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Background—Previous clinical trials of directional coronary atherectomy (DCA) have failed to show significant improvement in early or late outcomes compared with balloon angioplasty (PTCA). The present study tested the hypothesis that more aggressive "optimal" atherectomy could be performed safely to produce larger initial lumen diameters and a lower late restenosis rate.

Methods and Results—The present study was a prospective multicenter registry of consecutive patients undergoing optimal DCA of de novo or restenotic lesions in 3.0- to 4.5-mm native coronary arteries. Optimal DCA was defined as using a 7F atherectomy device and adjunctive PTCA if necessary to achieve a <15% residual stenosis. Six-month angiographic and 1-year clinical follow-up was planned in all patients. A total of 199 patients with 213 lesions met eligibility criteria for enrollment. Short-term procedural success was achieved in 97.5%, with a major complication rate (death, emergency bypass surgery, or Q-wave myocardial infarction [MI]) of 2.5%. There were no early deaths. Non–Q-wave MI (CK-MB >3 times normal) occurred in 14% of patients. Mean reference vessel diameter was 3.28 mm. Mean diameter stenosis was reduced from 63.5% to a final stenosis of 7%. Late 1-year clinical follow-up revealed one cardiac death and a target lesion revascularization rate of 17.8%. The angiographic restenosis rate at 6 months was 28.9%, with the major predictor of restenosis being a smaller postprocedure lumen diameter.

Conclusions—Optimal DCA produced a low residual percent diameter stenosis and a lower restenosis rate than seen in previous trials without an increase in early or late major adverse events. (***Circulation.*** 1998;97:332–339.)

Key Words: atherectomy ■ restenosis ■ angioplasty

Directional coronary atherectomy has been used for the nonsurgical removal of obstructive coronary atherosclerotic lesions in the United States since FDA approval in 1990. Although the initial results in the preapproval registry were encouraging,[1] the first two randomized trials comparing DCA with PTCA, CAVEAT[2] and CCAT,[3] failed to show significant improvement in early or late clinical and angiographic outcomes with DCA. Analysis of the angiographic results of CAVEAT demonstrated that the immediate posttreatment percent diameter stenosis after DCA was only slightly lower than that achieved by PTCA (29% versus 36%). This is important because the immediate result was highly predictive of late angiographic results for both treatments.[2] Other single-center studies of DCA, however, reported lower posttreatment percent diameter stenosis when they applied an atherectomy technique aimed at optimizing early gain in lumen diameter and reported lower late rates of restenosis.[4–7]

OARS was conceived to test the hypothesis that use of an "optimal" atherectomy technique to produce larger early lumen diameters would translate into a lower rate of late

clinical and angiographic restenosis than seen in CAVEAT and CCAT. The objectives were thus to determine (1) whether DCA could be performed more aggressively (with larger atherectomy devices and adjunct post-PTCA) to obtain larger angiographic posttreatment lumens than in the previous randomized studies, (2) whether the improved short-term results could be achieved safely without increasing the risk of major complications, (3) whether this approach would translate into a lower rate of late (≥6 months) angiographic and clinical restenosis, and (4) whether routine use of IVUS would help to identify lesion characteristics best suited for DCA and elucidate the immediate mechanism of DCA, specifically the contributions of plaque excision versus mechanical dilatation.

Methods

Study Design
The study was designed as a prospective multicenter (four sites) registry of 200 consecutive patients undergoing DCA of de novo or restenotic lesions in native coronary arteries. The technique of "optimal" DCA was defined as DCA performed with a 7F atherec-

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tomy device maximizing tissue removal by use of angiographic and documentary but optional guided IVUS, followed by adjunctive PTCA if necessary, to leave <15% diameter stenosis at the treatment site. Late angiographic (≥6 months) and clinical (1 year) follow-up was planned to evaluate long-term results relative to the results of CAVEAT and CCAT. The primary end points of this study were (1) 6-month angiographic restenosis rate (defined as percent diameter stenosis >50%) and (2) 1-year target vessel failure rate (initial procedure failure, target vessel revascularization, Q-wave MI, or death).

Patient Selection

From October 26, 1993, to January 12, 1995, all patients undergoing coronary intervention at the participating centers who met eligibility criteria were consecutively screened for entry. All patients treated by DCA during the study period were recorded in a log to determine the atherectomy "universe." Eligibility criteria for the OARS trial included patients 18 to 80 years old with angina or a positive functional study due to obstructive native coronary artery disease. The angiographic inclusion criteria were (1) target vessel reference diameter of ≥3.0 mm and ≤4.5 mm, making the lesion suitable for treatment with a 7F Simpson Atherocath; (2) one or more culprit lesions (same vessel) of ≥60% and <100% diameter stenosis and ≤15 mm in length; and (3) mild to moderate vessel tortuosity and no more than mild target lesion calcification. Patients with aspirin allergy; adjacent nontreated lesions in the target vessel of >40%; MI with CK >3 times normal within 5 days of treatment; history of bleeding diathesis, stroke, or transient ischemic neurological attacks within the past year; and women of child-bearing potential were excluded.

Patients reviewed the study protocol and consent form, previously approved by the Institutional Review Board at each study center, with a member of the study team and signed informed consent before entry into the trial.

DCA Procedure

After standard preparation and local anesthesia, a 10F sheath was placed into either the right or left femoral artery, and standard 10F (left coronary) or 9.5F (right coronary) atherectomy guiding catheters were advanced through it. Intracoronary nitroglycerin (200 to 300 μg) was administered, followed by cineangiography of the culprit lesion in two orthogonal views that minimized lesion foreshortening. Activated clotting time was measured, and intravenous heparin was given to achieve an activated clotting time between 300 and 350 seconds. Baseline IVUS was performed with either 2.9F or 3.2F imaging catheters (Cardiovascular Imaging Systems), and standard motorized pullback of the imaging crystal was performed at a rate of 0.5 mm/s from the distal normal-appearing coronary segment to the tip of the guiding catheter. DCA with a 7F, 7F graft, or 6F Simpson Atherocath

was performed by standard techniques with progressively increasing balloon pressures from 10 to a maximum of 60 psi. Multiple passes with the Atherocath were encouraged to achieve a visual estimate of <15% stenosis, after which adjunctive PTCA (balloon-to-artery ratio of 1 to 1.1:1) could be performed. Cineangiography at matched orthogonal angles with baseline images and IVUS were then performed after 200 to 300 μg nitroglycerin IC after the final atherectomy sequences and again after final adjunct PTCA (if necessary). Only if significant dissections, thrombus, or abrupt or threatened closure occurred could the investigator proceed with bailout procedures, such as perfusion PTCA, stents, or emergency CABG.

Patient Follow–Up

Careful in-hospital assessment was performed for all clinical outcomes, including hemorrhagic and vascular complications, by independent clinical data coordinators using standardized case report forms. Cardiac enzymes (CK-MB) were drawn before treatment, 4 to 6 hours after the procedure, and 24 hours after the procedure or before discharge, whichever came first. A 12-lead ECG was performed at baseline, immediately after the procedure, during any episode of suspected ischemia, and before hospital discharge. Standard sheath removal protocols at each institution were followed.

Clinical follow-up was obtained at 1, 3, and 6 months and 1 year for the occurrence of an adverse cardiac event (death, MI, or any repeat revascularization procedure). The potential relationships of such complications and repeat revascularizations to the index-randomized treatment strategy and target site were adjudicated by a Clinical Events Committee blinded to the study objectives. IVUS was also performed at follow-up with the same techniques as the initial procedure.

End Points

The primary angiographic end point was the 6-month angiographic restenosis rate, defined as >50% diameter stenosis. Other angiographic assessments included initial procedural success (defined as <50% residual diameter stenosis in the absence of severe dissections or flow limitation); MLD at baseline, after DCA, after the procedure, and at follow-up; and reference vessel diameter. All angiographic indices were assessed by the angiographic core laboratory.

The primary clinical end point was the 1-year target vessel failure rate, defined as initial procedure failure (residual diameter stenosis ≥50%), target vessel revascularization, Q-wave MI, or death. Deaths were classified as early (≤30 days after the procedure) or late (30 days to 1 year of follow-up); all deaths were considered cardiac unless clearly attributable to a noncardiac cause. The documentation of new, pathological Q waves in two or more contiguous leads by the ECG core laboratory associated with any elevation of CK-MB was required for the diagnosis of a Q-wave MI. Non–Q-wave MIs were determined with a ratio of peak periprocedural CK-MB to the upper limit of normal for each clinical institution.

The need for CABG or use of stenting was judged by the blinded Clinical Events Committee as emergent if performed for overt or threatened abrupt closure. Abrupt closure was defined as reduced coronary flow (TIMI grade 0 or 1) due to mechanical complications that persisted, led to reversal by CABG or use of a bailout device, or resulted in death, Q-wave MI, or non–Q-wave MI. Threatened abrupt closure was diagnosed by the presence of an NHLBI grade B dissection and ≥50% diameter stenosis, or any residual stenosis with an NHLBI grade C or worse dissection, after atherectomy. Repeat revascularizations of restenotic target sites (≥50% diameter stenosis by the angiographic core laboratory >14 days after the index treatment) in patients with recurrent angina and/or positive functional ischemia studies or treatment of target lesions with ≥70% diameter stenosis were considered target lesion revascularizations. Similar clinical criteria were used to adjudicate the clinical need for target vessel revascularization, including treatment of the target lesions elsewhere in the same major epicardial coronary artery or its branches. Major complications and repeat revascularizations were adjudicated by the Clinical Events Committee.

Data Analysis

Baseline clinical data included patient demographics, anginal status, coronary risk factors, history of prior MI or prior CABG, degree of coronary disease, and left ventricular function. Baseline and procedural angiographic measurements included reference vessel diameter and lesion severity (percent stenosis, MLD); lesion and vessel morphology, location, and length; TIMI flow; and collaterals. Procedural data included equipment resources used and clinical outcomes, including any complications that occurred during the procedure.

Follow-up clinical data included any MI, death, repeat revascularization, hemorrhagic/vascular complications, and stroke or transient neurological ischemic events. Late (6-month) angiographic measurements were similar to those made immediately after the procedure, and any repeat coronary angiography occurring for symptoms earlier than 6 months and followed by repeat revascularization was included as an end point angiogram for analysis. Baseline and early postintervention IVUS studies were quantified for CSA of the reference vessel, target lesion lumen, and plaque plus media. IVUS MLD and arc of calcium were also measured. All IVUS measurements were made at the intravascular core laboratories at the Washington Hospital Center (G.S.M.) and Stanford University Medical Center (P.J.F. and P.G.Y.).

Sequential cineangiograms were obtained before and after directional atherectomy, after adjunct PTCA (if performed), and at follow-up with identical imaging parameters. Intracoronary nitroglycerin, 50 to 200 μg, was given during the procedure and at follow-up to relieve any baseline spasm and thus standardize vasomotor tone. All procedural and follow-up cineangiograms were forwarded to the Washington Hospital Center Angiographic Core Laboratory for analysis. Standard criteria for lesion morphology were used to assess lesion complexity before the procedure and to identify complications after atherectomy or adjunct PTCA.[8] Quantitative angiography was performed using digitized cine frames that demonstrated the stenosis in its two sharpest and tightest views. With the contrast-filled injection catheter as the calibration standard, reference diameters and MLDs were determined with an automated edge-detection algorithm (CMS, Medis)[9]; these values were then used to calculate the percent diameter stenosis before and after atherectomy, after adjunct PTCA, if performed, and at follow-up. Early gain was defined as the initial improvement in MLD (in millimeters) obtained before and after the procedure; late loss was defined as the loss in MLD (in millimeters) during the follow-up period. Binary restenosis was defined as a >50% follow-up diameter stenosis.

All clinical and angiographic data were submitted to the Cardiovascular Data Analysis Center at the Beth Israel Deaconess Medical Center, Boston, Mass, for data entry, validation, end-point determination, and analysis. Primary quantitative coronary angiographic measurements were made at the Angiographic Core Laboratory of the Washington Hospital Center, Washington, DC. Data are presented as numerical means and SDs for all continuous measurements and percentages for count data. Multivariable logistic regression models were used to determine independent predictors of restenosis by stepwise selection; covariates examined included clinical characteristics (patient age, sex, history of diabetes mellitus, hypertension, dyslipidemia before MI, previous CABG, current cigarette smoking, Canadian Cardiovascular Society angina class), lesion morphological features (target vessel, lesion location, angulation, tortuosity, moderate to severe calcification, thrombus, eccentricity, bifurcation site), adjunctive PTCA, postprocedure dissection grade B or worse, and quantitative angiographic measures (preprocedure lesion length as well as reference vessel diameter, MLD, and diameter stenosis measured both before and after the procedure). All statistical analyses were performed with the SAS for Windows versions 6.08 to 6.12 (SAS Institute).[10,11] Cumulative frequency distribution curves were used to illustrate the distribution of the angiographic end points for the total study population.

Results

Patient Population and Lesion Characteristics

During the study period, 216 patients met eligibility requirements for OARS out of a total universe of 781 patients undergoing DCA at the four participating centers. Of the 565 patients excluded, 460 (82%) failed to meet eligibility criteria, 53 patients (9%) refused, and 52 physicians (9%) declined participation. Of the 216 patients enrolled, 17 patients were found to be ineligible and were not enrolled because of heavy lesion calcium by IVUS or fluoroscopy (11 patients), another lesion treated first resulting in exclusion (1 patient), no IVUS catheter available (1 patient), lesion <60% stenosis (2 patients), 2 previous restenosis episodes (1 patient), and hemodynamic deterioration before the procedure (1 patient). The total study group thus consisted of 199 patients, with 213 lesions treated.

Patient demographics and clinical status are listed in Table 1. The clinical profile shows a high percentage of patients with history of MI (46%), recent MI <2 months (26%), unstable angina (78%), and prior coronary intervention (29%). Thirteen patients (7%) had undergone a prior percutaneous intervention of the target lesion. The baseline lesion characteristics are listed in Table 2 for the 213 lesions treated according to the QCA core laboratory. The most common vessel treated was the left anterior descending coronary artery in 54%, followed by the right coronary artery in 31%, circumflex artery in 14%, and left main in 1%. The American Heart Association/American College of

TABLE 1. Baseline Clinical Characteristics

	n=199 Patients
Age, y (mean±SD)	58.3±10.8
Female, %	24
Diabetes mellitus, %	17
Hypertension, %	39
Cigarette smoking within 1 y, %	35
Dyslipidemia, %	28
Family history of premature CAD, %	49
Stable angina, %	16
Unstable angina, %	78
Prior PTCA, %	23
Prior CABG, %	6
Prior MI, %	46
Within 2 months, %	26
Left ventricular ejection fraction, %	54±12

TABLE 2. Baseline Angiographic Characteristics

	n=213 Lesions
Left anterior descending coronary artery, %	54
Ostial, %	13
Eccentric, %	57
Angle >45°, %	12
Moderate to severe calcification, %	18
Length >10 mm, %	21
TIMI flow <3, %	4
Bifurcation, %	4
Thrombus, %	3

TABLE 3.   Complications (In-Hospital)

	n=199 Patients
Major complications, %	
Death	0.0
Q-wave MI	1.5
Emergent CABG	1.0
Any major complication	2.5
Lesion complications, %	
Abrupt closure	2.0
Emergent stenting	3.5
Vessel perforation	1.0
Pericardial tamponade	0.0
Major vascular complications,* %	2.0

*Requiring surgical repair or transfusion

TABLE 4.   Angiography Summary Results

	DCA Alone n=28 Lesions	DCA Plus PTCA n=183 Lesions	Overall n=2116 Lesions
Reference, mm	3.36±0.40	3.28±0.46	3.28±0.46
Pre-MLD, mm	1.32±0.50	1.17±0.40	1.19±0.41
Post-MLD, mm	3.16±0.40	3.15±0.51	3.16±0.49
Acute gain, mm	1.85±0.51	1.97±0.55	1.96±0.55
Follow-up MLD, mm (n=176 lesions)			2.01±0.80
Late loss, mm	1.17±0.65	1.18±0.80	1.18±0.79
Loss index*	0.48±0.26	0.41±0.11	0.42±0.10

*Loss index=coefficient±SEM, representing the slope of the regression line of late loss as a function of acute gain.

Cardiology modified lesion classification grade was B2 in 59%, B1 in 33%, A in 7%, and C in 1%. Lesion location was predominantly in mid (50%) and proximal (32%) segments, and the majority of lesions were <10 mm long (78%). The target lesion was eccentric in 57%, mildly calcified in 80%, and included a bifurcation with side-branch involvement in 4%.

Short-term Procedural Results

Short-term procedural success, defined as residual diameter stenosis <50% without a major complication, was achieved in 194 patients (97.5%). Procedural failures included Q-wave MI in 3 patients (1.5%) and emergency CABG in 2 patients (1%), whereas no failure occurred as a result of inability to achieve <50% residual diameter stenosis. There were no in-hospital deaths. In-hospital complications are listed in Table 3. Other complications included abrupt closure unsuccessfully treated by PTCA in 4 patients (2%), salvage stent placement in 7 (3.5%), localized perforation without tamponade in 2 (1%), and vascular complications (bleeding or vascular surgery) in 4 (2%). Of the 7 patients receiving adjunctive stents, only 1 received a stent for a >50% residual stenosis, with the remainder being placed for residual dissections.

Ischemic complications were classified according to level of CK-MB elevation and ECG changes. Any CK-MB elevation above the investigator institution's upper limit of normal occurred in 74 patients (37%). Elevation >3 times normal was seen in 28 patients (14%), leaving 46 patients (23%) who had smaller (<3 times normal) elevations. The incidence of large MIs (predefined as Q-wave MI or CK-MB >8 times normal) was 3.5%.

Postprocedure lesion morphology analysis disclosed thrombus in 2 lesions (1%), ectasia in 41 (19%), TIMI 3 flow in 207 (97%), dissection worse than grade B in 27 (13%), and transient (not present on the final angiogram) distal embolism in 3 (1.4%). Loss of side branches in vessel segments occurred in 6 lesions (3%), none of which were bifurcation lesions.

Device usage included an average of 1.2 Atherocath catheters per procedure, with a predominance of 7F devices (7F standard in 90%, 7F graft in an additional 5%); 6F devices were used in only 5%. Directional atherectomy was performed with 18.8±9.6 cuts during 2.3±1.1 passes of the device. IVUS was used in all patients according to the protocol. Final balloon-to-artery ratio was 1.07±0.11.

Initial Angiographic Results

Preprocedure and postprocedure initial reference vessel diameter, lesion MLD, and percent stenosis by quantitative angiographic core laboratory analysis are shown in Table 4 and illustrated in Fig 1 for the overall group, DCA-alone group, and DCA-plus-PTCA group. The mean reference vessel size was 3.28 mm before and 3.41 mm after the procedure, whereas the baseline lesion MLD was 1.19 mm, increasing to 3.16 mm on the final postprocedure angiogram. Percent stenosis was reduced from a baseline mean of 63.5% diameter stenosis to a final of 7.1%. Similar final results were achieved in both the stand-alone DCA group (28 lesions) and the DCA plus adjunctive PTCA group (183 lesions, 87%), whereas adjunctive PTCA contributed 0.42 mm of early gain to the final MLD in this group. The goal of attaining <15% final diameter stenosis (by the angiographic core laboratory) was achieved in 82% of lesions.

IVUS Results and Evaluation of Mechanism

The initial IVUS results are illustrated in Fig 2 and represent the results in lesions for which complete and technically adequate data were available at all three time points (baseline, post-DCA, and final; 121 lesions). Lumen CSA increased from 2.0 mm² to 8.8 mm². The lesion plaque-plus-media CSA of 16.8 mm² before the procedure was reduced to 12.1 mm² after the procedure, yielding a reduction in plaque burden (plaque-plus-media CSA/CSA within the external elastic media) from 89% to 58%. By IVUS, lesion site MLD increased from 1.43 to a final of 3.00 mm. Plaque reduction accounted for 69% of the increase in lumen CSA.

Late Clinical and Angiographic Results

During the 1-year clinical follow-up, there was one cardiac death (0.5%) and no target vessel–related MI; target lesion revascularization was required in 38 lesions (17.8%) and target vessel revascularization in 45 vessels (21.1%); and there was target vessel failure in 50 patients (23.6%, Table 5). The single cardiac death occurred as a sudden death 3 weeks after hospital
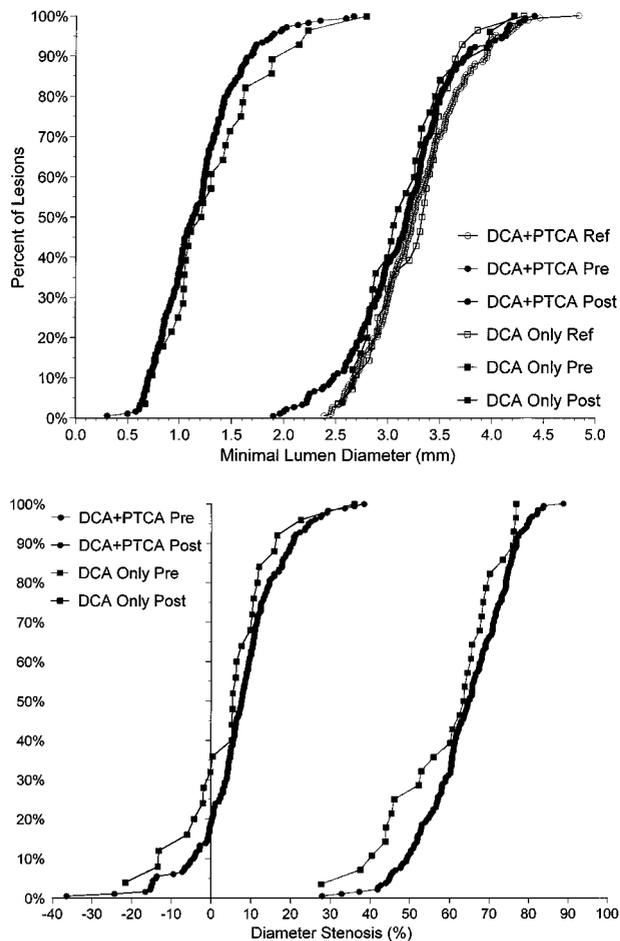
Figure 1. Baseline and acute angiographic results. A, Cumulative distribution of reference vessel diameter and MLD at baseline (preprocedure) and after final treatment (postprocedure). Reference vessel diameter was not different, but baseline MLD was slightly larger for group successfully treated with DCA alone. Postprocedural diameters were not significantly different for patients treated with DCA alone compared with patients treated with DCA plus adjunctive balloon angioplasty. B, Cumulative distribution of percent diameter stenosis at baseline (preprocedure) and after final treatment (postprocedure). Pretreatment diameter stenosis was slightly less for lesions successfully treated with DCA alone, whereas there was no difference in postprocedural diameter stenosis. More than 80% of patients achieved the desired result of <15% diameter stenosis.

Figure 2. Acute IVUS results. Stacked bar graph demonstrating lumen CSA and plaque+media CSA before treatment, after DCA, and after final treatment. A plaque burden of 58% (plaque+media CSA/CSA within the external elastic media) remained after final treatment despite marked improvement in lumen CSA. Plaque excision accounted for 69% of increase in lumen CSA, with remainder due to mechanical expansion.

group (>50% stenosis by the QCA core laboratory) was 28.9%.

Predictors of Restenosis

Potential predictors of angiographic and clinical restenosis were entered into multivariable models. The independent predictors of follow-up angiographic percent diameter stenosis were postprocedure MLD, increasing age, and current smoking status. The only significant predictor of target vessel revascularization was postprocedure MLD.

Discussion

The results of the present study indicate that an optimal or more aggressive technique for directional atherectomy using repetitive passes with almost exclusively 7F atherectomy catheters and frequent (87%) postatherectomy PTCA produced a high procedural success rate (97.5%), large average initial lumen (3.16 mm), and very low initial residual stenosis (7.1%). These results were achieved in this selected patient population meeting the prospectively defined entry criteria. A low major complication rate (2.5%) as well as a low incidence of other minor complications (Table 3) was also demonstrated.

The long-term angiographic and clinical outcomes at late follow-up of 1 year were also favorable, with low cardiac mortality (0.5%), all-cause mortality (1.0%), target vessel revascularization rate (21.1%), and angiographic restenosis (28.9%). The clinical and angiographic results achieved in the

discharge in a patient who had undergone an initially successful procedure with no complications (including no procedure-related CK-MB elevations). One additional patient suffered an accidental (noncardiac) death.

Late angiographic follow-up was obtained at an interval of 197±92 days in 176 of 211 eligible lesions with initially successful procedures (follow-up rate, 83.4%). These results are detailed in Table 4 and illustrated in Fig 3. The overall group at late follow-up showed a mean reference vessel diameter of 3.19 mm, lesion MLD of 2.01 mm, and mean diameter stenosis of 37%. Mean early gain during the initial procedure was 1.96 mm, and mean late loss was 1.18 mm, yielding a loss index (defined as the slope of the regression line relating late loss to early gain) of 0.42. The binary restenosis rate for the overall
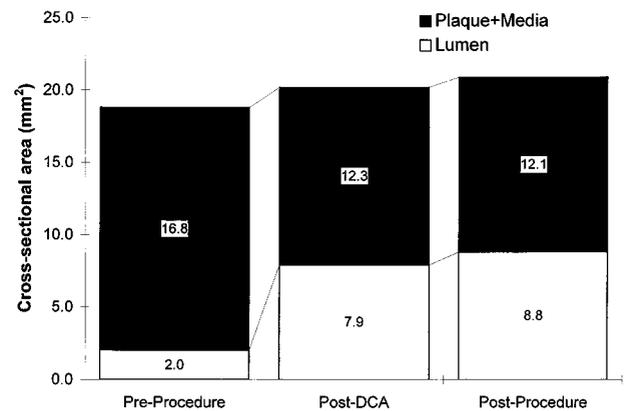
TABLE 5. Cumulative 1-Year Clinical Outcome

End Point	n=199 Patients
Death, %	1.0
Q-wave MI, %	1.5
Target site revascularization, %	17.8
Target vessel revascularization, %	21.1
Target vessel failure,* %	23.6

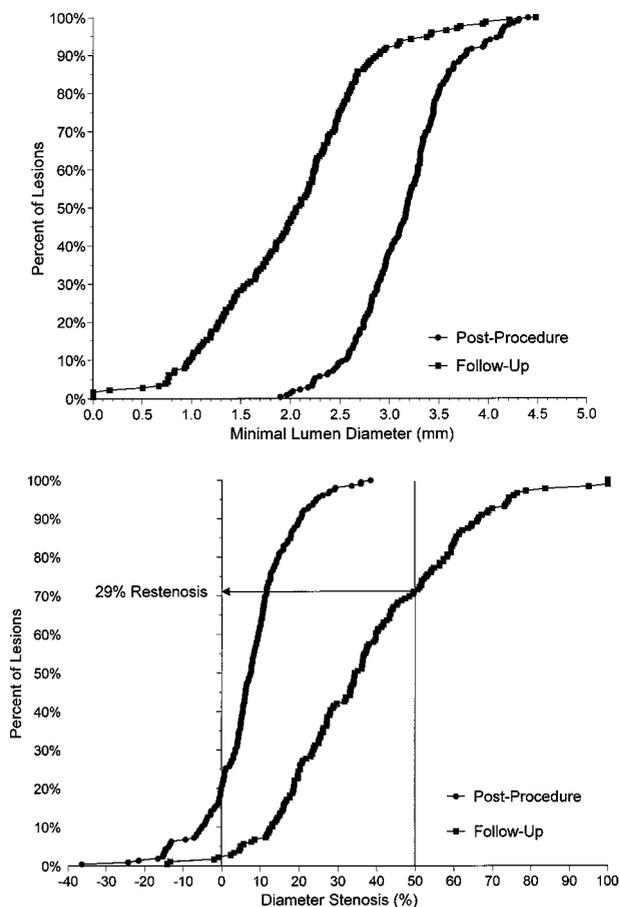*Death, Q-wave MI, or target vessel revascularization.

Figure 3. Acute and follow-up angiographic results. A, Cumulative distribution of MLD after the procedure (post) and at angiographic follow-up (F/U). The large MLD achieved post-procedure was not accompanied by an increased rate of late loss, thus resulting in persistent bigger diameters at follow-up. B, Cumulative distribution of percent diameter stenosis immediately post-procedure (post) and at angiographic follow-up. Diameter stenosis remains low at follow-up, with binary restenosis end point (defined as follow-up diameter stenosis >50%) occurring in only 28.9% of lesions.

present prospective registry confirm suggestions from earlier retrospective DCA studies: that DCA can be used to obtain a large initial lumen without compromising procedural safety.[4–7] DCA is a procedure well suited to tailoring a larger lumen, because progressively more plaque can be retrieved and larger lumen sizes achieved by gradually increasing the balloon pressure on the device during repeated passes. Of interest in this study, however, is that despite an excellent initial residual stenosis of 7.1% with regard to the adjacent normal-appearing coronary reference lumens, postprocedure IVUS showed a residual plaque burden of 58%, suggesting a dramatic compensatory overexpansion of the vessel outer diameter at the lesion site, as described by Glagov et al,[12] to accommodate plaque ingrowth.

The high incidence of mostly low-level (1 to 3 times normal) periprocedural CK-MB elevation (37%) in OARS was not associated with any increase in early or late adverse clinical events, but continued follow-up of these and other prospectively studied patients will be required to determine the ultimate effect of these generally mild and clinically silent periprocedural CK-MB elevations.

The effect of IVUS on optimizing the final procedural outcomes in this study was not directly tested, because each investigator was asked to obtain IVUS images before DCA, after DCA, and after adjunctive PTCA in all patients regardless of whether IVUS information was used in the decision making for the atherectomy procedure. There was a wide variation, therefore, in the extent to which IVUS information was used to guide the procedure. Thus, no specific intraprocedural or final IVUS end-point measurements were established as goals of the DCA procedure, and because all patients had IVUS, there was no control (non-IVUS) group for comparison. One of the main roles of IVUS was in screening out a small number of patients (11 patients, 5% of total) who demonstrated excessive lesion calcification for DCA and in elucidating the initial mechanism of DCA: 69% of the observed increase in lumen area was due to reduction in plaque burden (measured as CSA occupied by plaque plus media), and the remainder was due to mechanical expansion or plaque compression.

The influence of adjunctive, post-DCA PTCA on the overall outcomes is also difficult to discern, because the vast majority of patients (87%) had adjunctive postdilation. The early angiographic results of the stand-alone DCA group, however, were not significantly different from the adjunctive balloon group (5.5% versus 7.4% residual diameter stenosis, respectively), indicating that adjunctive PTCA is effective in attaining an optimal angiographic result in most cases in which plaque removal alone does not achieve an optimal result.

Compared with the results of the DCA arm in the previous major randomized study, CAVEAT,[2] the present results are extremely favorable. CAVEAT was performed at a time in the evolution of DCA when the leading hypothesis was that minimally traumatic excision of plaque, rather than aggressive excision and lumen size maximization, would inherently reduce the complications and the late restenosis rate compared with PTCA. Although the negative results from CAVEAT and CCAT were widely taken as an indictment of the procedure,[13] the OARS study raises the possibility that the findings may have been largely a result of an incomplete understanding of the technique. In the present study, an approach of aggressive tissue removal and adjunctive postprocedure PTCA was used to optimize the initial lumen size, providing a higher procedural success (97% versus 82%), lower major complications (2.5% versus 4.0%), less frequent target lesion revascularization (17.8% versus 33.7%),[14] and lower angiographic restenosis (28.9% versus 50.0%) than seen in the DCA arm of CAVEAT.[2] Although a detailed comparison of the angiographic results of these studies is limited by the different quantitative angiographic systems used in each study and OARS selection of somewhat larger vessels, immediate lumen dimensions were increased and major clinical end points were clearly improved in the present study. Importantly, the increased rate of early complications and late mortality among the DCA patients in CAVEAT was not apparent in the present study. Whether the improved results were due to use of the optimal DCA technique, more overall DCA experience, better patient selection within the similar eligibility criteria, or a combination of these factors cannot be definitively established by the present study.

Although aggressive plaque removal was a pivotal part of the OARS strategy, results from IVUS data show that mechanical dilation contributed significantly to final luminal improvement (30% of increase in lumen CSA due to expansion rather than plaque removal). This confirms an earlier study by Penny et al,[15] in which reduction in plaque volume (calculated from measurements of tissue weight) was shown to contribute <50% to the final increase in lumen volume in 35 of the 39 patients studied. The relative contribution of plaque removal in OARS (70%), however, was substantially greater and may explain, in part, the reduction in angiographic restenosis that was seen in OARS but not in CAVEAT or other previous studies[16] with less aggressive plaque excision.

If the assumption can be made that use of this approach to atherectomy with IVUS inspection and aggressive debulking resulted in a lower residual plaque burden than that achieved in CAVEAT, then the improved late restenosis results support the recent finding in the GUIDE II trial,[17] in which residual plaque burden at the lesion site was an important predictor of restenosis. Multivariable analysis of angiographic and ultrasound factors in the GUIDE II study showed that residual plaque burden was an independent predictor of late clinical restenosis, even in patients who had similar early angiographic results. The 58% residual plaque burden with an excellent angiographic result (7.1%) in OARS suggests that future atherectomy efforts should be directed toward even greater plaque debulking and development of new technologies that would promote more precise and complete plaque removal.

The impact of aggressive plaque removal by DCA on late restenosis is demonstrated in a recent randomized trial comparing stand-alone DCA to DCA with adjunctive PTCA, ABACAS.[18] This trial used routine IVUS to guide greater plaque excision by DCA and achieved a mean final stenosis of 11% with a residual plaque CSA of only 43%. These initial results were associated with a 6-month angiographic restenosis rate of 21.4% (40/187), even lower than the 28.9% restenosis rate seen in the present study, in which the final initial residual plaque CSA was 58%. Taken together, the progressively lower restenosis rates seen in CAVEAT, OARS, and ABACAS appear to corroborate the findings of GUIDE II that progressively lower angiographic restenosis can be obtained by progressive reduction in residual plaque burden.

Limitations

Although OARS demonstrates the improved efficacy and safety of atherectomy using the new optimal approach, the actual impact of DCA on late restenosis and repeat revascularization cannot be definitively determined by this registry. The general assumption that the technique can be widely applied is confounded by the results being drawn from four centers with a high level of DCA experience. Moreover, patient, vessel, and lesion characteristics selected for this study may have favored successful DCA procedures. These issues will be addressed in a controlled, randomized study, the Balloon versus Optimal Atherectomy Trial, to verify that the outcomes of this atherectomy technique are better than those of more conservative previous DCA techniques or conventional PTCA.

Summary

In summary, the OARS study evaluated the feasibility of a new technique for the directional coronary atherectomy procedure which previously had been found to have no significant benefit compared with PTCA for the treatment of single-vessel coronary artery disease. Under this study, an optimal technique that favored larger device size, more complete tissue removal, liberal use of balloon postdilatation, and a goal of achieving a postprocedural residual stenosis <15% was tested at four experienced centers for DCA. The achievement of a 7% posttreatment residual diameter stenosis was lower than that seen in two previous randomized trials of DCA, CAVEAT (29%) and CCAT (32%). This was achieved without an increase in major complications (death, Q-wave MI, emergency CABG, 2.5%) compared with 4.0% for CAVEAT. Although the incidence of CK–MB elevation >3 times normal was high (14%), there was no increase in 1-year mortality (0.5% cardiac, 1% overall). The larger initial lumen diameter achieved in OARS provided a significant reduction in angiographic restenosis of 29% and a target lesion revascularization rate of 17%, consistent with a restenosis rate expected in association with a residual stenosis <15%. Despite the optimal early results and low restenosis rates, IVUS demonstrated that 58% of the original plaque remained at the target lesion site, suggesting previous expansion remodeling of the coronary artery segment to accommodate accumulating plaque. The improved early and late clinical outcomes with an optimal DCA technique in this study, however, indicate that DCA is a safe and predictable procedure in selected patients.

Appendix

In addition to the study authors, the following investigators and research coordinators participated in the Optimal Atherectomy Restenosis Study.

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