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A COMPARISON OF DIRECTIONAL ATHERECTOMY WITH CORONARY ANGIOPLASTY IN PATIENTS WITH CORONARY ARTERY DISEASE

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Abstract *Background.* Directional coronary atherectomy is a new technique of coronary revascularization by which atherosclerotic plaque is excised and retrieved from target lesions. With respect to the rate of restenosis and clinical outcomes, it is not known how this procedure compares with balloon angioplasty, which relies on dilation of the plaque and vessel wall. We compared the rate of restenosis after angioplasty with that after atherectomy.

Methods. At 35 sites in the United States and Europe, 1012 patients were randomly assigned to either atherectomy (512 patients) or angioplasty (500 patients). The patients underwent coronary angiography at base line and again after six months; the paired angiograms were quantitatively assessed at one laboratory by investigators unaware of the treatment assignments.

Results. Stenosis was reduced to 50 percent or less more often with atherectomy than with angioplasty (89 percent vs. 80 percent, $P<0.001$), and there was a greater immediate increase in vessel caliber (1.05 vs. 0.86 mm, $P<0.001$). This was accompanied by a higher rate of early complications (11 percent vs. 5 percent, $P<0.001$) and higher in-hospital costs ($11,904 vs. $10,637; $P = 0.006$). At six months, the rate of restenosis was 50 percent for atherectomy and 57 percent for angioplasty ($P = 0.06$). However, the probability of death or myocardial infarction within six months was higher in the atherectomy group (8.6 percent vs. 4.6 percent, $P = 0.007$).

Conclusions. Removing coronary artery plaque with atherectomy led to a larger luminal diameter and a small reduction in angiographic restenosis, the latter being confined largely to the proximal left anterior descending coronary artery. However, atherectomy led to a higher rate of early complications, increased cost, and no apparent clinical benefit after six months of follow-up. (N Engl J Med 1993;329:221-7.)

DIRECTIONAL coronary atherectomy was developed by Simpson in 1984, and unlike balloon angioplasty, it allows the resection of coronary atherosclerotic plaque. From October 1986 through December 1989, 1020 procedures were performed at 14 investigational sites in the United States, with a success rate of 85 percent.[1] As a result, in September 1990 atherectomy was approved by the Food and Drug Administration for coronary revascularization. The procedure has since become widely used in the United States. In 1991, approximately 17,000 coronary-atherectomy procedures were performed, and it is estimated that in 1992 nearly 33,000 procedures were done, accounting for 10 percent of all nonsurgical coronary-revascularization procedures in the country.[2]

Balloon coronary angioplasty has a high rate of restenosis (30 to 50 percent), which detracts from its long-term success.[3] If the procedure involved removing part of the coronary lesion rather than stretching the diseased segment, it is theoretically possible that the restenosis rate could be reduced. In this randomized, multicenter trial, we tested the hypothesis that

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atherectomy would lead to a lower rate of restenosis than angioplasty, and we prospectively collected information about clinical, procedural, and economic outcomes.

Methods

Study Sites and Operators

The participating hospitals and investigators were selected on the basis of experience with both coronary angioplasty and atherectomy, as well as familiarity with clinical investigation in interventional cardiology. Thirty-five sites were chosen, 32 in the United States and 3 in Europe (the sites and investigators are listed in the Appendix). Each operator was required to have performed more than 400 coronary-angioplasty procedures with a success rate above 85 percent and more than 50 atherectomy procedures with a success rate above 80 percent; the protocol was reviewed and approved by the institutional review board at each site.

Patient Selection

Patients who had symptomatic ischemic heart disease deemed suitable for either atherectomy or angioplasty and who were willing to give informed consent to participate were considered for enrollment in the trial. The angiographic criteria for inclusion were the presence of diseased native coronary vessels that had not undergone previous coronary intervention, that had stenosis of at least 60 percent on visual assessment and a lesion length of 12 mm or less, and that were suitable for either a 6-French cutter or larger or a 3.0-mm balloon or larger. Patients with multivessel coronary disease were eligible, but a single vessel was specified as the target before the coronary intervention began. All the lesions in the target artery had to be amenable to both interventional techniques to allow conformity with assignment to a single treatment.

To ascertain the denominator of patients being screened for participation in the trial, a log was maintained at each site that included every atherectomy procedure performed. A sample of the "universe" of all coronary interventional procedures performed at the study sites was tallied during one week of active enrollment.

Randomization

After informed consent was given, the randomization center at Duke University was contacted through a telephone service that was in continuous operation. After a screening interview to document the patient's clinical and angiographic eligibility for the trial, a random assignment to either atherectomy or angioplasty was made. The randomization sequence was developed on a site-by-site basis in blocks of 12 treatment assignments so that approximately equal numbers of patients would be assigned to each treatment at each site.

Revascularization Procedures

The investigators agreed, as part of the protocol, ideally to obtain a final angiographic result with as little residual stenosis as possible. The goal was residual stenosis of less than 20 percent, although technical success has conventionally been defined as stenosis of 50 percent or less. The technical details of angioplasty and atherectomy have been reviewed elsewhere.[4,5] Crossover to the other treatment method was strongly discouraged, although it was recognized at the outset of the trial that in approximately 10 percent of patients the rigid atherectomy device would require pretreatment with balloon dilation before the atherectomy catheter could be advanced.[5] At the beginning and end of each procedure, a coronary angiogram of the target vessel was obtained in two orthogonal views with either a 7-French or an 8-French catheter after the administration of 200 μg of intracoronary nitroglycerin to standardize the quantitative coronary angiography. The same procedure was used at the follow-up coronary angiography performed at six months, to match the original views.

Before the procedure, aspirin was given in a dose of 160 mg per day or more for at least one day, and at least one dose of a calcium-channel blocker was administered. Heparin was administered as a bolus of 10,000 U, with additional boluses to maintain the activated clotting time above 350 seconds during the procedure. At the discretion of the investigator, the femoral access sheaths were removed 4 to 24 hours after the procedure, with attention paid to the adoption of a uniform protocol at each site regardless of the treatment assignment. Before and within 24 hours after the procedure, a 12-lead electrocardiogram was obtained, and creatine kinase levels with myocardial isoenzymes were measured serially every 8 hours after the procedure for a total of three samples. After the procedure, aspirin (325 mg per day) and a calcium-channel blocker were prescribed for one month. No other cardiovascular medications were recommended unless they were specifically prescribed by the investigators to treat other preexisting medical conditions.

Angiographic Laboratory

The cineangiograms were forwarded to the laboratory of the Cleveland Clinic Foundation for independent, blinded assessment of the initial and follow-up quantitative coronary angiograms. These assessments were made from the paired initial and follow-up angiograms, with the technicians unaware of the treatment assignments and with any images that showed the procedural devices spliced out. Although multiple views of each lesion were quantified, only the most severe hemiaxial view of the stenosis without foreshortening was selected for analysis. End-diastolic cine frames from orthogonal views were digitized with a cine-video converter and a computer-assisted edge-detection algorithm.[6]

Pathology Laboratory

Tissue specimens retrieved from the atherectomy catheter were immediately placed in 4 percent paraformaldehyde for 30 minutes, after which they were stored at 4°C in 30 percent sucrose–phosphate-buffered saline and forwarded to the laboratory at St. Elizabeth's Hospital in Boston. A portion of the specimen was postfixed in 10 percent formalin and analyzed by light microscopy and immunohistochemical analysis.

Economics and Quality-of-Life Assessment

At 19 of the 32 U.S. study sites, the investigators and research nurses volunteered to participate in a substudy examining hospital costs, other economic outcomes, and quality of life. All hospital bills covering the period from enrollment to the six-month follow-up assessment were collected prospectively. In addition, each patient had quality-of-life assessments at base line and at six months. Data on hospital charges were converted to hospital costs with revenue-center–specific Medicare cost-to-charge ratios and per diems from each hospital's Medicare Cost Report.[7]

End Points

The primary end point in the trial was angiographic restenosis, defined as stenosis of more than 50 percent six months after an initially successful procedure. The other angiographic indexes assessed included the success rate, with success defined as a reduction in stenosis to 50 percent or less as assessed by quantitative angiography, the actual percentage of stenosis before and after the procedure and at six months of follow-up, the absolute minimal luminal diameter of the target lesion, and the caliber of the target vessel. All these angiographic end points, including early success and restenosis, were assessed at the angiographic laboratory.

A composite early clinical end point, indicative of the safety of the procedures, was prospectively defined to include death, emergency coronary artery bypass surgery, acute myocardial infarction, and abrupt vessel closure during the period of hospitalization after randomization. A composite six-month clinical end point was also prospectively defined as described below. Myocardial infarction was diagnosed both clinically at the participating site and by an adjudication committee unaware of the treatment assignment, on

the basis of the development of new Q waves or the elevation of creatine kinase myocardial-band isoenzymes to more than three times the upper limit of normal for the site.

Data Management and Statistical Analysis

All the data were prospectively recorded by the research coordinator and investigators at each site in case-report form, forwarded to the coordinating center at Duke University, and verified by range and consistency checks and double data entry, with queries sent back to the sites about any missing or inconsistent data. To ensure the quality of the data, cardiology nurses at the coordinating center audited all case-report forms and documented a random 15 percent of the forms, using the source medical records at the site.

Continuous data were expressed as medians with 25th and 75th percentiles unless otherwise indicated. Selected base-line characteristics and key clinical and angiographic outcomes were compared between treatment groups by the chi-square test or Fisher's exact test in the case of discrete variables and by the Wilcoxon rank-sum test in the case of continuous variables. The occurrence of clinical outcomes during the six-month follow-up period was characterized with Kaplan–Meier survival curves, and the treatments were compared by the log-rank statistic.[8] The treatments were compared with respect to the six-month composite end point with use of ordinal logistic regression.[8] All tests of significance were two-tailed, and the treatments were compared by the intention-to-treat principle. Multiple linear regression analysis was used to assess the relative strength of the relation of the treatment and selected other clinical factors with the luminal diameter at six months. The clinical factors considered were minimal luminal diameter after the procedure, age, sex, the presence of diabetes, unstable as compared with stable angina, location of the lesion in the left anterior descending artery, vessel caliber, and the occurrence of acute procedural complications. For a prespecified subgroup that included patients with lesions in the proximal left anterior descending artery, an assessment of whether the effect of atherectomy on restenosis differed from its effect in other patients was made by logistic regression and testing for an interaction between treatment and subgroup.

Relationship with Sponsors

The steering committee, consisting of the principal investigators at each site, set firm standards for the design and execution of the protocol, which was conducted in a manner completely independent of the sponsors (Devices for Vascular Intervention, Redwood City, Calif., and Eli Lilly, Indianapolis). The steering committee, as well as the members of the Data and Safety Monitoring Committee and the coordinating center, were not permitted to have a financial interest in the sponsors or to serve as consultants or part-time employees of the sponsors. This requirement also applied to the investigators' spouses and family members. All the data generated in the trial were handled at the coordinating center. The study data were not made accessible to the investigators or sponsors until the six-month follow-up data were complete and the analysis had been performed.

Results

Characteristics of the Patients

Enrollment in the study began August 15, 1991, and ended April 30, 1992, by which time 1012 patients had been entered. The relevant base-line characteristics of the patients enrolled are shown in Table 1. The two groups were well balanced with respect to all cardiovascular risk factors. The population consisted predominantly of patients with unstable angina. This clinical diagnosis was supported by a diagnosis in the angiographic laboratory of thrombus in the lesion in nearly 20 percent of the patients in both groups; thrombus was identified histologically in 36 percent of the lesions treated by atherectomy.

Table 1. Base-Line Clinical and Angiographic Characteristics.*

Characteristic	Atherectomy (N = 512)	Angioplasty (N = 500)
Age (yr)	59 (51, 67)	59 (51, 67)
Male sex (%)	75	70
Weight (kg)	82 (73, 92)	82 (72, 93)
Height (cm)	172 (165, 178)	173 (165, 178)
Diabetes (%)	19	19
Current smoker (%)	29	28
Hypertension (%)	52	54
Hypercholesterolemia (%)	45	43
Cholesterol (mg/dl)†	217 (190, 250)	216 (188, 247)
History of MI (%)	44	41
Unstable angina (%)‡	66	70
Pain at rest	46	44
Pain with ECG changes	21	18
Angina after MI	18	16
Accelerating pattern	63	61
Target vessel (%)		
Left main	0.6	0.6
Left anterior descending	58	56
Left circumflex	14	10
Right coronary artery	28	34
Ejection fraction	58 (50, 65)	56 (50, 65)
No. of diseased vessels — % of group		
1	66	65
2	29	29
3	5	6
Thrombus (%)§	20	18
Lesion length (mm)§	8.9 (6.6, 11.6)	8.6 (6.4, 12.0)
Vessel caliber (mm)§	2.9 (2.5, 3.3)	2.9 (2.5, 3.2)
% Stenosis§	71 (63, 78)	73 (63, 79)

*Percentages shown are percentages of the study group. Numbers followed by parentheses are medians; the first number inside the parentheses is the 25th percentile, and the second number the 75th percentile. MI denotes myocardial infarction, and ECG electrocardiographic.

†To convert values to millimoles per liter, multiply by 0.02586.

‡Patients with unstable angina can be included in more than one subcategory.

§As determined by the angiographic laboratory; the median vessel calibers determined by the site investigators were 3.2 mm in the atherectomy group and 3.3 mm in the angioplasty group.

A sampling of the complete profile of interventional procedures in the "universe" sample indicated that 11 percent of the procedures at the participating centers were performed with directional atherectomy and that the patients who underwent them had larger target vessels with more proximal and eccentric lesions. Among the 1754 patients who underwent atherectomy at the study sites during the course of the trial, 470 patients (27 percent) were eligible for enrollment but underwent atherectomy on a nonrandomized basis because of the investigator's preference for the procedure; this selection bias occurred primarily at three sites where there was low enrollment.

Procedural and In-Hospital Outcomes

The principal results of the procedures are shown in Table 2. The rate of crossover from atherectomy to conventional balloon angioplasty was 17 percent; for crossover from angioplasty to atherectomy, it was 4 percent. Methods of revascularization other than that assigned, including perfusion balloons, stents, or

other atherectomy or laser devices, were used in 26 percent of the patients undergoing atherectomy as compared with 14 percent of those undergoing angioplasty. As evaluated by site investigators, the success rate (the rate at which a reduction in stenosis to 50 percent or less was achieved) was 96.4 percent in both groups, but angiographic review found a higher success rate for atherectomy than for angioplasty (89 percent vs. 80 percent, $P<0.001$). The success rates as defined on the basis of quantitative angiographic stenosis of 50 percent or less and no major complications (such as death, infarction, or emergency bypass surgery) were 82 percent and 76 percent, respectively ($P = 0.016$). Atherectomy led to a greater immediate gain in the diameter of the vessel than angioplasty (1.05 vs. 0.86 mm, $P<0.001$).

The in-hospital clinical outcomes are shown in Table 2. There was a higher rate of myocardial infarction among the patients undergoing atherectomy than among those undergoing angioplasty (6 percent vs. 3 percent, $P = 0.035$) and a higher rate of early composite events in the atherectomy group as compared with the angioplasty group (57 events [11 percent] vs. 27 events [5 percent], $P<0.001$). On blinded assessment of the serial creatine kinase enzyme measurements and electrocardiographic data, the overall frequency of myocardial infarction, including both clinical and laboratory diagnoses, was 19 percent for atherectomy as compared with 8 percent for angioplasty ($P<0.001$). Since the importance of myocardial infarction detected on the basis of abnormal enzyme levels alone, without clinical or electrocardiographic signs, is unknown in this setting, the data on enzyme-based diagnoses are reported in Table 2, but in the presentation of clinical end points only the clinical diagnosis is used.

Hospital costs are shown in Table 3 for 605 patients enrolled at the 19 sites participating in the substudy. With respect to base-line characteristics and results of the procedure, these patients were representative of the entire study population.

Table 2. Technical Features and Results of the Procedures.*

VARIABLE	ATHERECTOMY (N = 512)	ANGIOPLASTY (N = 500)
Procedural features		
Maximal size of equipment (%)		
Atherectomy catheter		
5-French	1	—
6-French	52	—
7-French	47	—
Balloon catheter (mm)		
<3.0	—	9
3.0–4.0	—	80
>4.0	—	11
Use of opposite technique (%)†	18	4
Use of perfusion balloon (%)	11	11
Stent or laser use (%)	1.2	0.4
Use of any other device (%)	26	14
Final % stenosis		
Assessed visually by site	15	20
Assessed quantitatively by angiographic laboratory	29	36
Final minimal luminal diameter (mm)	2.02	1.80
Perforation (%)	0.4	0.2
In-hospital outcomes (%)		
Death	0	0.4
Myocardial infarction		
Detected clinically by site	6	3
Q wave	2	2
Non–Q wave	4	1
Detected by adjudication, abnormal enzymes only	19	8
Emergency CABG	3	2
Abrupt vessel closure	7	3
Early-phase composite end point‡	11	5

*Percentages shown are percentages of patients in the study group. CABG denotes coronary artery bypass surgery.

†Includes balloon predilation, performed in 15 percent of the patients undergoing atherectomy in order to pass the device across the target lesion.

‡Includes death, emergency CABG, acute myocardial infarction, and abrupt vessel closure during hospitalization after randomization.

Restenosis and Clinical Outcomes at Six Months

Of the 959 eligible patients, 862 (90 percent) had angiographic follow-up. Follow-up angiography was not performed in the remaining patients for the following reasons: unwillingness to undergo the procedure (73 patients), death (9 patients), intercurrent illness (5 patients), and loss to follow-up (10 patients). The rate of restenosis according to the definition of the primary end point was 50 percent in the atherectomy group as compared with 57 percent in the angioplasty group in the 825 patients who could be evaluated and for whom there were technically adequate paired data ($P = 0.06$). Figure 1 shows plots of the distribution of minimal luminal diameter that incorporate all the patients in the trial who were included in the paired analysis, whether or not they had angiographic success initially. A regression analysis of the determinants of six-month minimal luminal diameter, with control for treatment assignment, revealed that the final minimal luminal diameter after the procedure was the single most important determinant of subsequent lumen caliber ($F = 84.7$, $P<0.001$). The only other important determinants were the vessel size before the intervention ($F = 15.6$, $P<0.001$), the presence of diabetes mellitus ($F = 10.5$, $P = 0.001$), and location of the lesion in the proximal left anterior descending artery ($F = 5.4$, $P = 0.02$).

The subgroup of patients with stenosis in the proximal left anterior descending artery who were identified at the outset of the trial appeared to have a lower rate of restenosis with atherectomy: among these patients, the rate was 51 percent in the atherectomy group as compared with 63 percent in the angioplasty group ($P = 0.04$). The restenosis rate for other lesions was 48 percent in the atherectomy group as compared with 50 percent in the angioplasty group. The minimal luminal diameter of the proximal left anterior descending artery at six months was 1.32 mm in the

Table 3. Mean Hospital Costs and Length of Stay for 605 Representative Study Patients.

VARIABLE	ATHEREC-TOMY (N = 308)	ANGIO-PLASTY (N = 297)	P VALUE
	dollars		
Total cost per patient	11,904	10,637	0.006
Room	856	688	
Coronary care unit	2,464	2,288	
Cardiac catheterization lab	4,367	3,628	
Laboratory	572	520	
Pharmacy	681	556	
Radiography/nuclear	204	168	
Operating room/anesthesia	376	151	
Blood bank	35	32	
Medical supplies	1,926	1,702	
Other	423	904	
Total charges	17,489	15,263	0.004
	days		
Length of stay	5.7	5.8	

atherectomy group as compared with 1.12 mm in the angioplasty group (P = 0.008); for lesions in the other target vessels, the final diameters were 1.42 and 1.44 mm, respectively. The interaction between treatment and subgroup was statistically significant (P = 0.03). The angiographic benefit in the subgroup of patients with lesions in the proximal left anterior descending coronary artery was not associated with any distinct advantages in clinical outcomes or reduced periprocedural complications.

The cumulative six-month clinical outcomes are shown in Table 4, and the actuarial analysis in Figure 2. All eight deaths in the atherectomy group occurred after the initial hospitalization. Three were related to peripheral vascular complications of the procedure, and five were from cardiovascular causes. The increased rate of myocardial infarction in the atherectomy group was statistically significant. Exercise testing, performed in 71 percent of the patients during follow-up, revealed no significant differences between the two groups. The median treadmill exercise time was 8.2 minutes in both groups. The patients in the atherectomy group and those in the angioplasty group had similar rates of positive exercise tests (30 percent vs. 32 percent, respectively) and ST-segment depression with exercise (32 percent vs. 38 percent, respectively).

DISCUSSION

This randomized trial comparing coronary atherectomy with angioplasty demonstrated a small reduction with atherectomy in the primary end point, angiographic restenosis at six months, at the expense of a higher rate of periprocedural complications. The latter finding was unanticipated and accounts in large part for the worse clinical outcomes at six months with atherectomy. Besides the concern about the safety of the newer procedure as compared with angioplasty, this trial provides insight into the importance of achieving a wide lumen to avoid angiographic restenosis.

Restenosis is the most important and vexing problem complicating balloon angioplasty. It occurs in a substantial minority of patients within a period of six months after the procedure and accounts for approximately $2 billion per year in health care expenditures in the United States for repeat angioplasty and bypass surgery.[9] There have been several large-scale, well-conducted trials testing pharmacologic strategies such as the use of angiotensin-converting–enzyme inhibitors, heparin fragments, steroids, and thromboxane antagonists,[10-14] none of which have reduced the rate of restenosis. The current trial shows that the rate of restenosis can be improved with atherectomy, but the overall rate was still quite high and the improvement relatively small.

The high rates of restenosis in both study groups can be attributed in part to the high prevalence of unstable angina, which is known to be an important base-line risk factor for restenosis after coronary angioplasty.[15,16] By quantitative coronary angiography it has been shown that luminal renarrowing follows a nearly Gaussian distribution after coronary angioplasty, atherectomy, and stenting,[17,18] and the time course is similar for the various revascularization techniques.[18-27] Although the observed rate of 50 percent for restenosis seems high, it approximates the rate reported by Nobuyoshi and colleagues in the landmark serial study of angiographic restenosis after angioplasty.[19] It is important to keep in mind the critical difference in rates between angiographic and clinical restenosis, since the latter is best estimated by the rate at which subsequent coronary revascularization is needed, which was approximately 35 percent in both groups in this study.

Our data reinforce the fundamental finding of Baim, Kuntz, and colleagues[18,20-23] that "bigger is better" in the sense that greater early luminal enlarge-

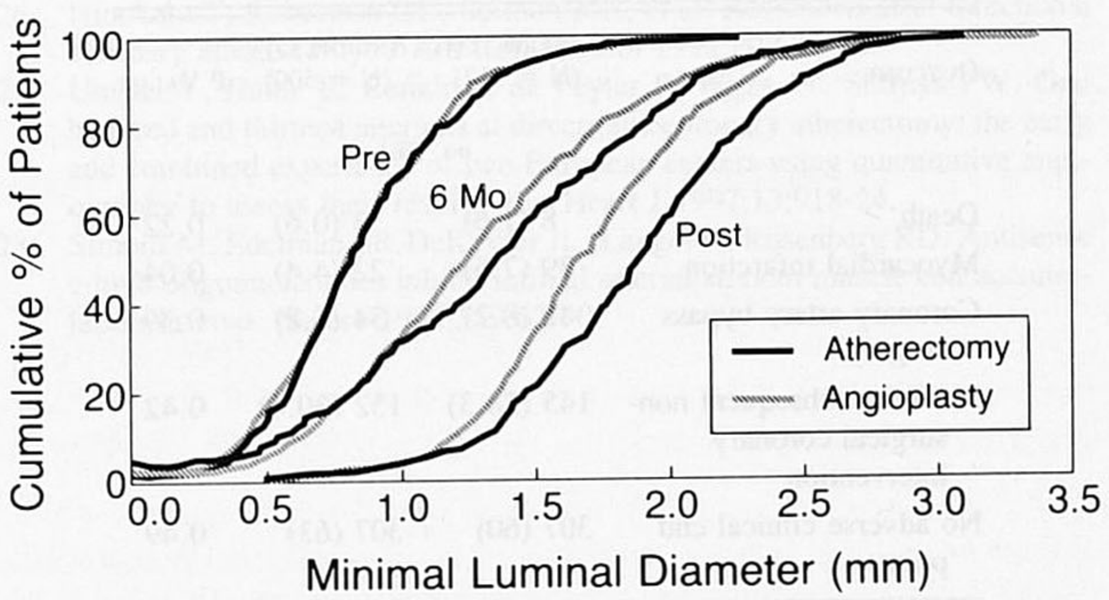

Figure 1. Cumulative Frequency Distribution of the Minimal Luminal Diameter of the Target Lesion in the Two Study Groups.

There was no difference in the base-line distribution (Pre), but at the end of the procedure (Post), more improvement was seen with atherectomy (P<0.001). At the six-month follow-up (6 Mo) the difference narrowed, but a trend favoring atherectomy remained (P = 0.08).

ment translates into greater net angiographic gain at six months. In accordance with these observations, the principal determinant of an improved coronary lumen at six months was the minimal diameter of the lumen after the procedure, whichever device is used to achieve it. The fact that patients undergoing atherectomy had a significantly higher rate of early success and a large post-procedural lumen that could not be obtained as frequently with balloon angioplasty probably explains the angiographic benefit of atherectomy in this trial. These results support the thesis that removing the coronary atherosclerotic lesion by directional atherectomy can produce a more widely patent arterial lumen, particularly in the left anterior descending coronary artery, thereby inviting further investigation of mechanical approaches to reducing restenosis. Of course, methods of modifying the underlying biologic response to vessel-wall injury, including the change of phenotype in smooth-muscle cells and the aggressive inflammatory response seen after these procedures, will also be required.[28]

Atherectomy resulted in a higher rate of early complications, chiefly consisting of abrupt vessel closure and non–Q-wave myocardial infarction. Because of the excess of periprocedural infarction and death during follow-up, the results for the clinical end point of death and nonfatal myocardial infarction were worse with atherectomy. The trial tested a rather broad application of coronary atherectomy, patients were enrolled on the basis of their suitability for either procedure, and the angiographic data indicate that atherectomy was not performed aggressively. In particular, it is impossible to know whether more plaque retrieval, probably reducing restenosis further, would have worsened or improved the rate of procedural complications. In other studies of atherectomy, larger post-procedural lumen diameters and lower rates of restenosis were obtained without substantially higher

Table 4. Cumulative Clinical Outcomes at the Six-Month Follow-up.*

Outcome	Atherectomy (N = 512)	Angioplasty (N = 500)	P Value
	no. (%)		
Death	8 (1.6)	3 (0.6)	0.22
Myocardial infarction	39 (7.6)	22 (4.4)	0.04
Coronary artery bypass surgery	42 (8.2)	34 (6.8)	0.39
Need for subsequent non-surgical coronary intervention	145 (28.3)	152 (30.4)	0.42
No adverse clinical end point	307 (60)	307 (63)	0.49

*For the cumulative outcomes, patients may be included in more than one category. In addition, the six-month composite clinical end point was prospectively defined as death, the worst outcome, followed in order of rank by myocardial infarction, coronary artery bypass surgery, and the need for subsequent coronary intervention. Patients were classified in the category that corresponded to the worst outcome they had experienced. By ordinal logistic regression, there was no significant difference between the two groups in the composite clinical end point (P = 0.19).

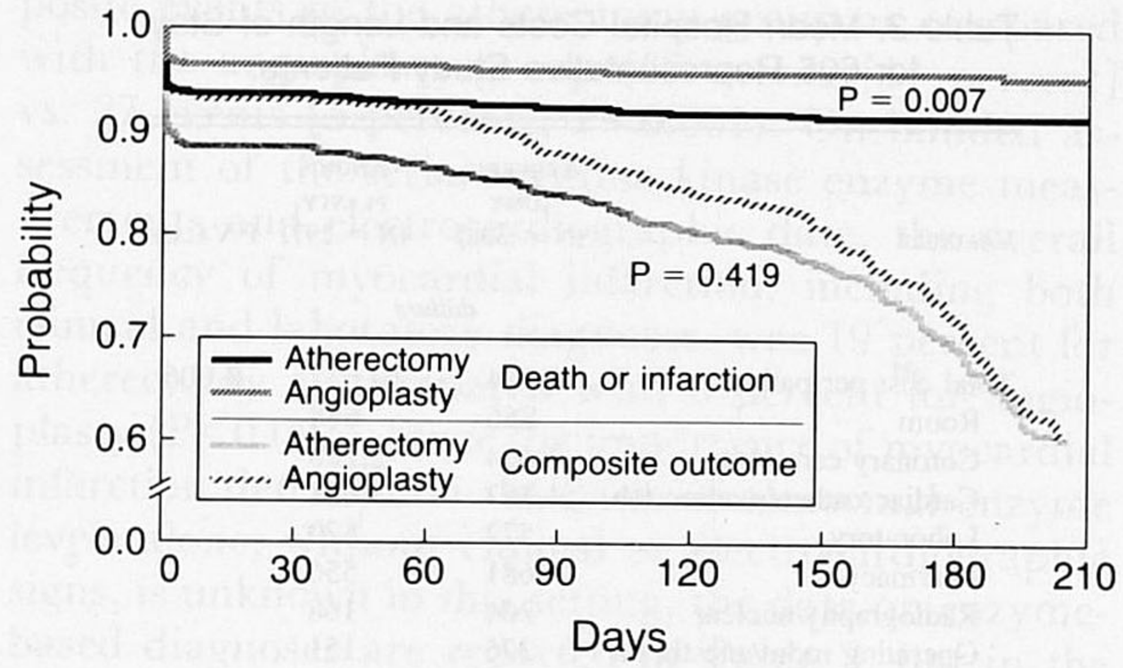

Figure 2. Kaplan–Meier Survival Curves for Patients Undergoing Atherectomy or Angioplasty, with Regard to Major Clinical Outcomes.

Survival curves are shown for the probability of death and myocardial infarction (P = 0.007) and for a composite outcome including death, myocardial infarction, coronary artery bypass surgery, and the need for subsequent coronary intervention (P = 0.419).

complication rates.[19-26] The optimal "therapeutic window" of atherectomy may thus require further definition in prospective, randomized trials.

Although atherectomy led to greater initial gain in lumen size and a small reduction in the rate of restenosis, this angiographic benefit was overshadowed by the increase in adverse clinical outcomes and cost. Removing plaque rather than dilating the diseased coronary artery thus remains an attractive concept, but balloon angioplasty is still the preferred approach overall unless and until techniques of atherectomy can be improved or until convincing, reproducible findings indicate that certain subgroups will benefit from atherectomy from a clinical as well as an angiographic standpoint.

Appendix

In addition to the study authors, the following investigators and study groups participated in the Coronary Angioplasty versus Excisional Atherectomy Trial. *Cleveland Clinic Foundation, Cleveland:* I. Franco, R. Raymond, and S. Deluca; *Loyola Medical Center, Chicago:* S. Johnson, E. Grassman, B. Lewis, and L. Wrona; *St. Vincent's Hospital, Indianapolis:* T. Peters and B. Ness; *Klinikum Grosshadern der Universität, Munich, Germany:* T. Kolbe; *Carolina's Medical Center, Charlotte, N.C.:* R.M. Bersin, J. Cedarholm, B. Wilson, and S. Lingelbach; *Jewish Hospital, Louisville, Ky.:* V. Miracle; *Midwest Heart Research Foundation, Lombard, Ill.:* L.S. McKeever, J. Marek, P. Kerwin, and E.L. Enger; *Graduate Hospital, Philadelphia:* R.S. Gottlieb and H. Hunter; *Maimonides Medical Center, Brooklyn, N.Y.:* J. Shani and N. Schulhoff; *University of Louvain Medical School, Brussels, Belgium:* W. Wijns, J. Renkin, and T. Baudhuin; *Methodist Hospital, Memphis, Tenn.:* F. Martin and K. Garrison; *Erasmus University, Rotterdam, the Netherlands:* P.J. de Feyter and V. Umans; *St. Vincent's Medical Center, Bridgeport, Conn.:* E. Kosinski and M. Capasso; *Johns Hopkins Hospital, Baltimore:* J. Brinker, M. Midei, J.R. Resar, and V.J. Coombs; *St. Francis Hospital, Beech Grove, Ind.:* M. Cohen, H. Hickman, and P. Cross; *St. Joseph's Hospital, Atlanta:* W. Knopf, C. Cates, and J. Shaftel; *Washington Cardiology Center, Washington, D.C.:* K. Kent, A. Pichard, L. Satler, J. Popma, and P. Shotts; *Maine Medical Center, Portland:* M. Kellett, Jr., J. Cutler, and J. Kane; *Boston University Medical Center, Boston:* A. Jacobs, D.P.

Faxon, and M. Mazur; *Minneapolis Heart Institute, Minneapolis:* M. Mooney, J. Madison, and E. Sawicki; *Mayo Foundation, Rochester, Minn.:* K. Garratt, J. Bresnahan, and J. Ramaker; *Ochsner Foundation Hospital, New Orleans:* C.J. White, S. Ramee, and B. Leasure; *Riverside Methodist Hospitals, Columbus, Ohio:* A. Chapekis, N.H. Kander, B.S. George, N. Kander, and C. Gilliland; *Southwest Cardiology Presbyterian Hospital, Albuquerque, N.M.:* H.J. White and R. Sexson; *Georgetown University, Washington, D.C.:* S.N. Oesterle and L. Barry; *Rhode Island Hospital, Providence:* B. Shariff and M. Grogan; *University of Louisville, Louisville, Ky.:* D.J. Talley and Z. Yussman; *Sequoia Hospital, Redwood City, Calif.:* L. Braden; *Emory University Hospital, Atlanta:* S. Mead; *St. Vincent Hospital, Portland, Oreg.:* P. Au, H. Garrison, and T. Glickman; *University of Washington, Seattle:* D.K. Stewart, J. Chambers, and J. Dalquist; *Beth Israel Hospital, Boston:* R. Kuntz, D. Baim, and C. Senerchia; *Christ Hospital, Cincinnati:* D. Kereiakes, C. Abbottsmith, and D. Lausten; *Good Samaritan, Phoenix, Ariz.:* M. Padnick, J. Schumacher, and A. Stephens; and *Medical College of Virginia, Richmond:* M. Cowley and K. Kelly.

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