Rotational Atherectomy for In-Stent Restenosis: Acute and Long-Term Results of the First 100 Cases

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Objectives. This study evaluated the clinical safety and long-term results of rotational atherectomy (RA) followed by low-pressure balloon dilatation (percutaneous transluminal coronary angioplasty [PTCA]) for the treatment of in-stent restenosis (ISR).

Background. In-stent restenosis is associated with a high incidence of recurrence after interventional treatment. Because ISR is due to neointimal hyperplasia, rotational ablation may be a more effective treatment than PTCA.

Methods. Between November 1995 and November 1996, 100 consecutive patients with first-time ISR were treated by RA. Quantitative coronary angiography and intravascular ultrasound (IVUS) were used to analyze the acute procedural results. The incidence of repeat in-stent restenosis and target vessel revascularization (TVR) at follow-up was determined.

Results. Procedural success without any major in-hospital complications was achieved in 100% of cases. Slow flow was observed in 3% and creatine kinase-MB enzyme elevation >3X normal occurred in 2%. The mean burr-to-artery ratio was 0.68 ± 0.18 and adjuvant balloon dilatation was performed at 4.2 ± 2.1 atm. Minimum luminal diameter increased from 0.86 ± 0.28 mm to 1.89 ± 0.21 mm after RA and to 2.56 ± 0.29 mm after adjunct PTCA. Quantitative IVUS analysis showed that 77% of the luminal gain occurred due to rotational ablation of the restenotic tissue and only 23% occurred after adjunct balloon dilation, and further stent expansion did not contribute to the luminal enlargement. At a mean follow-up of 13 ± 5 months, repeat in-stent restenosis occurred in 28% of patients with TVR of 26%. Univariate predictors of repeat restenosis were burr-to-artery ratio <0.6, ISR in <90 days of stenting, ostial lesion, stent for a restenotic lesion and diffuse type ISR.

Conclusions. Rotational atherectomy is a safe and feasible technique for treatment of ISR and is associated with a relatively low recurrent restenosis in comparison to historical controls of balloon angioplasty.

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In-stent restenosis (ISR) presents a novel challenge to interventional cardiologists. Although less frequent than restenosis after balloon angioplasty (1,2), the prevalence of ISR has been increasing along with the widespread use of stents for percutaneous revascularization of a wide variety of coronary lesions. Unlike restenosis after balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA]), which is predominantly due to geometric arterial remodeling (shrinkage) up to 65% (3), ISR appears to be solely due to neointimal proliferation [intimal hyperplasia, (IH)], and intracoronary ultrasound has shown absence of stent recoil or stent compression in this setting (4,5). In-stent restenosis cases that are not referred for coronary artery bypass graft surgery (CABG) have been traditionally treated by balloon angioplasty (PTCA) with recurrent restenosis rates of up to 85%, especially after diffuse ISR (6–9). In these cases of diffuse ISR, PTCA is limited by the large plaque volume and leaves a relatively high residual stenosis (20%–35%). For these reasons, pretreatment with an atheroablative technique prior to balloon dilatation might be a preferable treatment modality for ISR compared with PTCA alone. Excimer laser ablation followed by adjunct balloon dilatation recently has been reported to produce an increase in lumen on the basis of both stent expansion and IH ablation, and to have a trend toward a reduced target vessel revascularization (TVR) rate at follow-up in comparison with PTCA alone (10). Rotational ablation of neointimal tissue within stents has been reported preliminarily as a feasible technique (11,12). In this study we review our single-center results of treatment of the first 100 consecutive ISR cases with rotational atherectomy (RA) and adjunct balloon dilatation, including the acute in-hospital outcome as well as recurrent ISR and TVR rates. Intravascular ultrasound (IVUS) was performed in...
a fraction of cases to assess the mechanism of luminal enlargement in this setting.

**Methods**

Between November 1995 and November 1996, a total of 122 patients underwent percutaneous coronary intervention for the treatment of a symptomatic first-time, ISR of ≥3.0 mm balloon expandable stents at Mount Sinai Hospital, New York. In all patients, initial stents were deployed using a 3.0 mm or larger balloon inflated at high pressure (>12 atm). Of these, 16 patients were treated with PTCA and 6 with additional stent implantation. The remaining 100 consecutive patients with 100 ISR lesions were treated with RA and comprised the study population. In-stent restenosis was defined as >50% diameter stenosis within or at the edges of a stented lesion that presented at least 8 weeks after the stent deployment. All patients were either symptomatic or ischemic by noninvasive testing. Clinical, angiographic and procedural data were prospectively recorded during hospital stay and all patients were followed every 3 months by telephone call or physician visit.

**Rotational atherectomy.** Routine premedication with 325 mg of aspirin and 30 mg of oral diltiazem were used; beta-adrenergic blocking agents were discontinued for >24 h prior to RA in elective cases. An 8 to 10 F arterial sheath and a temporary pacemaker via a 5 F sheath in left circumflex or right coronary artery intervention were inserted transfemorally in all patients. Heparin was used in repeated boluses to achieve and maintain an activated clotting time >300 s. Abciximab (ReoPro; Centocor, Malvern, Pennsylvania) was used at the discretion of the interventionalist. A flushing solution containing verapamil, nitroglycerin and heparin was used routinely during the RA. An 8 to 10 F guide catheter was selected to accommodate the estimated final burr size. The ablation runs were limited to 30 to 40 s at a time with slow advancement and “pecking” motion, avoiding a >5,000 rpm drop during burring. In the initial 40 cases, there was no set defined target burr-to-artery ratio and it was left to the discretion of the operators. In later cases, with experience, the target burr-to-artery ratio was 0.7. If IVUS was used prior to RA, the final burr selected had a diameter of less than 80% of the narrowest stent diameter. After RA, adjunct PTCA was routinely performed with a balloon-to-artery ratio of 1:1 at an inflation pressure of 3–6 atm (required to achieve complete balloon expansion in these ISR lesions) for 90 to 180 s. Intracoronary nitroglycerin 0.1 to 0.2 mg was administered routinely before all cineangiograms. Serum creatine kinase (CK)-MB enzymes were recorded at baseline and every 8 h for 16 to 24 h after the procedure.

**Angiographic analysis.** A single operator (K.V.), using a previously validated system of quantitative coronary angiography on the cardiotrace analyzer (13; Cine Graphics, Grand Prairie, TX) analyzed all cineangiograms using the contrast-filled catheters as the calibration standard. Final results were the average of the two orthogonal views with the least amount of foreshortening and overlap. Reproducibility of the measurements by the operator was established by random repeated measurements. Reference vessel diameter, minimum luminal diameter and percent diameter stenosis were measured. Lesion length was measured with digital calipers. Slow flow was assessed visually and lesions were classified qualitatively according to the American College of Cardiology/American Heart Association (ACC/AHA) classification. Procedural success was defined as <30% residual diameter stenosis. Coronary dissection was classified according to National Heart, Lung and Blood Institute classification: type A–B as minor dissection and type C–F as major dissection.

**Intravascular ultrasound.** To understand the mechanism of lumen enlargement after RA, IVUS was performed in the first 15 cases (interpretable data in 10 cases) and consecutively in cases from 71 to 100 (interpretable data in 27 cases). Imaging runs were done preprocedure, after RA and after adjunct PTCA; intracoronary administration of 0.1 to 0.2 mg of nitroglycerin preceded each imaging run. The IVUS catheter was advanced approximately 10 mm distal to the target lesion, and an imaging run was performed with slow manual pullback from distal to the target lesion towards the aorto-ostial junction. Studies were recorded only during pullback onto 0.5 in, high-resolution VHS for off-line analysis. The commercially available Hewlett-Packard System with a 30 MHz beveled transducer rotating at 1,800 rpm within a 3.5 F short monorail imaging catheter was used, and was withdrawn manually with fluoroscopic guidance to obtain the image sequence. All data were analyzed by the same investigator (S.D.), who performed quantitative measurements (cross-sectional area [CSA]) in the lesion at each imaging run (14,15). Stent CSA was the mean of the stent CSA in proximal, mid and distal parts of the lesion. Lumen CSA was calculated at the narrowest part of the lesion. When the plaque encompassed the catheter, the lumen was assumed to be the size of the imaging catheter (1.0 mm). The IH CSA was calculated as stent CSA minus the lumen CSA.

**Statistics.** Results are presented as mean ± SD, or n (%). Comparisons were done with the two-tail Student t test, and statistical significance was defined at the level p < 0.05. The data were entered in a FileMaker Pro 2.1 (Claris Corp., Santa Clara, California) database and transferred to the statistical program StatView 4.1 (Abacus Concepts, Inc., Berkeley, California) for analysis. The composite outcome of death, bypass surgery or Q-wave infarction within the hospital stay, was used.
as the short-term end point, and the repeat ISR and TVR as the long-term end point. The contribution of clinical, angiographic and procedural variable to the TVR was calculated by univariate analysis and logistic regression analysis in a stepwise logistic regression model where selection of variables was achieved in a stepwise fashion. Probability values <0.05 were considered significant.

Results

Patient characteristics (Table 1). Significant angina (Canadian Cardiovascular Society class III to IV) was the presenting symptom in 66% of patients and nine patients had non-Q-wave myocardial infarction (CK-MB >3× normal). Mean duration from stent implantation to ISR was 154 ± 46 days (range 58 to 501 days). Early ISR, defined as <90 days of stent implantation, was present in 18 patients. Two or more conventional risk factors for coronary artery disease (hypertension, hypercholesterolemia, diabetes mellitus, smoking and family history) were present in 53% of cases. The Palmaz–Schatz stent was involved in 90% of cases; seven were coil stents (Gianturco–Roubin) and three had a tubulocellular design. Two stents (15 to 20 mm in length) had been used for initial stent implantation in 42% of cases and three or more in 19%. Multivessel disease was present in 28%, and nine patients required additional revascularization for other significant lesions. The mean left ventricular ejection fraction (LVEF) was 45% (with EF <30% in 14 patients). Abciximab (ReoPro) was used in 32 patients—very liberally in the initial 20 cases, but later only in cases of long lesion length (>30 mm) or if patient developed slow flow or chest pain during intervention. The initial stent was deployed for a restenotic lesion in 22% of cases.

Angiographic and procedural characteristics (Table 2). The target lesion and vessel was the left anterior descending artery in 51%, right coronary artery in 30%, circumflex in 16% and saphenous vein graft in 3%. The mean lesion length was 17 ± 11 mm with 81% being diffuse (>10 mm in length). The ACC/AHA type C lesion characteristics were present in 53%, mostly due to >20 mm lesion length. The mean burr-to-artery ratio was 0.68 ± 0.18, with 32 patients having a ratio of <0.6, mostly in the beginning (22 out of the first 40). Postdilatation with a noncompliant balloon at a mean inflation pressure of 4.2 ± 2.1 atm was performed in 90 cases. In the remaining 10 cases, adjunctive PTCA was not performed because a satisfactory angiographic lumen post RA had been achieved. Other procedural characteristics are shown in Table 2.

Acute angiographic results (Table 3). Quantitative coronary analysis (QCA) revealed a stepwise significant increase in minimum luminal diameter after RA (0.86 ± 0.28 to 1.89 ± 0.21 mm; acute gain of 1.05 ± 0.18 mm) and adjunct PTCA (2.56 ± 0.29 mm; net acute gain of 1.74 ± 0.22 mm). After RA (before adjunct balloon dilatation), despite intracoronary nitroglycerin, the reference vessel diameter was slightly less than the baseline, most likely due to vasospasm caused by the rotablation. The minimum luminal diameter of 1.89 mm after RA was smaller than the maximal mean burr size (2.15 mm) in this series. The exact reason for the disparity was unclear but
postulated to be some plaque compression in the stented vessel during ablation immediately followed by reexpansion after the completion of ablation. In all cases, angiographic contour of the vessel appeared smooth without any major dissection (Fig. 1).

Quantitative IVUS analysis (Fig. 2). Three sets of IVUS images (baseline, post RA and post–adjunct PTCA) in the first 10 and later 27 cases were analyzed to understand the mechanism of luminal gain after RA and to evaluate the safety of RA in this setting. In the 27 later cases, after RA, lumen CSA increased from 2.4 ± 0.5 mm² to 4.4 ± 0.9 mm² (acute gain of 2.0 mm² despite a maximal mean burr size of 2.15 mm). After adjunct PTCA, lumen CSA increased to 5.0 ± 1.1 mm² (additional acute gain of 0.6 mm²) due to additional reduction of restenotic tissue. The stent CSA remained unchanged in our series, perhaps due to the use of low-pressure balloon inflations. Therefore, 77% of the luminal gain was attributable to rotational ablation of restenotic plaque and 23% to adjunct PTCA causing compression and/or extrusion of the neointimal tissue (Fig. 3A to C). Stent reexpansion did not contribute to the luminal enlargement. In 22% of the cases, IVUS revealed that stents were not fully deployed (defined as minimal stent area <80% of the distal reference vessel area), but high-pressure balloon dilatation to further expand the stent struts after RA was not performed to remain consistent with the trial design of low-pressure balloon dilatation after RA. There were no cases of stent distortion, breakage, wire protrusion, perforation or intimal dissection.

In-hospital course. All procedures (100%) were successful angiographically with <30% diameter stenosis without the use of additional stents. There were no major angiographic dissections or cases of burr entrapment. Minor angiographic dissections were noted in 7%. Slow flow occurred in three patients. The short-term composite end point of death, bypass surgery or Q-wave infarction during the hospital stay, did not occur in any patient. One patient developed a femoral artery pseudoaneurysm requiring duplex ultrasound-guided compression and one required blood transfusion for a moderate-sized groin hematoma. Creatine kinase-MB enzyme elevation above baseline occurred in 11 patients, with >3× normal in 2 patients.

Late clinical results. All patients have completed at least 9 months of follow-up, with a mean of 13 ± 5 months.

Figure 1. Cineangiograms of diffuse ISR treated with RA and adjunctive PTCA. (A) Diffuse ISR (arrow) of the right coronary artery 94 days after three 3.5 mm Palmaz–Schatz stents implantation. (B) Thirty percent residual stenosis (arrow) post RA using 1.5, 2.0 and 2.25 mm rota burrs. (C) Less than 10% residual stenosis (arrow) post RA+PTCA using a 3.5/30 mm compliant balloon at 6 atm.
patients presented with uncomplicated non-Q-wave myocardial infarction due to repeat in-stent occlusion. There were no Q-wave myocardial infarctions. Recurrent ISR occurred in 28% (28 of 100) at a mean duration of 102 ± 52 days. Of these 28 patients, 2 were treated medically (due to total occlusions) and 6 were referred for coronary artery bypass graft (CABG) surgery. The other 20 patients underwent repeat percutaneous interventions: 8 underwent PTCA alone, 7 underwent repeat RA plus adjunct PTCA and 5 underwent repeat stent implantation. Therefore, TVR occurred in 26% of cases. During the follow-up period, 4 additional patients required percutaneous intervention of a nontarget vessel. At the completion of follow-up, 98 patients were alive (1 patient died post CABG and the other died suddenly 2 months after repeat stent implantation).

Predictors of repeat ISR (Table 4). To evaluate the predictors of repeat ISR after RA, various clinical, angiographic and procedural factors were analyzed by univariate and stepwise regression analysis. A burr-to-artery ratio of 0.6 was the strongest predictor of repeat ISR (64% vs. 19%, p < 0.0001; odds ratio [OR] 7.46). Early ISR in <90 days of stent implantation was significantly associated with recurrence compared to ISR occurring after 90 days of stent implantation (39% vs. 10%, p < 0.001; OR 6.0). Other predictors of repeat ISR were: ostial lesion, ACC/AHA type C lesion, initial stent implantation for a restenotic lesion and diffuse type ISR. Various other factors such as diabetes mellitus, unstable angina, LVEF <30%, use of abciximab, vessel disease, total ablation time and final minimum luminal diameter were not associated with recurrence.

Discussion

Rational of RA for ISR. Treatment of ISR has become an increasingly common challenge due to the continued growth of coronary stenting in a wide variety of coronary lesions. The vessel wall pathology in ISR consists of a nonrecoiled metallic stent (16) that provides a round scaffolding within which neointimal tissue proliferates and narrows the lumen (4,5). Angiographically, most ISR is of the diffuse type (40% to 78%) characterized by neointimal hyperplasia and a poor response to high-pressure balloon redilatation causing tissue compression and extrusion and plaque reexpansion (8–10). The diffuse, circumferential distribution of IH in (in-stent) restenotic lesions may favor rotational ablation by preventing direct contact between the rotablator burr and the stent struts. Furthermore, ablation rather than tissue compression and extrusion alone may offer an improvement in the treatment of ISR. Given the poorly characterized interaction between the rotablator and the metallic stent surface, interventional cardiologists have been skeptical regarding the use of RA for ISR (11,12). However, on theoretical grounds it is difficult to argue that stainless steel microparticles present a greater risk to the microcirculation than do microparticles derived from calcified, fibrotic, atherosclerotic plaque. In fact, it has been our experience that ISR patients tolerate aggressive RA more easily than patients with de novo calcified lesions.

Comparison with other studies. This study demonstrated the safety and efficacy of RA for the treatment of ISR. Our results showed an 100% safety rate, even with a burr-to-artery ratio of 0.7 in later cases (compared to a smaller burr-to-artery ratio of 0.55 in the first 20 cases). Rather, RA in ISR cases was very well tolerated with a very low incidence of slow flow (3%) despite a high prevalence of long lesions (51% being >20 mm). Also, with the present recommended technique of step burr approach, there were no unusual complications of burr entrapment, perforation and obvious stent distortion/damage on angiography or IVUS. Despite the initial experience in this field, there were no major ischemic procedure-related complications. Abciximab was used in 32% of our cases largely in the beginning, not knowing how RA would be tolerated in this setting. Later in the series it became evident that RA for ISR
is well tolerated and abciximab use was limited to very long lesions, cases of slow flow and significant chest pain or electrocardiographic changes during the intervention. Nevertheless in our series, abciximab use was not associated with lower TVR. Our long-term results showed a lower clinical restenosis rate (28%) and lower TVR (26%) compared with historic controls of PTCA in the treatment of ISR (6–10,17,18). Although in the present study there was no control group for direct comparison of ISR treatment by various techniques, our single center results have revealed TVR of 62% after PTCA and 40% after restent implantation for diffuse ISR treatment (10). With respect to diffuse ISR, our group had a TVR of 32% compared to 85% reported by Yokoi et al. (8). A recent report by Reimers et al. (19) revealed a low clinical restenosis (20%) and a low TVR rate of 11% after percutaneous intervention of ISR at a mean follow-up of 27.4 months. A relatively better outcome in this series of predominately PTCA-treated ISR was most likely attributed to a high number of patients with focal ISR (62% compared to 19% in our series). A multicenter BARASTER registry evaluated the early and long-term results of RA for ISR and revealed a high clinical success rate of 97.4% and 2.2% major complications (20). In this cumulative series of 153 lesions from 10 centers, recurrent restenosis occurred in 48% (57% with RA alone vs. 35% after RA + adjunct PTCA; p < 0.01). The relatively high recurrence rate in the BARASTER registry compared with 28% in our series may be due to the heterogeneous patient population, a small reference vessel size (2.75 ± 0.41 mm vs. 3.16 ± 0.31 mm in our series) and a lower final minimum luminal diameter (2.11 ± 0.41 mm vs. 2.56 ± 0.29 mm in our series). Moreover, the BARASTER registry demonstrated the importance of adjunct PTCA even after optimal RA (high burr-to-artery ratio of 0.76) in further reducing the recurrent restenosis. There is little difference in the TVR of 26% after RA in our series and the TVR of 21% after excimer laser angioplasty previously reported by Mehran et al. (10). The laser study included patients with several differences compared

Table 4. Univariate Predictors of Recurrent In-stent Restenosis after Rotational Atherectomy

<table>
<thead>
<tr>
<th>Variables</th>
<th>Restenosis (n = 28) (%)</th>
<th>No restenosis (n = 72) (%)</th>
<th>p Value</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burr-to-artery ratio ≤ 0.6</td>
<td>18 (64)</td>
<td>14 (19)</td>
<td>&lt; 0.001</td>
<td>7.46</td>
</tr>
<tr>
<td>Early ISR (&lt; 90 days)</td>
<td>11 (39)</td>
<td>7 (10)</td>
<td>&lt; 0.001</td>
<td>6.00</td>
</tr>
<tr>
<td>Ostial lesion</td>
<td>7 (25)</td>
<td>4 (6)</td>
<td>0.01</td>
<td>5.66</td>
</tr>
<tr>
<td>AHA/ACC type C lesion</td>
<td>20 (71)</td>
<td>33 (46)</td>
<td>0.02</td>
<td>2.95</td>
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<tr>
<td>Initial stent in restenotic lesion</td>
<td>10 (36)</td>
<td>12 (17)</td>
<td>0.04</td>
<td>2.78</td>
</tr>
<tr>
<td>Diffuse ISR</td>
<td>26 (93)</td>
<td>55 (76)</td>
<td>0.05</td>
<td>2.56</td>
</tr>
<tr>
<td>LVEF &lt; 30%</td>
<td>6 (21)</td>
<td>8 (11)</td>
<td>0.18</td>
<td></td>
</tr>
<tr>
<td>LAD location</td>
<td>17 (61)</td>
<td>34 (47)</td>
<td>0.22</td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>19 (68)</td>
<td>47 (65)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>8 (29)</td>
<td>16 (22)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Abciximab use</td>
<td>7 (25)</td>
<td>25 (35)</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Total ablation time (s)</td>
<td>228 ± 101</td>
<td>201 ± 109</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Final MLD (mm)</td>
<td>2.54 ± 0.21</td>
<td>2.59 ± 0.26</td>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>

ISR = in-stent restenosis; LAD = left anterior descending artery; LVEF = left ventricular ejection fraction; MLD = minimum luminal diameter; OR = odds ratio.
with our study population, including a relatively shorter follow-up period (5.4 vs. 13 months), more patients with short lesions <10 mm (53% vs. 19%), smaller vessel size (reference vessel diameter 2.64 ± 0.5 vs. 3.16 ± 0.31 mm), more saphenous vein graft interventions (36% vs. 3%) and more aorto-ostial lesions (26% vs. 11%). At present there is no direct comparative analysis of RA versus laser for treatment of ISR. In a small series, directional coronary atherectomy has been shown to be safe and effective for the treatment of ISR involving large stents (>3.5 mm), but long-term data are lacking and stent fragments have been retrieved in some cases (21).

Mechanism of luminal enlargement. The QCA and IVUS analyses indicated that the major part of the luminal gain was attained after RA (77%), with a small contribution by the adjunct low-pressure balloon dilatation. Mehran et al. (10) reported on the mechanism of luminal enlargement after excimer laser and adjunct high-pressure PTCA, showing a 40% contribution from additional stent expansion and a relatively equal contribution from laser ablation (29%) and adjunct PTCA (31%). The absence of stent expansion and the limited contribution of plaque compression and extrusion to the reduction of the percent area stenosis in our study is likely due to aggressive rotablation (mean maximum burr size of 2.15 mm) and the use of low- rather than high-pressure balloon dilatation (4.2 ± 2.1 vs. 16.5 ± 3.1 atm after laser) without oversized balloons (balloon-to-artery ratio 1:1 vs. 1.4:1 after laser).

Predictors of repeat TVR. Our analysis of predictors of recurrent ISR and TVR revealed that recurrent ISR after RA correlated with several characteristics that have also been associated with recurrent restenosis after balloon angioplasty such as ostial lesion, stent implantation for a restenotic lesion, ACC/AHA type C lesion and diffuse ISR lesions (17). Suboptimal debulking with small rota burrs (burr-to-artery ratio <0.6) correlated with a very high recurrence. This probably represents more PTCA effect rather than ablation in these cases. Of interest, similar to reports by Reimers et al. (19), early ISR within 90 days of stent implantation was found to be a strong correlate of recurrence after RA. Early ISR is probably a marker of very aggressive vascular response to injury caused by initial stent implantation, and even successful rotational ablation may not alter this aggressive intimal hyperplastic response.

Study limitations. The present study has several important limitations which should be considered before interpreting the final results. This study evaluated mainly ISR of Palmaz-Schatz stents (90%) and had no direct control group undergoing PTCA. Patient selection may therefore present a bias in the comparison of our results with historic controls of PTCA. We demonstrated a TVR of 26% in after RA for treatment of predominantly diffuse ISR lesions (81%), which is lower than the average TVR of 45% reported in the literature in this setting after PTCA. In addition, there was no routine angiographic follow-up (follow-up angiograms >3 months after RA are available in 44%). This may underestimate the incidence of recurrent angiographic ISR that may be clinically silent. Because the main aim of the present study was to reduce clinical restenosis, all patients were closely followed for clinical events and recurrence, as well as noninvasive testing. Finally, systematic IVUS analysis was performed in only 45 cases, with interpretable data in 37 patients, and the exact contribution of tissue compression versus tissue extrusion could not be determined. Also, if preprocedure IVUS revealed an underdeployed stent, a high-pressure balloon dilatation after RA was not used, to remain consistent with the trial design. Nonetheless, there were no major procedural complications, stent damage or burr entrapment in these patients, perhaps due to the presence of restenotic tissue covering the stent struts, thereby preventing burr-to-stent contact.

Conclusions and clinical implications. To our knowledge the present study reports the largest cohort of patients with ISR treated using RA. We have found that RA is safe and very well tolerated in the setting of ISR, particularly in comparison to RA of long, calcified lesions. These preliminary findings support the use of RA as a routine procedure for the treatment of diffuse ISR where PTCA appears to yield suboptimal acute angiographic results and a high restenosis rate. Based on these encouraging results, an IVUS-guided randomized trial comparing RA (burr-to-artery ratio 0.7) followed by low-pressure (3~6 atm) balloon dilatation to high-pressure (12~16 atm) PTCA for treatment of ISR (ROSTER trial) has been started (22).

References


