Detailed Angiographic Analysis of High-Speed Mechanical Rotational Atherectomy in Human Coronary Arteries

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Background. Several types of atherectomy devices have been developed recently for treatment of patients with ischemic heart disease.

Methods and Results. Mechanical rotational atherectomy (MRA) using a high-speed rotational burr (Rotablator) was performed on 116 lesions in 104 patients. MRA alone was performed in 27 lesions (23%), and conventional balloon angioplasty (PTCA) was performed after MRA in 89 lesions (77%). Diameter stenosis decreased from 78±13% before MRA to 54±23% after MRA, and the final diameter stenosis (after MRA alone or with adjunctive PTCA) was 30±20% (P<.001). Minimal lumen diameter increased from 1.0±0.5 mm before MRA to 1.4±0.7 mm after MRA, and the final minimal lumen diameter was 2.3±0.7 mm (P<.001). MRA resulted in a decrease in diameter stenosis of 20% or more in 44% of lesions, and the final diameter stenosis (after MRA alone or after PTCA) was less than 50% in 75% of lesions. Considering the small diameter of available burrs, the magnitude of lumen enlargement was equal to 91% of the burr diameter, and only 9% of the burr diameter was “lost” due to elastic recoil or spasm. These angiographic results were obtained despite the presence of complex lesion morphology, including the presence of calcification in 17% of lesions and ostial location in 26% of lesions. Significant angiographic complications included abrupt closure (13 lesions, 11.2%), no reflow (8 lesions, 7%), severe coronary vasospasm (16 lesions, 13.8%), and guide wire fracture (3 lesions, 2.7%). There were no coronary artery perforations. Adjunctive therapy, including salvage PTCA, thrombolytic agents, and vasodilators, was successful in treating angiographic complications in 42 of 49 lesions (86%). Clinical complications included Q-wave myocardial infarction (5 patients, 4.8%), non-Q-wave myocardial infarction (3 patients, 2.9%), femoral vascular injury requiring surgery (3 patients, 2.9%) or blood transfusion (8 patients, 7.7%), abrupt closure requiring emergency bypass graft surgery (2 patients, 1.9%), and in-hospital death (1 patient, 1.0%). Angiographic follow-up (mean follow-up interval, 5.8±2.0 months) was available in 84% of successfully treated patients and revealed a restenosis rate of 51%, defined as a residual diameter stenosis of more than 50%. There was no significant difference in restenosis rates between de novo lesions (50%) and restenosis (54%) lesions.

Conclusions. These data suggest that for the treatment of most coronary stenoses, PTCA is required after MRA to achieve satisfactory lumen enlargement or to salvage complications. Angiographic complications appear to be more common after MRA, and salvage PTCA often is required to manage these device-induced complications. The combination of MRA and PTCA does not prevent restenosis. (Circulation. 1993;88:961-968.)

Key Words • atherectomy • arteries • angioplasty

Several new interventional devices, including lasers, stents, and atherectomy catheters, are currently under investigation to determine their relative merits compared with conventional balloon angioplasty (PTCA).1 These devices have been developed for the purpose of revascularizing lesions in which PTCA may have limited immediate and long-term success.2-6

High-speed mechanical rotational atherectomy (MRA) is a relatively new percutaneous intervention that relies on high-speed rotation to pulverize plaque and “polish” the luminal surface of the artery.7 The purpose of this study was to evaluate the immediate and long-term results and complications of MRA in patients with coronary artery disease.

Methods

Patient Population

Between September 1988 and May 1991, high-speed MRA was performed on 116 coronary artery stenoses in 104 patients with a mean age of 58±11 years (78% male). Anginal symptoms were classified as I (12%), II
(15%), III (61%), or IV (12%) according to the Canadian Heart Association classification. Recent myocardial infarction (within 1 month) occurred in 14% of patients, and significant coronary artery disease (more than 50% diameter stenosis) was limited to one vessel in 38%, two vessels in 32%, and three vessels in 30% of patients. Prior coronary artery bypass surgery had been performed in 21% of patients. The mean left ventricular ejection fraction was 49±11%.

**Baseline Angiographic Findings**

Of 116 lesions treated, 81 (70%) were de novo lesions, and 35 (30%) were restenosis lesions that had developed after prior PTCA. The target lesion was located in the left main coronary artery in 7%, the left anterior descending coronary artery in 35%, the left circumflex or obtuse marginal arteries in 15%, the right coronary artery in 39%, and a saphenous vein bypass graft in 3%. The target lesion was located in a proximal vessel segment in 62%, a midvessel segment in 30%, and a distal vessel segment in 8%. Target lesions were selected on the basis of their suitability for conventional PTCA and alternative interventional techniques. Patients with acute myocardial infarction, with lesions more than 25 mm long, or with lesions in degenerated vein grafts were excluded.

**Coronary Atherectomy Procedure**

All coronary atherectomy procedures were performed according to a protocol approved by the Human Investigations Committee of William Beaumont Hospital. A temporary transvenous pacemaker was inserted prophylactically in all patients with target lesions in the right coronary artery. A standard 9F or 10F angioplasty guiding catheter was positioned at the vessel ostium, and a 0.014-in. 300-cm-long angioplasty guide wire (Advanced Cardiovascular Systems, Santa Clara, Calif) was advanced across the lesion. This wire was then exchanged for the rigid stainless-steel 0.009-in. Rotablator guide wire (Heart Technologies, Bellevue, Wash) by using a 2.5F infusion catheter (Cordis, Miami, Fla). Once the Rotablator guide wire was in the proper position, the Rotablator burr (Heart Technologies) was advanced into the guiding catheter (burr of less than 2.0 mm were used with 9F guiding catheters and burrs of 2.0 mm or more were used with 10F guiding catheters). The burr was then slowly advanced across the lesion using gentle forward pressure, while rotating at 170 000 to 200 000 rpm. Generally, two to five passes were performed, lasting 5 to 45 seconds. After MRA, repeat angiography was performed, and adjunctive PTCA was used if necessary to achieve a residual stenosis of less than 50% (Fig 1).

Several aspects of this procedure should be emphasized. First, it is important to place the Rotablator guide wire tip into the distal vessel to ensure that the stiff portion of the guide wire is across the lesion, so that the Rotablator is not activated along the flexible portion of the wire. Second, the rotational speed should not be allowed to fall below 130,000 rpm, and excessive forward force and “jack-hammering” should be avoided. Finally, the selection of burr sizes is largely empiric, but for longer segments of disease or de novo lesions, we generally recommend sequential increases in burr sizes.

**Fig 1. Baseline angiography of "stand-alone" high-speed mechanical rotational atherectomy (MRA) revealed an eccentric 90% stenosis (minimal lumen diameter, 0.3 mm) in a bend in the proximal left circumflex artery (top). MRA was performed using a 1.75-mm Rotablator burr (middle), leaving a 39% residual stenosis (reference diameter, 2.5 mm; minimal lumen diameter, 1.5 mm) without dissection.**

**Medications**

All patients were pretreated with aspirin, long-acting nitrates, and calcium channel blockers at least 24 hours before the procedure. β-Blockers were discontinued if possible to minimize the potential for coronary vasospasm. After insertion of the arterial sheath, 10 000 units heparin was administered, and additional heparin was given throughout the procedure to maintain the
activated clotting time at more than 300 seconds. Sublingual nifedipine and nitroglycerin infusion were given before atherectomy, and intracoronary nitroglycerin was administered after placement of the guiding catheter in the vessel ostium. The importance of this vigorous antispasm regimen cannot be overemphasized. After the procedure, patients were treated with overnight infusions of heparin and nitroglycerin, and long-acting nitrates, calcium channel blockers, and aspirin were prescribed for at least 6 weeks.

**Quantitative Angiography**

The single view that identified the most severe stenosis was selected for analysis. Measurements of minimal lumen diameter, reference diameter, and lesion length were obtained with electronic calipers (Chandler and Farquhar Co, Canton, Mass) using the guiding catheter as a reference object, as previously described. In all cases, measurements were obtained immediately before and after atherectomy and after PTCA, when performed (all measurements were performed by R.D.S.).

**Qualitative Lesion Assessment**

For purposes of analysis, lesion characteristics were categorized as dichotomous variables (present or absent). Lesions involving the aorta and the origin of the left main coronary artery, the right coronary artery, or saphenous vein grafts were classified as aorto-ostial lesions, whereas lesions involving the origin of all other vessels were classified as origin lesions. Lesions were considered eccentric if they occupied the outer fourth of the vessel lumen, and ulcerated lesions were defined as those with definite overhanging edges (lesions with simple contour irregularity were not considered ulcerated). Thrombus was considered to be present if there was a definite circumscripted filling defect, whereas intraluminal haziness alone was not considered sufficient evidence for thrombus. Lesion angulation was graded as none, mild (less than 45° angle), moderate (45 to 60° angle), or severe (more than 60° angle). Vessel tortuosity proximal to the lesion was graded as none, mild (one bend of 90° or less), moderate (two 90° bends), or severe (more than two 90° bends).

After MRA (and PTCA if performed), antegrade flow was graded using standard TIMI criteria. Dissection grades were assigned on a scale of 0 to 4 (0, no dissection; 1, mild focal dissection; 2, moderate dissection with less than 50% diameter stenosis; 3, severe dissection with more than 50% diameter stenosis; and 4, severe dissection with total occlusion), and dissection morphology was classified on a scale of 0 to 3 (0, no dissection; 1, focal dissection without dye stain; 2, focal dissection with dye stain; and 3, spiral dissection), as described previously.

**Follow-up**

Follow-up was performed by clinic visit or telephone contact with the patient or referring physician. Repeat angiography was recommended to all patients at 6 months or earlier if necessary for recurrence of symptoms.

**Definitions**

For purposes of this study, angiographic success was defined as a decrease in diameter stenosis of 20% or more after MRA, and overall procedural success was defined as a final diameter stenosis of less than 50% in the absence of a major complication (death, emergency bypass surgery, or Q-wave myocardial infarction). Non-Q-wave myocardial infarction was defined as elevation of creatine kinase more than three times the upper limit of normal in the absence of new pathological Q waves. No-reflow was defined as delayed antegrade flow (TIMI grade of less than 2) in the absence of a clear explanation for impaired flow (dissection, thrombus, spasm) at or adjacent to the original lesion. Angiographic restenosis was defined as a diameter stenosis of more than 50% at the time of follow-up. The RLD-D ratio was defined as the ratio of the residual lumen diameter (RLD) immediately after MRA to the final diameter (D) of the Rotablator burr. The RLD-D ratio is a measure of the relative lumen diameter achieved, normalized for the size of the burr, and is a direct measure of efficiency of lumen enlargement.

**Statistical Analysis**

Data are reported as mean±SD values. Comparisons were made using Student's t test for continuous variables. *P*<.05 was considered significant.

**Results**

**Baseline Lesion Morphology**

Using the modifications of the American College of Cardiology/American Heart Association (ACC/AHA) Task Force classification proposed by Ellis and colleagues, lesions were classified as A (20%), B1 (31%), B2 (45%), and C (4%) (Table 1). Complex lesion morphology (class B or C) was present in 80% of lesions, including eccentricity in 38%, aorto-ostial or origin location in 26%, moderate or severe angulation in 20%, and calcification in 17% of lesions (Fig 1).

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**Table 1. Morphology of 116 Lesions Treated by High-Speed Mechanical Rotational Atherectomy**

<table>
<thead>
<tr>
<th>Lesion characteristic</th>
<th>Percent of lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total occlusion</td>
<td>1</td>
</tr>
<tr>
<td>Aorto-ostial</td>
<td>13</td>
</tr>
<tr>
<td>Origin</td>
<td>13</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>10</td>
</tr>
<tr>
<td>Calcified</td>
<td>17</td>
</tr>
<tr>
<td>Eccentric</td>
<td>38</td>
</tr>
<tr>
<td>Ulcerated</td>
<td>8</td>
</tr>
<tr>
<td>Thrombus</td>
<td>3</td>
</tr>
<tr>
<td>Moderate-to-severe angulation*</td>
<td>20</td>
</tr>
<tr>
<td>Moderate-to-severe tortuosity†</td>
<td>6</td>
</tr>
<tr>
<td>Modified ACC/AHA class‡</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>20</td>
</tr>
<tr>
<td>B1</td>
<td>31</td>
</tr>
<tr>
<td>B2</td>
<td>45</td>
</tr>
<tr>
<td>C</td>
<td>4</td>
</tr>
</tbody>
</table>

ACC/AHA indicates American College of Cardiology/American Heart Association.

*Defined as more than 45° bend at site of lesion.
†Defined as more than two 90° bends proximal to lesion.
‡As described by Ellis and colleagues.

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Immediate Results

The Rotblator was successfully advanced through all 116 lesions. However, 20 lesions (17.3%) had delayed antegrade flow (TIMI flow of 2 or less) to the distal vessel after MRA (Table 2) and were considered angiographic failures due to abrupt closure (13 lesions, 11.2%) or "no-reflow" (7 lesions, 6.1%). After PTCA, normal antegrade flow (TIMI 3) was observed in 95.6% of lesions, although delayed antegrade flow persisted in 5 lesions (4.5%) due to abrupt closure (3 lesions, 2.7%) or "no-reflow" (2 lesions, 1.8%) (Table 3). When considering the immediate results based on diameter stenosis, only 50% of lesions had a diameter stenosis of less than 50% after MRA, whereas 75% of lesions had a final diameter stenosis of less than 50% stenosis after MRA alone or after PTCA (Fig 2). If success is defined as 20% or more change in stenosis, MRA success was 44%.

Adjunctive PTCA

MRA was performed as the sole intervention in 27 lesions (23%), and PTCA was performed after MRA in 89 lesions (77%). However, PTCA was ultimately used as an adjunct to further enlarge lumen dimensions after MRA in 69 lesions (60% of all lesions attempted) and as a salvage strategy after MRA-induced vessel occlusion in 20 lesions (17% of all lesions attempted).

Lesion Morphology

A smooth lumen contour was observed in 64% of lesions after MRA, and the final angiogram demonstrated a smooth lumen contour in 75% of lesions after MRA with or without PTCA. Angiographic evidence for dissection was detected in 29% of lesions after MRA and in 26% of lesions after final angiography. Mild or moderate degrees of dissection (grade 1 or 2) were detected after MRA in 13.1% of lesions, and severe dissections with high-grade residual stenoses (grade 3) or total occlusion of the vessel (grade 4, abrupt closure) were detected after MRA in 5.6% and 11.2% of lesions, respectively. However, with the use of subsequent PTCA, the final incidence of severe dissection (grade 3 or 4) was reduced to 6.4%, and only 3 lesions (2.7%) remained totally occluded. Most of the dissections leading to abrupt closure were due to long, spiral dissections (morphology grade 3), but in some cases more limited dissections resulted in abrupt closure.

Quantitative Angiography

The average lesion length was 6.6±6.6 mm, and the average diameter of the reference segment was 3.2±0.8 mm. The diameter stenosis decreased from 70±13% before MRA to 54±23% after MRA, and the final diameter stenosis with or without PTCA was 30±20% (P<.001). These corresponded to increases in minimal lumen diameter from 1.0±0.5 to 1.4±0.7 mm after MRA to 2.3±0.7 mm after final angiography (P<.001).

The final burr size was 1.25 mm (10.6%), 1.5 mm (19.4%), 1.75 mm (18.6%), 2.0 mm (44.2%), 2.25 mm (6.2%), and 2.5 mm (0.9%). The RLD-D ratio for all technically successful MRA procedures was 0.91±0.03. The average burr size was 1.8±0.3 mm, and the average balloon size was 3.1±0.4 mm. The average number of

| TABLE 2. Assessment of Antegrade Flow After MRA With or Without PTCA in 116 Lesions |
|---------------------------------|---|---|---|
| TIMI grade* | Baseline | After MRA | After MRA±PTCA |
| No. | % | No. | % | No. | % |
| 0 | 0 | 10 | 8.6 | 3 | 2.5 |
| 1 | 1 | 0.9 | 8 | 6.9 | 2 | 1.8 |
| 2 | 2 | 1.8 | 2 | 1.8 | 0 | 0 |
| 3 | 113 | 97.3 | 96 | 82.7 | 111 | 95.6 |

TIMI indicates Thrombolysis in Myocardial Infarction trial; MRA, high-speed mechanical rotational atherectomy; and ±PTCA, with or without balloon angioplasty.

*TIMI grades as defined in Reference 9.

| TABLE 3. Angiographic Complications After MRA With or Without PTCA in 116 Lesions |
|---------------------------------|---|---|---|
| Complication | Due to MRA | Due to PTCA | Salvage by PTCA | Persist after PTCA |
| No. | % | No. | % | No. | % | No. | % |
| Sidebranch occlusion | 2 | 1.8 | 1 | 0.9 | 2 | 1.8 | 1 | 0.9 |
| Distal embolization | 1 | 0.9 | 1 | 0.9 | 2 | 1.8 | 0 | 0 |
| No reflow | 7 | 6.1 | 1 | 0.9 | 6 | 5.4 | 2 | 1.8 |
| Abrupt closure | 13 | 11.2 | 0 | 0 | 10 | 8.9 | 3 | 2.7 |
| Guide wire fracture | 3 | 2.7 | 0 | 0 | 2* | 1.8* | 1* | 0.9* |
| Perforation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| New clot | 4 | 3.6 | 0 | 0 | 4 | 3.6 | 0 | 0 |
| Spasm | 16 | 13.8 | 0 | 0 | 16† | 13.8† | 0 | 0 |
| Total | 46 | 39.6 | 3 | 2.7 | 42 | 37.2 | 7 | 6.1 |

*MRA indicates high-speed mechanical rotational atherectomy; and PTCA, balloon angioplasty.

*Managed by percutaneous snare-loop technique.

†Managed by intracoronary nitroglycerin.
diameter stenosis expressed as a percent of all lesions treated with high-speed mechanical rotational atherectomy (MRA) (116 lesions). A indicates baseline diameter stenosis before MRA; B, diameter stenosis after MRA; and C, final diameter stenosis after MRA with or without PTCA.

Angiographic Complications

Significant angiographic complications were evident in 46 lesions (39.6%) after MRA, and 3 additional complications were attributed to PTCA (2.7%) (Table 3). Sidebranch occlusion occurred in 3 lesions (2.7%), two of which were successfully salvaged by PTCA. Distal embolization of atheromatous debris with persistent normal antegrade flow occurred in 2 lesions (1.8%) and was successfully managed by PTCA and large doses of intracoronary nitroglycerin. No-reflow was observed in 8 lesions (after MRA in 7 lesions, 6.1%; after MRA and PTCA in 1 lesion, 0.9%) and was presumed to be due to distal embolization of atheromatous debris resulting in no antegrade flow. In 6 of these lesions, normal antegrade flow was reestablished by combined therapeutic modalities of multiple overlapping balloon inflations, large doses of intracoronary nitroglycerin (more than 1 mg), intracoronary thrombolytic therapy, and intravenous dextran. Severe dissection leading to abrupt closure occurred in 13 lesions (11.2%, all after MRA) and was managed by successful PTCA in 10 lesions. However, despite salvage PTCA, severe dissection and abrupt closure persisted in 3 lesions (2.7%; 2 of these patients required emergency bypass graft surgery). Fracture of the Rotablator guide wire occurred after MRA in 3 lesions (2.7%), of which 1 was retrieved percutaneously by a snare-loop technique; the other 2 guide wires could not be retrieved, and these patients were treated with oral coumadin. New thrombus was identified after MRA in 4 lesions (3.6%) and was managed by PTCA and intracoronary thrombolytic therapy without sequelae. A frequent complication was the development of significant (more than 50% stenosis by visual estimate) coronary vasospasm adjacent or distal to the lesion after MRA, despite the vigorous antispasm regimen suggested earlier. Although significant spasm occurred in 16 lesions (13.8%) after MRA, it was readily reversed by intracoronary nitroglycerin (0.2 to 1.0 mg).

FIG 2. Plots of diameter stenosis expressed as a percent of all lesions treated with high-speed mechanical rotational atherectomy (MRA) (116 lesions). A indicates baseline diameter stenosis before MRA; B, diameter stenosis after MRA; and C, final diameter stenosis after MRA with or without PTCA.

TABLE 4. Clinical Complications of MRA and PTCA in 104 Patients

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. of patients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>5</td>
<td>4.4</td>
</tr>
<tr>
<td>Non-Q-wave MI</td>
<td>3</td>
<td>2.7</td>
</tr>
<tr>
<td>IA/BP</td>
<td>5</td>
<td>4.4</td>
</tr>
<tr>
<td>CPS</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Temporary pacert</td>
<td>2</td>
<td>1.8</td>
</tr>
<tr>
<td>Vascular repair</td>
<td>3</td>
<td>2.7</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>8</td>
<td>7.2</td>
</tr>
<tr>
<td>Stroke</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td>Renal failure</td>
<td>1</td>
<td>0.9</td>
</tr>
</tbody>
</table>

MRA indicates high-speed mechanical rotational atherectomy; PTCA, balloon angioplasty; CABG, coronary artery bypass graft surgery; MI, myocardial infarction; IABP, intra-aortic balloon pump; and CPS, percutaneous cardiopulmonary bypass support. *IABP and CPS were performed electively in one patient each, before atherectomy. †Prophylactic pacemakers were inserted in all patients with target lesions in the right coronary artery.

Therefore, of the 49 angiographic complications that were observed after MRA (with or without PTCA), 42 (86%) were managed successfully by percutaneous methods and/or combinations of vasodilators and thrombolytic therapy. Serious angiographic complications requiring emergency bypass graft surgery occurred in 2 patients (2 lesions, 1.9%).

Clinical Complications

Despite the observation of significant angiographic complications in nearly 40% of lesions, clinical sequelae were much less frequent (Table 4). As described above, 5 lesions in 5 patients were totally occluded at the completion of the procedure, mandating emergency bypass in 2 patients (1.9%) and conservative therapy without surgical intervention in 2 patients (1.9%). One (1.0%) of these 5 patients, who was not believed to be a surgical candidate, died within 24 hours despite percutaneous cardiopulmonary bypass (CPS). All 5 patients suffered Q-wave myocardial infarction (4.8%). Three patients with transient no-reflow or distal embolization had non-Q-wave myocardial infarction (2.9%). A total of 7 patients were placed on percutaneous support (6.7%), including 2 patients (1 intra-aortic balloon pump, 1 CPS) placed electively on percutaneous support because of poor baseline left ventricular function, 4 patients with emergency counterpulsation (2 patients who underwent emergency surgery and 2 patients with no-reflow who were managed with PTCA and nitroglycerin), and 1 patient on CPS who died. Temporary pacemakers were inserted in 2 patients (1.9%) because of bradycardia associated with transient no-reflow. Vascular injury requiring surgical repair under local anesthesia (2.9%) or blood transfusion (7.7%) occurred in 11 patients (10.6%). Several days after atherectomy, 1 patient suffered a hemorrhagic cerebral infarction (1.0%) for which no clear etiology was identified, and 1 patient developed transient worsening of baseline renal
Follow-up

Complete clinical follow-up was available in 95 of 99 patients (96%) who were discharged from the hospital after successful procedures. At an average follow-up interval of 5.0±2.0 months, anginal symptoms were improved (compared with before atherectomy) in 57 patients (60%), the same in 29 patients (31%), and worse in 9 patients (9%). Late recurrence of anginal symptoms was treated by medical therapy in 21 patients (22%), by repeat percutaneous intervention (PTCA or other device) in 26 patients (28%), and by coronary artery bypass graft surgery in 8 patients (8%). There were no late myocardial infarctions, and 2 patients died (2%) from cardiac causes during the follow-up period. Thirty-eight patients (40%) were asymptomatic throughout the follow-up period.

Angiographic follow-up was available in 83 of 99 patients (84%) who were discharged from the hospital after successful procedures (the 2 deaths occurred before angiographic follow-up was obtained). Quantitative angiography revealed a minimal lumen diameter of 1.4±0.8 mm, which corresponded to a diameter stenosis of 57±24%. The diameter of the reference segment was 3.2±0.8 mm, and the lesion length was 6.5±3.7 mm. If restenosis is defined as a diameter stenosis of more than 50%, then 51% of patients had angiographic evidence for restenosis at the time of follow-up angiography (Fig 3). There was no significant difference in restenosis rates for patients treated with MRA for de novo (50%) or restenosis (54%) lesions.

Discussion

In the past few years, several new interventional devices have been developed to address the limitations of conventional balloon angioplasty. In fact, Food and Drug Administration approval for many of these devices has been granted or is imminent. However, the role of these devices with respect to each other and with respect to balloon angioplasty is still unknown. The evaluation of these devices is currently a major area of interest of a new National Heart, Lung, and Blood Institute Registry.

Mechanism of Action

Unlike other atherectomy devices that rely on tissue cutting and retrieval (directional atherectomy) or cutting and aspiration (extraction atherectomy), high-speed MRA with the Rotablator relies on abrasion and pulverization of atheroma. Although the Rotablator is usually classified as an atherectomy device, tissue displacement occurs by distal embolization rather than tissue removal. However, experimental studies suggest that microparticle dimensions are dependent on the size of the burr and the speed of rotation, and it is generally assumed that in human coronary use, the majority of microparticles are less than 5 μm in diameter. Although particles of this size should pass harmlessly into the microcirculation, distal embolization leading to myocardial infarction has been reported. The relative contribution of tissue pulverization versus the “Dotter” effect (mechanical dilation of the lesion) is unknown.

Acute Results

Although the Rotablator successfully crossed all target lesions, the absolute magnitude of lumen enlargement was disappointing. After initial MRA, the average minimal lumen diameter was only 1.4±0.7 mm, which was similar to the minimal lumen diameter of 1.51 and 1.46 mm reported independently by Teirstein and colleagues and Bertrand and colleagues, respectively. The residual diameter stenosis of 54±23% after MRA was similar to the 42% residual stenosis reported by Bertrand and colleagues. Although Teirstein and colleagues reported a residual diameter stenosis of 37% after MRA, this was due to selection of smaller vessels with a reference diameter of less than 3 mm, in contrast to the reference diameter of 3.2±0.8 mm in the present study.

Although many investigators report the success of intervention on the basis of change in percent stenosis or residual diameter stenosis, these success rates are dependent on several factors that are independent of the device per se, including the severity of the baseline stenosis and the size of the reference segment. Nevertheless, when analyzed in these terms, 50% of the treated lesions had a residual stenosis of more than 50% after MRA and only 44% of lesions improved by 20% or more after MRA.

However, considering the small burr diameter used in coronary arteries, the relative lumen enlargement after MRA was excellent. The RLD-D ratio of 0.91 indicates that the magnitude of lumen enlargement was equal to 91% of the diameter of the burr (ie, a 2-mm burr resulted in a lumen diameter of 1.82 mm). This suggests that 9% of the burr diameter was “lost” due to elastic recoil or spasm, in contrast to the 30% acute loss of diameter immediately after PTCA (RLD-D ratio, 0.7) and the 20% acute loss of diameter immediately after laser balloon angioplasty (RLD-D ratio, 0.8).

Role of PTCA After MRA

The failure to effect major increases in lumen diameter with MRA alone is also reflected in the need for PTCA to further enlarge the lumen. While the details of
lumen enlargement after PTCA were not reported by Bertrand and colleagues\textsuperscript{14} and PTCA was not used by Teirstein and colleagues.\textsuperscript{13} PTCA in the present study was used both as an adjunct to MRA to achieve better lumen enlargement (minimal lumen diameter increased to 2.3±0.7 mm and diameter stenosis decreased to 30±20\% after PTCA) and as a means for salvaging MRA-induced complications in 24 of 46 lesions (52\%). Although the final diameter stenosis after adjunctive PTCA was similar to the 30\% to 40\% residual stenosis that has been reported after PTCA alone,\textsuperscript{3, 4} the types of lesions may not be comparable. Given the complexity of the lesions treated by MRA in this study, it is possible that MRA could have facilitated the results of subsequent PTCA,\textsuperscript{16} but this remains to be demonstrated in future investigations.

Lesion Morphology After MRA
By "polishing" the arterial lumen, the hope was that MRA would result in a smoother, dissection-free lumen compared with PTCA. The incidence of dissection in this study was approximately 30\%, which is somewhat lower than the 40\% to 50\% rate reported for PTCA\textsuperscript{17-19} but somewhat higher than the 2\% to 11\% rate of dissection reported for directional atherectomy.\textsuperscript{19, 20}

Safety
Several important observations were made regarding the safety of MRA. First, severe dissection leading to abrupt closure (11.2\%), distal embolization leading to no-reflow (6.1\%), and severe coronary vasospasm (13.8\%) were more common after MRA than suggested by recent reports of PTCA for complex lesions.\textsuperscript{20, 21} In a series of 1000 lesions treated by PTCA (92\% of these lesions were type B or C), abrupt closure was observed in only 3.5\%, and the overall incidence of serious complications was less than 2\%.\textsuperscript{22} Second, the majority (42 of 49, 86\%) of the angiographic complications observed in this study were managed successfully by a combination of PTCA, vasodilators, and thrombolytic agents. Third, despite these angiographic observations, the clinical sequelae of death (1.0\%) and emergency bypass graft surgery (1.9\%) compare favorably with that of PTCA, but the combined incidence (7.1\%) of Q-wave and non-Q-wave myocardial infarctions is higher than expected for patients undergoing PTCA. The lower incidence of non-Q-wave myocardial infarction (2.9\%) in this study compared with that of Teirstein and colleagues (19\%) may have been due to the selection of longer lesions (mean lesion length, 31 mm) in that study\textsuperscript{13} compared with ours (mean lesion length, 6.6 mm). Finally, although the lesions targeted by directional atherectomy may be different than those for MRA, the incidence of serious clinical complications is similar.\textsuperscript{23}

Restenosis
The overall restenosis rate of 51\% for patients treated with MRA (with or without adjunctive PTCA) is similar to the restenosis rate after MRA of 59\% reported by Bertrand and colleagues\textsuperscript{14} but is higher than the restenosis rate of 31\% reported by Teirstein and colleagues.\textsuperscript{13} Although larger numbers of patients in randomized trials will be necessary to accurately compare restenosis rates, it does not appear that MRA alone or in combination with PTCA has a dramatic influence on restenosis. Furthermore, there was no difference in restenosis rates after MRA for de novo or restenosis lesions.

Recommendations for Rotablator Use
Unfortunately, the retrospective nonrandomized design of this study precludes definitive recommendations about using the Rotablator, but some preliminary recommendations are reasonable. In this study, MRA (with or without PTCA) did not offer clear advantages over what might be expected for PTCA of comparable lesions, in terms of either immediate or long-term angiographic results or safety. Furthermore, current Rotablator technology is significantly limited by the small diameter of available burrs, the frequent development of angiographic complications requiring adjunctive or salvage PTCA, and the higher cost of procedures that rely on use of multiple technologies. For the time being, until data from randomized trials are available, MRA should be used for focal lesions that are least likely to benefit from PTCA alone, such as rigid nondilatable or heavily calcified stenoses, ostial lesions, or bifurcation lesions.

Study Limitations
There are several important limitations of this study. First, it is an uncontrolled observational study of a relatively small subset of patients who may not be representative of all patients considered for percutaneous intervention. Although complex lesion morphology (using the ACC/AHA classification) was common, new advances in balloon technology, such as high-pressure balloons, long balloons, and angled balloons, may address some of the remaining limitations of PTCA for which MRA may have been considered.\textsuperscript{22} Second, there are no data in this study to suggest that the combination of MRA and PTCA is superior to PTCA alone. Further controlled, randomized studies are needed to determine if MRA facilitates the results of subsequent PTCA compared with PTCA alone.

Finally, this study must be considered in the context of evaluating a first-generation device. Future modifications of the design and size of the Rotablator, as well as greater operator experience, could have a significant impact on improving the acute and long-term results of MRA.

Conclusions
High-speed MRA with the Rotablator can be applied successfully to a subset of patients with complex lesion morphology. However, the development of severe dissection, no-reflow, or inadequate lumen enlargement mandates the need for adjunctive or salvage balloon angioplasty in the majority of patients to achieve optimal angiographic and clinical results. The combination of MRA and PTCA does not appear to have any impact on restenosis.

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