

Influence of Procedural Success on Immediate and Long-Term Clinical Outcome of Patients Undergoing Percutaneous Revascularization of Occluded Coronary Artery Bypass Vein Grafts

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Objectives. This study sought to determine whether successful recanalization of an occluded vein graft is associated with improvement in long-term clinical outcome.

Background. Coronary angioplasty of occluded vein grafts is associated with a lower initial success rate and a higher complication rate than angioplasty of vein grafts with subtotal stenoses and native coronary arteries. Whether successful angioplasty improves clinical outcome is unknown.

Methods. We analyzed 77 consecutive patients who underwent angioplasty of an occluded saphenous vein coronary artery bypass graft between August 1983 and June 1994. Patients with a myocardial infarction in the previous 24 h were excluded from the study.

Results. The mean age of the study cohort was 65 years; the mean (\pm SD) age of the treated grafts was 7.5 ± 3.9 years. As an adjunct to balloon angioplasty, stents were used in 9% of procedures, laser in 30%, and atherectomy in 16%, and thrombolytic therapy was administered in 23% of patients. The angioplasty success rate was 71%. Major complications within 30 days of the

procedure included death in 5.2% of patients, Q wave myocardial infarction in 1.3% and repeat bypass surgery in 7.8%; these events occurred with similar frequency in patients in whom angiographic success was and was not achieved. Kaplan-Meier analysis comparing patients in whom angioplasty was successful ($n = 55$) and not successful ($n = 22$) revealed no differences in survival or occurrence of myocardial infarction or recurrent severe angina between the two groups in the 3 years after the procedure. Univariate analysis identified the age of the graft and use of newer interventional devices as predictors of death or myocardial infarction during this time period; procedural success was not associated with freedom from these adverse events after adjusting for these variables.

Conclusions. Angioplasty of occluded vein grafts is associated with a low initial success rate and a high complication rate. Successful angioplasty does not appear to reduce the occurrence of adverse events in the 3 years after the procedure.

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The long-term benefits of coronary artery bypass surgery are limited by the frequency with which vein grafts develop atherosclerosis. More than 50% of vein grafts have stenoses $>70\%$ at 5 years (1). The frequency with which percutaneous transluminal coronary angioplasty is performed in patients with previous coronary artery bypass surgery is increasing each year (2). In view of the high morbidity and mortality associated with repeat bypass surgery (3), cardiologists have attempted to avoid repeat surgery by using percutaneous revascularization strategies when possible. However, the results of percutaneous treatment of vein graft disease have been disappointing. The second Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT II) (4), in which balloon angioplasty and

directional atherectomy were compared in the treatment of stenotic vein grafts, confirmed the results of previous studies indicating a lower success rate and a higher complication rate with both balloon angioplasty and directional atherectomy of vein grafts than has been reported for the native coronary arteries (5).

The results of angioplasty of occluded vein grafts have been even less favorable (6-9). Success rates ranging from 27% to 73% have led some cardiologists to suggest that angioplasty of occluded vein grafts "is a challenge that should be resisted" (6-9). Nevertheless, reports of improved success rates with new interventional devices or prolonged infusions of thrombolytic agents have provided impetus for continuing to attempt these difficult procedures (10,11). However, whether patients with occluded vein grafts in whom angioplasty is successful derive long-term clinical benefit from the procedure remains unclear. Therefore, we performed the present study to determine the frequency of success and complications in patients in whom percutaneous revascularization of an occluded saphenous vein bypass graft was attempted and to determine

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Abbreviations and Acronyms

CAVEAT II	= second Coronary Angioplasty Versus Excisional Atherectomy Trial
CI	= confidence interval
CK	= creatine kinase
ECG	= electrocardiogram
RR	= relative risk

whether adverse cardiovascular events were reduced after the procedure in patients in whom the procedure was successful.

Methods

Patients. We performed a retrospective analysis of the cardiac catheterization laboratory databank and reviewed all coronary interventional procedures performed at our institution between October 1979 and September 1994. Seventy-seven patients who had undergone attempted percutaneous revascularization of an occluded saphenous vein bypass graft, with no acute myocardial infarction in the 24 h before the procedure, were identified. These 77 patients, who were treated between August 1983 and June 1994, form the study cohort. This study was approved by the Institutional Review Board of the Mayo Clinic.

Definitions. *Angiographic success* was achieved when the final residual lumen diameter stenosis in the treated vein graft was <50%. Severity of coronary artery stenoses was determined by hand-held calipers or visual assessment by two observers using orthogonal views. Angina was classified according to the Canadian Cardiovascular Society classification scheme. *Severe angina* was defined as class III or IV angina. *Single-vessel disease* was considered to be present when a single native coronary artery had a $\geq 70\%$ diameter stenosis that was either not grafted or was supplied by a graft with a $\geq 70\%$ diameter stenosis. *Two- and three-vessel disease* were considered to be present when a $\geq 70\%$ diameter stenosis was present in an ungrafted coronary artery or vein graft and a second or third native coronary artery had a $\geq 50\%$ diameter stenosis or were supplied by bypass grafts in which a $\geq 50\%$ diameter stenosis was present. *Complete revascularization* was considered to have been achieved when there was no remaining diameter stenosis $\geq 70\%$ in a bypass graft or ungrafted coronary artery. *Myocardial infarction* during the follow-up period was considered to have occurred when two of the following three criteria were met: 1) prolonged chest pain thought to be the result of myocardial ischemia by the patient's physician; 2) serum creatine kinase (CK) elevation to two times normal levels or elevated MB isoenzyme; or 3) development of new Q waves or significant ST-T wave changes on the electrocardiogram (ECG).

Left ventricular ejection fraction was calculated using a modified Simpson's rule from ventriculography performed in a 30° right anterior oblique projection.

Follow-up. Patients were contacted 6 and 12 months after the procedure and at yearly intervals thereafter and were interviewed by telephone. The case records of all patients followed up at this institution were examined. Documentation of adverse events that occurred at other institutions during the follow-up period was sought from the attending physicians at those institutions. Follow-up angiography was generally only performed for clinical indications at the discretion of the attending physician, such as the recurrence of severe angina or an early positive functional test.

Major end points during follow-up were the occurrence of death, myocardial infarction (Q wave or non-Q wave) and severe (Canadian Cardiovascular Society class III or IV) angina. The frequency of repeat coronary angioplasty and coronary artery bypass surgery were also analyzed.

Statistical analysis. Results are presented as either mean value \pm SD, medians (25th and 75th percentiles [in tables]) or as a percent. Kaplan-Meier curves using the endpoints of death, myocardial infarction, recurrent severe angina and the need for repeat coronary artery bypass surgery or coronary angioplasty were computed for patients in whom angiographic success was and was not achieved; the log-rank statistic was used to compare the two groups. The effect of angiographic success was evaluated using a Cox proportional hazards model after adjusting for other significant variables. The Cox models were developed using the forward-selection process. The variables evaluated in the model process were age, gender, graft age, multivessel disease, medication prescribed at the time of discharge (including beta-adrenergic blocking agents, calcium channel blocking agents, nitrates, aspirin and Coumadin), myocardial infarction in the 2 to 7 preceding days and use of interventional devices other than balloon angioplasty catheters. Differences were considered to be statistically significant at $p < 0.05$.

Results

Baseline characteristics. The baseline clinical characteristics of the 77 study patients are shown in Table 1. The mean age of the study cohort was 65 ± 9 years, and 87% were male. A previous myocardial infarction had occurred in 79% of patients; 29% had had a myocardial infarction in the preceding 2 to 7 days. Two-vessel disease was present in 44% of patients and three-vessel disease in 29%. The occluded bypass graft was to the left anterior descending coronary artery in 39% of patients, the left circumflex coronary artery in 31% and the right coronary artery in 29%. The mean age of the occluded vein graft was 7.7 ± 3.8 years.

Procedural characteristics. Adjunctive device use changed throughout the study period as new devices became available and as knowledge and experience with them increased. Balloon angioplasty alone was used in 52% of the procedures. Intra-coronary or biliary stents were used in 9% of patients. Excimer laser was used in 30% of patients. The transluminal extraction catheter was used in 10% of cases; directional atherectomy was

Table 1. Baseline Clinical and Angiographic Characteristics of 77 Patients Who Underwent Angioplasty of an Occluded Saphenous Vein Bypass Graft

Characteristic	Entire Study Cohort (n = 77)	Group 1 (n = 55)	Group 2 (n = 22)	p Value
No. of procedures	77 (100)	55 (71)	22 (29)	
Age (yr)				
Mean \pm SD	65 \pm 9	65 \pm 9	65 \pm 9	0.88
Median (25th, 75th percentiles)	66 (57, 71)	66 (57, 70)	66 (57, 72)	
Range	45-85	45-85	49-79	
Male	67 (87)	49 (89)	18 (82)	0.39
CCS angina class III/IV	61 (79)	42 (76)	19 (86)	0.59
Diabetes mellitus	19 (25)	11 (20)	8 (36)	0.13
Hx of hypertension	42 (55)	29 (53)	13 (59)	0.61
Hx of hypercholesterolemia	40 (52)	33 (60)	7 (32)	0.08
Hx of smoking	58 (75)	44 (80)	14 (64)	0.13
Current smoker	8 (10)	5 (9)	3 (14)	0.34
Hx of heart failure	20 (26)	15 (27)	5 (23)	0.27
Hx of MI	61 (79)	42 (76)	19 (86)	0.59
MI within previous 2-7 days	22 (29)	15 (27)	7 (32)	0.93
2-VD	34 (44)	23 (42)	11 (50)	0.51
3-VD	22 (29)	16 (29)	6 (27)	0.87
LVEF (%)				
Mean \pm SD (n = 28)	52 \pm 17	54 \pm 15	47 \pm 23	0.40
Median (25th, 75th percentiles)	55 (41, 66)	55 (39, 66)	54 (48, 64)	
Native coronary artery grafted:				
LAD	39 (39)	29 (42)	10 (33)	0.42
LCx	31 (31)	19 (28)	12 (40)	0.22
RCA	29 (29)	21 (30)	8 (27)	0.71
Graft age (yr)				
Mean \pm SD	7.7 \pm 3.8	8.5 \pm 3.5	6.0 \pm 4.1	0.002
Median (25th, 75th percentiles)	8 (5, 10)	9 (6, 11)	6 (3, 10)	

Data presented are number (%) of patients, unless otherwise indicated. CCS = Canadian Cardiovascular Society; Group 1 = angiographic success achieved; Group 2 = angiographic success not achieved; Hx = history; LAD = left anterior descending coronary artery; LCx = left circumflex artery; MI = myocardial infarction; RCA = right coronary artery; VD = vessel disease.

used in 6%. Intracoronary thrombolytic therapy was administered during the procedure in 23% of the procedures.

During the angioplasty procedure, a coronary artery or subtotal vein graft stenosis was dilated in 30% of patients. The mean number of coronary artery segments or vein grafts dilated was 1.6. Complete revascularization was achieved in 40% of patients.

Comparison of patients in whom angiographic success was and was not achieved. Angiographic success was achieved in 55 (71%) of 77 patients. When these 55 patients in whom angiographic success was achieved (Group 1) were compared with the 22 patients in whom it was not achieved (Group 2), there were no differences in the baseline clinical and angiographic characteristics between the two groups, except that the age of the treated graft was slightly greater in Group 1 than Group 2 patients (8.1 ± 3.7 vs. 6.0 ± 4.0 years, $p = 0.04$).

Angiographic results and immediate clinical outcome. The mean postprocedural lumen diameter stenosis in Group 1 patients was $26 \pm 13\%$. Among Group 2 patients, the mean postprocedural lumen diameter stenosis was $72 \pm 31\%$; the vein graft remained completely occluded in 14 patients, and 11 patients had "partial success," with stenoses ranging from 50% to 90%.

A major complication (death, Q wave myocardial infarction or repeat coronary artery bypass surgery) occurred within 30 days of the procedure in 10 patients (13.0%) (Table 2). There were no differences in the frequency of these major adverse cardiovascular events or in the frequency of less severe adverse events (angiographically evident distal embolization or elevation of CK levels) between patients in whom angiographic success was and was not achieved. There was also no difference in the frequency of a major complication between patients in whom a myocardial infarction had occurred in the 2 to 7 days before the procedure and the remaining patients (death 9.1% vs. 3.6%; Q wave myocardial infarction 4.5% vs. 0, bypass surgery 9.1% vs. 7.3%; any of these complications occurred in 18.2% vs. 10.9%, $p = \text{NS}$ for all comparisons). All complications occurred during the hospital period in which the angioplasty procedure was performed.

Medications at time of discharge. Among patients with and without angiographic success, medications prescribed at the time of discharge included, respectively, beta-blockers in 53% and 45% ($p = 0.55$); oral or topical nitrates in 79% and 70% ($p = 0.41$); calcium channel blockers in 64% and 68% ($p = 0.72$); aspirin in 69% and 80% ($p = 0.38$); and Coumadin in 77% and 35% ($p = 0.001$).

Table 2. Angiographic Outcome and Frequency of Adverse Events During 30 Days After Attempted Angioplasty of an Occluded Vein Graft

	Entire Study Cohort (n = 77)	Group 1 (n = 55)	Group 2 (n = 22)	p Value
Complications ≤30 days				
Death	4 (5.2)	2 (3.6)	2 (9.1)	0.33
Q wave MI	1 (1.3)	1 (1.8)	0 (0)	0.52
Bypass surgery	6 (7.8)	4 (7.2)	2 (9.1)	0.79
Within 24 h	2 (2.6)	1 (1.8)	1 (4.5)	0.63
Any of above	10 (13.0)	6 (10.9)	4 (18.2)	0.39
Distal embolization	9 (11.7)	7 (12.7)	2 (9.1)	0.98
Elevation of CK	16/37 (43)	11/23 (48)	5/14 (36)	0.54

Data presented are number (%) of patients. CK = creatine kinase (measured in only 37 patients of the study cohort); other abbreviations as in Table 1.

Adverse events during follow-up. The 77 patients in whom angioplasty was attempted were followed up for a median of 1.8 years (mean 2.0 ± 1.9). Kaplan-Meier curves of the occurrence of adverse events in the 3 years after the procedure in patients in whom angiographic success was (n = 55) and was not achieved (n = 22) are displayed in Figure 1. Compared with patients in whom angiographic success was achieved, the probability of survival in patients in whom angiographic success was not achieved was similar at 3 years after the procedure (68% vs. 76%, respectively, p = 0.69), as was freedom from the combined endpoints of death and myocardial infarction (55% vs. 66%, respectively, p = 0.35) and death, myocardial infarction and recurrent severe angina (23% vs. 29%, respectively, p = 0.82). Freedom from repeat bypass surgery (65% vs. 51%, respectively, p = 0.05) was greater among patients in whom angioplasty had been successful, although repeat coronary angioplasty (67% vs. 91%, respectively, p = 0.10) tended to be more frequent among patients in whom angioplasty had been successful in the 3 years after the procedure.

Repeat angiography during the follow-up period was performed for clinical indications in 26 patients in whom angiographic success had been achieved. The median time to follow-up angiography was 9 months. Reocclusion had occurred in 9 patients; restenosis had occurred in an additional 15. Therefore, restenosis or reocclusion occurred in 24 (92%) of 26 patients undergoing repeat angiography and in at least 24 (44%) of 55 of patients in whom the procedure had initially been successful. Repeat coronary angioplasty of the vein graft was attempted in 14 patients, 3 of whom ultimately underwent repeat bypass surgery. Four patients underwent repeat bypass surgery without undergoing repeat coronary angioplasty.

Predictors of adverse events. Univariate analysis revealed that the age of the vein graft (risk ratio [RR] 1.11, 95% confidence interval [CI] 1.00 to 1.23, p = 0.05) and the use of newer interventional devices in addition to balloon angioplasty (RR 3.01, 95% CI 1.27 to 7.11, p = 0.01) were associated with the combined endpoint of death and myocardial infarction. Failure to achieve angiographic success was not associated with death and myocardial infarction in the 3 years after the procedure (RR 1.50, 95% CI 0.63 to 3.54, p = 0.37). Procedural success was not associated with freedom from these

adverse events after adjusting for these other variables (RR 1.01, 95% CI 0.40 to 2.55, p = 0.98).

Discussion

The most important findings of this study are that coronary angioplasty of occluded vein grafts is associated with a low success rate and a high complication rate and that even in patients in whom angiographic success was achieved, adverse cardiovascular events occur as frequently in the subsequent 3 years as in patients in whom angiographic success was not achieved.

Although coronary artery bypass surgery has been shown (12-16) to increase survival in certain subsets of patients and to reduce symptoms of angina in others, the temporary duration of the benefit remains a problem. Five years after coronary artery bypass surgery, 25% of vein grafts are occluded (1), and >50% of vein grafts are occluded at 10 years (1). Reoperation in such patients is performed with increasing frequency. However, repeat bypass surgery is associated with an approximately threefold greater risk of in-hospital death and myocardial infarction than initial bypass surgery (3). In addition, repeat bypass surgery is associated with less complete relief of angina and reduced graft patency (17,18).

Accordingly, cardiologists have sought to develop percutaneous means of revascularization in such patients. Whenever possible, the native coronary circulation is targeted for intervention because of the greater success rate, lower complication rate and lower restenosis rate than angioplasty of vein grafts (19,20). When the native coronary circulation is not amenable to percutaneous treatment, multiple approaches have been used for the treatment of vein graft disease, including balloon angioplasty (4,6-10,20), directional atherectomy (21), transluminal extraction catheter (22), excimer laser (23) coronary and "biliary" stents (10,24-26) and prolonged infusions of thrombolytic therapy directly into the occluded graft (11). Only a single randomized trial comparing any of these therapies with balloon angioplasty has been reported (CAVEAT II [4]). The results of CAVEAT II indicated that the frequency of angiographic restenosis after balloon angioplasty of vein grafts was similar to that after directional coronary atherec-

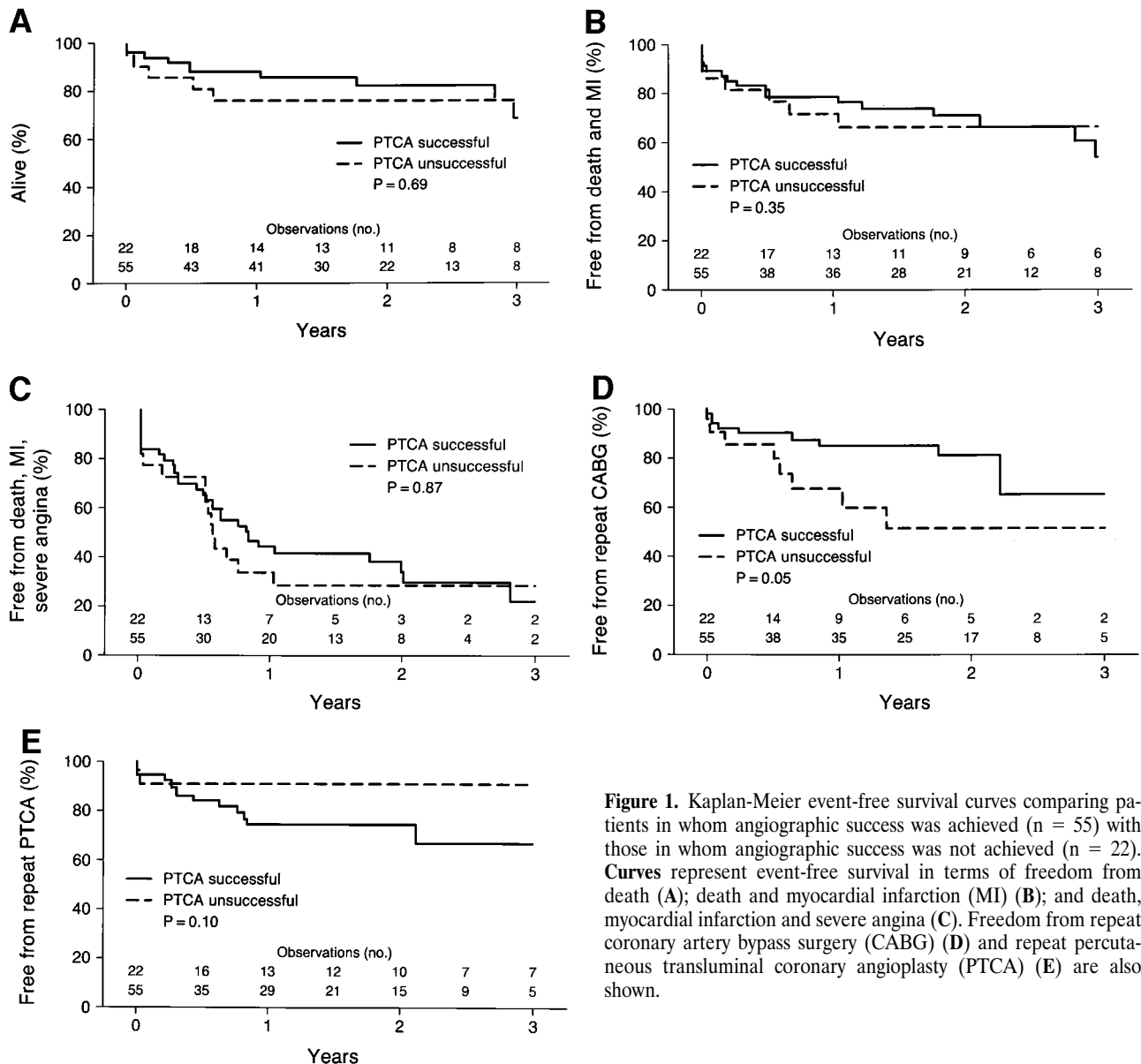


Figure 1. Kaplan-Meier event-free survival curves comparing patients in whom angiographic success was achieved ($n = 55$) with those in whom angiographic success was not achieved ($n = 22$). Curves represent event-free survival in terms of freedom from death (A); death and myocardial infarction (MI) (B); and death, myocardial infarction and severe angina (C). Freedom from repeat coronary artery bypass surgery (CABG) (D) and repeat percutaneous transluminal coronary angioplasty (PTCA) (E) are also shown.

tomy; patients with occluded vein grafts were not eligible for the study (4). It should be emphasized that angioplasty of occluded vein grafts is associated with an even lower success rate, a higher complication rate and a higher restenosis rate than angioplasty of vein grafts with subtotal stenoses; patients with occluded vein grafts were not eligible for inclusion in CAVEAT II (4).

In the present study, we performed a retrospective analysis of patients undergoing percutaneous interventions in totally occluded vein grafts. Although the 71% angiographic success rate in these patients is similar to our previously reported 69% angiographic success rate in patients undergoing angioplasty of occluded coronary arteries (27), there was undoubtedly greater selection bias in choosing which patients with occluded vein grafts to treat. Occluded vein grafts are generally more difficult to restore antegrade flow in than are occluded coronary

arteries because of the greater length of the occlusion and the larger thrombus burden in occluded grafts. However, even in the patients in the present study in whom angiographic success was achieved, there was no apparent clinical benefit in terms of freedom from adverse cardiovascular events compared with those in whom angiographic success could not be achieved. This disappointing finding is probably due to a combination of factors, including the occurrence of early complications in patients despite angiographic success having been achieved; a high restenosis and reocclusion rate in successfully treated grafts; and progression of disease elsewhere in the treated graft, in other grafts and in the native coronary circulation.

Adjunctive therapies to balloon angioplasty, used in 48% of the procedures in the present study, may have influenced the immediate and long-term outcome of our patients. Univariate analysis suggested that their use was associated with an in-

creased occurrence of death and myocardial infarction in the 3 years after the procedure. This finding may be the result of selection bias; more difficult cases may have been attempted with these newer devices than would have been attempted with balloon angioplasty alone. Whether the use of newer devices influences the success, complication and restenosis rates associated with angioplasty of occluded vein grafts will require randomized trials to be determined. Evidence from other studies indicating benefit from use of stents in vein grafts with subtotal stenoses argues for the inclusion of a percutaneous intervention arm in future randomized trials comparing bypass surgery with medical therapy in the treatment of patients with vein graft disease (10,24-26). However, whether stents will be as effective in vein grafts filled with thrombus and atherosclerotic debris is unclear.

Limitations of the study. The occluded grafts in the present study generally contained an enormous thrombus burden, and many revealed persistent thrombus even after the procedure was successful and Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow was restored. Current practice would be to place stents in vein graft stenoses if, after predilation, significant thrombus was no longer apparent. Although this was not the case with the majority of vein grafts in this series, it is likely that at least some of the patients in this study would have received stents if their procedure were performed today, and the infrequent use of stents may have affected the poor outcome of patients in the study. Randomized trials comparing balloon angioplasty with stents in the treatment of stenotic vein grafts are ongoing, although patients with occluded vein grafts are excluded from these trials. The retrospective nature of the present study and the small numbers of patients treated with stents, other new interventional devices and thrombolytic therapy preclude a determination of whether and to what extent each of these therapies influenced the immediate and long-term outcome of patients in this study. Although in patients with a recent myocardial infarction the vein graft that was treated was believed to have been the infarct-related vessel, this could not be determined with certainty. The duration of the occlusion in patients without a recent infarction could not be determined in many cases.

Conclusions. Angioplasty of occluded vein grafts is associated with a low initial success rate and a high complication rate, whether or not a recent myocardial infarction has occurred. Successful angioplasty does not appear to reduce the occurrence of adverse events in the 3 years after the procedure.

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