JACC Vol. 26, No. 4
October 1995:955–60

Percutaneous Revascularization of Ostial Saphenous Vein Graft Stenoses

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Objectives. **This study sought to evaluate the short-term results and long-term outcome of percutaneous revascularization of ostial saphenous vein graft stenoses in a large patient series.**

Background. **Previous studies have demonstrated that the results of balloon angioplasty for native coronary ostial stenoses are significantly worse than those for nonostial lesions. However, it is controversial whether interventions in patients with ostial saphenous vein grafts carry a similar prognosis.**

Methods. **We identified 68 consecutive patients with ostial (group I) and 72 consecutive patients with proximal, nonostial (group II) saphenous vein graft stenoses who underwent percutaneous angioplasty or directional atherectomy for a single new stenosis at the Cleveland Clinic between 1986 and 1992.**

Results. **Success was achieved in 61 patients (89.7%) in group I and 64 (88.9%) in group II (p = 0.88). There were no differences in major procedural complications (death, Q wave infarction and bypass surgery) between the two groups. At a mean (±SD) follow-up of 23 ± 17 months, 36 patients (64%) in group I had one or more adverse events (death, infarction, repeat coronary revascularization or cardiac-related hospital admission) compared with 34 patients (58%) in group II (p = 0.87). Twenty-eight patients (50%) were angina free in group I compared with 33 (56%) in group II (p = 0.65). During the follow-up period in group I, 7 patients died (13%), 10 had a myocardial infarction (18%), 11 had repeat bypass surgery (20%), 8 had repeat percutaneous interventions (14%), and 30 had one or more cardiac-related hospital admissions (54%). The incidence of these events was similar in group II except for a slightly higher incidence of myocardial infarction: 6 patients died (10%), 3 had a myocardial infarction (5%), 12 had repeat bypass surgery (20%), 12 had repeat percutaneous interventions (20%), and 26 had one or more cardiac-related hospital admissions (44%).**

Conclusions. **Unlike ostial native coronary disease, the clinical, procedural and follow-up profile of ostial saphenous vein graft revascularization is not significantly worse than proximal nonostial disease. This finding may be related to the overall suboptimal results of percutaneous revascularization in saphenous vein grafts compared with native coronary arteries or to the unfavorable intrinsic properties of ostial native coronary arteries compared with ostial vein grafts.**

(J Am Coll Cardiol 1995;26:955–60)

Several studies (1–5) have demonstrated that the short- and long-term results of angioplasty of saphenous vein grafts are superior when the procedure involves the distal anastomotic site compared with the proximal or midsegments of the grafts. However, whether the poor results of angioplasty of the proximal segments of vein grafts are related to a "true" ostial location of the stenoses or other factors inherent in the proximal segment of the vein graft as a whole has not been addressed.

Studies of balloon angioplasty of native coronary arteries (6,7) have shown significantly worse results for coronary ostial stenoses than for nonostial lesions, with low rates of procedural success and high rates of acute complications and restenosis. These poor results have been explained by technical difficulties during the procedure and the atypical composition of the coronary ostial lesions (8,9) and have prompted the use of new devices (i.e., rotational atherectomy, excimer laser angioplasty or stents) for the treatment of ostial native coronary stenoses in an attempt to improve the short- and long-term results of these procedures. The use of these new devices has been extrapolated to ostial saphenous vein grafts based, in part, on the reported unfavorable experience of angioplasty of ostial native and ostial renal artery stenoses (6,10,11).

An attempt to characterize ostial saphenous vein grafts separately from proximal nonostial vein segments is not simply of academic interest, rather, it might clarify whether ostial vein graft stenoses themselves do indeed necessitate different or additional interventions compared with proximal nonostial vein stenoses, in the same way that ostial native stenoses necessitate different or additional interventions compared with proximal nonostial native stenoses.

The present study was undertaken to evaluate the short-term results and long-term outcome of percutaneous revascu-

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Manuscript received January 12, 1995, accepted April 28, 1995.

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0735-1097/95/$9.50
0735-1097(95)00266-7

larization of ostial saphenous vein grafts compared with that for proximal nonostial saphenous vein grafts in a large series of patients with ostial saphenous vein graft revascularization. The results of long-term follow-up of these patients and their relation to the ostial location of the stenoses are also presented.

Methods

Patients. The Cleveland Clinic Interventional Database was accessed to identify all patients undergoing percutaneous transluminal angioplasty or directional atherectomy for a single new ostial or proximal stenosis of saphenous vein grafts between January 1986 and January 1992. Patients with acute myocardial infarction within 36 h and those with total occlusions were excluded. We identified 68 consecutive patients with ostial (group I) and 72 consecutive patients with proximal nonostial (group II) saphenous vein graft stenoses who constituted the study group.

Procedural techniques. The angioplasty and atherectomy procedures were performed as described in detail elsewhere (12,13). Routine preprocedural and postprocedural care were followed for all patients, including pretreatment with aspirin and a calcium channel blocking agent. Intravenous heparin (10,000 to 15,000 U) was administered at the beginning of the procedure, followed by additional boluses as needed. After completion of the procedure, the patients were monitored in an intensive care unit or a postprocedure telemetry ward. An electrocardiogram was routinely recorded after the procedure, on the following day, and in the event of any chest pain suggesting ischemia. Patients received maintenance therapy with aspirin, and a calcium channel blocker was administered for at least 48 h after the procedure.

Clinical and procedural variables. Clinical information at the time of the initial presentation and data obtained at the time of the procedure and at discharge were recorded prospectively on standard case report forms and entered into the Cleveland Clinic Interventional Database. An experienced angiographer reviewed the diagnostic and procedural cineangiograms to code for lesion-related morphologic variables (eccentricity, length, calcification, complex and thrombus-containing lesions). Angiographic measurements before and after the procedure were performed by using hand-held calipers in the projection showing the most severe stenosis, with the guiding catheter serving as the reference standard. Angiographic data were also entered prospectively into the registry data base.

Follow-up. Clinical follow-up data were obtained by trained Interventional Registry personnel who made telephone contact calls with the referral patients in this study and by visits of patients followed up at our institution. The patients were questioned as to the recurrence of symptoms, myocardial infarction, coronary revascularization and cardiac-related hospital admission (for angina, heart failure or arrhythmias). Follow-up events were analyzed and classified by a physician.

Table 1. Clinical Demographics for 140 Study Patients

	Ostial Lesions (n = 68)	Nonostial Lesions (n = 72)	p Value
Mean age (yr)	63	62	0.62
Gender (% male)	82	72	0.15
Previous myocardial infarction (%)	44	53	0.39
Unstable angina (%)	71	72	0.65
LVEF <0.45 (%)	24	36	0.54
Risk factors			
Smoking (%)	71	66	0.67
Diabetes (%)	25	34	0.26
Hypertension (%)	64	59	0.54
Family history (%)	46	42	0.51
Cholesterol >200 mg/dl (%)	52	56	0.68

LVEF = left ventricular ejection fraction.

Definitions. *Ostial stenosis* was defined as a lesion >50% diameter reduction within 3 mm of the vessel orifice. *Proximal nonostial stenosis* was defined as a lesion localized in the proximal one-third of the vein graft but not within 3 mm of the ostium. *Success* was defined as an increase ≥20% in lumen diameter with a final percent diameter stenosis <50% and no major complications. *Major complications* were considered bypass surgery, Q wave myocardial infarction or death and were defined according to the National Heart, Lung and Blood Institute definitions (14). The angiographic definitions used in this analysis have been used in the evaluation of the results of angioplasty and atherectomy and were previously published elsewhere (15,16).

Statistical analysis. Statistical analysis was performed using a computerized statistical analysis program (SAS Institute Inc.). The two groups were compared using the chi-square test or the Fisher exact test to test differences in categoric variables. The Student *t* test was used to assess differences in continuous variables. A significance level of 0.05 was assumed. On the basis of sample size, the study had an 80% power to detect a 16% difference in procedural success between the two groups (one-sided test; alpha level of 0.05).

Results

Demographics. The baseline patient information for each of the two groups was comparable (Table 1). The patients in this study were predominantly men with unstable angina and preserved left ventricular function. Hypertension, hypercholesterolemia and a family history of coronary artery disease were prevalent in these patients.

Morphologic and procedural characteristics. The ages of the saphenous vein grafts were similar for the two groups (Table 2). Most of the stenoses were discrete and eccentric. There was a slightly higher incidence of diffuse disease in the nonostial saphenous vein graft group and a trend toward more complex lesions in the same group. There was no difference in the number of inflations or maximal inflation pressure for the two groups.

Table 2. Morphologic and Procedural Characteristics

	Ostial Lesions	Nonostial Lesions	p Value
Graft age (mo)	68	75	0.45
Lesion morphology			
Lesion length (mm)	6	7	0.06
Discrete lesion (%)	54	57	0.98
Eccentric lesion (%)	47	63	0.40
Diffuse disease (%)	2	13	0.04
Calcified lesion (%)	2	3	0.95
Filling defect (%)	9	19	0.19
Complex lesion (%)	6	18	0.09
Vessel grafted (%)			
LAD	39	32	0.29
RCA	23	35	
Cx	38	33	
Procedure			
Stand-alone angioplasty (%)	71	67	0.88
Atherectomy ± angioplasty (%)	29	33	
No. of inflations*	3	4	0.19
Maximal pressure (atm)*	9	9	0.97

*For angioplasty procedures. Data presented are mean value or percent of patients. Cx = circumflex coronary artery; LAD = left anterior descending coronary artery; RCA = right coronary artery.

Procedural results. Success was achieved in 61 patients in group I (89.7%) versus 64 patients in group II (88.9%, p = 0.88) (Table 3). Failures occurred in saphenous vein grafts supplying the distribution of the left anterior descending coronary artery in five patients, right coronary artery in seven and circumflex artery in three. There was no difference in percent stenosis before or after the procedure. In group I there were one death, one Q wave infarction and two bypass surgery procedures. Three patients in group I had unsuccessful, uncomplicated procedures. In group II, there were three deaths, two Q wave infarctions and four bypass surgery procedures. Three of the four repeat bypass surgery procedures in group II were performed emergently. One patient had persistent hypotension after operation and died shortly thereafter. The other two patients underwent successful repeat bypass surgery and had a non-Q wave myocardial infarction only. Two patients in group I and three in group II had a non-Q wave infarction.

Table 3. Procedural Results

	Ostial Lesions (n = 68)	Nonostial Lesions (n = 72)	p Value
Success	61/68 (89.7%)	64/72 (88.9%)	0.88
Stenosis			
Preprocedure	85%	86%	0.71
Postprocedure	24%	22%	0.60
Death	1 (1.5%)	3 (4.2%)	0.62
Q wave infarction	1 (1.5%)	2 (2.8%)	1.00
Non-Q wave infarction	2 (2.9%)	3 (4.2%)	1.00
Bypass surgery	2 (2.9%)	4 (5.6%)	0.68

Data presented are number or percent of patients.

There were no significant differences in major procedural complications between the two groups.

Follow-up. The mean (±SD) follow-up period was 23 ± 17 months. Seven patients lived in foreign countries and were therefore excluded from follow-up. Clinical follow-up results were available for 115 (97.5%) of 118 patients with successful procedures: 56 patients in group I and 59 in group II. Three patients were lost to follow-up. During the follow-up period, 36 patients (64%) in group I had one or more adverse events (death, infarction, repeat bypass surgery, repeat percutaneous intervention or cardiac-related hospital admission) compared with 34 patients (58%) in group II (p = 0.87). In group I, 7 patients died (13%), 10 had a myocardial infarction (18%), 11 had repeat bypass surgery (20%), 8 had repeat percutaneous interventions (14%), and 30 (54%) had one or more cardiac-related hospital admissions. The incidence of these events was similar in group II except for a slightly higher, statistically nonsignificant incidence of myocardial infarction: 6 patients died (10%), 3 had a myocardial infarction (5%), 12 had repeat bypass surgery (20%), 12 had repeat percutaneous interventions (20%), and 26 patients (44%) had one or more cardiac-related hospital admissions. At the end of the follow-up period, 28 patients (50%) were angina free in group I compared with 33 (56%) in group II (p = 0.65).

Discussion

The results of balloon angioplasty of ostial native coronary lesions have been reported to be much worse than those of nonostial lesions (6,7). In the only substantial series of patients with aortocoronary lesions, Topol et al. (6) described the results of balloon angioplasty in 53 patients with right coronary artery ostial stenoses and reported low rates for procedural and long-term success (79% and 49%, respectively) and high rates for procedural complications (9% for emergency bypass surgery, 48% for clinical recurrence and 38% for restenosis) despite a favorable risk profile within their patient cohort. Mathias et al. (7) reported similar results for stenoses at the ostium of a coronary branch vessel.

These unfavorable results of percutaneous revascularization of ostial native coronaries and similar unfavorable results of angioplasty of ostial renal artery stenoses have been extrapolated to percutaneous revascularization of ostial saphenous vein grafts, and it has been suggested (11) that the results of angioplasty of proximal vein graft anastomoses are similarly unfavorable as the reported experience with ostial right coronary artery and ostial renal artery stenoses. A few small series studying ostial saphenous vein grafts as subgroups of larger studies have also suggested that angioplasty of ostial saphenous vein graft carries an adverse prognosis compared with that for nonostial disease (Table 4). The initial success rates of angioplasty of the proximal segments (including ostial stenoses) in these series varied from 50% to 94%, with a combined overall success of 84% compared with a success rate of 67% to 100% and a combined overall success rate of 93% for angioplasty of the midsegment of vein grafts (Table 4). However, no

Table 4. Initial Success and Restenosis Rates After Angioplasty of Proximal and Mid-Saphenous Vein Grafts*

Ref No.	Initial Success			Restenosis		
	Ostial	Proximal (+ostial)	Mid	Ostial	Proximal (+ostial)	Mid
1	NR	4/5 (80%)	22/23 (96%)	NR	1/2 (50%)	9/17 (53%)
26†	NR	NR	NR	3/7 (43%)	10/19 (53%)	0/8 (0%)
33	NR	NR	NR	1/2 (50%)	1/2 (50%)	8/15 (53%)
31	NR	10/12 (83%)	7/8 (88%)	NR	8/10 (80%)	2/7 (29%)
17	NR	23/26 (88%)	7/7 (100%)	NR	NR (31%)	NR (23%)
34	NR	NR	NR	NR	2/3 (67%)	3/5 (60%)
35	NR	NR	NR	NR	11/14 (79%)	40/65 (62%)
21†	NR	NR	NR	3/9 (33%)	5/19 (26%)	2/7 (29%)
18	NR	11/14 (79%)	8/8 (100%)	NR	3/5 (60%)	3/7 (43%)
22	NR	34/36 (94%)	26/29 (90%)	1/3 (33%)	1/3 (33%)	3/5 (60%)
19	NR	5/9 (56%)	2/3 (67%)	NR	NR	NR
20	NR	47/53 (89%)	24/24 (100%)	NR	21/42 (50%)	9/20 (45%)
3	NR	47/59 (80%)	39/45 (86%)	NR	NR (60%)	NR (46%)
36	NR	24/28 (86%)	32/33 (97%)	NR	NR	NR
4	NR	NR	NR	NR	7/11 (64%)	20/32 (63%)
25‡	NR	NR	NR	NR	1/5 (20%)	7/25 (28%)
5	NR	4/8 (50%)	NR	NR	5/6 (83%)	4/10 (40%)
Total	NR	209/250 (84%)	167/180 (93%)	8/21 (38%)	76/141 (54%)	110/223 (49%)

*Includes all published studies of angioplasty of saphenous vein grafts that reported the success or restenosis rates classified by vein graft segment. †No correlation between site of stenosis and initial success reported. ‡No correlation between site of stenosis and restenosis reported. Data presented are number (%) of patients. NR = not reported; Ref = reference.

study addressed the success rates for ostial stenoses separately. The restenosis rates from these studies varied from 31% to 83% for proximal segments with a combined rate of 54% compared with rates of 0% to 63% with a combined rate of 49% for midsegments (Table 4). These results prompted the recommendation that angioplasty of ostial vein graft stenoses should be undertaken with much less enthusiasm and initiated a great interest in nonballoon strategies for this site. However, the long-term outcome after nonballoon interventions is not yet known, and a relatively short follow-up period of 6 to 12 months indicates that restenosis occurs in ~60% of patients after laser angioplasty and in 40% to 50% after rotational or extraction atherectomy (2).

Although several investigators (1,2,5,17–20) have suggested that lesions at the proximal anastomosis generally yield less favorable initial and long-term results compared with other sites, other studies (21–26) did not corroborate these findings. Also, the reported results of angioplasty of ostial saphenous vein grafts are based on a very small number of patients who were evaluated as subgroups of the original studies, and the vast majority of these studies included ostial stenoses and proximal shaft stenoses in the same group (Table 4). Indeed, the small number of patients who underwent angioplasty for true "ostial" vein stenoses in these studies showed restenosis rates of 33% to 50% (Table 4). However, the very small number of patients and the inadequacy of follow-up preclude an ability to draw meaningful conclusions. A related issue is that the disappointing results noted earlier for balloon angioplasty may reflect the procedure as practiced in the early 1980s. Indeed, results of recent series of patients with aortoostial lesions treated by balloon angioplasty suggest that improved immediate success and a lower incidence of complications may be attainable (21,22,24,25). However, the computation of pooled success and restenosis rates in Table 4 has to be interpreted with caution because it is impossible to account for "between-study" differences.

The overall unfavorable results of angioplasty of ostial native coronary arteries have been explained in part by technical difficulties encountered during the procedure. Guide catheter seating is often inadequate, making manipulation difficult. Further, with guide catheter intubation, trauma to the diseased intima may lead to dissection and abrupt closure. Atypical lesion composition is a further possible explanation for the suboptimal results associated with these stenoses. Some investigators have suggested congenital arterial hypoplasia with age-related intimal thickening (27) and the presence of a muscular sphincter at the ostium (28). In addition, the vessel ostium contains regions in which there is high wall shear stress, which has been suggested (29) to predispose to intimal fibrosis, endothelial damage and subsequent platelet deposition. Such lesions may be resistant to dilation (requiring high inflation pressures to "crack") and may show exaggerated elastic recoil with consequent procedural failure or restenosis (9). Pathologically, the ostial saphenous vein graft site presents an entirely different problem compared with ostial native lesions. In addition to the inherent distinctions between vein and artery, the surgical anastomosis itself involves an artificial opening in the thick elastic wall of the aorta and cannot be viewed as similar to a native ostium. Stenoses in this area, unlike ostial native disease, have been attributed (11,30,31) to excessively acute angulation of the graft from the aortic wall or too large an aortotomy. These lesions are usually not calcified and

originate from a funnel-shaped anastomosis and may therefore behave differently from ostial native disease.

More recent studies (21,22,24) specifically evaluating ostial saphenous vein graft stenoses found that lesions at this site are not a significant predictor of failure. Using a stepwise multiple regression analysis, Cote et al. (21) showed that the percent diameter stenosis immediately after dilation was the strongest predictor of percent diameter stenosis at follow-up. In their series, there was no significant difference in postangioplasty percent diameter stenosis at the various sites in the grafts, leading Cote et al. (21) to suggest that perhaps the higher residual stenosis at angioplasty at the proximal anastomotic site may explain the higher recurrence rates previously noted. Our findings confirm the conclusions of these recent studies and show that unlike ostial native disease, the clinical, procedural and follow-up profile of ostial saphenous vein grafts is not significantly worse than that for proximal nonostial disease.

These findings contrasted markedly with our experience in percutaneous revascularization of ostial native coronary stenoses over the same time period (32). In a group of 1,150 patients, we reported a significantly lower success rate for ostial native coronary stenoses compared with that for proximal nonostial stenoses (81% vs. 90%, $p = 0.02$). Compared with patients with proximal nonostial native disease, patients with ostial native coronary disease were older (62 vs. 59 years, $p = 0.03$), included more women (38% vs. 27%, $p = 0.03$) and had more calcified lesions (9% vs. 3%, $p < 0.0001$). There was a higher residual stenosis in this group (33% vs. 24%, $p = 0.01$) and a relatively high incidence (14.1%) of in-hospital procedure-related complications (death, Q wave infarction, emergency bypass surgery). This experience is consistent with the previously reported results (6,7) of percutaneous revascularization in patients with ostial native coronary disease.

Study limitations. This is a retrospective analysis; it is possible that other known risk factors, not assessed in the present study, might have added prognostic information. Although, to our knowledge, this is the largest reported series of percutaneous revascularization of ostial saphenous vein grafts, the number of patients is still relatively small, and therefore, beta-error cannot be excluded. Also, because of the small number of patients undergoing other new interventional modalities during the time frame of the study (1986 to 1992), we did not assess the results of newer percutaneous interventions, which hold promise for the treatment of ostial lesions (excimer laser angioplasty, rotational atherectomy and stenting).

Conclusions. In a large series of patients, this study shows that unlike ostial native disease, the clinical, procedural and follow-up profile of ostial saphenous vein graft percutaneous revascularization is not significantly worse than that for proximal nonostial disease. This finding may be related to the overall suboptimal results of percutaneous revascularization in saphenous vein grafts compared with native coronary arteries or unfavorable intrinsic properties of ostial native coronary arteries compared with ostial saphenous vein grafts. We propose that angioplasty and atherectomy are viable methods for percutaneous revascularization at this site and should not be excluded in trials evaluating the results of newer revascularization options for patients with ostial saphenous vein graft disease.

We gratefully acknowledge Gan Howell, Deborah Lynch, Freddie Ford, J. Patrick Lang and all the staff of the Interventional Registry at the Cleveland Clinic for their effort in the collection of data.

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