 in the University Hospital Maastricht, and a Hewlett Packard Sonos 2000 in the Sint Antonius Hospital. In the three centers a 7.5 MHz transducer was applied, unless the vein graft was deep, in which case

a 5.0 MHz transducer was used. The examination technique such as the use of similar angles of insonation of the pulsed Doppler with respect to the vessel axis, sites of velocity measurements, ankle pressure measurements, and reactive hyperemia induction was uniform in the participating vascular laboratories. The vein graft was examined from the groin down the entire length to below the distal anastomosis on to the first centimeters of the recipient runoff artery. Color-coded images were studied for stenotic flow patterns, and a percent DR was measured by use of color image at the stenosis and at a nearby normal graft segment. After an image of the graft was obtained, midstream pulsed Doppler velocity spectral signals were recorded from diseased and normal vessel segments. The following parameters were evaluated: (1) the peak systolic velocity at a normal mid-thigh graft segment (PSV graft, centimeters / second), (2) the PSV at the most severe stenotic site (PSV-max, centimeters / second), (3) the ratio of the PSV-max and the PSV at a nearby normal segment, proximally (or distally in case the graft stenosis was near the proximal anastomosis) of the stenosis (PSV ratio), (4) the end-diastolic velocity at the site of the stenosis or in normal grafts at the narrowest segment of the bypass below the knee (centimeters / second), (5) diameter reduction of the stenosis on the color image (DR%), (6) the duplex measured flow in resting conditions at the mid-thigh graft (flow-rest, milliliters / minute), (7) flow at the mid-thigh graft during reactive hyperemia (flow RH, milliliters / minute), (8) ABP at rest (millimeters of mercury), (9) ABI, and (10) ABI at RH.

Study end points, data analysis. All data were prospectively recorded and entered into a computerized database. The 10 surveillance parameters were correlated in a univariate analysis with angiographic outcomes. In this part the study is based on the DSAs performed in the corresponding time interval. The criterion of an angiographic DR of 70% was selected because in previous studies this degree of lesion has been associated with a high risk of graft failure.[8-10,13] Angiograms were dichotomized into groups with a DR of 0% to 70% and a DR ≥70%. A univariate comparison of both outcomes was performed with the use of the Mann-Whitney test. All noninvasive factors that demonstrated a significant difference ($p < 0.05$) for the angiographic categories in the univariate comparison were subjected to a multivariate analysis with logistic regression models.[14] Variables with an independent correlation with the angiographic severity of stenoses were identified by backward elimination of the factors that contributed the least to the model. Cumulative primary and secondary patency rates as defined by the Ad Hoc Committee on Reporting standards were determined by life table methods.[12] Receiver operating characteristic curves were used to determine threshold values that provided the best separation in lesion categories.[15]

The occurrence of primary events in relation with the presence of a time-dependent risk factor such as a PSV ratio greater than a predefined level can be determined by a Cumulative Hazard Analysis and Transient State Method with Kaplan-Meier curves.[16,17] With this method the cumulative primary patency rate is assessed in two groups of observations. Group A involves all patients as long as a surveillance measurement remains within specified limits, for example a PSV ratio <3.0 (Fig. 1) . In this group the observation time starts at the time of the procedure (T = 0). If the PSV ratio exceeds 3.0, a patient ceases to be part of group A and is further represented in group B. Patients are part of group B from the moment their surveillance parameters have exceeded the threshold value (T = 0). In both groups any patient reaching an end point of primary patency (primary event, i.e., a graft revision or occlusion) is represented as a drop in patency. Basically, this method, which was described by Mantel and Byar[16] in 1974, allows a comparison of patency rates between patients with and without a time-dependent risk factor.[18] A perfect predictive value of a risk factor regarding the occurrence of events is represented by a 100% patency in group A and a zero patency in group B.

RESULTS

Angiograms, graft revisions, and patencies. In the 300 patients 351 DSA studies were performed during follow-up. A total of 182 DSA studies were performed for a change in surveillance parameters, most commonly a PSV ratio >2.0, whereas 169 normal control DSA studies were performed in vein grafts without focal increase of PSV. Excluded from the study were 22 angiograms: 8 patients had an angiogram but failed to appear for noninvasive examinations, 5 patients had a graft occlusion without identified stenosis, and 9 patients had a complete occlusion of the runoff artery immediately distal of their bypass. All graft or runoff occlusions were accurately diagnosed by color imaging and absence of flow signals allowing determination of clinical management. For correlation of angiographic findings and listed surveillance parameters, 329 DSA studies were available.

The median follow-up period was 20 months (range, 1 to 40 months). Localization of revised

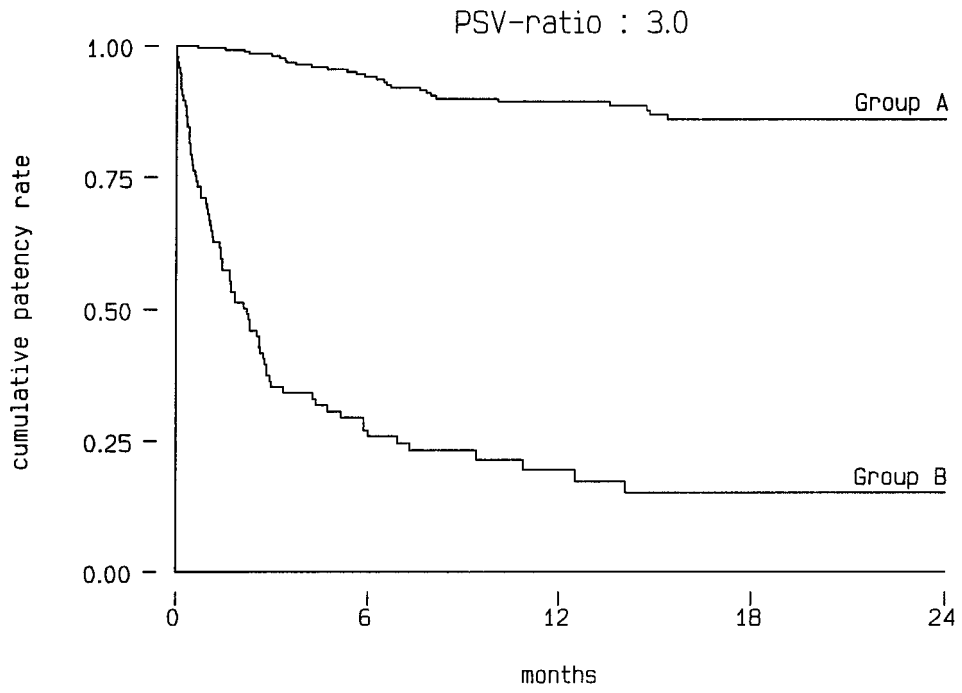

Fig. 1. Primary patency rates represented by Kaplan-Meier curves of patients with PSV ratio <3.0 (group A) and patients with PSV ratio ≥3.0 (group B). In group A, T = 0 coincided with time of operation, and in group B, T = 0 coincided with first time observed PSV ratio was ≥3.0. Curve of group A depicts patency as long as PSV ratio has not exceeded 3.0 (Transient State Method).

stenoses, types of revision, and numbers of graft occlusions are summarized in Table II. Interventions were performed in 84 (28%) of the grafts, and the total number of revisions including multiple stenoses and recurrences was 144. Primary graft occlusions were diagnosed in 31 cases. In 16 patients the occlusion occurred without obvious cause, but in 15 the presence of a high-grade lesion was known. In the latter cases there usually was a delay to revise the graft and sometimes refusal or inability of the patient to return for the procedure. The 2-year primary patency determined by standard Kaplan-Meier life table analysis was 58% (SE 3%), and the secondary patency was 84% (SE 2%) for the total study group (Appendix A, see also footnotes to Table II).

Seventy percent angiographic diameter reduction as a risk factor of occlusion. A validation was performed whether graft stenoses of 70% angiographic diameter reduction or greater imposed the greatest risk for occlusion. Therefore the secondary patency rate was compared for grafts with different degrees of stenosis with the Transient State Method. In this analysis the onset of the observation periods coincided with the time of the arteriogram determining the classification. The 18-month secondary patency rate in patients with <50% DR angiographic stenoses was 99%, in stenoses of 50% to 70% DR the patency was 87%, and in stenoses ≥70% it was 78% ($p < 0.05$ for the latter category compared with the two other categories, Appendix B). It should be noted that as per protocol patients with a degree of stenosis less than 70% were not revised in this study, whereas all patients with a 70% lesion or greater had a graft revision planned. The validity of a 70% DR threshold value as a discriminator between grafts with a high risk of failure or otherwise was clearly supported by this observation.

Graft surveillance parameters. All duplex- and ABP-derived parameters were correlated for groups with DSA-confirmed lesions <70% and ≥70% DR (Table III). Differences were observed for all parameters except for graft flow-RH, and the significance was borderline for the resting graft flow. Despite statistical differences a considerable overlap of parameter outcomes occurred in the DSA study groups. The best discrimination between grafts with and without significant stenoses was observed in PSV-max and PSV ratio, which are by definition strongly related to

Table II. Graft stenoses, revisions, and occlusions in 300 patients during follow-up

	No.
Localization of revised stenoses (DSA) (n = 144 stenoses)*	
Inflow artery	1
Proximal anastomosis	30
Graft above the knee	27
Graft at the knee	18
Graft below the knee	17
Distal anastomosis	39
Runoff artery	12
Type of first time revision (n = 84 revisions)†	
PTA (atherectomy, stent)	35
Patchplasty	17
Interposition graft	14
Jump graft	18
Simultaneous revision of multiple stenoses (no. of revisions)	13
Subsequent revisions (no. of patients)	
2 revisions	31
3 revisions	8
Graft occlusions as primary event (n = 31 occlusions)†	
Occlusion without obvious cause	16
Occlusion with known high grade stenosis	15

*The total number of 144 revised stenoses involved the first time revisions (n = 84), simultaneous revisions of multiple stenoses (n = 13), and subsequent second and third revisions (n = 47).
†The total of 31 occlusions together with 84 first-time revisions constituted the patients with a primary event (n = 115) in the regular life table primary graft patency analysis for 300 patients (Appendix A). In 12 patients the occlusion was later than 6 months after the last surveillance examinations, rendering any relation uncertain. Therefore these were not considered as a primary event in the Transient State life table, leaving 103 primary event patients for analysis (Appendix B, C, and D).

Table III. Univariate correlation of duplex and ankle blood pressure derived parameters and DSA category with a DR <70% and a DR ≥70% stenosis

	DSA <70% mean (± SD)	*DSA ≥70% mean (± SD)*	*Significance two-tailed*
PSV graft	60.1 (± 23.9)	46.9 (± 23.2)	<0.001
PSV-max	147.4 (± 76.7)	270.0 (± 108.2)	< 0.001
PSV ratio	1.92 (± 1.1)	5.44 (± 2.64)	<0.001
EDV	6.3 (±16.3)	33.9 (± 48.5)	<0.001
DR %	24.1 (± 22.7)	53.9 (± 19.2)	<0.001
Flow rest	189.8 (± 203.3)	164.4 (± 170.1)	0.019
Flow RH	267.9 (± 285.4)	257.6 (± 294.6)	0.164
ABP	147.7 (± 39.8)	120.4 (± 38.4)	<0.001
ABI	0.95 (± 0.253)	0.79 (± 0.26)	<0.001
ABI RH	0.92 (± 0.249)	0.73 (± 0.28)	<0.001

EDV, End-diastolic volume.

Table IV. Logistic regression model relating two variables to the probability of stenosis with ≥70% DR

Variable	β	*Standard error*	*Wald test**	*p Value*
^{10}log (PSV ratio)	6.81	0.78	75.87	<0.0001
ABP (mm Hg)	-0.014	0.004	9.86	0.002
Constant	-1.61	0.74	-	-

*Degrees of freedom = 1.

each other. No differences were seen in the correlation of the PSV ratio and the angiographic degree of stenosis among the three participating centers. Eight variables that demonstrated a significant difference in the univariate analysis were subjected to a multivariate analysis by logistic regression. This resulted in a model containing two variables (PSV ratio and ABP) with an independent association with the presence of a high-grade stenosis (Table IV).

As a next step receiver operating characteristic curves were used to evaluate the sensitivity and specificity of the PSV ratio alone and combined with the ABP to identify graft stenoses ≥70% DR. Of PSV ratio alone a value of 3.0 provided the best outcome and was associated with a sensitivity of 80% and a specificity of 84%. Use of the combined parameter "PSV ratio and ABP" provided little improvement in sensitivity and specificity compared with the PSV ratio alone (Fig. 2). Therefore it was concluded that to distinguish angiographic lesions of ≥70% from grafts with less severe stenosis, use of the PSV ratio only was sufficient. In an additional multivariate analysis in graft subgroups, it was demonstrated that of the eight surveillance parameters, the PSV ratio had the best correlation with the presence of high-grade lesions in in situ or ectopic nonreversed grafts, in reversed grafts, in femoropopliteal grafts, and in infrapopliteal grafts.

Graft patency relative to surveillance parameters. During the total follow-up-period 103 (34%) of 300 patients reached a primary patency end point (84 revisions and 19 primary occlusions within 6 months of the last surveillance duplex examination). Redo interventions were not included for this analysis. (See the notes to Table II for a detailed account of graft revisions and occlusions in life table analysis.) From the investigation described previously it appeared that the PSV ratio was the best indicator of a high-grade graft stenosis. Therefore a series of cut-off values of this parameter was correlated with the occurrence of primary clinical events by Cumulative Hazard Analysis with the Transient State Method and Kaplan-Meier graphs. It is of note that in this study the only indication for revision of a graft lesion was a stenosis of 70% DR or greater at angiography. The first assessment was for a PSV ratio of 3.0. Of the

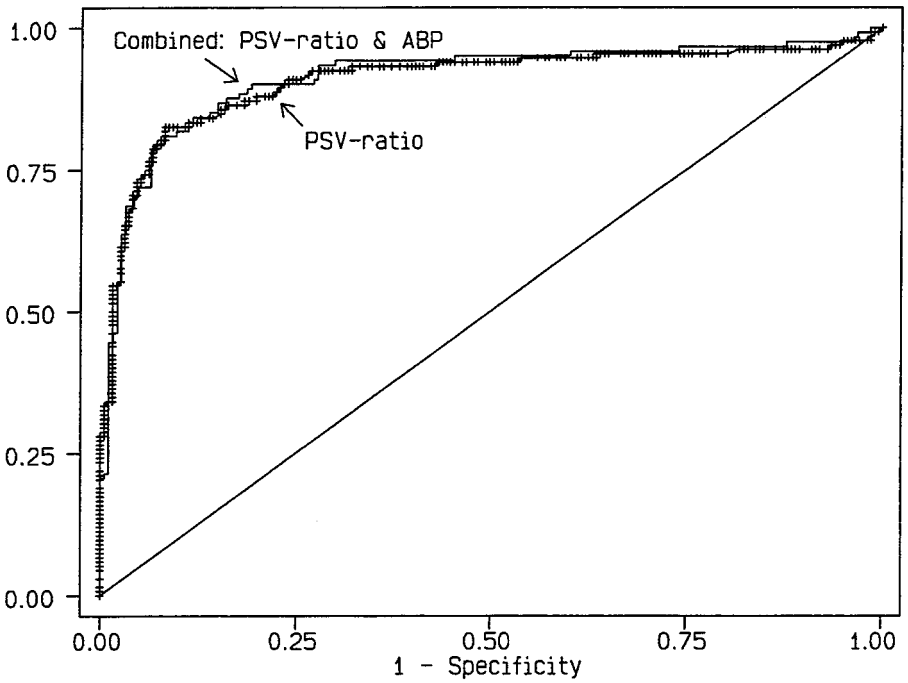

Fig. 2. Receiver operating characteristic curves of PSV ratio and of combined parameter PSV ratio and ABP.

300 patients in the study population, 264 initially had a PSV ratio <3.0 and therefore belonged to group A, whereas 97 patients either had a PSV ratio ≥3.0 at their initial surveillance examination or at a later time during follow-up to be part of group B (Fig. 1, Appendix C). The 18-month primary patency rate of group A was 86%, and in group B it was 15%. Alternatively, these findings may be expressed as NPV, represented by the primary patency in group A, and PPV, which is equal to 100 minus the primary patency in group B. Thus the 18-month NPV of a PSV ratio 3.0 is 86%, and the PPV is 85%. This represents a just moderate agreement with the actual clinical course. Primary events despite a PSV ratio <3.0 occurred in 27 patients, and in 21 patients events failed to appear, although they had a PSV ratio ≥3.0. For clinical application an algorithm based on a single surveillance parameter does not appear sufficiently accurate to replace prerevision angiography.

In 23 patients the PSV ratio progressed from <2.5 to ≥4.0 during the surveillance period. The PPV and NPV of PSV ratios 2.5, 3.0, and 4.0 are represented together in Fig. 3. None of these criteria was entirely correct in indicating whether a primary event would or would not occur, that is, the PPV and NPV were less than 100% (Table V). A PSV ratio of 2.5 was associated with an 18-month patency rate of 89% in group A, whereas a PSV ratio of 4.0 had a patency rate of 7% in group B. If the best predictive values were combined with the use of PSV ratios 2.5 and 4.0 in one algorithm, a better correlation with the occurrence of primary events was obtained than with one cutoff value of 3.0 (Figs. 3 and 4 and Appendix D). The accuracy of this criterion was represented by an NPV of 89% and a PPV of 93% (Table V). If used as an algorithm, the observation of a PSV ratio <2.5 may be interpreted as a graft not at risk, and graft surveillance should be continued. If a PSV ratio ≥4.0 is recorded, a graft is at high risk for failure, and a revision should be scheduled without the need of a pretreatment angiogram. Cases with PSV ratios between 2.5 and 4.0 represent an intermediate risk group, and an angiographic study is indicated to verify whether a stenosis of 70% DR or greater is present.

In Table VI the consequences of the two-parameter algorithm are summarized. If this algorithm had been applied, five patients with a PSV ratio ≥4.0 would have undergone an intervention but in fact had no revision, because their angiographic stenoses were less than 70% (false-positive observations). The angiographic stenoses in these five patients had a DR of 60%, 55%, 55%, 45%, and 40%. Had interventions been performed on the basis of duplex findings,

these may have been considered unnecessary treatment. Twenty grafts had a primary event despite a PSV ratio <2.5 (false-negative observation). This category included a sudden graft occlusion without obvious cause in 8 patients and revision of high-grade lesions on the basis of arteriograms in 12 patients. These latter patients, although they had no signs of a localized velocity increase, still had lesions in the graft, the inflow, or the runoff. Angiograms were requested because of a "low flow state" (PSV graft <45 cm/sec) in seven of these patients and a return of severe symptoms in four patients, and in only one patient the stenosis was detected coincidentally on a protocol-directed control DSA.

Moreover, in the two-parameter algorithm 64 DSAs were required in patients with a PSV ratio between 2.5 and 4.0 (Table VI), whereas a graft revision without angiography would have been scheduled in 61 patients (true-positive diagnosis, i.e., patients with a PSV ≥4.0 and terminal event, Appendix D). This result implied a 49% reduction in DSAs compared with a policy of requesting an angiogram in any patient with a PSV ratio of 2.5 or greater. On the basis of these observations it was concluded that a two-parameter algorithm could be practically applied in a surveillance program to limit the use of angiographic studies.

DISCUSSION

It is generally accepted that the follow-up of patients with infrainguinal vein grafts should be directed toward the identification of failing grafts. At this stage relatively minor procedures can often avert impending graft failure.[19,20] For the identification of grafts with stenotic lesions ABP measurements and more recently duplex and color-flow duplex examinations have been used.[4,21-24] With duplex examinations low-velocity and high-velocity criteria can be distinguished. The former criterion requires only measurements of the PSV at a fixed point at mid-graft level (PSV graft). It has been observed, however, that this criterion has a low sensitivity for focal lesions and that low PSV graft values (low-flow state grafts) are frequently caused by runoff or inflow disease.[13,25,26] At present the most commonly used color-flow duplex examination includes tracing of the entire graft, identification of sites with flow disturbance, and measurement of the PSV at the stenosis. Absolute PSV values and the ratio of the PSV at the stenosis and a normal adjacent arterial segment are used. Threshold values for the PSV ratio vary in the literature from 1.5 to 3.5.[4,10,23,25,27,28]

In this study the correlation of a set of 10 duplex- and ABP-derived parameters, all reported in the literature, were determined. In addition to the parameters described previously, reactive hyperemia tests combined with ABI- and duplex-derived volume flow measurements were included.[29,30] End-diastolic velocities were recorded as well. This variable has been indicated as a correlant with high-grade graft lesions, a relationship of which the hemodynamic background was recently described by Idu et al.[9] and Papanicolaou et al.[31] Correlation of all parameters and the degree of stenosis as measured on the angiograms was performed. All angiographic diameter reductions and surveillance variables were obtained in a strictly uniform fashion in the three institutions that participated in this carefully monitored prospective study. The surveillance parameters were determined by different duplex apparatus by a group of nine vascular laboratory technicians. Nevertheless, correlation of key surveillance and angiographic variables resulted in comparable outcomes in the institutions. With multivariate analysis the PSV ratio and the ABP appeared to be the most important independent predictors of a significant stenosis, overtoning all other parameters. The combination of these two variables, however, provided hardly a better sensitivity and specificity to identify graft stenosis ≥70% than the PSV ratio alone. A PSV ratio >3.0 was a reasonable indicator of the presence of a stenosis ≥70%, with a sensitivity of 80% and a specificity of 84%. Therefore the PSV ratio was used as the only variable for further analysis.

Most vascular surgeons still consider intraarterial DSA mandatory before performing an intervention on a graft stenosis detected by noninvasive surveillance methods. However, there is some variation in the severity of the stenosis that is considered to represent a considerable risk of graft failure. A DR of 50% has been proposed as the critical level by several authors,[4,23,25,32,33] whereas others believe a lesion with a 70% DR indicates a failing vein graft.[2,8-10,13,27] It may be assumed that these differences at least partly account for the variations in the critical PSV ratios that have been reported in the literature. In this study the angiographic DR was measured by radiologists blinded for the findings at duplex examinations. In a validating assessment we found that a 70% threshold correlated significantly with graft failure. Nonrevised stenoses of 50% to 70% had a better patency than stenoses of 70% DR or greater, which fell in the patient category with revisions.

Angiography to confirm a suspected asymptomatic graft lesion is cumbersome, and it causes delay

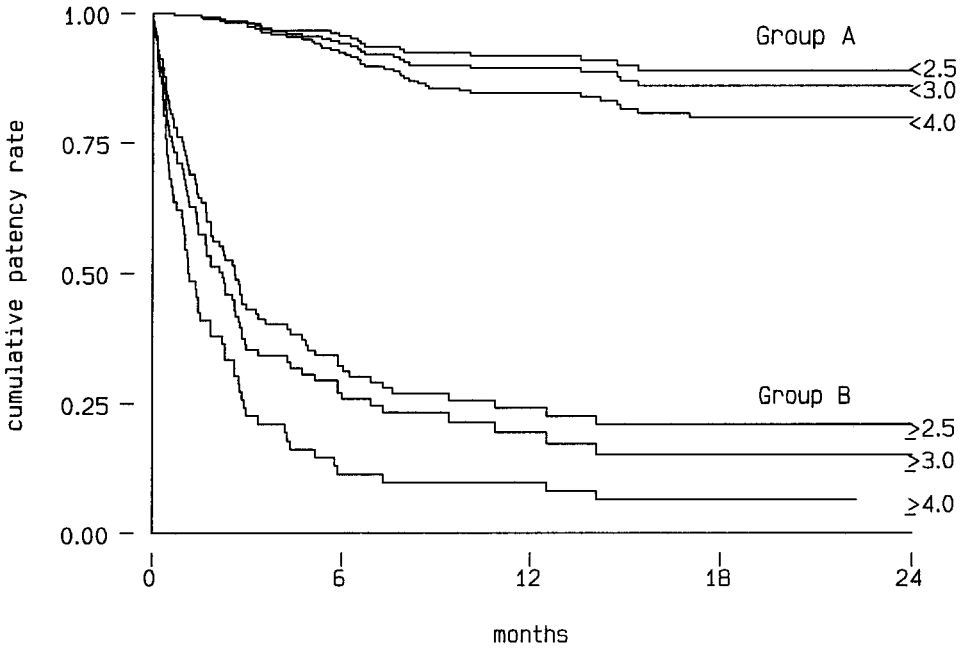

Fig. 3. Primary patency rates represented by Kaplan-Meier curves of patients with PSV ratios less (*upper curves*) or greater (*lower curves*) than 2.5, 3.0, and 4.0 (Transient State Method).

of effective treatment, which may result in graft failure if the stenosis is high-grade. In this prospective study 15 vein grafts with known presence of a stenosis failed during the interval between the last surveillance visit and the intervention. In addition, angiographic evaluation adds considerably to the cost of follow-up, making surveillance programs less cost-effective. A surveillance schedule by which angiography is avoided altogether would be ideal.[11] It was examined whether a single-parameter surveillance algorithm based on a PSV ratio of 3.0 provided such a scheme. However, an NPV of 86% (27 patients false-negative) and a PPV of 85% (21 patients false-positive) was not satisfactory. To compare the positive and negative predictive values of different surveillance parameters, an appropriate statistical technique was used.[18] This statistic is very similar to the log rank statistics, except that group membership is not fixed along time. With Cumulative Hazard Analysis and the Transient State Method using Kaplan-Meier life tables, PSV ratios above a threshold value were considered risk factors, and their agreement with the actual occurrence of primary events was assessed. In this analysis patients with normal PSV ratios served as a pseudocontrol group.

Although not all grafts with a high-grade stenosis occlude and some without lesions still fail, no surveillance algorithm will be perfect. Requirements for an algorithm in our view should include as a first priority the avoidance of unnecessary interventions, which corresponds with a high PPV. The second priority is to miss as few severe stenoses as possible, corresponding with a high NPV. The final requirement is to avoid angiography or at least a portion of it. The two-parameter algorithm outlined in this study distinguished three risk classes for graft failure requiring different management strategies. The algorithm implicated a conservative approach in patients with a PSV ratio <2.5, a revision without preceding angiography with PSV ratios >4.0, and a DSA in patients with PSV ratios between 2.5 and 4.0. The noninvasive diagnostic criteria when correlated with the actual angiographic findings had a PPV of 93% and an NPV of 89%. Of the five patients with a false-positive diagnosis, three had a stenosis greater than 50% at the time of angiography, which

Table V. Prediction of end points of primary patency by different PSV ratios

PSV ratio threshold value	*NPV (%)*	*PPV (%)*
2.5	89	79
3.0	86	85
4.0	80	93

Indicated NPV and PPV represent 18-month value.

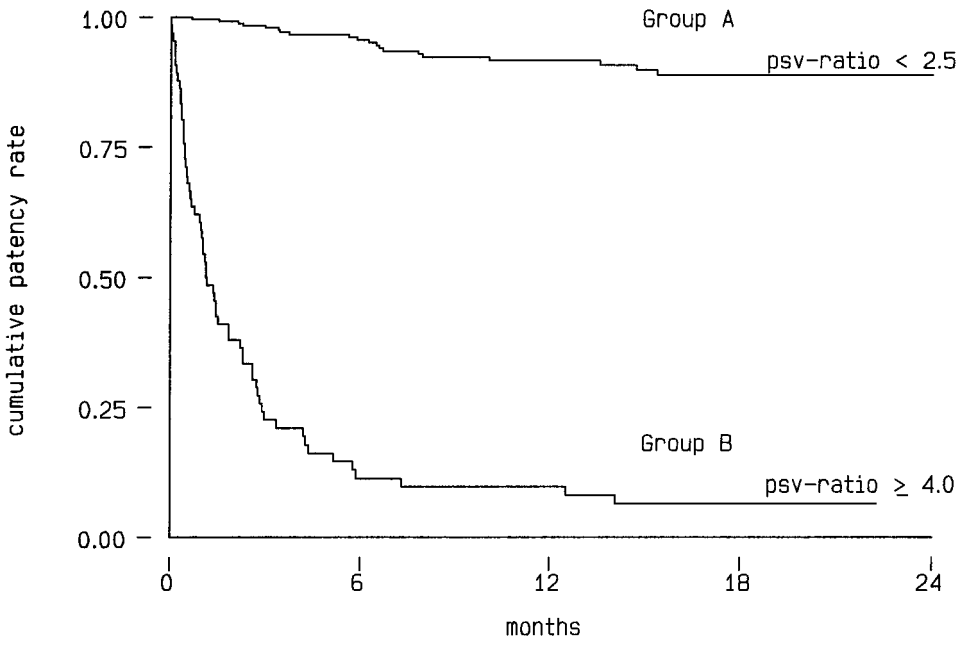

Fig. 4. Primary patency rates represented by Kaplan-Meier curves of patients with PSV ratio <2.5 (group A) and patients with PSV-ratio ≥4.0 (group B) (Transient State Method).

Table VI. Unnecessary revisions, improper no-treatments, and required angiograms with a two-parameter surveillance algorithm

Diagnosis	*Consequences if algorithm was applied*	*No. of patients*
False-positive (PSV ratio ≥4.0)	Unnecessary revisions (of lesions with DR <70%)	5
False-negative (PSV ratio <2.5)	Acute occlusion, or improper no-treatment (despite lesions with DR ≥70%)	20
Uncertain (PSV ratio 2.5 - 4.0)	DSAs required	64

Two-parameter algorithm includes conservative approach in PSV ratios <2.5, DSA in PSV ratios 2.5 to 4.0 to determine the degree of stenosis (as the basis to decide about graft revision) and whether an intervention is indicated, and intervention without angiogram in PSV ratios ≥4.0.

perhaps might have justified a revision. Of the 20 patients with a false-negative diagnosis, 8 had a graft occlusion without any previous duplex or angiographic evidence of a stenotic lesion. We assume that these grafts could not have been salvaged by a revision. Of the other patients, only one had a completely missed stenosis, whereas the other patients had either "low-flow state" grafts or recurrent clinical symptoms. Although these variables are poor indicators of graft stenoses in statistical models, they do have clinical significance and should be considered combined with high-velocity criteria.[33,34] Thus it could be argued that with a structured noninvasive diagnostic protocol and a reduced use of angiography in a series of 300 patients, only 2 with a false-positive diagnosis and 1 with a false-negative diagnosis would have received inappropriate treatment, which seems an acceptably low rate.

The two-parameter algorithm should be evaluated in a future prospective study. Other aspects than the degree of stenosis that may influence planning of interventions are length and multiplicity of lesions. Both features can be studied adequately by modern color-flow duplex equipment. Lesions of less than 1 cm can be scheduled for percutaneous angioplasty and longer lesions for operative repair either by patch angioplasty or by interposition grafting.[35]

In conclusion, of many surveillance parameters the PSV ratio has the best correlation with the angiographic degree of stenosis. An algorithm with two cutoff levels to delineate patient groups with a low, an intermediate, and a high risk of graft failure seems applicable. Clinical management can be based on this decision tree. The number of angiograms during follow-up in patients with a significantly increased PSV ratio can be reduced considerably, because these must be requested in the intermediate group only.

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Appendix A. Life table primary and secondary graft patency analysis for 300 infrainguinal vein grafts

Interval (mo)	*No. grafts at risk*	*No. grafts with terminal events*	*No. grafts withdrawn*	*Interval patency rate*	*Cumulative patency rate*	*Standard error*
Primary patency						
0-3	300	36	3	0.88	0.88	0.02
3-6	261	35	10	0.86	0.76	0.02
6-9	216	26	10	0.88	0.67	0.03
9-12	180	5	25	0.97	0.65	0.03
12-15	150	7	37	0.95	0.61	0.03
15-18	106	3	10	0.97	0.59	0.03
18-21	93	1	18	0.99	0.59	0.03
21-24	74	1	13	0.99	0.58	0.03
24-27	60	0	13	1.00	0.58	0.03
Secondary patency						
0-3	300	2	5	0.99	0.99	0.01
3-6	293	16	11	0.94	0.94	0.01
6-9	266	6	12	0.98	0.92	0.02
9-12	248	2	36	0.99	0.91	0.02
12-15	210	3	44	0.99	0.89	0.02
15-18	163	2	17	1.00	0.88	0.02
18-21	144	0	24	0.99	0.87	0.02
21-24	120	1	22	0.99	0.86	0.02
24-27	97	1	25	0.97	0.84	0.02

Appendix B. Life table secondary graft patency analysis for 300 patients with infrainguinal vein grafts relative to the angiographic diameter reduction (Transient State Method)

Interval (mo)	*No. grafts at risk*	*No. grafts with terminal events*	*No. grafts withdrawn*	*Interval patency rate*	*Cumulative patency rate*	*Standard error*
Angiographic DR <50%						
0-3	117	1	17	0.99	0.99	0.01
3-6	99	0	26	1.00	0.99	0.01
6-9	67	0	6	1.00	0.99	0.01
9-12	67	0	20	1.00	0.99	0.01
12-15	47	0	4	1.00	0.99	0.01
15-18	43	0	16	1.00	0.99	0.01
18-21	27	0	7	1.00	0.99	0.01
21-24	20	0	9	1.00	0.99	0.01
Angiographic DR 50% - 70%						
0-3	36	1	3	0.97	0.97	0.03
3-6	32	1	4	0.97	0.94	0.04
6-9	27	0	4	1.00	0.94	0.04
9-12	23	0	6	1.00	0.94	0.04
12-15	17	0	0	1.00	0.94	0.04
15-18	17	1	5	0.93	0.87	0.07
18-21	11	0	3	1.00	0.87	0.07
21-24	8	0	3	1.00	0.87	0.07
Angiographic DR ≥70%						
0-3	88	13	5	0.85	0.85	0.04
3-6	70	2	2	0.97	0.82	0.04
6-9	66	2	9	0.97	0.80	0.04
9-12	55	1	6	0.98	0.78	0.05
12-15	48	0	11	1.00	0.78	0.05
15-18	37	0	10	1.00	0.78	0.05
18-21	27	0	6	1.00	0.78	0.05
21-24	21	1	3	0.95	0.74	0.06

Appendix C. Life table primary graft patency analysis for 300 patients with infrainguinal vein grafts relative to observed PSV ratio <3.0 or ≥3.0 (Transient State Method)

Interval (mo)	*No. grafts at risk*	*No. grafts with terminal events*	*No. grafts withdrawn*	*Interval patency rate*	*Cumulative patency rate*	*Standard error*
Group A: PSV <3.0						
0-3	264	5	10	0.98	0.98	0.01
3-6	249	9	45	0.96	0.94	0.02
6-9	195	8	21	0.96	0.90	0.02
9-12	166	1	31	0.99	0.89	0.02
12-15	134	3	34	0.97	0.87	0.02
15-18	97	1	11	0.99	0.86	0.03
18-21	85	0	17	1.00	0.86	0.03
21-24	68	0	13	1.00	0.86	0.03
Group B: PSV ≥3.0						
0-3	97	62	2	0.35	0.35	0.05
3-6	33	7	3	0.78	0.27	0.05
6-9	23	3	5	0.85	0.23	0.04
9-12	15	2	4	0.85	0.20	0.04
12-15	9	2	0	0.78	0.15	0.04
15-18	7	0	0	1.00	0.15	0.04
18-21	7	0	3	1.00	0.15	0.04
21-24	4	0	3	1.00	0.15	0.04

Appendix D. Life table primary graft patency analysis for 300 patients with infrainguinal vein grafts relative to observed PSV ratio (Transient State Method)

Interval (mo)	*No. grafts at risk*	*No. grafts with terminal events*	*No. grafts withdrawn*	*Interval patency rate*	*Cumulative patency rate*	*Standard error*
PSV ratio: 2.5						
Group A (PSV ratio <2.5)						
0-3	252	5	8	0.98	0.98	0.01
3-6	239	5	46	0.98	0.96	0.01
6-9	188	6	22	0.97	0.92	0.02
9-12	160	1	31	0.99	0.92	0.02
12-15	128	2	36	0.98	0.90	0.02
15-18	90	1	10	0.99	0.89	0.02
18-21	79	0	12	1.00	0.89	0.02
21-24	64	0	12	1.00	0.89	0.02
Group B (PSV ratio ≥2.5)						
0-3	113	63	4	0.43	0.43	0.05
3-6	46	11	3	0.75	0.33	0.05
6-9	32	5	5	0.83	0.27	0.04
9-12	22	2	4	0.90	0.24	0.04
12-15	16	2	2	0.87	0.21	0.04
15-18	12	0	0	1.00	0.21	0.04
18-21	12	0	4	1.00	0.21	0.04
21-24	8	0	6	1.00	0.21	0.04
PSV ratio: 4.0						
Group A (PSV ratio <4.0)						
0-3	273	7	10	0.97	0.97	0.01
3-6	256	12	32	0.95	0.93	0.02
6-9	212	15	17	0.93	0.86	0.02
9-12	180	2	30	0.99	0.85	0.02
12-15	148	4	41	0.97	0.82	0.03
15-18	103	2	11	0.98	0.80	0.03
18-21	90	0	18	1.00	0.80	0.03
21-24	72	0	13	1.00	0.80	0.03
Group B (PSV ratio ≥4.0)						
0-3	66	51	0	0.23	0.23	0.05
3-6	15	7	1	0.52	0.12	0.04
6-9	7	1	0	0.86	0.10	0.04
9-12	6	0	0	1.00	0.10	0.04
12-15	6	2	0	0.67	0.07	0.03
15-18	4	0	1	1.00	0.07	0.03
18-21	3	0	2	1.00	0.07	0.03
21-24	1	0	1	1.00	0.07	0.03

DISCUSSION

Dr. Joseph L. Mills (Tucson, Ariz.). Dr. Idu, Dr. Buth, and associates have just presented in detail the results of a careful prospective duplex surveillance study of 300 patients who underwent infrainguinal vein bypass grafting. This study was a multicenter trial that was performed at three centers of excellence in The Netherlands and that typifies the meticulous and thoughtful analysis of data for which these authors are known. The following two objectives were stated for the study: first, to assess the accuracy of various duplex parameters to detect graft stenosis and, second, to investigate whether graft revision without angiography is justifiable.

With regard to the first objective, the authors evaluated 10 different parameters that included peak systolic velocity at the site of the stenosis, velocity ratio, and ABI, and they determined that velocity ratio was the most accurate predictor of the prevalence of a greater than 70% stenosis as determined by angiography. With both standard and rather complex statistical methods that included ROC curves and the transient state methodology, the authors determined that a velocity ratio of 3 had a better correlation with a high-grade stenosis than a ratio of either 2.5 or 4. This conclusion leads to my first question.

Did the authors evaluate the sensitivity, specificity, and accuracy of a velocity ratio of 3.5? This velocity ratio has been determined and derived independently by multiple North American investigators, including Dr. Joseph Sladen in British Columbia and Strandness's group in Seattle. This ratio was confirmed recently in a prospective study by our own group and published in January 1997. We noted that for regression or stabilization of 20 lesions in a series of 101 consecutive vein grafts, the mean velocity ratio for lesions that resolved completely was 3.2. This ratio exceeds the threshold value recommended here by the authors.

Anecdotally, over the last 5 years we have followed over 300 grafts, and we have had only one graft with a ratio that exceeded 3.5 in which the stenosis actually resolved completely. I think that clinically useful threshold criteria for repair are more accurately obtained from serial observations of graft flow of abnormalities over time than by any overreliance on angiography.

Now, the authors did report confirmation that grafts with serial normal surveillance studies have an extremely low failure rate. In addition, they recommend repair of all graft lesions that have high-grade stenoses with ratios that are greater than 4. Lastly, they suggested performing angiography of all grafts with intermediate stenoses. I maintain that the angiography of grafts of intermediate lesions is unnecessary and will increase rather than decrease the use of angiography. Intermediate lesions—which we have defined as stenoses with peak systolic velocities that are less than 300 cm / sec and velocity ratios that are between 2 and 3.4—should merely be subjected to continued surveillance, albeit at increased frequency, perhaps every 4 to 6 weeks. We have found that with this method more than half of intermediate lesions stabilize or regress completely, and this follow-up approach avoids unnecessary angiography or repair. However, about 45% of these lesions progress and require repair. With this approach, we then have a minimal rate of spontaneous graft thrombosis, and the period of resolution or progression usually occurs over a span of 4 to 5 months.

Finally, I would like to emphasize that to perform duplex surveillance and base the decision for intervention on high-velocity criteria such as the velocity ratio would be unreasonable. Low-velocity criteria, such as a drop in ABI or the development of a low graft flow state that is less than 45 cm / sec, may not be statistically significant but are highly clinically significant when present. In this series, 84 grafts ultimately required revision, and 12 of those grafts were identified because the graft flow velocity or the ABI fell, although no focal increased peak systolic ratio was within the graft. Arteriography thus would be mandatory in such cases to identify graft-threatening inflow or outflow lesions and potential stenoses that could be missed by duplex.

I have three brief questions:

1. Did the authors evaluate the specificity, sensitivity, and accuracy of the velocity ratio of 3.5?
2. Would the authors agree that low-velocity criteria, which perhaps are not statistically significant, are very useful clinically and that a velocity ratio by itself should not be a sole criterion to dictate intervention?
3. Why subject intermediate grade lesions to angiography? One of the main advantages of duplex ultrasound is that the technique is noninvasive and permits serial observations. Thus duplex ultrasound would avoid both angiography and unnecessary operation by serial observations of the intermediate lesions.

Finally, I would agree generally that preoperative angiography is unnecessary in many lesions, particularly if the lesions have been followed over a long period. However, a graft should be assessed completely in the operating room with angiography or duplex scanning, because it is well known that duplex scanning has a weakness of discovering the first stenosis in a series. Yet, for example, when a high-grade proximal stenosis exists, a distal stenosis may be missed if the entire graft is not assessed.

I would like to thank the authors, and I recommend the reading of their manuscript, which is complete and meticulous. I would also like to thank the Society for the privilege of discussion.

Dr. Jacob Buth. Dr. Mills, thank you for your comments. We studied your previous work and your articles extensively during the preparation of this study and manuscript.

You advised the use of duplex ultrasound studies with increased frequency instead of arteriography in the group that we defined as having the intermediate risk. That method has pros and cons. Obviously, the number of angiograms performed during follow-up can be reduced, but is this reduction safe? In this study, 64 patients fell into the intermediate category, and about 20 primary events occurred, among which were five occlusions and 15 revisions. These 15 revisions, if they had not been discovered immediately by an angiogram, would have been subjected to continued surveillance. The period for which the patients were at risk would be prolonged, and they may have had occlusion in the interval. These 15 patients, if they had all had occlusion, would make up for a total decrease of the secondary patency rate in the overall series by 5%.

Your first question asked whether we investigated the sensitivity, specificity, and predictive values of other duplex ratios, in particular a ratio of 3.5? Yes, we did, and a number of these transient-state curves were shown, but we found that 3.0 was the most precise cutoff value, and we stuck to it. We did not use the 3.5 threshold.

You mentioned that regression was a possibility and would appear in a sizable proportion of the patients. According to the literature—which included your own studies—only a minority actually regress. The total number of patients who progress and remain stable is larger than the number of patients who regress. We admit that the regression lesions would benefit most from a protocol of continued surveillance, but the progressive lesions are the ones that cause worry.

We are safer performing an angiogram in the intermediate category, determining the precise angiographic severity of the lesion, and, if the severity is less than 70%, continuing surveillance from there. At this point we have evidence that an angiographic reduction of 70% or greater is the most solid criterion for a graft at risk for failure.

You have reconfirmed our observation that even in an algorithm that uses the most optimal criterion of a PSV ratio some additional criteria are useful, in particular the low velocity criteria, the low-flow state of the graft, and the return of severe symptoms that invariably are associated with a reduction of the interval ankle blood pressures. I think we have shown that the decisions of when to intervene or do an angiogram cannot be made completely on a computerized algorithm.

I think that I have answered most of your questions. Your recommendation of performing an intraoperative angiogram or an intraoperative duplex scan during the procedure is a good point that I think most people follow as we do.

Dr. J. Dennis Baker (Los Angeles, Calif.) My question addresses in part the topic you just mentioned. My concern about operating on the basis of just the duplex scan is that a percentage of these lesions are not focal stenoses that are easily repaired but are stenoses that may have either a focal stenosis with a long stricture distal to it or just a long segment of stricture. In our experience we have not been able to identify these long lesions very accurately, which is one of the reasons we have used angiography at some point before the repair. Have you encountered this type of lesion? We have seen this lesion in primarily in situ–type reconstructions.

Dr. Buth. Dr. Baker, I agree that we have focused on just one aspect, the severity of stenosis, but the other characteristics of stenosis are important, too. For instance, length determines the choice between treating a graft stenosis by balloon angioplasty or by surgery, which makes a lot of difference in your planning. However, we feel that with the modern color-flow duplex equipment you usually are able to determine the length of the stenosis, multiplicity, and runoff lesions that coincide with the graft stenosis.