Interventional Rounds

Current Status of Rotational Atherectomy

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Despite the increasing use of percutaneous transluminal coronary angioplasty and intracoronary stent placement for the treatment of obstructive coronary artery disease, a large subset of coronary lesions cannot be adequately treated with balloon angioplasty and/or intracoronary stenting alone. Such lesions are often heavily calcified or fibrotic and undilatable with the present balloon technology and attempts to treat them with balloon angioplasty or intracoronary stent placement often lead to vessel dissection or incomplete stent deployment with resultant adverse outcomes. Rotational atherectomy remains a useful niche device for the percutaneous treatment of such complex lesions, usually as an adjunct to subsequent balloon angioplasty and/or intracoronary stent placement. In contrast to balloon angioplasty or stent placement that widen the coronary lumen by displacing atherosclerotic plaque, rotational atherectomy removes plaque by ablating the atherosclerotic material, which is dispersed into the distal coronary circulation. Other lesion subtypes amenable to treatment with this modality include ostial and branch-ostial lesions, chronic total occlusions, and in-stent restenosis. This review discusses the technique and principles of rotational atherectomy, the various treatment strategies for its use (including adjunctive pharmacotherapy), the lesion-specific applications for this device, and the complications unique to this modality. Recommendations are also made for its use in the current interventional era. *Catheter Cardiovasc Interv 2004;62:485–498.* © 2004 Wiley-Liss, Inc.

Key words: rotational atherectomy; calcification; complex lesions

INTRODUCTION

Since its introduction in 1977, percutaneous transluminal coronary angioplasty (PTCA) has become a widely accepted form of treatment for obstructive coronary disease [1]. While the procedure was initially reserved for the treatment of discrete noncalcified proximal lesions, increased operator experience and improved technology expanded its application to more complex lesions. In addition, the introduction of stents has improved the procedural success and the high restenosis rate seen with balloon angioplasty [2]. A major limitation of balloon angioplasty (and for that matter intracoronary stent placement) remains the inability to dilate certain types of lesions. This is particularly the case with heavily calcified lesions, where even high-pressure inflations may fail to dilate fully a very rigid lesion. This could lead to vessel dissection or, in the case of attempted stent placement, incomplete deployment of the stent, with the attendant risks of stent thrombosis and restenosis. Atherectomy devices were developed to remove the obstructive atherosclerotic plaque physically. Unlike balloon angio-

plasty or stent placement, which widens the coronary lumen by merely displacing atherosclerotic plaque, atherectomy techniques widen the lumen by actually removing tissue from the vessel wall. Several atherectomy devices have been developed, including directional, transluminal excisional, rotational, and laser atherectomy. High-speed rotational atherectomy (RA) removes plaque by ablating the atherosclerotic material, produc-

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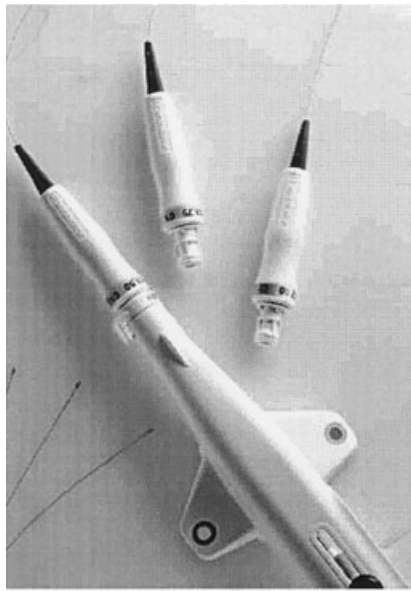[2]Department of Medicine, Division of Cardiology, State University of New York Health Science Center at Brooklyn, Brooklyn, New York

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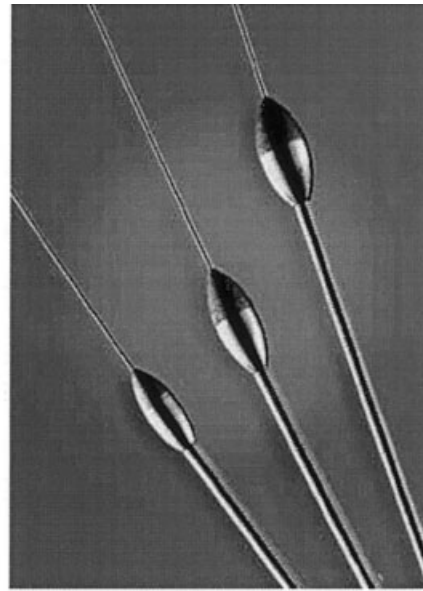E-mail: samin.sharma@msnyuhealth.org

Rotalink™ Advancer

Diamond-coated burrs

Rotablator console

Fig. 1.   The components of the Rotablator (Scimed, Boston Scientific Corporation, Boston, MA) system.

ing small particles (5–10 μm) that are dispersed into the distal coronary circulation. David Auth first investigated the possibility of using a rotational device to debulk atherosclerotic plaque in the early 1980s [3]. Subsequently, after several experimental studies in animals, Fourier et al. [4] performed the first case of RA in human coronary arteries in 1988.

In this review, we discuss the RA technique with the Rotablator (Scimed, Boston Scientific, Boston, MA) device (Fig. 1), the mechanisms and principles of rotary ablation, the various treatment strategies using this de-

vice, the impact of lesion characteristics on results, and the complications of this treatment modality. We conclude by making recommendations for the use of this device in the current era.

MECHANISMS OF ROTABLATION

High-speed mechanical RA relies on plaque ablation and pulverization by the abrasive diamond-coated burr. The Rotablator is able to ablate inelastic tissue selectively (i.e., plaque) while maintaining the integrity of
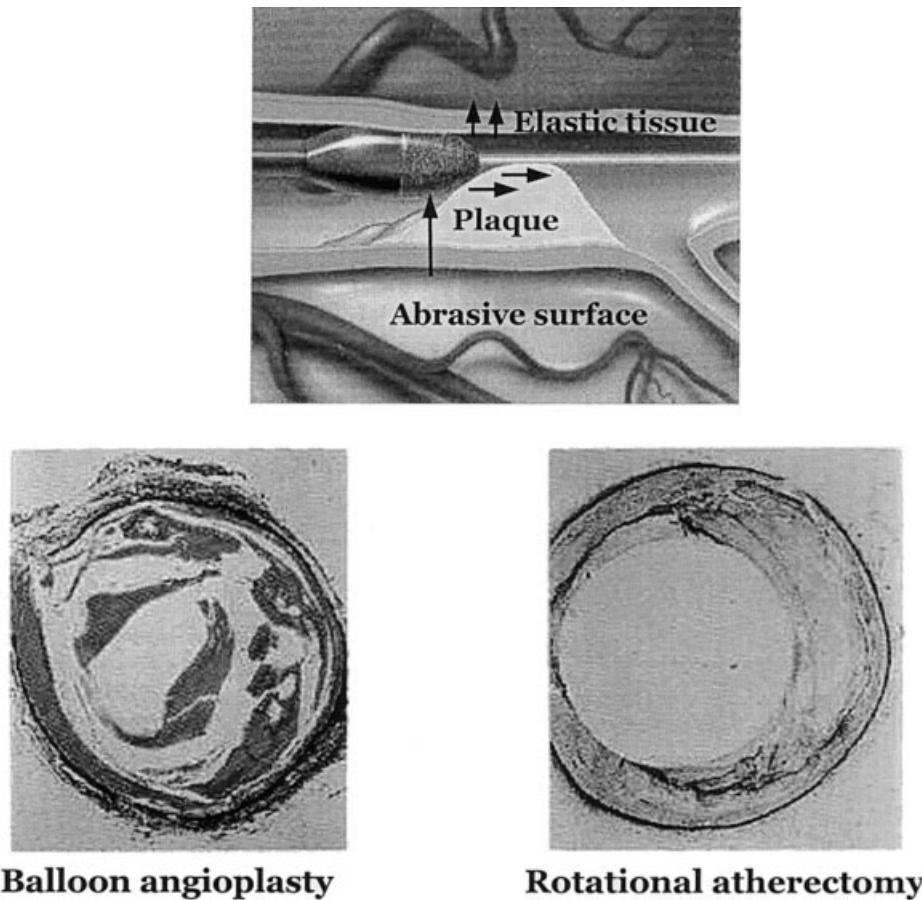
Fig. 2. Differential cutting by rotational atherectomy resulting in a smooth, concentric lumen in comparison with multiple intimal dissections after balloon angioplasty [5].

elastic tissue (i.e., the normal vessel wall) due to the principle of differential cutting. Differential cutting is defined as the ability to ablate one material selectively while sparing and maintaining the integrity of another, based on differences in substrate composition, resulting in a polished smooth lumen (Fig. 2) [5] compared to multiple intimal tears/dissections with balloon angioplasty. The other physical principle, which governs the effectiveness of RA, is that of orthogonal displacement of friction. At rotational speeds $> 60,000$ rpm, the friction, which occurs when sliding surfaces are in contact, is virtually eliminated. As a result, there is reduced surface drag and unimpeded advancement and withdrawal of the burr, allowing the rotating burr to pass through tortuous and diseased segments of the coronary tree. The abraded plaque is pulverized into microparticles, which are 5–10 μm in diameter. These particles are small enough to pass through the coronary microcirculation and ultimately undergo phagocytosis in the liver, spleen, and lung [3]. However, these particles may have a detrimental effect on the myocardial microcirculation that can be prevented by glycoprotein (GP) IIb/IIIa inhibitors, suggesting a role for the interaction of the atherosclerotic plaque with platelets resulting in reduction in distal microperfusion [6]. Rotablator is most effective in hard inelastic lesions, while it will not be effective in soft and thrombus-containing lesions as present in acute myocardial infarction or saphenous vein graft lesions, where its use is contraindicated.

ADJUNCTIVE THERAPIES

Patients undergoing RA are treated in a similar pharmacological manner to patients undergoing balloon angioplasty. However, there are several important differences, which relate to the prevention of complications that are unique to the use of this technology. As with all coronary interventions, aspirin in a dose of 325 mg/day is administered to the patient prior to the procedure. Heparin is administered to maintain the activated clotting time > 300 sec or ~ 250 sec if a GP IIb/IIIa inhibitor is used. Because the GP IIb/IIIa inhibitors have been asso-

ciated with a 50% reduction in cardiac enzymes elevation during the procedure, as well as a reduction in burr-induced platelet aggregation [6,7], they are often used routinely in many interventional laboratories. This beneficial effect of the GP IIb/IIIa inhibitors underscores the importance of the activation of platelets and their interaction with atheromatous debris in causing slow flow and other adverse procedural events during RA. Abciximab is the most commonly used GP IIb/IIIa inhibitor and was shown to reduce both procedural morbidity and creatine kinase-MB (CK-MB) elevation by approximately 50% in a small randomized trial of 100 patients [8]. However, caution is advised in the upfront use of the GP IIb/IIIa inhibitors in angulated, heavily calcified lesions undergoing RA, where the risk of coronary perforation is increased. In such cases, the GP IIb/IIIa inhibitor should be administered after the completion of RA. One of the potentially disastrous complications of RA is the development of coronary slow flow/no-reflow [9]. Coronary slow flow/no-reflow is defined as a decrease or cessation of blood flow in the absence of an apparent occlusive dissection or spasm and is believed to occur as a result of distal microparticle embolization. Contrary to epicardial vessel spasm, it is usually treated with vasodilators, such as calcium channel blockers (verapamil, diltiazem, or nicardipine), adenosine or nitroprusside, which have their effect at the microcirculation. Many catheterization laboratories routinely use a cocktail of nitroglycerin, verapamil, and heparin in the flush solution that has been shown to reduce the incidence of spasm and slow flow [10,11]. Another unique but rare complication of RA is the development of severe coronary spasm. Intracoronary nitroglycerin or other vasodilator such as verapamil should be readily available in the event of this complication. Finally, Rotaglide lubricant (consisting of a lubricious lipid emulsion) used to reduce friction between the drive coil and guidewire is added to the flush bag with resultant decreased heat production. Whether this flush solution, by virtue of its ability to decrease friction and heat production, can favorably affect the short- and long-term outcome remains to be proven in a well-controlled clinical trial.

EVOLUTION OF TECHNIQUE OF ROTATIONAL ATHERECTOMY

Since its introduction into clinical practice over 10 years ago, there have been numerous developments in the technique of RA and changes in the strategies for its use [11]. These changes include improvements in operator technique, advances in the understanding of the mechanisms of RA, and clinical studies, which have specifically addressed and compared the various technical approaches. Improvements in technique have included the use of verapamil/nitroglycerin flush solution, the upfront use of the GP IIb/IIIa inhibitors, slow burr advancement, to-and-fro pecking motion of the burr, shorter burr run times (15–20 sec), lower burr speeds (140,000–150,000 rpm), and strict avoidance of significant drops in rpm. These improvements and adjunctive therapies have resulted in significant reductions in the incidence of no-reflow, coronary artery spasm, and CK-MB release.

Using an in vitro model, Reisman et al. [12] demonstrated a relationship between the degree of platelet aggregation and burr speeds. Based on these in vitro experiments, the optimal burr speed associated with the lowest platelet aggregation was 140,000 rpm. Similarly, using two different experimental models, Reisman et al. [13] demonstrated that excessive drops in speed and aggressive advancement of the burr were related to significant increases in temperature and potential thermal injury. Indeed, clinical studies have corroborated these experimental findings. In the randomized Study to Determine Rotablator and Transluminal Angioplasty Strategy (STRATAS) trial, decelerations $> 5,000$ rpm from baseline for a cumulative time > 5 sec were associated with both an increase in CK-MB elevation and restenosis [14].

In addition to the advances in technique, there has been a resolution of the long-standing controversy regarding the use of an aggressive vs. a conservative approach for RA. This controversy had centered on the optimal sizing of burrs and the ideal balloon inflation pressures of adjunctive balloon angioplasty. The proponents of the aggressive approach recommended an aggressive burr-to-artery ratio to ablate plaque optimally followed by low balloon inflation pressures to avoid deep tissue injury, which may translate into lower restenosis. In contrast, the conservative lesion modification approach recommended undersizing the burr with the goal of altering the compliance of the lesion and facilitating subsequent adjunctive balloon angioplasty (to pressure as needed to obtain a satisfactory angiographic result). Two randomized trials have specifically addressed this issue.

The first study was the STRATAS trial, which randomized 500 patients to either an aggressive rotablation strategy (burr/artery ratio > 0.7 followed by no angioplasty, or angioplasty < 1 atm) or to routine RA (maximum burr/artery ratio < 0.7, followed by routine balloon angioplasty > 4 atm) [14]. Although clinical success was high ($> 90\%$) and similar for the two approaches, there was a trend toward a higher incidence of CK-MB elevation > 5 times normal in patients treated with aggressive strategy (11% vs. 7%; $P = 0.12$). Furthermore, both target lesion revascularization (TLR; 23.5% vs. 21.1%) and angiographic restenosis (58% vs. 52%) at 6–9 months were insignificantly higher in the aggressive strategy group. Thus, in this study, the aggres-

TABLE I. Rota Stenting*

Studies	Year published	Study design	Lesion morphology	Number of lesions (L) and patients (P)	Procedural success	Restenosis
Moussa et al. [17]	1997	Retrospective analysis of consecutive patients treated with RA prior to stenting	Complex, calcified	106 (L), 75 (P)	93.4%	22.5% at the rate 4.6 ± 1.9 months (82.5% angiographic follow-up)
Hoffmann et al. [18]	1998	Retrospective matching analysis of three different treatment modalities:	Large, calcified	306 (L), 306 (P)		Restenosis rates not reported; event-free survival at the rate 9 months:
		RA + PTCA vs.		147	98.6%	67%
		ICS alone vs.		103	98.0%	77%
		RA + ICS		56	98.2%	85%; $P = 0.063$
Kobayashi et al. [19]	1999	Nonrandomized and retrospective analysis of a series of consecutive patients treated with two different strategies:	Complex, calcified	162 (L), 126 (P)		
		aggressive debulking vs.		56 (L)	98%	31%
		routine debulking		106 (L)	100%	50%; $P < 0.05$
EDRES [20]	1998	Prospective randomized trial of:	Complex, calcified	150 (P)	Not reported	Binary angiographic restenosis at the rate 6 months:
		rota + stent (RS) vs.		75 (P)		27%
		stent (S)		75 (P)		34%; $P = 0.05$
SPORT [21]	2000	Multicenter prospective randomized trial of:	Complex, calcified	735 (P)		
		PTCA + ICS vs.		375 (P)	88%	27.6%
		RA + ICS		360 (P)	93.6%; $P = 0.01$	30.4%; $P = NS$

*ICS, intracoronary stenting.

sive RA strategy was associated with a trend toward worse short- and long-term outcomes compared to routine strategy.

Another study, the Coronary Angioplasty and Rotablator Atherectomy Trial (CARAT), designed to compare a routine lesion modification strategy employing small burrs (burr/artery ratio < 0.7) with a more aggressive debulking strategy (burr/artery ratio > 0.7), prospectively enrolled 222 patients randomly assigned to large or small burrs [15]. There were no differences in procedural success, the extent of immediate lumen enlargement, in-hospital ischemic complications, or late target vessel revascularization (TVR). However, compared with small burrs, patients randomized to large burrs were more likely to experience serious angiographic complications (5.1% vs. 12.7%; $P < 0.05$) after RA. This study suggested that a routine lesion modification strategy employing small burrs achieves similar immediate lumen enlargement and late TVR compared with a more aggressive debulking strategy, but with fewer angiographic complications.

Based on the results of the STRATAS and CARAT trials, most operators today use a lesion modification

approach to improve the compliance of the vessel and prepare it for full balloon or stent expansion, generally applying a burr/artery ratio of 0.6. There is now general agreement that outcomes with the use of RA follow a bell-shaped curve with regards to burr size, with optimal results occurring at a burr-to-artery ratio of 0.6–0.7. Based on the principle of moderate debulking, the majority of cases can be performed using a 1.5 or 1.75 mm single rota burr.

ROTA STENTING

Although stenting has been associated with lower restenosis rates compared to balloon angioplasty, stenting of calcified lesions has not been extensively applied because of concerns about the inability to expand the stent fully due to lesion calcification and rigidity [16]. In such instances, the combination of RA followed by stenting (rota stenting) has been particularly useful. Because RA changes lesion compliance, better stent expansion may be obtained when stents are implanted in calcified lesions following RA. Several nonrandomized studies (Table I) have demonstrated improved procedural suc-

TABLE II. Complex Lesion Morphology

Studies	Year	Study design	Number of lesions (L) and patients (P)	Adjunctive therapy	Procedural success	Results/conclusions
COBRA [22]	2001	Prospective randomized trial comparing PTCA vs. RA	250 (P) 252 (P)	PTCA RA	76% 80%	6-month angiographic restenosis rate similar 37% (RA) vs. 35% (PTCA), P = NS
Kiesz et al. [23]	1999	Prospective nonrandomized noncomparative study of modified ablation technique	146 (L) 111 (P)	PTCA	98.1%	4.5% non-Q-wave MI; 18.8% TLR; 28.1% binary angiographic restenosis at 6 months
Levin et al. [24]	1998	Retrospective analysis	240 (L), 178(P)	PTCA	94%	6% acute complication rate; 14% TVR at 1 year
ERBAC [25]	1997	Randomized and prospective comparison of three different strategies for complex lesions:	685 (P)			Procedural success rate was greatest for RA; incidence of angiographic restenosis was high in all three groups:
		PTCA	222 (P)	—	79.7%	47%
		excimer laser	232 (P)	PTCA (93%)	77.2%	59%
		RA	231 (P)	PTCA (93%)	89.2%; P < 0.05	57%; P = NS
Moussa et al. [17]	1997	Retrospective analysis of consecutive patients treated with RA prior to stenting	106 (L) 75 (P)	Stent	93.4%	18% TLR at 6.4 $\pm$ 3 months; 22.5% restenosis rate at 4.6 $\pm$ 1.9 months (82.5% angiographic follow-up)

cess rates and a trend toward lower restenosis in calcified lesions with the use of RA prior to stenting vs. stenting alone [17–21].

There have been two randomized studies to date that examined the effect of debulking with RA prior to stenting vs. stenting alone, which reported somewhat conflicting results. In the Effects of Debulking on Restenosis (EDRES) trial, 150 patients were randomized to stenting alone vs. RA with stenting. Rota stenting did not improve final stent diameter, but did reduce binary angiographic restenosis at 6 months [20]. In the larger multicenter Stenting Post Rotational Atherectomy Trial (SPORT) study, 750 patients were randomized to receive either balloon dilatation or rotational ablation prior to stent implantation [21]. The mean burr-to-artery ratio was 0.7 $\pm$ 0.1 in the RA group. While procedural and clinical success were higher in the rota stenting group, there were no differences in the rates of in-hospital major adverse cardiac events. Despite a greater posttreatment minimum lumen diameter in the rota stenting group, there was no difference in the incidence of angiographic restenosis or TLR between the two groups at 6-month follow-up. It has been suggested that the ineffectiveness of de-

bulking prior to stenting in the SPORT trial may be explained by operator bias in not including heavily calcified lesions and protocol mandated full lesion coverage by the stent.

LESION-SPECIFIC INDICATIONS
Complex Lesions

Complex coronary artery lesions (ACC/AHA type B2 and C) usually have higher plaque burden and are more difficult to treat than simple lesions, especially with balloon angioplasty. Therefore, RA has been used in these lesion subsets in nonrandomized and randomized studies (Table II) with high procedural success rates (80–98%) [17,22–25]. Despite comparable or even better procedural success with the use of RA in this setting, the randomized Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) [25] and Comparison of Balloon vs. Rotational Angioplasty (COBRA) [22] trials were not able to demonstrate a superiority of RA over balloon angioplasty in terms of either angiographic or clinical restenosis.

TABLE III. Calcified Lesions

Studies	Year	Study design	Number of patients (P) and lesions (L)	Adjunctive treatment	Procedural success	Results/conclusions
Singh et al. [27]	2001	Retrospective nonrandomized matched comparison	447 (P) 2,065 (P)	PTCA ± stent (with RA) PTCA ± stent (no RA)	Not reported	RA associated with improved angiographic success; no difference in in-hospital MACE; greater TLR with RA at mean 2.7 years
Kiesz et al. [23]	1999	Prospective nonrandomized noncomparative study of modified ablation technique	111 (P), 146 (L)	PTCA	98.1%	4.5% non-Q-wave myocardial infarction; 18.8% TLR; 28.1% binary angiographic restenosis at 6 months
Hoffmann et al. [18]	1998	Retrospective matching analysis of three different treatment modalities	147 (P) 103 (P) 56 (P)	RA + PTCA Stent alone RA + stent	98.6% 98.0% 98.2%	Event-free survival at 9 months: 67% 77% 85%; P = 0.063
Moussa et al. [17]	1997	Retrospective analysis of consecutive patients treated with RA prior to stenting	75 (P), 106 (L)	Stent	93.4%	18% TLR at 6.4 ± 3 months; 22.5% restenosis rate at 4.6 ± 1.9 months (82.5% angiographic follow-up)
MacIsaac et al. [28]	1995	Data from Multicenter Rotablator Registry comparing RA in calcified and noncalcified lesions	1,078 (L) (calcified) 1,083 (L) (noncalcified)	PTCA (82.9%) PTCA (66.9%)	94.3% 95.2%	Success rate of RA was not reduced by calcification despite the fact that these lesions were more complex

Calcified Lesions

Treatment of heavily calcified coronary lesions by balloon angioplasty has been associated with decreased angiographic success and increased complications [26]. RA has been found to be especially promising for calcified lesions due to its ability to ablate calcific plaque selectively. Several nonrandomized series (Table III) involving large numbers of patients have demonstrated high procedural success and acceptable complication rates for the treatment of calcified lesions with the use of RA [17,18,23,27–29]. Despite the absence of randomized and prospective data, it is now generally accepted that rotablator is the preferred device for the percutaneous treatment of calcified lesions.

Chronic Total Occlusions

Revascularization of chronic total coronary occlusions remains an important challenge to interventionalist. Despite the fact that the primary crossing rate has improved

with the development of new guidewires, patients with total occlusions have an unacceptable high restenosis rate (50–70%) after balloon angioplasty alone [30], and 20–30% after stenting [31,32]. Plaque debulking prior to stenting may render additional benefits by removing the increased plaque burden seen in this type of lesion and also allow for the optimal stent deployment. Several nonrandomized studies (Table IV) have analyzed the use of RA as a debulking strategy in the treatment of chronic total occlusions [33–35]. In general, once the chronic total occlusion had been crossed with the stiff guidewires (then exchanged for the rotawire), the procedural success rates have been close to 100% in all of the recent series with restenosis rates under 30%, which compares favorably to historical controls.

Ostial Lesions

Coronary interventions of ostial lesions (both aorto and nonaorto) remain a challenging task with a high rate

TABLE IV. Chronic Total Occlusions*

Studies	Year	Study design	Number of lesions	Adjunctive treatment	Procedural success	Restenosis
Gruberg et al. [33]	2000	Retrospective analysis of any debulking (laser, rota or DCA) + stenting (DS) vs. stenting alone (ICS); only 19% of debulking were done with rota	50 (DS) vs. 126 (ICS)	Stent (100%)	100% (DS) vs. 97.1% (ICS)	Any TLR at mean 14 ± 8 months: 16.3% (DS) vs. 14.4% (ICS); P = NS
Kini et al. [34]	2000	Nonrandomized consecutive series	201	PTCA, stent (38%)	99.5%	20% TVR at 11 ± 4 months
Braden et al. [35]	1999	Nonrandomized consecutive series	139	PTCA, stent (20%), DCA (2%)	98%	20% at 46.2 ± 6 months (clinical and angiographic)

*DCA, directional coronary atherectomy.

TABLE V. Ostial Lesions*

Studies	Year	Study design	Number of patients (P) and lesions (L)	Lesion type and location	Adjunctive Therapy	Procedural Success	Restenosis Rate
Tan et al. [39]	2001	Retrospective nonrandomized	192 (P)	Nonaorto-ostial in large vessels	Three strategies compared:		TLR at 9 ± 4 months:
					RA vs.	98.2%	30% (P < 0.2)
					Stent vs.	97.4%	15%
					Rota stent	98.3%	12%
Motwani et al. [40]	2000	Registry	119 (P)	RCA only	PTCA/stent (108/11)	97.5%	16% TLR at 2 years
Koller et al. [41]	1994	Retrospective nonrandomized	29 (P)	Aorto-ostial (16), branch ostial (12), SVG (1)	PTCA	93%	39.1% (angiographic)
Zimarino et al. [42]	1994	Retrospective nonrandomized	63 (P) 69 (L)	Aorto-ostial (15) and branch ostial (54)	PTCA	92%	43% at 6 months (angiographic)

*SVG, saphenous vein graft.

of procedural complications and restenosis [36–38]. It has been proposed that RA, due to its ability to pulverize atheroma, may result in improved procedural and perhaps even long-term outcomes. Several nonrandomized studies (Table V) have reported the RA utility for this purpose [39–43]. In general, these studies have shown that compared to balloon angioplasty, RA of ostial lesions improves procedural and clinical success and decreases the need for side-branch intervention, while the restenosis rates are favorable in rota stenting vs. stenting alone in these ostial lesions. Many of these lesions are presently treated by the cutting balloon, followed by stenting.

Bifurcation Lesions

Side-branch occlusion is a well-known complication of balloon angioplasty or coronary stent placement, which can be associated with increased rates of nonfatal myocardial infarction and emergency coronary artery bypass graft (CABG) surgery [44]. It has been proposed that RA can be performed safely in vessels containing significant side branches [45,46]. The incidence of side-branch occlusion with the use of RA has ranged widely from 1.5% to 7.5% (Table VI), but with high procedural success in the range of 95–100%, and is additionally associated with decreased incidence of side-branch occlusion perhaps due to less plaque shift ("snow plow" effect). However, there is no randomized study that evaluated either the incidence of side-branch occlusion or restenosis with RA vs. either PTCA alone or stents alone for the treatment of bifurcation lesions.

In-Stent Restenosis

Unlike restenosis after balloon angioplasty, which is predominantly due to geometric arterial remodeling (shrinkage), in-stent restenosis appears to be solely due

TABLE VI. Bifurcation Lesions

Studies	Year	Study design	Number of patients	Adjunctive therapy	Procedural success	Side-branch occlusion	Results/conclusions
Cho et al. [45]	2000	Retrospective comparison of side-branch occlusion after RA for in-stent restenosis vs. for native coronaries	34 ISR	PTCA	100%	Before adjunctive PTCA: 14% (ISR) vs. 0% $P < 0.05$	3% TLR (ISR) vs. 17% TLR (native) at 12.6 ± 8.5 months, P = NS; nonsignificant increase in risk of non-Q-wave MI in ISR group; predictors of side-branch occlusion were side-branch ostial disease and ISR
			30 native	PTCA	100%	After adjunctive PTCA: 33% (ISR) vs. 2.5% (native) $P < 0.05$	
Walton et al. [46]	1996	Retrospective detailed analysis of pre- and postintervention angiograms	418	PTCA (operator discretion)	—	7.5%	29% incidence of MI in those with side-branch occlusion; loss occurred more in smaller vessels with more ostial disease

to neointimal proliferation. In-stent restenosis cases treated by balloon angioplasty have been associated with recurrent restenosis rates of up to 85%, especially of the diffuse type [47]. In diffuse in-stent restenosis, balloon angioplasty is limited by the large intimal hyperplasia volume and leaves a relatively high residual stenosis. For these reasons, pretreatment with an atheroablative technique prior to balloon dilatation might be a preferable treatment modality for in-stent restenosis compared with balloon angioplasty alone.

There have been numerous nonrandomized reports (Table VII) evaluating the safety and efficacy of RA for the treatment of in-stent restenosis [48–55], most of them reporting high procedural success rates with a very low risk of major complications and lower recurrent restenosis rate compared to historical controls of balloon angioplasty for the treatment of in-stent restenosis, particularly of the diffuse type. There are two randomized trials for this purpose that have reported discrepant results. The single-center Rotational Atherectomy vs. Balloon Angioplasty for Diffuse In-Stent Restenosis (ROSTER) trial [56], conducted in the United States, demonstrated a favorable effect of RA on restenosis, while the multi-center European Angioplasty vs. Rotational Atherectomy for Treatment of Diffuse In-Stent Restenosis Trial (ARTIST) [57] did not show a similar beneficial effect. In fact, patients treated with balloon angioplasty in the ARTIST trial had a better clinical and angiographic outcome as compared to those treated with RA. One major difference between these two trials was the fact that all patients in ROSTER had baseline intravascular ultrasound, which led to the exclusion of one-third of screened patients due

to underdeployment of stents. Rotational atherectomy prior to intracoronary brachytherapy using ^{188}Re-MAG$_3$-filled balloon in treatment of diffuse in-stent restenosis has been shown to be safe and associated with low angiographic (10%) and clinical (2%) restenosis in a small series of 50 patients [58]. Other trials of intracoronary brachytherapy have not shown additional benefit of RA in radiation-treated patients. Based on these conflicting results, the use of RA in in-stent restenosis has declined significantly and these lesions are being treated presently by cutting balloon followed by intracoronary brachytherapy [59].

Stent Jail

One of the major limitations of coronary stenting is the creation of a stent jail resulting from the placement of a stent across a side branch [60,61], which may lead to ischemia or infarction acutely and may preclude the ability to intervene the side branch at a future date in the event of restenosis or development of a new lesion in the side branch. Although the traditional modality for treatment of jailed side branches has been balloon angioplasty, this approach has been associated with suboptimal angiographic results and dissection [62], perhaps due to the presence of high plaque burden and elastic recoil at such sites. While stenting may improve the acute outcome in these cases, there is a high incidence of restenosis when such bifurcation stenting is performed [63,64]. Finally, it is sometimes not possible to pass either a balloon or a stent to the jailed vessel despite being able to wire the lesion. Due to its ability to ablate inelastic stent metal and atheroma, RA has been pro-

TABLE VII. In-Stent Restenosis*

Studies	Year	Study design	Number of patients	Device	Adjunctive therapy	Procedural success	Repeat event
ARTIST [57]	2002	Multicenter randomized prospective	152	RA	PTCA (low atm)	88%	65%
			146	PTCA		89%; P = NS	51%; $P < 0.05$
ROSTER [56]	2000	Single-center randomized trial with IVUS guidance	100	RA	PTCA (low atm)	100%	32% TLR at 9 months
			100	PTCA	PTCA (high atm)	99%	45% TLR at 9 months; $P < 0.05$
Radke et al. [55]	2001	Nonrandomized use of RA in a consecutive series of patients; no control group	84	RA	PTCA stent (11%)	98%	45% ARS and 35% TLR at 6 months; cumulative event-free survival at 3 years = 57% for entire group
Adamian et al. [54]	2001	Retrospective matching analysis of four different treatment modalities for ISR; nonrandomized	74 79 48 57	PTCA Stent RA CBA		96% 97% 98% 100%; P = NS	45.2% (PTCA) 41.4% (stent) 35.9% (RA) 20% (CBA); $P < 0.05$; recurrent ISR rate significantly lower in CBA compared to other groups
BARASTER [53]	2000	Multicenter registry; observational study	46	RA alone		87%	48% TLR
			151	RA + PTCA		95%	37% TLR
			107	PTCA alone		89%; P = NS	47% TLR; P = NS
Mehran et al. [52]	2000	Retrospective analysis of consecutive series of patients; nonrandomized	119	ELCA + PTCA		96%	TLR at one year: 26.2% (ELCA) vs. 27.9% (RA); P = NS
			130	RA + PTCA		98%	
vom Dahl et al. [50]	1999	Prospective, consecutive recruitment	100	RA	PTCA (92%; low atm)	97%	49% ARS and 35% TLR at 128 ± 44 days
Sharma et al. [49]	1998	Nonrandomized consecutive series; prospective follow-up	100	RA	PTCA (low atm)	100%	Recurrent ISR rate of 28% at 13 ± 5 months; 26% TVR
Lee et al. [48]	1998	Consecutive prospective but nonrandomized	36	RA + PTCA	PTCA	100%	RA had less clinical recurrence rate (25% vs. 47%; $P < 0.05$) and better angina-free survival at 6 months (72% vs. 49%; P = 0.02)
			45	PTCA alone		100%	

*CBA, cutting balloon atherectomy; ELCA, excimer laser; ARS, angiographic restenosis.

posed as a modality of treatment for jailed side branches. Numerous case reports have demonstrated the safety and efficacy of this approach [61,65]. Despite the initial concern about the potentially dangerous interaction between the two metal surfaces resulting in the generation of heat and metal particles, no clinical complications have been reported. Another concern of possible burr entrapment in the side branch beyond the stent struts can be avoided with the use of proper technique (i.e., careful initial burr selection, step burr approach, and slow burr advancement into the jailed side branch through the stent struts). Therefore, RA can be performed safely, especially in cases where balloon cannot be advanced over the guidewire into the stent jailed side branch.

Undilatable Lesions/Unexpanded Stents

Despite success in crossing some lesions with a guidewire, failure to perform balloon angioplasty or to deploy a stent successfully can still result from inability to dilate the lesion adequately [66]. These failures are often due to lesion rigidity resulting from a combination of fibrosis and calcification [66–69]. RA has been proposed as a means of treating such lesions, resistant to balloon angioplasty. By partially ablating the fibrocalcific plaque, RA can alter the compliance of the lesion and render it more amenable to subsequent adjunct balloon angioplasty and/or stent delivery and deployment. Several reports of the RA use in this setting revealed acute success rates in excess of 90% with a low incidence of complications [70]. It has also been suggested that if lesions do not crack despite the use of high-pressure noncompliant balloon dilatations, subsequent RA using small burrs can still be performed safely so long as there are no angiographically visible dissections. In such cases, RA may permit successful balloon expansion and/or stent deployment where initially it was not possible. Similarly, stents, which remain underexpanded despite the use of high-pressure noncompliant balloon inflations, are associated with a high incidence of restenosis. When such cases of in-stent restenosis do occur, RA can ablate the stent-calcium complex and allow subsequent balloon and stent expansion [71].

COMPLICATIONS

The clinical complications of RA are similar to those of balloon angioplasty. Based on the multicenter registry and numerous observational studies, these complications include death in approximately 1%, Q-wave myocardial infarction in 1.2–1.3%, and emergency CABG in 1.0–2.5%. An elevated CK-MB > 3 times the upper limit of normal has been observed in 4–6% of cases. In addition to the clinical complications, the angiographic complications of RA include dissection (10–13%), abrupt closure (1.8–11.2%), slow-flow phenomenon (1.2–7.6%), perforation (0–1.5%), and severe spasm (1.6–6.6%). Another unique but rare complication of RA is dissection caused by wire bias in the angulated lesion, which can be decreased by bending the rotawire or using a small-size initial burr. The differences in the complication rates between the various series are undoubtedly due to differences in the definitions used, the variable and increasing operator experience with the device, and the evolution of the technique. The risk of significant bleeding and other vascular complications related to large sheath size has been reported in the range of 1.0–5.0%, which is probably lower today, since large burrs requiring sheaths > 8 Fr are rarely used.

RECOMMENDATIONS

Based on the available evidence, the main indication for the use of RA at the present time is to alter lesion compliance in calcified and/or undilatable lesions in order to facilitate stent delivery and expansion and to reduce acute procedural complications. Long-term data regarding the effect on restenosis are lacking, and this continues to be the Achilles' heel of RA. Therefore, RA should be followed by stenting in most lesions where possible. This led to an overall decrease in the use of RA to approximately 4–5% of percutaneous interventions performed in the United States, as shown in the American College of Cardiology–National Cardiovascular Data Registry [72]. In our opinion, the following are the most appropriate indications for rotational atherectomy along with the main reasons for its use: in calcified lesions, for facilitating stent delivery and expansion; in undilatable lesions, for facilitating stent delivery and expansion; in ostial lesions, for reducing plaque shift and side-branch occlusion; and in selected cases of diffuse in-stent restenosis, for decreasing intimal hyperplasia volume and subsequent balloon slippage and for reducing the need for restenting.

Therefore, rotational atherectomy has become a niche device of great utility in treating heavily calcified and complex lesions by rendering the procedure simple and effective, but without any effect on restenosis or long-term clinical events. This plaque modification approach may become more important in the drug-eluting stent era when stents need to be delivered to the lesion with minimal resistance in the proximal vessel and be able to expand fully with moderate inflation pressure (12–16 atm), avoiding high-pressure injury dissection caused by the overhanging balloon of the drug-eluting stent. For this reason, the use of RA may increase in the future.

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