Meta-Analysis of Randomized Trials of Percutaneous Transluminal Coronary Angioplasty Versus Atherectomy, Cutting Balloon Atherotomy, or Laser Angioplasty

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OBJECTIVES We conducted a systematic overview (meta-analysis) of randomized trials of balloon angioplasty versus coronary atherectomy, laser angioplasty, or cutting balloon atherotomy to evaluate the effects of plaque modification during percutaneous coronary intervention.

BACKGROUND Several mechanical approaches have been developed that ablate or section atheromatous plaque during percutaneous coronary interventions to optimize acute results, minimize intimal injury, and reduce complications and restenosis.

METHODS Sixteen trials (9,222 patients) constitute the randomized controlled experience with atherectomy, laser, or atherotomy versus balloon angioplasty with or without coronary stenting. Each trial tested the hypothesis that ablative therapy would result in better clinical or angiographic results than balloon dilation alone.

RESULTS Short-term death rates (<31 days) were not improved by the use of ablative procedures (0.3% vs. 0.4%, odds ratio [OR] 0.94 [95% confidence interval 0.46 to 1.92]), but periprocedural myocardial infarctions (4.4% vs. 2.5%, OR 1.83 [95% CI 1.43 to 2.34]) and major adverse cardiac events (5.1% vs. 3.3%, OR 1.54 [95% CI 1.25 to 1.89]) were increased. Angiographic restenosis rates (6,958 patients) were not improved with the ablative devices (38.9% vs. 37.4%, OR 1.06 [95% CI 0.97 to 1.17]). No reduction in revascularization rates (25.2% vs. 24.5%, OR 1.04 [95% CI 0.94 to 1.14]) or cumulative adverse cardiac events rates up to one year after treatment were seen with ablative devices (27.8% vs. 26.1%, OR 1.09 [95% CI 0.99 to 1.20]).

CONCLUSIONS The combined experience from randomized trials suggests that ablative devices failed to achieve predefined clinical and angiographic outcomes. This meta-analysis does not support the hypothesis that routine ablation or sectioning of atheromatous tissue is beneficial during percutaneous coronary interventions. (J Am Coll Cardiol 2004;43:936–42) © 2004 by the American College of Cardiology Foundation

Although percutaneous transluminal coronary angioplasty has been a significant advance in the treatment of coronary artery disease, it has been limited by acute ischemic complications and restenosis. Simpson (1) introduced the concept that plaque excision would reduce the risk of abrupt vessel closure and restenosis after coronary angioplasty. The first clinical approach, directional coronary atherectomy (DCA), premiered in 1987, and several other mechanical approaches followed. By 1988, excimer laser coronary angioplasty (ELA) (2), percutaneous transluminal rotational atherectomy (PTRA) (3), and transluminal extraction coronary atherectomy appeared (4). The holmium laser debuted in 1990 (5) and cutting balloon angioplasty (CBA) debuted in 1991 (6).

Although each ablative device used disparate mechanisms for incising, excising, cutting, or scoring atheromatous plaque, they shared the common goal of controlled sectioning to optimize acute results, minimize intimal injury, and reduce restenosis. Preclinical studies (7) and clinical analyses (8) suggested that the neointimal healing response was directly proportional to the degree of underlying injury and that the restenosis response was uniform for any amount of gain achieved with a broad range of interventional devices. Several randomized trials of coronary angioplasty versus atherectomy, laser, or cutting balloon atherotomy have further tested these concepts, both in the presence and absence of coronary stenting (9–20). These randomized trials all used a common comparator: conventional coronary angioplasty.

Presentation of each trial evoked numerous concerns about sample size, enrollment criteria, and generalizability of results. No single study could definitively test whether tissue ablation improved clinical and angiographic outcomes after percutaneous coronary intervention. A method to integrate the available findings has been needed. This report provides a meta-analysis of all available randomized studies to establish a current milestone for ablative coronary interventions from a large sample of randomly allocated treatments.
Abbreviations and Acronyms
CBA = coronary balloon atherotomy
CI = confidence interval
DCA = directional coronary atherectomy
ELA = excimer laser coronary angioplasty
LA = (excimer or holmium) laser angioplasty
MACE = major adverse cardiac events
MI = myocardial infarction
OR = odds ratio
PTRA = percutaneous transluminal rotational atherectomy

METHODS
Randomized controlled trials of coronary ablative devices were identified through a PubMed search of reports published between 1993 and 2002. To avoid publication bias (21), we also included unpublished multicenter studies reported from 1993 to 2002 at Scientific Sessions of the American Heart Association, American College of Cardiology, and Transcatheter Therapeutics. Unpublished single-center studies were not included in this meta-analysis. Sixteen randomized trials met criteria for inclusion (Table 1).

End points. Clinical outcomes included death, myocardial infarction (MI), and revascularization at an early time point (<31 days) and at a late time point (180 to 365 days). Angiographic restenosis was studied at 90 to 360 days. Because target-lesion and target-vessel revascularization rates were not consistently reported, total revascularization rates were analyzed.

Primary source documentation. The original definitions of major adverse cardiac events (MACE) from each study were used for this analysis. Numbers of events were obtained directly or calculated from rates given in tables and text. All events were calculated from the total population of patients given for each time point in follow-up. When total numbers were not provided, values were calculated on an intent-to-treat basis (all patients initially enrolled). All angiographic restenosis events and rates were calculated from the population of patients undergoing follow-up angiography, which was smaller than that originally enrolled.

For the Amsterdam Rotterdam Randomized Trial (AMRO) (22), individual events were obtained from Table 2 from reference 9 and MACE events were obtained from a doctoral thesis (22). Long-term events were from Tables 2 and 3 from reference 9. For Atherectomy before Multi-Link Improves Luminal Gain and Clinical Outcomes (AMIGO) trial, events were calculated from rates provided (Antonio Colombo, MD, Columbus Hospital, Milan, Italy, American College of Cardiology 2002, unpublished data, June 2003). For Angioplasty/Rotational Atherectomy for Treatment of Diffuse In-Stent Restenosis Trial (ARTIST) (10), short-term MACE events were obtained from Table 4 from reference 10, after subtracting puncture site events from “any complication,” and long-term revascularization events and rates were obtained directly from text. Restenosis events were calculated from the Table entitled Meta-Analysis of Ablative Therapies for 245 eligible patients shown in Figure 2 from reference 10. For Balloon/Optimal Atherectomy Trial (BOAT) (11), short-term death, “larger” MIs, and any major complication events (death, Q-wave MI, or emergent bypass surgery) were calculated from rates in Table 3 and in the section entitled “Short-Term Complications” from reference 11.

For Cutting balloon atherectomy vs. Plain Old Balloon Angioplasty Study (CAPAS) (12), events were obtained from Table 5 from reference 12. Although creatine kinase-MB measurements were made in all patients, only Q-wave MIs were presented in the report. For Comparison of Balloon Angioplasty/Rotational Atherectomy (COBRA) trial (16), short-term events and rates were calculated from the section entitled “In-Hospital Outcome” from reference 16. Cumulative events were calculated by adding events in the section entitled “Six-Month Clinical Outcome” from reference 16. For Coronary Angioplasty Versus Binary Excisional Atherectomy Trial (CAVEAT-I) (13), short-term events were obtained from Table 2 from reference 13. Angiographic events were obtained from the section entitled “Restenosis and Clinical Outcomes at Six Months” from reference 13 for the 699 patients who had successful interventions, defined as a residual stenosis ≤50%. Long-term events were obtained in Table 4 of the follow-up publication (23).

For CAVEAT-II (14), events were obtained from Tables 6, 7, and 8 of reference 14. For Canadian Coronary Atherectomy Trial (CCAT) (15), short-term events were obtained from text and Table 2 of reference 15. Angiographic restenosis events were calculated from total restenosis rates described in the section “Angiographic Restenosis” from reference 15. For Dilatation/Ablation Revascularization Trial (DART) (17), short-term and long-term events and rates were obtained from Table IV of reference 17. The binary restenosis events and rates were calculated from Table V of reference 17 for 219 patients with angiographic follow-up.

For Excimer Rotablator Balloon Angioplasty Comparison (ERBAC) trial (18), short-term and long-term events were obtained from Tables 2 and 3 of reference 18. For Global Randomized Trial (GRT) (19), events were obtained from Tables 3 and 4 of reference 19. Revascularization events and rates and angiographic restenosis events and rates were obtained from Table 4 of reference 19 (Cutting Balloon Monorail Instructions for Use) (Boston Scientific Interventional Technologies; unpublished data, 2002). For Laser Angioplasty/Coronary Angioplasty (LAVA) trial (20), events were obtained from Table 7 and data from Figure 1 of reference 20. For Restenosis Reduction by Cutting Balloon Evaluation 1 (REDUCE 1) trial, events were calculated from slides 13, 17, and 24 (Tetsu Yamaguchi, MD, Toranomon Hospital, Japan, Transcatheter Therapeutics 2001, unpublished data, June 2003). For RESCUT, events were obtained from slides 21, 23, 25, and 26 (Remo Albiero, MD, Clinica San Rocca di Franciacorta,
For Stenting Post Rotational Atherectomy Trial (SPORT), events were obtained from slides 12 and 13 for 735 patients (Theodore M. Bass, MD, Shands Jacksonville Hospital, Jacksonville, Florida, unpublished data, February 2003).

### Statistical Analysis

Data tables were constructed in duplicate from primary sources. Odds ratios (OR) summarizing the effectiveness of ablative procedures against control treatments (coronary angioplasty) were calculated from individual studies using the method of Woolf (24). Pooled ORs were calculated to estimate the overall effect of ablative therapies versus that of coronary angioplasty using an empirical Bayes model. The empirical Bayes model is a random-effects model that coincides with a fixed-effects model when all studies are homogeneous. In the presence of between-study heterogeneity, the random-effects model yields wider confidence intervals (CIs).

The extent of heterogeneity among the 16 trials in this meta-analysis was tested with two methods. The modified Cochran Q-statistic of DerSimonian and Laird (25) ranged from a low value of 29.66 for long-term MI to a high value of 938 Bittl et al. JACC Vol. 43, No. 6, 2004 938–42

### Table 1. Alphabetical List of Randomized Trials of Atherectomy, Atherotomy, or Laser Angioplasty Versus Percutaneous Transluminal Coronary Angioplasty

<table>
<thead>
<tr>
<th>Eponym</th>
<th>Definition</th>
<th>Primary End Point*</th>
<th>Patients (n)</th>
<th>Year†</th>
<th>Indications</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMIGO‡</td>
<td>Atherectomy before Multi-Link Improves Luminal Gain and Clinical Outcomes</td>
<td>Binary restenosis</td>
<td>753</td>
<td>2002</td>
<td>Stenting in native vessels</td>
<td>DCA/PTCA</td>
</tr>
<tr>
<td>AMRO (9)</td>
<td>Amsterdam Rotterdam Randomised Trial</td>
<td>6-month MACE</td>
<td>308</td>
<td>1993</td>
<td>Native vessel</td>
<td>ELA/PTCA</td>
</tr>
<tr>
<td>ARTIST (10)</td>
<td>Angioplasty/Rotational Atherectomy for Treatment of Diffuse In-Stent Restenosis Trial</td>
<td>6-month MACE</td>
<td>298</td>
<td>2002</td>
<td>In-stent</td>
<td>PTRA/PTCA</td>
</tr>
<tr>
<td>BOAT (11)</td>
<td>Balloon/Optimal Atherectomy Trial</td>
<td>Binary restenosis</td>
<td>989</td>
<td>1995</td>
<td>Native vessel</td>
<td>DCA/PTCA</td>
</tr>
<tr>
<td>CAPAS (12)</td>
<td>Cutting Balloon Atherotomy vs. Plain Old Balloon Angioplasty Study</td>
<td>Binary restenosis</td>
<td>232</td>
<td>1997</td>
<td>Native vessel</td>
<td>CBA/PTCA</td>
</tr>
<tr>
<td>CAVEAT-I (13)</td>
<td>Coronary Angioplasty Versus Excisional Atherectomy Trial</td>
<td>Binary restenosis</td>
<td>1,012</td>
<td>1992</td>
<td>Native vessel</td>
<td>DCA/PTCA</td>
</tr>
<tr>
<td>CAVEAT-II (14)</td>
<td>Coronary Angioplasty Versus Excisional Atherectomy Trial II</td>
<td>Binary restenosis</td>
<td>305</td>
<td>1993</td>
<td>SVG</td>
<td>DCA/PTCA</td>
</tr>
<tr>
<td>CCAT (15)</td>
<td>Canadian Coronary Atherectomy Trial</td>
<td>Binary restenosis</td>
<td>274</td>
<td>1992</td>
<td>LAD</td>
<td>DCA/PTCA</td>
</tr>
<tr>
<td>COBRA (16)</td>
<td>Comparison of Balloon Angioplasty/Rotational Atherectomy</td>
<td>Binary restenosis</td>
<td>502</td>
<td>1996</td>
<td>Native vessel</td>
<td>PTRA/PTCA</td>
</tr>
<tr>
<td>DART (17)</td>
<td>Dilatation/Ablation Revascularization Trial</td>
<td>Binary restenosis</td>
<td>446</td>
<td>1998</td>
<td>Small vessel</td>
<td>PTRA/PTCA</td>
</tr>
<tr>
<td>ERBAC (18)</td>
<td>Excimer Rotablator Balloon Angioplasty Comparison</td>
<td>Procedural success</td>
<td>454†</td>
<td>1996</td>
<td>Native vessel</td>
<td>ELA/PTCA</td>
</tr>
<tr>
<td>ERBAC (18)</td>
<td>Excimer Rotablator Balloon Angioplasty Comparison</td>
<td>Procedural success</td>
<td>453†</td>
<td>1996</td>
<td>Native vessel</td>
<td>PTRA/PTCA</td>
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<td>GRT (19)</td>
<td>Global Randomized Trial</td>
<td>Binary restenosis</td>
<td>1,238</td>
<td>1997</td>
<td>Native vessel</td>
<td>CBA/PTCA</td>
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<tr>
<td>LAVA (20)</td>
<td>Laser Angioplasty/Coronary Angioplasty</td>
<td>6-month MACE</td>
<td>215</td>
<td>1997</td>
<td>Native vessel</td>
<td>HLA/PTCA</td>
</tr>
<tr>
<td>REDUCE 1‡</td>
<td>Restenosis Reduction by Cutting Balloon Evaluation 1</td>
<td>Binary restenosis</td>
<td>802</td>
<td>2001</td>
<td>Native vessel</td>
<td>CBA/PTCA</td>
</tr>
<tr>
<td>RESCUT‡</td>
<td>Restenosis Cutting Balloon Evaluation</td>
<td>Binary restenosis</td>
<td>428</td>
<td>2002</td>
<td>In-stent</td>
<td>CBA/PTCA</td>
</tr>
<tr>
<td>SPORT‡</td>
<td>Stenting Post Rotational Atherectomy Trial</td>
<td>30-day MACE</td>
<td>735</td>
<td>1999</td>
<td>Stenting in calcified vessels</td>
<td>DCA/PTCA</td>
</tr>
<tr>
<td>Pooled</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9,222§</td>
</tr>
</tbody>
</table>

*If the primary end point was not explicitly stated or if multiple primary end points were listed, the endpoint used in power calculations for sample size estimation was used. †Year patient recruitment was completed. Otherwise, the year study was reported or published. ‡Unpublished. §All calculations of total populations and events account for duplicate control groups of 222 PTCA patients in the ERBAC trial.

CBA = cutting balloon atherectomy; DCA = directional coronary atherectomy; ELCA = excimer laser coronary angioplasty; HLA = holmium laser angioplasty; LAD = proximal segment of the left anterior descending artery; MACE = major adverse cardiac event (death, myocardial infarction, or revascularization); PTRA = percutaneous transluminal rotational atherectomy; SVG = saphenous vein graft.
of 51.52 for angiographic restenosis, yielding nonsignificant p values for heterogeneity testing (0.75). An additional check for heterogeneity involved the Peto-modified Mantel-Haenszel method (26), which generated ORs that were indistinguishable from the fixed-effects model. Thus, ORs from the fixed-effects model were used throughout the report, but ORs from the random-effects model and for each ablation type were also presented for comparison.

Significance was determined by the width of the 95% CIs. The constancy of procedural success rates reported for the coronary angioplasty control groups for the studies covered in this meta-analysis did not vary significantly with time (p = 0.30).

### RESULTS

Sixteen trials involving 9,222 patients constituted the randomized controlled experience with atherectomy, laser, or cutting balloon atherectomy versus balloon angioplasty.

Short-term death rates <31 days after treatment (Fig. 1) were not improved by the use of ablative procedures (0.3% vs. 0.4%, odds ratio [OR] 0.94 [95% CI 0.46 to 1.92]). Periprocedural MI rates up to 30 days were 83% higher (4.4% vs. 2.5%, OR 1.83 [95% CI 1.43 to 2.34]). A random-effects model yielded indistinguishable ORs and CIs. De novo lesions also had increased risks after ablative therapy than after coronary angioplasty (4.6% vs. 2.7%, OR 1.72 [95% CI 1.34 to 2.21]). Each type of ablative therapy showed an increase in MIs over that seen for coronary angioplasty: CBA (OR 1.66 [95% CI 0.91 to 3.02]), DCA (OR 1.85 [95% CI 1.35 to 2.55]), LA (OR 1.39 [95% CI 0.69 to 2.82]), and PTRA (OR 2.18 [95% CI 1.06 to 4.50]).

The rates of MACE up to 30 days (Fig. 3) were also higher after the use of ablative therapies than after conventional coronary angioplasty (5.1% vs. 3.4%, OR 1.54 [95% CI 1.25 to 1.89]). The random-effects model generated indistinguishable ORs and CIs. De novo lesions also had increased risks after ablative therapy than after coronary angioplasty (4.6% vs. 2.7%, OR 1.72 [95% CI 1.34 to 2.21]). Each type of ablative therapy showed an increase in MIs over that seen for coronary angioplasty: CBA (OR 1.66 [95% CI 0.91 to 3.02]), DCA (OR 1.85 [95% CI 1.35 to 2.55]), LA (OR 1.39 [95% CI 0.69 to 2.82]), and PTRA (OR 2.18 [95% CI 1.06 to 4.50]).

The rates of MACE up to 30 days (Fig. 3) were also higher after the use of ablative therapies than after conventional coronary angioplasty (5.1% vs. 3.4%, OR 1.54 [95% CI 1.25 to 1.89]). The random-effects model generated indistinguishable ORs and CIs. Rates of MACE for de novo lesions were also increased after treatment with ablative therapies (5.3% vs. 3.4%, OR 1.58 [95% CI 1.27 to 1.96]).

Ten studies identified angiographic restenosis as the primary end point. Angiographic follow-up was achieved in 6,958 of 9,222 patients (75%). The rate of angiographic restenosis (Fig. 4) was 38.9% in the ablative group versus 37.4% in the coronary angioplasty group (OR 1.06 [95% CI 0.97 to 1.17]). Group statistics showed a trend toward reduced restenosis for DCA, neutral effects for CBA, and a
significant increase in restenosis for both LA and PTRA: DCA (OR 0.90 [95% CI 0.77 to 1.05]), CBA (OR 1.01 [95% CI 0.85 to 1.21]), LA (OR 1.55 [95% CI 1.09 to 2.20]), and PTRA (OR 1.25 [95% CI 1.02 to 1.54]). The failure of ablative therapies to reduce angiographic restenosis may have been influenced by confounding factors. Patients assigned to ablative therapy were less likely than those treated with coronary angioplasty to receive bailout stents (6.9% vs. 11.8%; OR 0.55 [95% CI 0.47 to 0.65]). The use of bailout stents increased over time and ranged from 0% in the ablative trials carried out before 1995 to 0.9% in the 1996 ERBAC (18) and up to a maximal use of 42% in 2001 in REDUCE 1 (Tetsu Yamaguchi, MD, Toranomon Hospital, Japan, Transcatheter Therapeutics 2001, unpublished data, June 2003). However, studies carried out before 1995 versus those carried out after the introduction of bailout stenting showed no difference in restenosis rates.

No reduction in overall revascularization rates was seen after the use of ablative therapies (Fig. 5). The rate of revascularization (target-lesion, target-vessel, percutaneous coronary intervention, or bypass surgery) was 25.2% in the ablative group versus 24.5% in the coronary angioplasty group (OR 1.04 [95% CI 0.94 to 1.14]). For the 15 studies reporting long-term event rates, cumulative MI rates remained significantly higher in the ablative group than in the coronary angioplasty group (OR 1.32 [95% CI 1.01 to 1.73]), and PTRA (OR 1.52 [95% CI 1.24 to 1.87]).

DISCUSSION

This meta-analysis evaluated all published and unpublished multicenter randomized trials reported over a 10-year period.
to define the clinical and angiographic advantages of ablative techniques. The pooled results of 16 studies, which are generalizable across several centers and directly compared with the benchmark therapy of coronary angioplasty, suggest that ablative techniques have not been able to achieve prospectively defined end points in the presence or absence of coronary stents.

The ablative procedures evaluated in this meta-analysis remain in common use, as reflected by rates of use in contemporary databases, frequent publication of reports in the current literature, and oral presentations at contemporary meetings. Ablative procedures were used in 1,533 of 14,498 patients (10.6%) in the Northern New England database (27) reported in 1999 and, in particular, the use of PTRA increased from 3.6% in the early era (1994 to 1995) to 8.7% in the most recent era (1998 to 1999) reported in 2002 (28). The cutting balloon is one of the most common types of balloon catheter used in the U.S. (Boston Scientific Corp., Natick, Massachusetts).

It has been difficult to reconcile the favorable results of registry experiences with negative results of randomized trials, but several explanations have appeared. In CAVEAT-I (13), concern was raised about inadequate tissue extraction. In BOAT (11), more aggressive debulking was associated with reduced rates of angiographic restenosis, but this was not associated with reduced target-vessel revascularization or improved clinical outcome. A different approach using PTRA for in-stent restenosis was taken in ARTIST (10). Although a promising restenosis rate of <30% was seen in a pilot study when PTRA was followed by low-pressure balloon inflation (29), serial intravascular ultrasound measurements in ARTIST suggested that PTRA ablated only minimal neointimal tissue from within stents and that post-PTRA low-pressure balloon inflation achieved less stent expansion that high-pressure balloon inflation alone without PTRA (30). When a more aggressive PTRA strategy was compared with conventional PTRA in Study to Determine Rotablator and Transluminal Angioplasty Strategy (STRATAS), restenosis rates were paradoxically increased (58% vs. 52%) (31).

Although multicenter randomized trials remain the best mechanism to control for confounding factors during the evaluation of new therapies, they may not be the optimal venue for studying relatively complex ablative techniques that are dependent on operator expertise and selection of appropriate lesions for ablation, such as bifurcation lesions, ostial stenoses, certain calcified stenoses, or undilatable lesions (32,33). The techniques used in various centers in randomized trials may not have uniformly achieved desired degrees of debulking. In the AMIGO trial, for example, protocol-prescribed aggressive debulking was achieved in only 26.5% of lesions in the overall study population. At two centers in the AMIGO Trial where more optimal atherectomy was performed, binary restenosis rates were significantly reduced from 32% to 14% (Antonio Colombo, MD, Columbus Hospital, Milan, Italy, American College of Cardiology 2002, unpublished data, June 2003). Other technical factors may also lead to the selection of ablative devices. For example, cutting balloons are much less likely to slip inside narrowed stents than are bare balloons, defining an immediate practical advantage.

This meta-analysis raises the larger biologic issue of whether the broad application of ablation techniques is the optimal means of treating coronary atherosclerosis, because these techniques may be more injurious than initially thought. For example, laser angioplasty was originally proposed to ablate atheromatous plaque by the vascular-sparing process of photochemical dissociation, but this was disproved when excimer and holmium laser angioplasty were both shown to cause similar and striking barotraumatic injury with virtually no plaque removal in experimental studies (34). Likewise, rotational atherectomy was observed to injure vascular tissue from excessive heat generation (35) and platelet aggregation (36). Aggressive DCA performed in BOAT (11) produced a larger relative increase in the rate of periprocedural MIs than that seen in CAVEAT-I (13). Directional atherectomy doubled the rates of embolization in saphenous vein grafts as compared with coronary angioplasty in CAVEAT-II (13.4% vs. 5.1%) (14). Cutting balloon atherotomy caused higher rates of vessel perforation than coronary angioplasty in GRT (0.8% vs. 0.0%), as did PTRA in ARTIST (1.3% vs. 0.0%) (10).

This meta-analysis was limited by the protocols used to measure postprocedural events. Because most trials did not systematically measure postprocedural creatine kinase MB values, the rates of MI have been underreported and the differences in periprocedural MI rates have been underestimated. Unequal use of bailout stenting in more recent studies may have biased the angiographic restenosis rates in favor of coronary angioplasty, but earlier studies before the introduction of bailout stenting showed no advantage of ablative therapy over coronary angioplasty. The inclusion of CBA in this meta-analysis has been justified on the grounds that CBA, like the ablative devices, was developed to reduce intimal injury during coronary angioplasty (6,12,37), and almost every report has discussed CBA as an alternative to coronary angioplasty, DCA, PTRA, or laser angioplasty.

In conclusion, mechanical approaches involving plaque ablation or sectioning have not been associated with improved clinical outcomes or lower restenosis in randomized trials. This meta-analysis does not condemn a technology that has 20 years of scientific development and promise for specific indications. Instead, it simply provides a milestone for where we currently stand. New innovations in tissue ablation should be identified before any new large clinical trials are launched. The solution to the problem of restenosis in native coronary arteries will likely come not from mechanical removal of atheromatous plaque, but from vascular brachytherapy or molecular interventions such as drug-eluting stents that alter vascular biology (38,39).
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