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COOPERATIVE STUDIES

Clinical, Angiographic and Procedural Correlates of Quantitative Coronary Dimensions After Directional Coronary Atherectomy

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To define the clinical, angiographic and procedural correlates of quantitative coronary dimensions after directional coronary atherectomy, 400 lesions in 378 patients were analyzed with use of qualitative morphologic and quantitative angiographic methods. Successful atherectomy, defined by a <75% residual area stenosis, tissue retrieval and the absence of in-hospital ischemic complications, was performed in 351 lesions (87.7%). After atherectomy, minimal cross-sectional area increased from 1.2 ± 1.1 to 6.6 ± 4.4 mm^2 ($p < 0.001$) and percent area stenosis was reduced from 87 ± 10% to 31 ± 42% ($p < 0.001$).

By univariate analysis, device size ($p < 0.001$) and left circumflex artery lesion location ($p = 0.004$) were associated with a larger final minimal cross-sectional area. Conversely, restenotic lesion ($p = 0.002$), lesion length ≥10 mm ($p = 0.018$) and lesion calcification ($p = 0.035$) were quantitatively associated with a smaller final minimum cross-sectional area. With use of stepwise multivariate analysis to control for the reference area, atherectomy device size ($p = 0.003$) and left circumflex lesion location ($p = 0.007$) were independently associated with a larger final minimal cross-sectional area, whereas restenotic lesion ($p = 0.010$), diffuse proximal disease ($p = 0.033$), lesion length ≥10 mm ($p = 0.026$) and lesion calcification ($p = 0.081$) were significantly correlated with a smaller final minimal cross-sectional area. The number of specimens excised, the number of atherectomy passes and atherectomy balloon inflation pressure did not correlate with the final minimal cross-sectional area.

Thus, directional atherectomy results in marked improvement of coronary lumen dimensions, at least in part correlated with the presence of certain clinical, angiographic and procedural factors at the time of atherectomy.

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Coronary angioplasty is a widely accepted method of nonsurgical revascularization in patients with coronary artery disease (1–9). Despite its widespread use, coronary angioplasty is limited by a 4% to 7% incidence of abrupt vessel closure (1,2) and a 30% to 40% incidence of delayed restenosis (3). Moreover, although the arterial segment has been effectively distended by balloon inflation, a 26% to 42% diameter stenosis may persist after balloon deflation (4–8). The immediate anatomic and physiologic interpretation of the angiographic result may be further complicated by varying degrees of progressive elastic recoil (7), arterial vasoconstriction (8,9) and intraluminal haziness resulting from angioplasty-induced vascular barotrauma (5,10). In an effort to provide a more effective initial revascularization, alternative methods, which may reduce the extent of vascular trauma and elastic recoil associated with standard techniques, have been introduced (11–13). One of these techniques, directional coronary atherectomy (11), was recently approved for marketing by the U.S. Food and Drug Administration. Mediated, at least in part, by atheroma excision and mechanical coronary dilation, both clinical and angiographic improvement have been demonstrated (6,11,14,15) after directional coronary atherectomy in selected patients with coronary artery disease. Although marked increases in quantitative coronary dimensions have been reported (6,14), no previous study has examined the factors associated with a favorable angiographic outcome immediately

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after coronary atherectomy. With the imminent availability of coronary atherectomy, these factors may be of importance for appropriate case selection and for comparison with angiographic results obtained with standard techniques such as coronary angioplasty.

To define the clinical, angiographic and procedural correlates of quantitative coronary dimensions after atherectomy, we performed qualitative morphologic and quantitative angiographic analysis of 400 lesions in 378 patients from six high volume interventional centers. These results provide further insight into the mechanism of improvement in arterial dimensions achieved by coronary atherectomy.

Methods

Study patients. Between January 1988 and May 1990, directional coronary atherectomy was attempted in 400 lesions in 378 patients at six centers (see Appendix). The Simpson Coronary AtheroCath (Devices for Vascular Intervention [DVI]) was used in all interventions. Proximal lesions and lesions with marked eccentricity or irregularity located in coronary arteries of sufficient caliber to allow passage of the atherectomy device (≥2.5 mm) were generally considered suitable for directional coronary atherectomy. Before coronary atherectomy, all patients gave informed consent under the guidelines of the respective Institutional Review Boards.

Atherectomy procedure. Unless contraindicated, all patients were pretreated with aspirin and a calcium channel antagonist. A 10F or 11F sheath was secured in the femoral artery and, in some cases, femoral vein cannulation was also performed in the unlikely event that an emergency transvenous pacemaker would be required or for rapid fluid administration. After a 10,000- to 15,000-U bolus injection of heparin, a specially designed 9.5F to 11F guiding catheter with side holes (AtheroCath, DVI) was advanced to the coronary ostium. After coronary intubation, a 0.014-in. (0.036-cm) coronary guidewire was advanced across the coronary stenosis and positioned in the distal vessel. In 59 lesions (14.7%), predilation with standard coronary angioplasty was performed to facilitate passage of the atherectomy device. In the remaining lesions, the device was directly advanced across the coronary stenosis. A 7F device was generally selected in patients with a stenosis in arterial segments >3 mm, a 6F device in segments 2.5 to 3 mm and a 5.5F device for smaller arterial segments.

Once the device was positioned across the lesion, the unilateral balloon was inflated to 10 psi, and the rotating cutter, driven by an external detachable motor drive unit, was fully withdrawn into the cylindrical housing. In most cases, balloon inflation was then increased to 20 to 60 psi. The cutter was advanced forward longitudinally inside the housing, excising any tissue protruding into the device window and storing it in the distal housing. After balloon deflation, the atherectomy device was rotated 30° to 90°, and the atherectomy procedure was repeated. After several excisions, the atherectomy device was removed from the body and the tissue specimens were flushed from the device. The number of discrete tissue fragments from each lesion was recorded. Angiographic assessment of the coronary artery was then obtained, and when a significant coronary stenosis remained, the procedure was repeated.

Criteria for continued directional coronary atherectomy varied somewhat during the study period. Until November 1989, the majority of investigators attempted to remove all of the angiographically apparent atheroma. Thereafter, because of concern about coronary perforation (16), a less aggressive approach to atheroma resection was taken. Furthermore, in most centers, the peak balloon inflation pressure was lowered to <30 psi.

Successful atherectomy was defined by the presence of each of the following criteria: a final residual percent area stenosis <75%, tissue retrieval and the absence of clinical evidence of myocardial ischemia (abrupt vessel closure, myocardial infarction, coronary bypass surgery or death) until hospital discharge.

Clinical and procedural variables. Cases report forms provided by the principal investigators were reviewed for selected clinical features including age, gender, angina status, presence of diabetes mellitus, history of prior restenosis and multivessel coronary artery disease. In addition, the size of the atherectomy device, the peak balloon inflation pressure, the number of specimens excised and the number of atherectomy cuts were recorded.

Qualitative morphologic analyses. Consecutive cineangiograms obtained from the 378 patients undergoing atherectomy were collected at the University of Michigan Angiographic Core Laboratory and reviewed by observers who had no knowledge of the clinical outcome. Lesions were visualized in multiple projections and scored for the presence or absence of the following 10 angiographic variables according to the criteria developed by Ellis and coworkers (17,18):

Diffuse proximal disease was considered present when ≥33% of the vessel proximal to the coronary stenosis had angiographically apparent lumen irregularities or stenoses.

Proximal vessel tortuosity was considered present when the atherectomy catheter had to traverse two or more areas of vessel angulation ≥75° or one or more areas of angulation ≥90° in order to cross the stenosis as determined from a nonforeshortened and end-diastolic projection.

Lesion length ≥10 mm was measured by calipers as the distance from the proximal to the distal shoulder of the lesion in the projection that best elongated the stenosis.

Lesion eccentricity was defined as present when the lumen extended to the outer 25% of apparently normal lumen.

A lesion bend was considered present when the angle formed by the centerline through the lumen proximal to the stenosis and a centerline formed through the lumen distal to the stenosis in the least foreshortened view was ≥45° at the site of atherectomy.

Lesion irregularity was defined by the presence of an irregular "sawtooth" contour of the vascular margin.

Lesion calcification was identified by the presence of patchy or nodular radiodensities within the diseased vascular wall of the artery at the site of the stenosis.

A bifurcation lesion was present if a branch vessel of medium or large size (>1.5 mm) originated within the stenosis and if the side branch was completely surrounded by significant stenotic portions of the lesion to be dilated.

Thrombus was defined by the presence of a discrete intraluminal filling defect anchored, at least in part, to the adjacent vessel wall with or without associated contrast staining.

The modified American College of Cardiology/American Heart Association (ACC/AHA) Lesion Score (18) was used to classify lesions into categories A, B1 (one adverse B characteristic present), B2 (two or more adverse B characteristics present) and C according to the ACC/AHA Task Force lesion morphologic criteria (19).

The device/artery ratio was measured by calipers and defined by the ratio of the atherectomy device and the normal adjacent coronary artery for the largest device that crossed the stenosis.

Abrupt vessel closure was defined by the transient or persistent occurrence of thrombotic occlusion associated with reduced coronary blood flow (Thrombolysis in Myocardial Infarction [TIMI] grade 0 to 2 flow) (20).

Quantitative coronary analysis. End-diastolic cineframes from angiograms obtained before and after coronary atherectomy were digitized with a cine-video converter. A computer-assisted edge-detection algorithm was then applied to the digitized images (21). Reference and minimal lumen diameters were determined by using the guiding catheter as the calibration standard. Because of the previously demonstrated importance of orthogonal angiographic projections after coronary intervention (5,10), reference and minimal cross-sectional areas were calculated (7). Postprocedural ectasia was defined as a final lesion cross-sectional area larger than the adjacent reference segment after directional atherectomy.

Statistical analysis. All continuous variables are expressed as mean values ± 1 SD. Differences between continuous variables were compared with use of Student's t-test for two groups and analysis of variance for multiple comparisons with the post-hoc Newman-Keuls test for multiple groups. Differences between dichotomized variables were compared by using chi-square analysis. Univariate and stepwise multivariate analyses were performed with SYSTAT software. Features with <20 observations were not included in the multivariate analysis.

Results

Patient characteristics, procedural success and clinical outcome (Table 1). Three hundred seventy-eight patients (400 lesions) constituted the study group. Procedural success was obtained in 351 lesions (87.7%); major ischemic complications (death, myocardial infarction, emergency bypass surgery) occurred in 6.3% of patients. The clinical and morphologic predictors of procedural success and complications after directional coronary atherectomy have been reported in detail elsewhere (17).

Table 1. Clinical Demographics of 378 Patients With 400 Lesions Undergoing Coronary Atherectomy

	%
Age (yr) (mean ± SD)	59 ± 11
Male gender	78.7
Angina status	
Stable angina	49.4
Unstable angina	49
Postinfarction angina	1.1
Positive exercise treadmill test only	0.5
Diabetes mellitus	15
Restenotic lesion	47.9
Multivessel disease	46.9

Qualitative morphologic analysis (Table 2). Because no a priori hypotheses were entertained to account for differences in lesion morphology by vessel, statistical analysis of these subgroups was not performed. However, lesions involving the right coronary artery were associated with more proximal vessel tortuosity and diffuse disease and lesions involving the left anterior descending artery were more frequently calcified. Lesion eccentricity occurred in 59% of lesions in all vessels. The majority of lesions selected for directional coronary atherectomy were classified in modified ACC/AHA Task Force lesion complexity class A or B1. Lesion class C was extremely infrequent, comprising 1% of all lesions.

Quantitative angiographic analysis (Table 3). After atherectomy, minimal cross-sectional area increased from 1.2 ± 1.1 to 6.6 ± 4.4 mm^2 and percent area stenosis was reduced from 87 ± 10% to 31 ± 42% ($p < 0.001$). Final minimal cross-sectional area was significantly higher in lesions within the left circumflex artery than in lesions involving other vessels (9.3 ± 5.4 mm^2 vs. 6.2 ± 4.2, 6.3 ± 4.2 and 7.3 ± 5 mm^2 for the left anterior descending artery, right coronary artery and saphenous vein graft, respectively, $p < 0.05$). The minimal cross-sectional area was greatest after atherectomy in the distal left circumflex artery (Table 3). Notably, postprocedural ectasia was also present more frequently in the left circumflex coronary artery than in other vessels (30.4% compared with 8.3%, 5.5% and 20% for the left anterior descending artery, right coronary artery and saphenous vein grafts, respectively, $p < 0.05$).

Correlates of postatherectomy minimal cross-sectional area (Table 4). Selected clinical, angiographic and procedural variables were evaluated using univariate analysis for their correlation with final minimal cross-sectional area. Univariate positive correlates of final minimal cross-sectional area included circumflex artery lesions ($p = 0.004$) and the size of the atherectomy device ($p = 0.001$). Negative correlates

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Table 2. Morphologic Features of 400 Lesions Before Directional Coronary Atherectomy

	LAD* (n = 229)	RCA (n = 96)	LCx (n = 24)	SVG (n = 51)	Overall (n = 400)
Proximal vessel					
Diffuse disease	4.9	29.1	9.1	14	12.2
Tortuosity	0.5	12.5	8.3	7.8	4.8
Lesion					
Length ≥10 mm	9.3	15.6	4.2	11.8	10.8
Eccentricity	59.1	64.6	52.2	58.9	59.3
Bend ≥45°	10.6	8.3	0	7.8	9
Irregularity	16.8	14.6	29.2	17.6	17
Calcification	20	7.3	4.2	0	12
Ostial	8.7	9.1	0	15.7	8.9
Bifurcation	15.7	1	16.7	0	10
Thrombus	3.7	9.4	8.3	11.7	6.4
Modified ACC/AHA lesion criteria					
A	42.8	46.9	45.8	43.1	44
B1	36.2	34.4	41.7	43.1	37
B2	20.1	17.7	12.5	11.8	18
C	0.9	1	0	2	1

All data indicate percent of lesions demonstrating the feature. *Includes 3 patients with left main coronary artery stenosis. ACC/AHA = modified American College of Cardiology/American Heart Association Task Force; LAD = left anterior descending coronary artery; LCx = circumflex coronary artery; RCA = right coronary artery; SVG = saphenous vein graft.

included a restenotic lesion ($p = 0.002$), lesion length ≥10 mm ($p = 0.018$) and lesion calcification ($p = 0.035$). By stepwise multivariate analysis factoring in the reference cross-sectional area, atherectomy device size ($p = 0.003$) and circumflex artery lesions ($p = 0.008$) were associated with larger final minimal cross-sectional areas, whereas a restenotic lesion ($p = 0.010$), lesion length ≥10 mm ($p = 0.026$), diffuse proximal disease ($p = 0.033$) and lesion calcific deposits ($p = 0.081$) were associated with smaller final minimal cross-sectional areas ($R = 0.436$; SEE = 3.73; $p < 0.001$). The device/artery ratio, number of specimens excised and number of atherectomy passes were not correlated with final minimal cross-sectional area.

Discussion

In single-center series, directional coronary atherectomy has been demonstrated to be an effective alternative to coronary angioplasty in selected patients with coronary artery disease (11,14,15), and may be particularly well suited for complex, thrombus-containing lesions (17) and for those lesions with abnormal contour (22), total occlusion (23) or involvement of the right coronary ostium (24). The present study was designed to examine whether clinical, angiographic or procedural features were associated with final minimal lesion cross-sectional area, which, in the absence of ectasia, defines a favorable angiographic result. In this series of nearly 400 patients, restenotic lesion, lesion length ≥10 mm, diffuse proximal disease and, to a lesser extent, lesion calcific deposits, were associated with smaller final minimal cross-sectional areas. Because these features may also be associated with a suboptimal angiographic result after coronary angioplasty (19), valid comparison of the final quantitative results obtained with coronary angioplasty and coronary atherectomy will require a controlled, randomized trial.

Mechanisms whereby coronary dimensions are improved after coronary atherectomy. These remain incompletely defined (14,25). Whereas the initial improvements of coronary atherectomy had been attributed to atheroma resection, in a study by Safian et al. (14), the average weight per specimen, 18.5 mg (range 5.8 to 45.1), was insufficient to account for the improvement in coronary dimensions as assessed angiographically. Similarly, Sharaf et al. (25) demonstrated that mechanical dilation of the stenosis may be the principal mechanism of angiographic improvement after directional coronary atherectomy. Despite the demonstrated safety of deep arterial resection with coronary atherectomy (26), the infrequent occurrence of coronary perforation has resulted in a less aggressive approach to atheroma resection by the investigators. Although of lesser importance, barotrauma introduced by low atherectomy balloon inflation pressures (10 to 40 psi) may be sufficient to cause some degree of balloon dilation of the vessel.

Role of lesion morphology in predicting success and complication rates. Because of the importance of lesion morphology for the angiographic results after coronary angioplasty, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force has developed criteria whereby lesion morphology is used to predict the initial success and complication rates after coronary angioplasty

Table 3. Quantitative Coronary Dimensions of 400 Lesions Before (Pre) and After (Post) Directional Atherectomy

Coronary Artery	Reference Cross-Sectional Area (mm²)	Minimal Cross-Sectional Area (mm²)	Percent Area Stenosis
Left main (n = 3)			
Pre	11.2 ± 6.7	2.4 ± 2	82 ± 7
Post	13.4 ± 6.2	6.1 ± 0.4	49 ± 20
Left anterior descending			
Proximal (n = 147)			
Pre	9.2 ± 3.3	1.2 ± 0.9	87 ± 9
Post	9.7 ± 3.5	6.4 ± 4.4	32 ± 39
Mid/distal (n = 79)			
Pre	8.2 ± 3.3	0.9 ± 0.7	89 ± 8
Post	8.6 ± 3.3	6 ± 3.7	26 ± 56
Left circumflex			
Proximal (n = 17)			
Pre	10.6 ± 3.3	1 ± 0.6	91 ± 8
Post	11.2 ± 3.6	8.7 ± 4.5	20 ± 39
Distal (n = 7)			
Pre	7.9 ± 2.4	0.9 ± 0.5	88 ± 8
Post	10.3 ± 4.3	10.4 ± 6.9	2 ± 47
Right			
Proximal (n = 33)			
Pre	11.2 ± 5.3	1.3 ± 0.9	88 ± 7
Post	10.6 ± 4	6.6 ± 3.9	37 ± 32
Mid/distal (n = 63)			
Pre	10.3 ± 3.5	1.6 ± 1.5	85 ± 13
Post	9.8 ± 3.4	6.1 ± 4.3	39 ± 33
Saphenous vein graft (n = 51)			
Pre	10.4 ± 4.8	1.3 ± 1.3	86 ± 11
Post	10.1 ± 4.9	7.3 ± 5	23 ± 43

(19). These criteria were recently validated in patients with multivessel coronary artery disease undergoing coronary angioplasty (18) and in patients undergoing directional atherectomy (17). Lesion morphology may also be an important correlate of the degree of angiographic improvement after atherectomy, as defined by the final minimal cross-sectional area. For example, lesions of excessive length, containing more atheroma burden than shorter, discrete lesions, may be more difficult to adequately resect or dilate. Other morphologic factors, such as coronary calcification or extensive fibrocellularity due to prior restenosis, may limit protrusion of the atheroma into the device cutting window, thus preventing effective atheroma resection. Because of elastic recoil, these lesions may also be resistant to the effects of mechanical dilation imposed by the atherectomy device. Finally, excessive vessel tortuousity or proximal atherosclerotic disease may limit the ability of the atherectomy device to be properly positioned and rotated at the level of the lesion. In the present study, a restenotic lesion ($p = 0.010$), lesion length ≥10 mm ($p = 0.026$), diffuse proximal disease ($p = 0.033$) and lesion calcific deposits ($p = 0.046$) were associated with a smaller final minimal cross-sectional area. Notably, the final minimal cross-sectional area was not adversely affected by the presence of lesion eccentricity, irregularity or thrombus. These lesion subsets may be particularly suited for coronary atherectomy, but controlled trials with coronary angioplasty are needed. In the present study, final minimal cross-sectional area was directly correlated with the size of the atherectomy device, even controlling for the normal area of the vessel. However, the amount of tissue resected, as assessed by the number of specimens excised, the device/artery ratio and the atherectomy balloon inflation pressure were not correlated with the final angiographic result. Thus, similar to previous reports (14,25), the present study suggests that at least part of the improvements in coronary dimensions after atherectomy are related to mechanical dilation of the vessel.

The effects of directional atherectomy on final coronary dimensions within circumflex artery lesions should be interpreted cautiously. Although final minimal cross-sectional area was significantly higher for lesions in the circumflex coronary artery, these lesions were associated with significantly higher rates of postprocedural ectasia and presumably deeper tissue resection. Resection of media and adventitia after directional atherectomy has been associated with higher rates of late restenosis (27) and follow-up angio-

Table 4. Clinical, Angiographic and Procedural Correlates of Final Minimal Cross-Sectional Area (mm^2) After Directional Atherectomy

	Univariate		Multivariate	
	Coefficient	p Value	Coefficient	p Value
Constant			3.654	0
Clinical factors				
Restenotic lesion	−1.409	0.002	−1.166	0.010
Male gender	−0.110	NS	—	—
Unstable angina	0.440	NS	—	—
Angiographic factors				
Circumflex artery	2.898	0.004	2.681	0.007
Calcification	−1.499	0.035	−1.615	0.081
ACC/AHA B2/C	−0.105	0.064	−1.531	NS
Diffuse proximal disease	−0.442	NS	−1.374	0.033
Lesion length ≥10 mm	−1.778	0.018	−0.080	0.026
Proximal tortuosity	−0.361	NS	—	—
Bend ≥45°	−0.880	NS	—	—
Irregularity	−0.147	NS	—	—
Bifurcation	−0.618	NS	—	—
Thrombus	−0.266	NS	—	—
Multivessel disease	0.033	NS	—	—
Procedural factors				
Device size	2.139	0.001	1.386	0.003
Number of specimens	0.040	NS	—	—
Number of passes	0.087	NS	—	—
Device/artery ratio	0.264	NS	—	—
Balloon inflation pressure	−0.050	NS	—	—
			Multiple R	0.436
			SEE	3.73
			p	<0.001

graphic studies will be needed to determine whether these initial results within the circumflex artery are maintained.

Coronary atherectomy versus coronary angioplasty. In the absence of a randomized study, comparison of the absolute dimensional changes between coronary angioplasty and coronary atherectomy remains speculative. However, in a case-controlled series by Muller et al. (6), minimal residual lumen diameter was significantly greater in patients undergoing directional atherectomy than in similarly matched patients undergoing coronary angioplasty (2.5 ± 0.6 vs. 1.6 ± 0.5 mm, $p < 0.05$). Although others (5,8) have demonstrated larger residual coronary dimensions after coronary angioplasty (2.2 ± 0.6 mm), the residual minimal lumen diameter after coronary atherectomy in the present study (2.9 ± 2.4 mm) suggests either that coronary atherectomy results in larger residual coronary dimensions or that it is applied consistently to larger vessels.

Limitations. The current study has several important limitations. First, despite the identification of several univariate and multivariate correlates of final minimal cross-sectional area, the correlation coefficient (0.436) and SEE (3.73 mm^2) suggest that a significant degree of variance cannot be explained by the presence or absence of the identified variables. Thus, similar to coronary angioplasty, the predictive value of the presence of any specific variable may be poor and the use of these features in selecting patients suitable for directional atherectomy may be limited. Furthermore, despite the overall precision and accuracy of quantitative arteriography, the use of a single variable to assess angiographic outcome may be problematic. However, similar results were obtained with use of the final percent area stenosis, change in minimal cross-sectional area or change in percent area stenosis. Although follow-up angiography may be less than complete, 6-month minimal cross-sectional area may be the best single index for long-term clinical outcome. Nevertheless, the present study is the first to evaluate the quantitative improvements in coronary dimensions after directional atherectomy by using a computer-assisted edge detection method. Use of a central angiographic core laboratory may potentially reduce the bias that could be introduced by in-house analysis.

Conclusions. The use of directional coronary atherectomy in patients with symptomatic coronary artery disease has been demonstrated in this multicenter experience to be an effective method of coronary revascularization. Certain clinical and angiographic features, such as a history of restenosis, diffuse proximal disease, lesion length ≥10 mm and coronary calcific deposits, may be important factors limiting an optimal initial angiographic result. Furthermore, the size of the atherectomy device itself rather than the amount of tissue resected or balloon inflation pressure appears to be the most important procedural determinant of final minimal-cross-sectional area, supporting mechanical dilation as an important mechanism to the improved lumen caliber after coronary atherectomy. Controlled trials comparing initial angiographic results in these subgroups of patients treated with coronary atherectomy and coronary angioplasty are needed to determine which method is the preferred form of coronary revascularization in these clinical and angiographic subsets.

Appendix

Participants in the Study

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