Factors Affecting Symptomatic vs Asymptomatic Vein Graft Stenoses in Lower Extremity Bypass Grafts

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Objective: To determine differences in patients undergoing lower extremity vein graft revisions presenting with and without recurrence of preoperative symptoms.

Design: Retrospective case-control study of a prospectively maintained database.

Setting: University and veterans' administration hospitals

Patients: Two hundred nineteen lower extremity vein graft revisions were performed in 161 patients from January 1995 to January 2007. Patients were categorized as asymptomatic or symptomatic (recurrence of initial symptoms) at the time of revision.

Main Outcome Measures: Univariate analysis was performed to assess differences in patient demographics, details of initial operation, site of recurrent lesion, and follow-up surveillance data between symptomatic and asymptomatic patients. Independent predictors of symptomatic recurrence were identified with multivariate logistic regression. Primary assisted patency was compared between revisions performed for symptomatic and asymptomatic lesions.

Results: Vein graft stenoses were asymptomatic in 125 cases (57%) and symptomatic in 94 cases (43%). Symptomatic recurrences were associated with a significantly greater drop in ankle brachial index than asymptomatic lesions (mean [SD], 0.21 [0.03] vs 0.11 [0.02]; P=.003). Distal graft or outflow lesions were significantly associated with symptom recurrence (P=.048). Multivariate analysis identified ankle brachial index decrease (odds ratio, 6.803; 95% confidence interval, 1.418-32.258; P=.02) and the use of alternate graft conduit (odds ratio, 2.633, 95% confidence interval, 1.243-5.578; P=.01) as independent predictors of recurrent symptoms. Overall 5-year patency was the same regardless of preoperative symptoms (82% symptomatic and 88% asymptomatic; P=.30).

Conclusions: Symptomatic recurrences are associated with larger decreases in ankle brachial index, distal lesions, and alternate conduit grafts. Duplex surveillance is necessary to identify asymptomatic vein graft stenoses. Because graft patency is independent of preoperative symptoms, surveillance consisting of clinical follow-up with ankle brachial index evaluation warrants further consideration.

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It is recognized that lower extremity vein grafts occasionally develop stenoses that threaten the patency of the graft. Approximately 20% to 30% of lower extremity vein grafts are treated for critical stenoses, either surgically or endovascularly.1,2 Most stenoses are found as part of a duplex surveillance program. Criteria for revision vary from center to center. In general, a focal peak systolic velocity (PSV) exceeding 300 cm/s or a prestenotic to intrastenotic systolic velocity ratio exceeding 3:4 are indications for either surgical or endovascular repair.3,4

One of the reasons for regular duplex surveillance is that not all vein graft stenoses are associated with symptoms. Asymptomatic vein graft stenosis is common, though the reasons for this are not known. This study was undertaken to assess differences in vein graft stenoses that present asymptptomatically compared with those that present with recurrence of symptoms.

METHODS

Patients (maintained in a prospective database) undergoing lower extremity vein graft revisions at the Oregon Health & Science University and Portland Veterans Administration Hospital from 1993 to 2007 were included in the study. Information in the database included patient demographics, operative indication, operative details (inflow, outflow, and conduit), vascular laboratory follow-up data, details of surgical revisions, and long-term follow-up data following revision. At the time of revision, it was recorded whether or not the pa-
tient had recurrence or worsening of symptoms or had an asymptomatic stenosis. Symptomatic recurrences were defined as recurrence or worsening of intermittent claudication, rest pain, or ischemic ulcers.

Criteria for considering vein graft revision included a focal PSV in the graft of greater than 300 cm/s, a preintralesional to intrastenotic velocity ratio of greater than 3.5:1, uniformly low PSVs throughout the graft (suggesting either inflow or outflow disease outside of the graft), or a change in clinical status. All patients underwent arteriography either prior to the vein graft revision or intraoperatively to confirm the presence and severity of stenosis. Intraoperative assessment of the revised graft included arteriography, duplex scanning, or continuous wave Doppler analysis at the discretion of the surgeon. The types of surgical revision included vein patch angioplasty for focal (<2 cm) lesions or vein interposition grafts for longer lesions or lesions that involved the native arterial inflow or outflow. All data were stored in a password-protected Microsoft Access 2003 database (Microsoft Corp, Redmond, Washington).

The focus of this article is to determine differences in grafts and patients who presented with symptomatic vs asymptomatic recurrences. Univariate analysis included independent samples t test for continuous variables, χ² analysis for categorical variables, and the Mann-Whitney test for ordinal variables. Continuous variables are presented as mean (SD) unless otherwise specified. All variables with a P value < .05 were entered into a stepwise logistic regression model to assess independent risk factors for symptomatic recurrence. The validity of the logistic regression model was evaluated with the Hosmer-Lemeshow goodness-of-fit test, which accounts for both continuous and categorical predictors for symptomatic recurrence. Differences in patency curves were assessed with log-rank analysis. All statistical analyses were performed with SPSS, version 15.0 (SPSS Inc, Chicago, Illinois).

RESULTS

During the study period, 219 lower extremity vein graft revisions were performed in 161 patients. Ninety-four revisions (43%) were performed for symptomatic stenoses and 125 (57%) were performed for asymptomatic stenoses. One hundred forty-seven revisions (65%) were performed within 1 year of the initial operation, 32 (15%) were performed between 1 and 2 years, and 45 (20%) were performed more than 2 years after. Symptomatic stenoses were significantly more frequent in revisions performed between 1 and 2 years (34%) than within the first year (37%, P = .003). Median follow-up of all grafts was 30 months (mean, 43.9 [42.7] months). Patient, graft, and surveillance characteristics for asymptomatic and symptomatic stenoses are presented in Table 1.

In the univariate analysis, no demographic characteristics were significantly different between patients with symptomatic or asymptomatic stenoses. There was a strong trend for symptomatic recurrence in patients with other manifestations of systemic atherosclerosis. A history of coronary artery disease was present in 62% of patients with symptomatic stenosis vs 49% in patients with asymptomatic stenoses (P = .06). A history of cerebrovascular disease was present in 38% of patients with symptomatic stenoses vs 26% in patients with asymptomatic stenoses (P = .06). These factors, along with a history of hyperlipidemia (P = .15), were subsequently entered into the multivariate model.

Characteristics of the original operative procedure are presented in Table 2. In univariate analysis, the details of the initial operation did not significantly predict symptomatic recurrences. There were some nonsignificant trends toward a greater number of symptomatic stenoses in patients whose initial operation was for critical limb ischemia (P = .17) and in patients in whom alternate vein bypasses (arm vein and composite vein) were performed (P = .06). Original graft inflow (P = .11) and outflow (P = .18)
were also nonsignificant predictors of symptomatic recurrence, with a higher percentage of symptomatic recurrences arising from the profunda femoral artery (36% vs 24%) and anastomosed distally to a tibial artery (63% vs 53%). The time interval between the initial operation and revision did not influence the nature of symptoms at the time of recurrence. Indication, conduit, and graft inflow and outflow were all entered into the multivariate model.

When patients did have a symptomatic lesion, the recurrent symptoms closely correlated with their symptoms prior to the initial operation. When the initial operation was performed for claudication, all recurrent symptoms were also claudication. When rest pain was the initial operative indication, recurrent symptoms were rest pain in 64% of cases, claudication in 22%, and ulcers or gangrene in 14%. When the initial operation was performed for ischemic ulcers or gangrene, recurrent ulcers or gangrene was present in 62% of symptomatic recurrence, with claudication in 14% and rest pain in 24% of cases.

Table 3 details the sites of stenoses in both symptomatic and asymptomatic vein grafts. Lesions involving the inflow proximal to the graft or involving the proximal graft did not predict the nature of symptomatic recurrence in univariate analysis. In contrast, patients with asymptomatic recurrence were more likely to have a midgraft lesion (26% vs 15%, \( P=.05 \)), while patients with symptomatic recurrences were more likely to have a lesion involving the distal part of the graft or native arterial outflow (30% vs 18%, \( P=.048 \)). Both midgraft lesions and distal lesions were entered into the multivariate model.

The effect of follow-up surveillance data on symptomatic recurrences is listed in Table 4. Patients with recurrent symptoms had a lower ankle brachial index (ABI) at the time of revision and a larger drop in ABI from the time of prior surveillance (Figure 1). There was a strong linear correlation between ABI at the time of revision and change in ABI (\( R^2=0.578, P<.001 \)) (Figure 2). The change in ABI is a more relevant clinical marker in a duplex surveillance program and therefore, to prevent confounding, only change in ABI was entered into the multivariate model, as including both terms would not beneficially add to the parsimony of the multivariate model.

Change in ABI was also examined as an ordinal variable (category 0, change in ABI = 0; category 1, change in ABI = 0.0-0.2; category 2, change in ABI = 0.2-0.4; category 3, change in ABI ≥ 0.4). As seen in Figure 3, there...
were significantly greater asymptomatic stenoses in the lower ABI categories (P = .005, Mann-Whitney test). Lesions were asymptomatic in 70% of category 0 patients, 63% of category 1 patients, 43% of category 2 patients, and 45% of category 3 patients (P = .03, χ² test) (Figure 4).

Peak systolic velocities were lower in patients with symptomatic recurrence. There were 29 revisions performed for uniformly low PSVs throughout the graft. The data were filtered to remove these cases, which resulted in a reduction in the difference between PSV in symptomatic and asymptomatic cases. However, symptomatic cases still demonstrated a lower PSV.

Owing to a greater number of symptomatic cases that had distal lesions, PSV was stratified by location of lesion. Proximal (inflow, proximal anastomosis, and proximal graft) and midgraft lesions had similar mean PSVs (415 ± 105 cm/s vs 406 ± 132 cm/s; P = .70, analysis of variance with Bonferroni correction), while distal lesions (distal graft, distal anastomosis, and outflow) had significantly lower mean PSVs (347 ± 108 cm/s; P = .01, analysis of variance with Bonferroni correction). Because absolute PSV was confounded by lesion site, only lesion site was entered into the multivariate model.

A backward stepwise logistic regression model was created with the absence or presence of symptoms as the dependent variable, and the previously noted variables (hypercholesterolemia, coronary artery disease, cerebrovascular disease, graft conduit, operative indication, graft inflow, graft outflow, midgraft lesion, distal lesion, and change in ABI) as independent variables. The backward stepwise model begins with all factors entered in the model and then removes nonsignificant factors in a stepwise fashion, such that only statistically significant factors are retained in the final model. In the final model, use of an alternate conduit (odds ratio, 2.633; 95% confidence interval, 1.243-5.578; P = .01) and change in ABI (odds ratio, 6.803; 95% confidence interval, 1.418-32.258; P = .02) were significant predictors of recurrent symptoms at the time of revision. No other factors were significant in the multivariate model. There was a nonsignificant trend toward the presence of a midgraft lesion predicting asymptomatic lesions (odds ratio, 2.307; 95% confidence interval, 0.957-5.561; P = .06).

Assisted primary patency of revised grafts at 1, 3, and 5 years, respectively, was 94.0%, 84.5%, and 82.1% in patients presenting with symptoms and 96.9%, 93.1%, and 87.8% in patients presenting with asymptomatic stenoses (P = .30, log-rank test) (Figure 5).

**COMMENT**

This study differentiates and defines patients with lower extremity vein graft stenoses who present with recurrent symptoms vs those who present with asymptomatic stenoses. Historically, 20% to 30% of patients undergoing lower extremity vein grafts develop graft stenoses, most frequently within the first year. However, the reason for the symptomatic nature of stenoses has not been defined. The results of the univariate analysis in this study sug-
gested multiple features—including patients’ demographic factors, graft and operative characteristics, and surveillance data—that predicted the recurrence of symptoms with the development of vein graft stenoses.

There were no demographic factors that were significantly predictive of symptomatic recurrence in either univariate or multivariate analysis. There was a strong trend toward significant symptomatic recurrence in patients with more severe disease at the outset or patients who had already undergone previous revascularization procedures in the same leg. This was also demonstrated in our previous study in which patients with profunda femoral inflow were more likely to have multiple lesions that were not completely delineated on duplex surveillance. Others have shown the increased need for revision in tibial bypasses. In contrast, patients with saphenous vein grafts arising from the common femoral artery and going to the popliteal artery had a trend for asymptomatic recurrence.

In the multivariate model, the use of alternate conduit was a significant predictor of symptomatic recurrence. Alternate conduit bypass grafts are clearly disadvantaged from the outset; nonetheless, excellent patency can be achieved with these grafts. Armstrong et al recently demonstrated a 3-year assisted primary patency of 91% in brachial vein bypasses, though half of all brachial vein grafts required revision and one-third required more than 1 revision. These revisions were based on duplex surveillance data, and the symptomatic nature of these lesions was not reported.

Lesion site was a strong predictor of symptomatic recurrence. Lesions of the graft inflow or proximal portions of the graft did not predict symptomatic recurrence. Isolated lesions within the body of the graft were more frequently asymptomatic, while lesions involving the distal graft or arterial outflow were more likely to be symptomatic. The clinical significance of proximal inflow lesions as a threat to graft patency has been questioned. One could certainly argue that asymptomatic proximal graft lesions can be managed conservatively and that the routine surveillance of this region of the graft may be unnecessary. Likewise, routine surveillance of the graft outflow may be unnecessary. Since these lesions are more likely to present with clinical symptoms and changes in ABI, clinical follow-up alone is probably sufficient. Duplex surveillance therefore seems most appropriate for the midbody of the graft, where high-grade lesions can occur without recurrent symptoms and with minimal ABI changes.

In this study, there was no significant patency difference between grafts that presented with asymptomatic stenoses and those that presented with symptomatic stenoses. This leads to the question of whether duplex surveillance is necessary at all following the placement of lower extremity vein grafts or if it is sufficient to follow patients clinically and wait until symptoms recur before assessing the graft. This was recently addressed in a multicenter randomized trial from the United Kingdom. In this study, there were no differences in patency, limb salvage, or health-related quality of life between the groups that were observed with clinical and duplex surveillance. However, costs incurred were significantly greater in the group observed with duplex surveillance. Approximately one-third of patients in this study had claudication, with only one-third of bypasses performed in vessels distal to the popliteal artery, and more than 90% of grafts performed in the saphenous vein. Thus, it is not clear how these data apply to a group of patients with more compromised graft anatomy.

In contrast, in a similar study by Fasih and associates, 97 patients with claudication and critical limb ischemia who were undergoing revascularization were randomized to clinical vs duplex surveillance. In this study, graft patency and limb salvage were significantly greater in the duplex surveillance group at both 1 and 3 years, suggesting the importance of ongoing duplex surveillance.

It has been shown that the failure to undergo early duplex surveillance following bypass is an independent risk factor for lower extremity reversed vein graft occlusion. In a previous study, Giswold et al demonstrated that failure to undergo duplex scanning within the first 3 months following bypass resulted in a hazard ratio of 2.43 (95% confidence interval, 3.07-13.51; P < .001) for graft occlusion. Others have also demonstrated beneficial effects of early duplex surveillance, with an increased incidence of significant graft stenoses in patients with early duplex abnormalities, an increased threat to graft patency in unrevised lesions, and an increased cost of treating graft occlusions within the first year vs prophylactic repair of graft-threatening lesions.

Duplex surveillance beyond the first year is more controversial. The majority of vein graft stenoses occur within the first year though, in this and previous studies, as many as one-third of graft revisions occur after the first year. The finding in this study that the majority of revisions after the first year were related with symptoms supports the argument that less vigilant duplex surveillance beyond the first year is justified. However, clinical follow-up remains important. A weakness of the data in our study is that it includes only patients who underwent revision and does not include patients whose grafts occluded without revision. Nonetheless, accumulating data suggest that a reappraisal of the role of duplex surveillance following lower extremity vein grafts is warranted. Aggressive duplex surveillance in the first year after bypass followed by less frequent, primarily clinical follow-up with ABI assessment thereafter may be an appropriate surveillance strategy.

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REFERENCES


DISCUSSION

James Peck, MD, Portland, Oregon: The Achilles heel of autogenous vein bypass grafting for infrarenal arterial reconstruction is vein graft stenosis. This lesion most commonly results from preexisting conduit defects or intimal hyperplasia that develops after arterIALIZATION. Szilagyi 34 years ago identified these lesions in a third of 377 patient vein bypasses using arteriograms.

Duplex ultrasound surveillance is now widely accepted. Vein grafts with no stenosis do well. Those with critical stenoses do not do well. High-grade stenoses are frequent precursors to thrombosis. Early-appearing lesions noted at the first duplex ultrasound postop or lesions that are already there when we implant the graft are more aggressive than lesions detected later.

The focus of this paper was to determine the differences in patients with lower extremity vein bypass grafts who presented with symptoms compared to those who were asymptomatic. In this study, 219 patients over 12 years, 1 to 2 patients a month were revised; 57% were asymptomatic.

In symptomatic patients, the simple change in ABI was the most relevant clinical marker. Patients who were asymptomatic were more likely to have midgraft lesions, while symptomatic patients were more likely to have a stenosis in the distal part of the graft or the native arterial outflow. Alternative conduits (arm veins) were significant predictors of recurrent symptoms.

Assisted primary patency of the revised vein grafts at 1, 3, and 5 years in asymptomatic patients was 97%, 93%, and 88%; but even in symptomatic patients it was 94%, 88%, and 82%, with no significant patency difference.

At this time, arteriosclerosis is incurable. With recent advances in medical and cardiac care, some series have reported 50% survival at 10 years. My own bias and the authors Landry and Moneta are published proponents of duplex ultrasound surveillance for the life of the graft. Even the best lower extremity vein graft is at risk due to progression of disease many years after successful implantation. Landry and Moneta in the Journal of Vascular Surgery in 2002 documented excellent patency of revised grafts through 10 years and recommended “an aggressive regimen of duplex surveillance for the life of the graft.”

As John Porter used to say “what is remarkable here” is that this paper concludes with the statement “a reappraisal of the role of duplex surveillance following lower extremity vein graft is warranted,” since the majority of the revisions after the first year were symptomatic and identifiable with clinical follow-up alone and a change in the ankle brachial index. Symptomatic proximal graft lesions can be managed conservatively and routine surveillance is thus superfluous. Likewise, routine surveillance of graft outflow is superfluous, since clinical follow-up and simple ABI is all that is needed.

A major consideration within the current health care climate is cost-effectiveness. A duplex surveillance program is expensive to establish, expensive to maintain both the machine and the trained vascular technologist, and expensive to fund additional interventions. All patients in this series had arteriography. Arteriography is expensive and occasionally morbid.

The authors cited a 2005 article in Circulation of 594 patients in a multicenter, prospective, randomized, controlled trial from the UK. It showed no improvement in limb salvage or quality of life with duplex ultrasound surveillance, only an increase in cost.


Jour-
clusion. How many grafts were occluded without revision in this 12-year time span? (4) Finally, based on this study, what is your current recommendation for the practicing vascular surgeon in the community? Is less vigilant duplex ultrasound surveillance after the first year reasonable?

Dr Moneta: Thank you very much, Dr Peck. We are grateful for the opportunity to present these data. I emphasize that no matter what axiom you have in surgery, you have to continue to reexamine your methods of doing things based on new data. The UK study that was alluded to in both Dr Landry’s talk and in Dr Peck’s discussion was a good study although I do not necessarily agree with all the conclusions. In that study, beyond 1 year, the trend was for better limb salvage with routine surveillance, but that was not a primary end point of the study.

With respect to Dr Peck’s questions, he asked about intermediate velocity levels. We do worry about vein grafts where the peak systolic velocity exceeds 200 cm/s or where the velocity ratio exceeds 3. On the other hand, those grafts aren’t routinely revised. Those patients are ones we try to bring back for more frequent surveillance studies. Revision is pretty much limited to grafts with velocity ratios greater than 3.5:4 and peak systolic velocities greater than 300 cm/s. There are very few revisions for those lower levels of velocities.

With respect to angiography, essentially all of the patients underwent angiography preoperatively. In recent years, we have done some more intraoperative angiograms. I recall a few false-positive duplex studies where the angiogram was normal and indicated a possible reason for a false-positive duplex examination, such as a nearby collateral vessel. I therefore tend to try to get the angiogram preoperatively to avoid a potentially unnecessary trip to the operating room. When there is nonconcordance between the angiogram and the duplex study, I believe the duplex study. If there is even a minimal angiographic abnormality in the area of the elevated velocity, I will perform a revision. I haven’t been disappointed with that policy.

Dr Peck asked about patient risk factors for those whose grafts occluded and weren’t revised. We have addressed this issue in a previous paper. The two biggest risk factors for unheralded graft occlusion in our practice are failure to return for surveillance and being on warfarin. I believe warfarin indicates a group of patients with high-risk grafts. Probably, it is an ineffective therapy for high-risk grafts.

Finally, Dr Peck wanted to know if there was any reason to continue surveillance after the first year postoperatively. Until I am convinced that we can get patients to recognize vascular-related symptoms and reliably return to the physician when they have symptoms, especially if they have a high-risk conduit, I think we should continue surveillance beyond the first year for most patients in the fashion that we have been doing. I am, however, willing to consider that a good-quality saphenous vein to the popliteal artery that hasn’t had any trouble for the first year may be one that we can follow less intensely.

Cornelius Olcott, MD, Stanford, California: Dr Moneta, thanks a lot. I enjoyed your paper. I would like to flip this around a little bit and ask a question about a problem that plagues us at Stanford, and that is the patient who is asymptomatic and has a normal duplex study but shows up a few months later with an occluded graft. I think our laboratory is pretty good though probably not flawless, but every year we have 3 or 4 patients that occlude their graft between surveillance appointments. We follow very much the same surveillance protocol you do because of John Harris’ and Ron Dalman’s training at Oregon. These patients are asymptomatic and they have a good duplex that does not show any significant findings, and then between duplex evaluations they present with an occluded graft. This obviously is perplexing and it’s the very problem you are trying to prevent by prophylactic duplex scanning. I wonder if you have any thoughts about how to avoid this particular problem and prevent graft failure.

Dr Moneta: We have had the same experience you are describing. There is an occasional patient that comes back with a graft that is occluded and the previous duplex study seemed adequate and normal and the patient had no symptoms. I don’t know how to identify those patients. I assume a few of them are patients in whom we missed the lesion. Some may occur for reasons unrelated to graft stenosis. It is a source of frustration. Fortunately it doesn’t happen all that often. I don’t think it means we should stop surveillance because of this occasional unexpected graft occlusion.

Steve Etheredge, MD, Oakland, California: Greg, another nice paper from Oregon. We appreciate that. I was wondering if you could stratify somewhat your lesions. Were any of these atherosclerotic inflow lesions? Were these valve ring stenosis? Were these segments of veins that were just inadequate? What is the real cause of what you have going on, not just the stenotic process, but what was the cause of the stenotic process?

Dr Moneta: I think the stenotic process in most cases is an intimal hyperplastic lesion within the vein graft. We have looked at other people’s data and our own data and backed off from revising most asymptomatic inflow arterial lesions. Those patients seem to do okay without revision.

The large majority of the revisions were for lesions within the graft or it’s at the anastomoses, and occasionally for an atherosclerotic lesion just beyond the anastomosis. I guess well over 90% of the revisions were for intimal hyperplastic lesions either in the graft or at an anastomosis.

Fred Weaver, MD, Los Angeles, California: Greg, since you have been a leader in this area, I thought I would take the opportunity to see how you are managing these vein graft stenoses and changes that have occurred in your management over the years. First, do you routinely, at the close of operation, do a completion study, and is it a completion duplex or arteriogram? I ask this because of the finding that proximal inflow lesions were a major source of vein graft stenosis. In our own experience with completion duplex where we imaged the entire graft, we found our proximal anastomoses to be more of a problem than the distal anastomoses. This finding actually made us more technically attentive to the proximal anastomosis and lowered our incidence of proximal graft stenoses.

The second question is once you find a stenosis, are you routinely repairing these by open methods or have you moved toward endovascular treatment with the cutting balloon technology? And finally, when you categorize into symptomatic and asymptomatic, this is kind of a simplistic question, but what do you mean by symptomatic? Are we talking about somebody coming back with a new ulcer, toe gangrene, or is it just extremity pain? If it is extremity pain, how in your database do you distinguish pain from osteoarthritis vs claudication vs neurogenic pain?

Dr Moneta: I will try to answer your questions in order. With regard to completion studies, my personal tendency has been to just use continuous wave Doppler. Some of my other colleagues now will routinely or almost routinely do an angiographic completion study at the end of the procedure. We don’t use intraoperative duplex routinely.

In the past, all revisions were done open. Now, many are done with endovascular techniques. We’re a little picky on which ones to do endovascularly. Candidates for endovascular revision are focal lesions, in a relatively good-sized vein graft that has been in place more than 3 months. A very early graft stenosis, a long stenosis, or stenoses in smaller caliber grafts I think should be revised surgically.

It is very difficult sometimes for the patients to distinguish what are important symptoms. For this study, we tried to be a little careful about that. Symptoms were a new ulcer, new or recurrent gangrene, and/or recurrence of classic claudication symptoms.

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