A Synergistic Approach to Optimal Stenting

Directional Coronary Atherectomy Prior to Coronary Artery Stent Implantation—the AtheroLink Registry

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OBJECTIVES

The AtheroLink registry sought to observe the effect of plaque burden reduction by directional coronary atherectomy (DCA) prior to stenting on acute lesion success rate, on the clinical success rate and on the incidence of in-stent restenosis six months after intervention.

BACKGROUND

Although coronary stenting has reduced restenosis, its effect has been less favorable in complex lesions with a high plaque burden that results from suboptimal stent expansion. Therefore, plaque removal by DCA may improve the results of coronary stenting.

METHODS

A total of 167 patients with >60% stenosis in a native coronary artery of 2.8 to 4.0 mm in diameter were enrolled in 10 study centers on an intention-to-treat basis. All patients underwent DCA aimed at an optimal result (residual diameter stenosis <20%) followed by stenting. Angiographic follow-up was performed in 120 (71.8%) patients at 5.3 ± 2.8 months.

RESULTS

Lesion success was achieved in 164/167 (98.2%) patients, and the clinical success rate was 95.2% (159/167 patients). The overall restenosis rate in the 120 patients with angiographic follow-up was 10.8% (13/120). Incidence of restenosis was lower (8.4%) in patients with optimal stent deployment following DCA compared to patients with a persisting caliber reduction >15% (restenosis rate 15.3%) and restenosis occurred with a significantly higher frequency (p < 0.04) in distal lesions (37.5%) compared to proximal stenoses (9.0%).

CONCLUSIONS

This observational multicenter registry points to a potential reduction in restenosis by a synergistic approach of DCA and stenting performed under routinely accessible angiographic guidance. Therefore, multicenter-based randomized clinical trials are clearly warranted to finally clarify the validity of this complex approach versus conventional angioplasty plus stenting.

Although coronary stenting has significantly reduced stenosis (1,2) its effect has been less favorable in more complex stenoses (3) and in lesions with a high plaque burden, which limits optimal stent expansion and may additionally contribute to the induction of intimal hyperplasia after stent implantation (4). In addition, data from intravascular ultrasound (IVUS) studies indicate that in-stent restenosis has a tendency to occur at the original lesion site where the plaque burden is usually largest (5). Therefore, plaque removal prior to stent implantation could be a clinically feasible approach to further improve acute and long-term results of stent deployment. Directional coronary atherectomy (DCA) as a tool for debulking obstructive coronary lesions was originally developed as a potential replacement for stand-alone balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA]) (6). However, the results of early randomized studies comparing PTCA and DCA were unexpectedly disappointing since they demonstrated that DCA was associated with a higher incidence of death and myocardial infarction than PTCA and yielded similar restenosis rates despite the removal of plaque material (7,8). In contrast, Baim et al. (9) could show in a recently published study that a technically optimized DCA procedure achieved a larger initial lumen and a higher procedural success rate than PTCA, without an increased risk of death, Q-wave myocardial infarction and need for coronary artery bypass surgery. Furthermore, DCA resulted in a lower rate of restenosis than did PTCA. However, the challenge of DCA today is not to be better than PTCA but to be better than PTCA plus stenting, a goal that may be achieved by optimal preparation of the vessel before stent deployment in terms of plaque removal using DCA.

Moussa (10) et al. recently demonstrated in a monocentric evaluation that such a reduction of plaque burden by DCA with subsequent stenting of the respective lesion can be performed with a high clinical success rate (96%) and strikingly low incidence (11%) of angiographic restenosis at six months’ follow-up. In the present study we tried to confirm these promising results by a nonrandomized, open multicenter approach (AtheroLink registry), which was chosen to assess the clinical and lesion success rate of DCA plus stenting and to evaluate the incidence of stent restenosis.
Methods

Center selection. Special care was taken to select centers with current DCA experience. All operators must have performed at least 25 DCA procedures and 10 within the year of study onset. The main principles of the AtheroLink registry were 1) to remove as much tissue as considered safe by the operator; 2) to obtain a final residual stenosis <20% after DCA whenever possible; and 3) to complete the procedure by optimal stent deployment (residual diameter stenosis <15%) by use of a Multilink stent. Use of IVUS was allowed but neither encouraged nor required (15% of the enrolled patients).

Study design and patient selection. The AtheroLink registry is a prospective, nonrandomized, open multicenter observation of patients undergoing DCA prior to stenting. Eligible patients were invited to participate in the trial, and informed consent was obtained under a protocol approved by the institutional review board at each participating center. Between January 1997 and June 1998, a total of 167 patients were recruited on an intention-to-treat basis according to the following predetermined criteria: 1) clinical or functional evidence of myocardial ischemia; 2) no myocardial infarction within 72 h, cardiogenic shock, or bail-out situations (i.e., threatened or abrupt closure after a previous interventional approach); 3) all the following: vessel size by quantitative coronary angiography (QCA) 2.8 to 4.0 mm, diameter stenosis ≥60% or ≥50% in highly eccentric lesions; lesion length <30 mm, no in-stent restenosis, no moderate to severe calcification proximal to the target lesion, no bifurcational lesions with a side branch of ≥2 mm by means of QCA. Patients with ostial lesions, restenotic lesions, and lesions requiring a preintervention in order to perform DCA (e.g., chronic total occlusions) were considered for enrollment.

Detailed case report forms concerning baseline demographic and clinical data, procedural details, and in-hospital outcome (including routine ascertainment of CK [creatine kinase] and CK-MB [CK-MB fraction] before treatment and 12 to 24 h after intervention; further determinations were required if either CK or CK-MB was elevated) were completed after the procedure, at hospital discharge and at six-month follow-up by the clinical coordinator at each site and were submitted to the data coordinating center.

Analysis of cineangiograms was performed at each participating center by computer-assisted analysis (QCA with digital coronary imaging by Philips and CAAS/II by Piemedica) and these data were forwarded to the study coordinating center. Lesions were classified with respect to the American College of Cardiology/American Heart Association classification (11). Prior to any QCA measurement, intracoronary application of 200 μg nitroglycerin was mandatory. Quantitative analysis of coronary angiography in one optimal view was required, and this view was preferably used for all QCA measurements, including the follow-up angiography. However, the view demonstrating the highest grade of stenosis in each step was more relevant. Proximal and distal reference diameter (RfD), minimal lumen diameter (MLD), and % stenosis were determined by QCA using the contrast-filled injection catheter as the calibration standard. Based on QCA analysis, lesion success was defined as the ability to reduce lesion severity by DCA and stenting with a final result of <50% diameter stenosis. The clinical success rate was defined as MLD <50% of reference, no in-lab or in-hospital non-Q-wave or Q-wave myocardial infarction as defined by new appearance of significant Q waves in a minimum of two leads, urgent bypass operation, or death within the subacute phase (days 1–7).

Clinical and angiographic follow-up was obtained routinely at six months, unless earlier follow-up was required for clinical reasons. The prespecified primary end point was angiographic restenosis (diameter stenosis of the target vessel ≥50%). Secondary end points included short-term lesion and clinical success, procedural safety, acute and subacute stent thrombosis, in-hospital non-Q-wave infarction (any CK-release and/or CK-MB release >3 times the upper limit of the individual laboratory without Q waves), intraaortic balloon pump or ReoPro usage to prevent acute or subacute stent thrombosis and clinical restenosis surrogate.

DCA and stent implantation. Directional coronary atherectomy was performed by use of the Simpson Atherocath (Devices for Vascular Interventions) as previously described (12). Predilatation procedures were at the operator’s discretion. The aim was to achieve a residual diameter stenosis <20% confirmed with QCA by multiple cuts, which were performed by a maximum inflation of 4 bar. At the end of the procedure, removed bulk was semiquantitatively evaluated using the following scale: 0 = no material; 1 = some pieces of material; 2 = sufficient amount of material relative to plaque burden, but not all tissue removed; 3 = almost all tissue removed.

Coronary stenting was performed with multicellular stents (Multilink, Guidant Corp.) aiming at an optimal result (MLD >distal reference diameter and MLD >proximal reference diameter minus 15%). For initial stent deployment an inflation pressure of 8 bar was used with the option of further inflations to optimize angiographic results.
by using a short high-pressure balloon. A stepwise pressure application with the short balloon positioned within the stented area was recommended with the following steps: 10-12-14-15 and 16 bar.

Preinterventional and postinterventional management. All patients were pretreated with aspirin (100 to 500 mg) once a day and ticlopidine (250 to 500 mg) twice a day 48 h before interventional procedures. Ticlopidine was given for at least two to four weeks and aspirin for at least six months after intervention.

Statistical analysis. Continuous variables were expressed as mean values ± 1 SD. Categorical variables were compared by chi-square analysis. Analysis of variance (repeated measures ANOVA using SPSS 9.0 for Windows with a multiple comparison procedure and Bonferroni correction) was performed on preinterventional, postinterventional and follow-up QCA data with respect to the RfD, MLD, and diameter stenosis. The null hypothesis was rejected at the 95% confidence level, considering a p value <0.05 as statistically significant.

RESULTS

Patient characteristics. Of 167 patients (128 men [77%], 39 women [23%]; mean age: 55.8 ± 18.8 years; previous myocardial infarct: 45%; left ventricular ejection fraction <35%: 7%; triple vessel disease: 19%) who were initially enrolled on an intention-to-treat basis, 120 patients (71.8%) completed the entire study protocol. Of the remaining 47 patients, 3 patients (1.8%) died within the study period, 3 more (1.8%) had unsuccessful DCA, 17 patients (10.2%) had a premature angiographic follow-up and/or additional revascularization procedures due to angina or infarction, and 24 patients (14.4%) did not return for control coronary angiography. Most of these patients (21/24) had a clinical follow-up, but three patients could not be contacted within the control period. A flow-sheet demonstrating the patient recruitment until the final evaluation including angiographic follow-up is summarized in Figure 1. Baseline and angiographic characteristics of the patients with a complete follow-up are presented in Table 1.

Procedure performance. In 164 of 167 patients, DCA was performed using 13 ± 7 cuts per lesion. In the other three patients the DCA device could not be adequately positioned in the lesion area owing to extreme tortuosity proximal to the target lesion. In these three patients conventional PTCA with additive stenting in one patient was successfully performed. In 64% of procedures, final device size was 7F. A 6F cutter was used in the remaining 36% of procedures. Optimal DCA (residual diameter stenosis <20% by QCA) was achieved in 71 (59%) lesions. Semiquantitative estimation of the total material removed by DCA yielded the following results: grade 0 (3%), grade 1 (2%), grade 2 (26%), grade 3 (69%).

The length of implanted stents was 15 mm in 69%, 25 mm in 26% and 35 mm in 5% of stent deployments. The balloon size was 3.0 mm in 24%, 3.25 mm in 2%, 3.5 mm in 56%, and 4.0 mm in 18% of interventions. The mean maximal inflation pressure was 12 ± 3 bar. A total of 13

![Figure 1. Flowchart characterizing the study population, observation periods and related clinical complications, frequency of restenosis and need of target lesion revascularization.](image-url)
patients (10.8%) received two or more stents following DCA.

**Short-term results and procedural complications.** In 164 of 167 patients the combined approach of DCA and stenting could be successfully performed, resulting in an initial lesion success rate (posttreatment diameter stenosis <50%) of 98.2%. There were no patients who underwent DCA and stenting in more than one lesion. Two patients (1.2%) developed a vessel perforation at the site of atherectomy, a situation that could be controlled by stent deployment.

In the subacute phase (days 1 to 7), four patients (2.4%) developed a non-Q-wave and one patient (0.6%) a Q-wave myocardial infarction. Consequently, the clinical success rate (including all events controlled by stent deployment) was 95.2% (159/167 patients). No patient developed acute or subacute stent thrombosis or was additionally treated with glycoprotein IIb/IIIa receptor blocking agents.

In the follow-up period (5.3 ± 2.8 months) major complications included 1 cardiogenic death (0.6%), 4 bypass operations (2.3%), 2 Q-wave myocardial infarctions (1.1%), and 6 non-Q-wave myocardial infarctions (3.6%). Two patients (1.3%) died of noncardiac reasons during the control period. Clinical success rate, including all events during the acute, subacute and follow-up period and excluding those three patients who did not come to a clinical or angiographically controlled situation that could be controlled by stent deployment, was 85.9% (141/164).

**Overall incidence of restenosis and target lesion revascularization.** Angiographic follow-up was performed in 120/167 (71.8%) patients. The QCA measurements before intervention, after DCA, after stenting and at control coronary angiography of the 120 patients with complete follow-up are demonstrated in Table 2. Angiographic restenosis was found in 13 of 120 lesions (10.8%). The incidence of restenosis was lower in patients with optimal stenting by QCA (8.4%) compared to patients in whom optimal stenting could not be achieved (restenosis rate = 15.3%). Restenosis was detected in 10.3% of de novo lesions and in 15.4% of restenotic lesions. In the 13 vessels with restenosis, target-lesion revascularization was mandatory in 9 lesions—that is, a target-lesion revascularization rate of 7.5% with respect to the 120 angiographically controlled patients. In the subset of patients with diabetes (n = 14), no restenosis could be detected.

**Incidence of restenosis with respect to the vessel size.** The relation between vessel size and restenosis rate was analyzed by assigning vessels from 2.8 to 3.0 mm (n = 62), 3.1 to 3.5 mm (n = 42) and 3.6 to 4.0 mm (n = 16) to various categories. The different incidence of restenosis in these three vessel-size categories did not reach the level of significance (16.1% for vessels ranging from 2.8 to 3.0 mm; 7.1% for vessels ranging from 3.1 to 3.5 mm, and 6.2% for vessels ranging from 3.6 to 4 mm; p = NS for the comparison of all categories). However, there was a tendency toward a higher restenosis rate (16.1%) in smaller vessels (vessel size 2.8 to 3.0 mm).

**Incidence of restenosis with respect to individual coronary arteries and lesion location within the vessel.** Incidence of restenosis was not significantly different for left anterior descending, left circumflex, and right coronary artery (9.7% vs. 11.1% vs. 12.8%, respectively). In contrast, the site of the lesion had a significant influence on the incidence of restenosis. Restenosis rate was significantly higher (p < 0.04) in distal lesions (37.5%) compared to lesions located in the mid- (8.8%) or proximal (9.0%) aspect of a particular coronary vessel.

### Table 1. Baseline and Angiographic Characteristics of Patients With Postinterventional Angiographic Follow-up

<table>
<thead>
<tr>
<th>Patients (n = 120)</th>
<th>Risk Factors</th>
<th>Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs) 51.9 ± 23</td>
<td>Smoking 65 (54%)</td>
<td>LAD 72 (60%)</td>
</tr>
<tr>
<td>Men 98 (83%)</td>
<td>Hypertension 74 (62%)</td>
<td>LCX 9 (7.5%)</td>
</tr>
<tr>
<td>Unstable angina 40 (33%)</td>
<td>Diabetes 14 (12%)</td>
<td>RCA 39 (32.5%)</td>
</tr>
<tr>
<td>LVEF &lt;35% 10 (8%)</td>
<td>Hyperlipidemia 90 (75%)</td>
<td>Proximal 78 (65%)</td>
</tr>
<tr>
<td>Multivessel disease 22 (18%)</td>
<td>Family history 56 (47%)</td>
<td>Mid 34 (28%)</td>
</tr>
<tr>
<td>Previous PTCA 63 (53%)</td>
<td></td>
<td>Distal 8 (7%)</td>
</tr>
<tr>
<td>Previous CAGB 13 (11%)</td>
<td></td>
<td></td>
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<tr>
<td>Previous infarct 63 (53%)</td>
<td></td>
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</tr>
</tbody>
</table>

LAD = left anterior descending coronary artery; LCX = left circumflex coronary artery; LVEF = left ventricular ejection fraction; RCA = right coronary artery.

### Table 2. Preintervention, Post-DCA and Stenting and Follow-up Quantitative Angiographic Measurements (QCA Analysis)

<table>
<thead>
<tr>
<th>QCA Analysis</th>
<th>Preintervention</th>
<th>Post-DCA and Stenting</th>
<th>Angiographic Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rfd (mm)</td>
<td>3.5 ± 0.8</td>
<td>3.8 ± 0.6</td>
<td>3.4 ± 0.9</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>1.0 ± 1.0</td>
<td>3.6 ± 0.6*</td>
<td>3.1 ± 1.1</td>
</tr>
<tr>
<td>Diameter stenosis (%)</td>
<td>76.2 ± 12.5</td>
<td>5.4 ± 6.6*</td>
<td>23.6 ± 20.1**</td>
</tr>
</tbody>
</table>

Values shown for reference diameter (Rfd), minimal lumen diameter (MLD), and diameter stenosis based on quantitative coronary angiography (QCA) analysis are the mean ± SD. Significant differences are indicated: *p < 0.01 for preintervention versus post-DCA and stenting and **p < 0.01 for post-DCA and stenting versus six-month angiographic follow-up.
DISCUSSION

Clinical background for a synergistic strategy of DCA and stenting. Stent deployment is associated with a dramatic decline in acute complication rates after angioplasty, and it proved to reduce the incidence of restenosis as demonstrated in the STRESS (13) and BENESTENT (1) studies. However, it is important to consider that the particular benefit of stent implantation in lesions with complex characteristics that, by design, were excluded from STRESS and BENESTENT, such as long lesions requiring multiple stents, lesions involving vessel ostia or bifurcations, and lesions in smaller vessels or distal locations, has not been confirmed in a randomized fashion. For example, in a series of 700 consecutive patients with 745 lesions treated with coronary stents, Sawada et al. (14) found that only 20% of the lesions would have been eligible for inclusion in STRESS and BENESTENT. Although the six-month restenosis rate in this series was 11% for STRESS/BENESTENT equivalent lesions, restenosis occurred in >30% of lesions that would have been excluded from these randomized trials.

In a separate series, among 522 consecutive patients in a multicenter registry who underwent stent implantation, only 7% would have qualified for enrollment in STRESS/BENESTENT (15). These observational reports suggest that when applied to a less selected group of patients than those studies in the randomized trials, the relative advantages of stent implantation with respect to the incidence of restenosis may be significantly attenuated. Therefore, a synergistic interventional concept like plaque debulking prior to optimal stent deployment may be promising with respect to a further reduction of restenosis.

Study findings. The underlying concept of the AtheroLink registry was to observe whether debulking of coronary lesions by DCA prior to stenting performed on a multicenter basis under angiographic guidance alone may be an effective and clinically safe approach for the prevention of restenosis. In fact, the principal finding of this multicenter registry is that the synergistic approach of DCA and stenting was associated with a high lesion (98.2%) and clinical success rate (95.2%) and a low incidence of overall angiographic restenosis (10.8%) after six-months’ follow-up, which is obviously lower than restenosis rates reported from stent trials without control by intravascular ultrasound (1,13). Furthermore, restenosis rates were not significantly different between lesions assigned to specific coronary arteries but yielded a significant difference with respect to stenosis localization—that is, distal stenoses had a significantly higher incidence of restenosis than did lesions in the mid- and proximal aspect of the respective vessel. Although the analysis of vessel size with respect to the incidence of restenosis did not yield a significant difference for the three vessel-size categories, ranging from 2.8 mm to 3.0 mm, 3.1 to 3.5 mm, and 3.6 to 4.0 mm, there was a tendency toward a higher incidence of restenosis in vessels ranging from 2.8 to 3 mm. This finding is in agreement with an observational study of Savage et al. (3), who reported that the incidence of restenosis following stent deployment in smaller coronary vessels is significantly greater than in discrete lesions of larger coronary arteries. The QCA analysis showed that the magnitude of acute gain after stent deployment was identical (2.6 mm for SOLD and AtheroLink registry) with a lower late loss for the AtheroLink registry (0.5 mm vs. 0.91 mm). A case example of combined DCA and stenting of the right coronary artery is shown in Figure 2.

Comparison with previous studies. In a recently published monocenter study, Moussa et al. (10) included 71 patients in a prospective registry to establish whether plaque removal by DCA before stent deployment would improve long-term patency beyond what is achievable by stent implantation alone. Similar as in the present study, all patients, most of them with higher lesion complexity, underwent elective intervention. In both studies the synergistic interventional approach was safe. Major cardiac events
(cardiogenic death, Q-wave myocardial infarction, or the need for reintervention or bypass grafting) occurred in 4.2% of patients in the SOLD registry versus 4.1% in the present study. These results are comparable to the STRESS study (13) with major cardiac events reported from 4.9% of patients at 30 days. The occurrence of non-Q-wave myocardial infarction, which was defined as elevation of cardiac enzymes to more than twice normal, was reported as 11.3% of patients in the SOLD registry compared to a lower rate of 5.4% in the present study. The lower incidence of non-Q-wave myocardial infarction in the present trial may be related to differences in the patient populations and a different definition threshold for non-Q-wave infarcts. The SOLD registry enrolled 56% of patients with multivessel disease, in contrast to 18% of patients with two or more stenosed vessels included in the AtheroLink registry. Moreover, in the SOLD registry 13 patients (21%) had more than one lesion, which was treated by DCA and stenting, in contrast to the AtheroLink registry, which had only one treated lesion per patient.

Clinical success was higher in the AtheroLink registry (95.2%) and almost identical to what was reported from the SOLD registry (96%). Angiographic follow-up in the SOLD registry was performed in 62/70 (89%) eligible patients and showed a remarkably low angiographic restenosis rate of 10.7%, with a need for target-vessel revascularization in only 6.7% of patients. Restenosis rate and target-vessel revascularization were significantly lower compared to a stent-alone group (matched comparison) in the SOLD registry. Almost identical results could be achieved in the present multicenter approach, with an overall angiographic restenosis rate of 10.8% (13/120 lesions), although angiographic guidance was used for DCA and stenting in contrast to the SOLD registry, which was additionally based on intravascular ultrasound guidance. Target-lesion revascularization was required in 7.5% of patients. A matched comparison was not performed in the present study; however, a comparison of the data with retrospectively evaluated stent-alone patient populations with heterogeneous stenosis morphology (inclusion of long and complex lesions) shows a striking reduction of restenosis rate and target-lesion revascularization. Mehran et al. (16) reported a restenosis rate of 22% after stenting of discrete lesions and 28% restenosis rate in lesions >15 mm.

Angiographic restenosis was detected in 10.3% of de novo lesions and in 15.4% of restenotic lesions. A similar observation was made by Kornowski et al. (17), who reported on the clinical outcome of patients who had stent implantation in 3.25-mm vessels. In that trial, the need for target-lesion revascularization was lower in de novo than in restenotic lesions (14% vs. 22%, respectively). However, it should be mentioned that follow-up in this patient population was based on clinical findings that may lead to underestimation of the incidence of significant luminal renarrowing.

Effectiveness of DCA and stenting for the prevention of restenosis. In the SOLD registry, differentiation of the study population in two groups with respect to the plaque burden at the lesion site after DCA expressed as percent plaque area suggests that more aggressive debulking leads to further reduction in late lumen loss and restenosis. In the present study, debulking was evaluated in a semiquantitative fashion. Although almost all tissue (grade 3) could be removed by DCA in most of the patients, we could not demonstrate a significant difference between the incidence of restenosis for the combined grades 0 to 2 (37 patients = 30%) versus grade 3 (83 patients = 70%). This observation may be explained by the low absolute number of restenoses (n = 13) and the semiquantitative estimation of the removed material, which was not assessed in relation to the total plaque burden. Assessment of total plaque burden by IVUS in relation to the amount of removed material by DCA would have been a more appropriate approach to analyze the relation between debulking and the incidence of restenosis. However, the concept of the present study was based on a routinely achievable angiographic guidance of the combined DCA and stenting procedure. In contrast to the semiquantitatively evaluated debulking effect of DCA, the achievement of optimal stenting controled by QCA showed a tendency of reduced restenosis compared to suboptimal stenting (10% vs. 18%). Moreover, smaller vessels by QCA (2.8 to 3 mm) had a strong tendency toward a higher incidence of restenosis (16.1% vs. 6.2%) compared to larger vessels (3.6 mm to 4.0 mm).

Study limitations. One study limitation that merits comment is the number of patients (24/167 patients; 14.4%) who did not comply with the preestablished study protocol, and for which they had given written consent. To compensate for this noncompliance, we tried to collect clinical data on an outpatient basis. A subgroup of 12 patients was free of angina and had no exercise-inducible angina. Nine patients could be reached by telephone interview and reported to be free of angina. Three patients could not be evaluated because they moved to their country of origin. Thus, a clinical follow-up in 21/24 (87%) patients could be achieved.

Another study limitation is the fact that the concept of this multicenter registry was primarily based on a local QCA analysis by each participating center, which was controled by the study coordinating center. However, the QCA measurements were performed by different operators, which could have influenced the results.

Conclusions. The synergistic approach of DCA and stenting performed on a multicenter basis yielded encouraging data with respect to a potential reduction of angiographic restenosis and the reduced need for repeated target-vessel revascularization in a selected patient population. This is in good agreement with a previously reported monocenter registry on the combined use of DCA and stenting (10). Because the efficacy of repeat angioplasty for the treatment of in-stent restenosis appears to be poor (18,19), potentially
effective, safe and predictable strategies for prevention of in-stent restenosis like the use of DCA before stenting should be evaluated further. The open question is whether DCA plus stenting proves superior to stenting alone with respect to the incidence of restenosis; this will be addressed by a prospective randomized multicenter study (Atherectomy before Multilink Improves Lumen gain and Clinical Outcomes [AMIGO]). The result of this study will show whether DCA will remain alive as a preparative tool for optimal stenting or will further decline to an infrequently used “niche” technique for the treatment of ostial stenosis or cellular studies on plaque composition.

APPENDIX

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REFERENCES


