JACC: CARDIOVASCULAR INTERVENTIONS © 2014 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER INC. VOL. 7, NO. 4, 2014 ISSN 1936-8798/\$36.00 http://dx.doi.org/10.1016/j.jcin.2013.12.196

CORONARY State-of-the-Art Paper

Current Status of Rotational Atherectomy

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Rotational atherectomy facilitates percutaneous coronary intervention for complex de novo lesions with severe calcification. A strategy of routine rotational atherectomy has not, however, conferred reduction in restenosis or major adverse cardiac events. As it is technically demanding, rotational atherectomy is also uncommon. At this 25-year anniversary since the introduction of rotational atherectomy, we sought to review the current state-of-the-art in rotational atherectomy technique, safety, and efficacy data in the modern era of drug-eluting stents, strategies to prevent and manage complications, including slow-flow/ no-reflow and burr entrapment, and appropriate use in the context of the broader evolution in the management of stable ischemic heart disease. Fundamental elements of optimal technique include use of a single burr with burr-to-artery ratio of 0.5 to 0.6-rotational speed of 140,000 to 150,000 rpm, gradual burr advancement using a pecking motion, short ablation runs of 15 to 20 s, and avoidance of decelerations >5,000 rpm. Combined with meticulous technique, optimal antiplatelet therapy, vasodilators, flush solution, and provisional use of atropine, temporary pacing, vasopressors, and mechanical support may prevent slow-flow/no-reflow, which in contemporary series is reported in 0.0% to 2.6% of cases. On the basis of the results of recent large clinical trials, a subset of patients with complex coronary artery disease previously assigned to rotational atherectomy may be directed instead to medical therapy alone or bypass surgery. For patients with de novo severely calcified lesions for which rotational atherectomy remains appropriate, referral centers of excellence are required. (J Am Coll Cardiol Intv 2014;7:345–53) © 2014 by the American College of Cardiology Foundation

The year 2012 marked the 25th year since Jerome Ritchie, David Auth, and colleagues (1) introduced rotational atherectomy (RA) as a technique for the endovascular treatment of obstructive atherosclerotic disease. RA emerged in the 1990s as one of several tools to treat luminal obstruction via physical removal of plaque. Although initially explored as an alternative to balloon angioplasty, RA proved complementary, facilitating angioplasty and, later, stenting of complex lesions, particularly those affected by heavy calcification. Beyond immediate procedural success, however, data have not shown a consistent long-term benefit of lesion modification by RA for restenosis and major adverse cardiovascular events (MACE). Today, RA use is infrequent. At one time, RA was involved in up to 10% of percutaneous coronary interventions (PCI) (2). In more recent series, RA use has fallen to 3% to 5% in select high-volume centers and <1% in others (3).

Though uncommon, RA maintains purpose in the modern cardiac catheterization laboratory. In the context of recent developments in management of stable ischemic heart disease, including improvement in medical therapy, advances in design and delivery of drug-eluting stents (DES), and advances in noninvasive and intravascular coronary imaging, we sought to review the state-ofthe-art in RA. On the basis of a systematic search of MEDLINE literature for "rotational atherectomy" and "rotablation," we reviewed optimal technique, avoidance and management of complications, recent data on complications and outcomes

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Manuscript received June 16, 2013; revised manuscript received December 5, 2013, accepted December 19, 2013.

of RA with DES, and appropriate application of RA in the modern cardiac catheterization laboratory.

Principles

RA produces lumen enlargement by physical removal of plaque and reduction in plaque rigidity, facilitating dilation. The commercially available Rotablator (Boston Scientific, Natick, Massachusetts), invented by Auth and described by Ritchie and colleagues (4), ablates plaque using a diamondencrusted elliptical burr, rotated at high speeds (140,000 to 180,000 rpm) by a helical driveshaft, that advances gradually across a lesion over a guidewire. The burr preferentially ablates hard, inelastic material, such as calcified plaque, that is less able to stretch away from the advancing burr than is healthy arterial wall (differential cutting). High rotational speeds facilitate longitudinal burr movement across calcific

Abbreviations and Acronyms

BMS = bare-metal stent(s) CABG = coronary artery bypass graft surgery DES = drug-eluting stent(s) ISR = in-stent restenosis IVUS = intravascular ultrasound

MACE = major adverse cardiovascular events

MI = myocardial infarction

OCT = optical coherence tomography

PCI = percutaneous coronary intervention

RA = rotational atherectomy

lesions by orthogonal displacement of friction. A guidewire helps to keep the burr's abrasive tip coaxial with the vessel lumen, although wire bias in highly tortuous or angulated segments may predispose to dissection or perforation. The guidewire should be positioned distal to the target lesion in the largest distal vessel, avoiding small side branches and distal narrow vasculature, and avoiding bends, kinks, or loops.

Unlike balloon angioplasty, which tends to produce intimal splits and medial dissections in calcified lesions, RA yields a relatively smooth luminal surface with cylindrical geometry and mini-

mal tissue injury (Fig. 1) (5–7). Lumen enlargement, typically larger than the largest burr used, occurs mainly by selective ablation of inelastic plaque without significant arterial expansion (8). Lumina are not always cylindrical after RA. In regions of tortuosity or eccentric plaque, crater or gutter formation can occur (lesion bias). This may impede stent deployment or yield lumen enlargement greater than burr size.

Friction between the burr and plaque generates heat. Heat varies with technique from 2.6°C using intermittent ablation and permitting minimal decelerations (4,000 to 6,000 rpm), to 13.9°C using continuous ablation allowing excessive decelerations (14,000 to 18,000 rpm) in experimental modeling (9). Along with microembolization of debris, thermal injury may contribute to increased risk of periprocedural myocardial infarction (MI) and restenosis associated with excessive decelerations (10). Modern technique, favoring gradual, intermittent ablation with a pecking motion, aims to minimize decelerations and thermal injury.

Slower burr speeds of 140,000 to 150,000 rpm further reduce platelet aggregation associated with RA (11).

RA particulate must traverse coronary microvasculature before clearance by the reticuloendothelial system. Microvascular obstruction can cause reduced contractility in subtended myocardium, slow-flow/no-reflow, and MI. Most particles are sufficiently small to permit ready passage; 98% are <10 μ m, with a mean diameter of 5 μ m, which is smaller than normal mature erythrocytes (4). Strategies to enhance microvascular clearance, including vasodilators, short runs with a pecking motion (to preserve antegrade flow), and maintenance of arterial blood pressure, reduce the risk of these complications (12–14). The fundamentals of optimal technique are summarized in Table 1.

Prevention of Complications

Patients undergoing RA experience clinical complications common to PCI, including vascular access complications, stroke, MI, urgent coronary artery bypass graft surgery (CABG), and death, as well as angiographic complications, including dissection, perforation, short-term closure, side branch loss, and the slow-flow/no-reflow phenomenon (15). Frequencies of these complications reported in recent series of RA before DES implantation are presented in Table 2 (16–25). Additional complications of particular importance to RA include vasospasm (1.6% to 6.6%) and burr entrapment (0.5% to 1%).

Smaller burr sizing (burr-to-artery ratio <0.7) reduces angiographic complications and periprocedural creatine kinase-myocardial band release, with similar procedural and angiographic success, compared with more aggressive sizing (burr-to-artery ratio >0.7) (10,26). Smaller burrs permit use of smaller guiding catheters and, in turn, smaller arterial sheaths, fewer catheter and sheath exchanges, and fewer vascular complications.

Smaller sheath sizes are associated with less major femoral bleeding (27) and permit radial access, an established bleeding avoidance strategy (28). Among patients undergoing RA, a recent retrospective experience shows comparable rates of procedural success, procedure time, and patient radiation exposure with radial access compared with femoral access (29).

Use of fewer, smaller guiding catheters may limit RAassociated stroke. In a series of 21,794 PCI hospitalizations between 1994 and 2008, RA was more often used in cases of PCI-associated stroke than in propensity-matched controls (30). Stroke cases tended to involve larger catheters and more catheter exchanges—factors linked to mobilization of aortic debris in a prior study (31). It is likely that patient features also contribute to stroke risk, because patients undergoing RA are often also affected by a greater burden of atherosclerosis, vascular calcification, and advanced age.



Slow-flow and no-reflow during RA are believed to relate to microvascular embolization of atherosclerotic debris and associated thrombi. Strategies to prevent these phenomena include antiplatelet therapy, scrupulous technique, and vasodilators. The benefit of antiplatelet therapy was established with the glycoprotein IIb/IIIa inhibitor abciximab (32). Comparable rates of death, MI, and urgent coronary artery bypass graft surgery (CABG) have since been reported with the direct thrombin inhibitor bivalirudin (33). Vasodilators used for the purpose of reducing slow-flow and no-reflow, alone or in combination as a "cocktail" (34), include adenosine, calcium antagonists, nitroglycerin, and nicorandil (not available in the United States). A summary of strategies to prevent and treat slow-flow and no-reflow is presented in Table 3.

Burrs are susceptible to entrapment. If the burr passes distal to an incompletely ablated segment of lesion, proximal movement is restricted by absence of diamond chips on the back of the burr, prohibiting retrograde ablation. Use of smaller burrs and a technique of gradual, intermittent burr advancement may help avoid entrapment. The burr should never be allowed to stop spinning within a lesion. During ablation, the operator should be attentive to potential

Table 1. Fundamental Elements of Optimal RA Technique
Single burr with burr-to-artery ratio of 0.5 to 0.6
Rotational speed of 140,000 to 150,000 rpm
Gradual burr advancement using a pecking motion
Short ablation runs of 15 to 20 s
Avoidance of decelerations >5,000 rpm
Final polishing run
RA = rotational atherectomy.

warning signs, which may be visual (lack of smooth advancement under fluoroscopy), auditory (pitch changes with variation in resistance encountered by burr), or tactile (resistance in advancer knob or excessive driveshaft vibration). If entrapment occurs, timely action is required to remove the entrapped burr. Sulimov et al. (35) among others (36,37), recently divided catheter-based solutions into 2 general approaches: balloon angioplasty and deep catheter intubation. In order to deliver additional interventional devices, access may be obtained either via a second arterial puncture or disassembly of the RA apparatus. If catheterbased solutions are unsuccessful, surgical removal and CABG are required.

Indications

The cardinal indication for RA is the calcific lesion, which, in the absence of plaque modification, confers an increased likelihood of procedural failure, stent underdeployment, restenosis, and major complications (38). Retrospective series of RA describe high rates of short-term procedural success (range 93.4% to 98.6%), superior to rates reported separately in the absence of preceding plaque modification (39–41).

Consideration of RA requires determining calcification severity, because benefits of RA are attenuated when calcification is mild or absent. In practice, calcification severity is customarily graded by qualitative assessment of angiography, with severe calcification defined by radio-opacities noted without cardiac motion before contrast injection, generally involving both sides of the arterial wall, and moderate calcification defined by densities noted only during the cardiac cycle before contrast injection (42).

Table 2. Reported Complications of RA and DES Implantation											
Trial/First Author (Ref. #)	Year	N	Death, %	MI, %	Urgent CABG, %	Vascular, %	Dissection, %	Perforation, %	Acute Closure, %	Side Branch Loss, %	Slow Flow/ No Reflow, %
ROTAXUS (16)	2013	120	1.7	1.7	0.8	5.8	3.3	1.7	_	_	0.0
Abdel-Wahab et al. (17)	2013	205	1.5	2.4	—	_	4.4	0.5	_	_	2.0
Naito et al. (18)	2012	233	0.0	1.3	_	_	1.7	0.4	_	—	_
Benezet et al. (19)	2011	102	1.0	1.0	_	_	2.9	0.0	_	_	_
Dardas et al. (20)	2011	184	0.0	_	—	—	_	—	-	—	—
Garcia de Lara et al. (21)	2010	50	4.0	14.0	0.0	_	2.0	2.0	2.0	4.0	0.0
Rathore et al. (22)	2010	391	1.0	6.9	0.0	_	5.9	2.0	0.3	3.6	2.6
Vaquerizo et al. (23)	2010	63	0.0	3.2	0.0	1.6	_	_	1.6	—	—
Furuichi et al. (24)	2009	95	0.0	3.2	_	_	2.1	1.1	—	—	1.1
Clavijo et al. (25)	2006	81	0.0	19.8	_	_	1.9	_	_	-	_
CABG = coronary artery bypass graft surgery; DES = drug-eluting stent(s); MI = myocardial infarction; RA= rotational atherectomy.											

Angiography is insensitive for detection of calcification in comparison with intravascular ultrasound (IVUS), but visible calcification on angiography predicts a larger arc of calcification on IVUS (43). Intravascular imaging with IVUS or optical coherence tomography (OCT) further permits discrimination of superficial (near the intima–lumen interface) and deep (at the media/adventitia border) calcium (44,45).

RA facilitates procedural success in PCI of complex (American College of Cardiology/American Heart Association types B2 and C) lesions (46,47), including chronic total occlusions (48,49), ostial lesions (50–52), and bifurcation lesions, which may be associated with both bulky plaque and vessel geometry unfavorable for stent deployment. Selected studies have demonstrated favorable long-term results of a debulking strategy with RA or directional atherectomy for chronic total occlusions (53), bifurcation lesions (54,55), and side branch ostia, alone or in combination with the main vessel (56,57).

Table 3. Potential Mechanisms of Slow-Flow/No-Reflow During RA and Associated Strategies for Prevention and Treatment						
Mechanism	Therapeutic Strategy					
Atheromatous debris embolism	Small burr sizing Intermittent ablation Avoidance of significant decelerations					
Platelet activation, aggregation, and lysis	Optimal antiplatelet therapy, including use of a glycoprotein Ilb/Illa inhibitor					
Microcirculatory vasospasm	Vasodilators Liberal use of flush solution					
Neurohumoral reflex bradycardia	Atropine Temporary venous pacemaker (especially for lesions in a dominant right coronary artery)					
Intraprocedural hypotension	Vasopressors (in particular, phenylephrine) Intra-aortic balloon counterpulsation					
RA = rotational atherectomy.						

Although studied previously for treatment of in-stent restenosis (ISR) with favorable short-term and late outcomes, in the DES era, RA has largely been supplanted for this purpose by balloon angioplasty, drug-coated balloons, cutting or scoring balloons, same or different DES, vascular brachytherapy, or CABG (58). It is worth noting that the benefits of RA, when used for ISR, likely depend on the mechanism of restenosis-an observation explaining the discrepancy between the 2 randomized trials on the subject. In ROSTER (Randomized Trial of Rotational Atherectomy Versus Balloon Angioplasty for Diffuse In-Stent Restenosis), which randomized 200 patients with IVUSconfirmed diffuse ISR to RA plus low-pressure balloon dilation or to high-pressure balloon dilation alone, RA was associated with a significant reduction in intimal hyperplasia area, repeat stenting (10% vs. 31%, p < 0.001), and target lesion revascularization (32% vs. 45%, p = 0.042) at a mean follow-up of 12 months (59). By contrast, in the ARTIST trial (Angioplasty Versus Rotational Atherectomy for Treatment of Diffuse In-Stent Restenosis), which did not exclude stent underexpansion by IVUS, RA was associated with inferior stent expansion and a higher incidence of binary restenosis (65% vs. 51%, p = 0.039) at 6 months (60). It is intuitive that RA is most beneficial for removal of intimal hyperplasia and less effective for radial expansion of an underexpanded stent. If RA is contemplated for use in DES ISR, pre-treatment imaging with IVUS or OCT may be warranted to first elucidate the mechanism of restenosis.

The RA burr is capable of ablating metallic stent struts and does so preferentially because of differential cutting. This has permitted careful application of RA to treatment of underexpanded or crushed stents embedded in obstructive, calcific lesions (61). Analysis of metallic particulate generated by stent ablation reveals particles similar in average size to those generated by atheroablation, $5.6 \pm 3.6 \ \mu m$ (62), with 95% <15 μm (63).

Table 4. Long-Term Outcomes After RA and DES Implantation									
First Author									
(Ref. #)	Year	Patients	Follow-Up	MACE, %	Repeat Revascularization, %	ST , %			
Abdel-Wahab et al. (17)	2013	205 DES	15 months	17.7	9.9 TVR, 6.8 TLR	1.0			
Mangiacapra et al. (72)	2012	104 DES	1 yr	12.0*	5 TVR*	3.0			
		83 BMS		23.5	12.3 TVR	4.9			
Naito et al. (18)	2012	179 SES	630 days	14.8	6.8 TVR, 4.9 TLR				
		54 PES	625 days	13.7	11.8 TVR, 9.8 TLR				
Benezet et al. (19)	2011	102 DES	15 months	12.7	8.8 TLR	2.9			
Dardas et al. (20)	2011	184 DES	49 months	14.9	3.3 TVR, 2.8 TLR				
Fujimoto et al. (73)	2010	54 DES	12 months						
		26 RA+			11.5 TLR*	0			
		28 RA-			35.7 TLR	7.1			
Garcia de Lara et al. (21)	2010	50 DES	1 yr	6 (CV death)	6 TLR				
Rathore et al. (22)	2010	391 DES	6–9 months		10.6 TLR*	0.8			
		125 BMS			25.0 TLR	0.8			
Vaquerizo et al. (23)	2010	63 DES	15 months	9.5	4.8 TLR	2.8			
Furuichi et al. (24)	2009	96 DES	15 months	15.8	11.6 TVR, 9.5 TLR	4.2			
Tamekiyo et al. (74)	2009	79 DES	2 yrs	30.1*	25.0 TLR*				
		144 BMS		43.1	39.1 TLR				
Clavijo et al. (25)	2006	150 DES	6 months	(Death)					
		81 RA+		6.8	4.2				
		69 RA-		7.9	4.9				
*Statistically significant.									
BMS = bare-metal stent(s); CV = cardiovascular; MACE = major adverse cardiovascular events; PES = paclitaxel-eluting stent(s); RA+ =									
rotational atherectomy used; RA- = rotational atherectomy not used; ST = stent thrombosis; SES = sirolimus-eluting stent(s); TLR = target lesion									

revascularization; TVR = target vessel revascularization; other abbreviations as in Table 2.

Labeled contraindications to RA include saphenous vein graft lesions, thrombus, dissection, and occlusions through which a guidewire will not pass. Relative contraindications include unavailability of bypass surgery (whether due to patient ineligibility or lack of cardiac surgery on site), severe 3-vessel or unprotected left main disease, severe left ventricular dysfunction, lesion length in excess of 25 mm, and lesion angulation in excess of 45°.

Exceptional reports of successful use of RA despite contraindications exist in recent literature, such as for cases of severely calcified nondilatable saphenous vein graft lesions (64), iatrogenic coronary artery dissection (65,66), residual nondilatable plaque after stent delivery in a case of acute MI (67), and calcified unprotected left main lesions in patients deemed ineligible for bypass surgery (68). Use of RA in the presence of 1 or more high-risk features has been associated with more slow-flow (30% vs. 18%, p = 0.06) and periprocedural MI (8.8% vs. 2.1%, p = 0.04) (69).

Outcomes

Prior reviews summarizing outcomes of RA in conjunction with angioplasty and stenting have emphasized experience with bare-metal stents (BMS) (15,70). Today, DES account for most implanted stents (71). In broad populations, the benefits of DES above BMS for reduction in restenosis are well established. Over the last 5 years, several case series have

reported intermediate and long-term outcomes after DES with adjunctive RA (Table 4) (17-25,72-74). Most of these studies report rates of target lesion revascularization <10% within 1 to 2 years.

DES are associated with improved outcomes after RA. In patients treated with RA, rates of MACE are lower with DES compared with BMS in 3 recent series (22,72,74). This difference was primarily driven by less repeat revascularization. This finding is consistent with broader trials of DES versus BMS (75,76) and propensitymatched comparison of DES versus BMS in patients with calcified lesions in the National Heart, Lung, and Blood Institute's Dynamic Registry (38).

It is unclear, however, whether RA improves outcomes with DES. In theory, preparation of a smooth cylindrical lumen might facilitate superior stent deployment and, in turn, reduced restenosis. This benefit has not yet been shown. Results are inconsistent in observational studies (25,73) and difficult to interpret because of selection biases influencing assignment to RA (calcification, disease severity), which may independently influence outcomes. Long-term benefit was again absent in the recent ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) study, the first randomized trial to directly test the impact of RA on long-term outcomes of DES placement (16). In a series of 240 patients with moderately or severely calcified obstructive lesions treated with or without RA before paclitaxel-eluting stent implantation, there was greater strategy success and short-term lumen gain with RA. However, routine angiographic follow-up at 9 months showed no difference in MACE and greater late lumen loss (77) with an RA strategy. ROTAXUS had limitations, including missing angiographic follow-up in 1 in 5 patients, insufficient power to compare clinical outcomes, a preponderance of moderately calcified lesions, and confounding factors in the RA group that may have offset putative benefits of RA, such as longer lesion length and lower maximum predilation balloon pressure. Nonetheless, the authors' conclusions are appropriate that there is a continued lack of evidence

tomography; PCI = percutaneous coronary intervention.

to recommend RA as a routine lesion modification strategy before DES implantation in calcified lesions.

Appropriate Use

Over the past 5 years, seminal clinical trials have shaped understanding of the appropriate use of PCI in stable ischemic heart disease, addressing scenarios of complex coronary anatomy and comorbid diabetes mellitus (78–81). We view RA as a tool to make PCI possible in complex lesions with moderate or severe calcification when clinical variables make PCI appropriate. An algorithm for application of



RA in clinical practice is presented in Figure 2. Of note, when the severity of calcification is indeterminate at angiography, IVUS or OCT may be useful for reclassification.

In select high-risk cases, mechanical circulatory assistance may be warranted. It is important to recognize that use of a mechanical circulatory assist device does not constitute a license for unfettered RA. In the PROTECT II study (Protect II, A Prospective, Multicenter Randomized Controlled Trial of the IMPELLA RECOVER LP 2.5 System Versus Intra Aortic Balloon Pump [IABP] in Patients Undergoing Non Emergent High Risk PCI), which randomized 452 symptomatic patients with complex disease and severe left ventricular dysfunction to intra-aortic balloon counterpulsation or the Impella 2.5 (Abiomed, Danvers, Massachusetts) axial flow rotary blood pump during elective PCI, more extensive RA in the Impella group was associated with an increased risk of major adverse events, driven by periprocedural non–Q-wave MI (82).

For patients with ISR, RA is advisable only as a second choice in select cases. RA may be useful when a lesion cannot be crossed with a balloon, or when multiple jailed side branches exist, using plaque debulking to minimize "snow plow" plaque displacement in the context of balloon dilation. In cases where metallic stent struts contribute directly to luminal obstruction, RA may be utilized for stent ablation. Otherwise, non-RA strategies, such as highpressure balloon, drug-coated balloon, or cutting balloon dilation, are preferred, especially for cases of stent underexpansion.

Conclusions and Directions for Future Research

Literature from the inception of RA has consistently demonstrated the utility of RA in facilitating procedural success in treatment of calcified, complex lesions. The safety of doing so has improved with accumulated experience and maturation of technique, including the opportunity to further reduce complications with increased use of smaller burrs and guiding catheters, fewer catheter exchanges, and radial arterial access. We believe that RA remains an integral tool to permit optimal angiographic outcomes in treatment of complex coronary disease involving moderately to severely calcified lesions.

Evidence has yet to demonstrate that routine RA before DES reduces restenosis. Long-term follow-up from the ROTAXUS trial may offer additional insights. It is possible that the impact of RA on repeat revascularization is most pronounced for a subset of heavily calcified lesions. Beyond angiographic examination, IVUS or OCT may prove useful in identifying features of plaque morphology predictive of benefit. Further research is also needed to clarify the utility of combining RA with other modalities such as cutting or drug-coated balloons in treatment of calcific lesions (83). Pivotal trials in acute coronary syndromes over the past 5 years have led to introduction of novel antiplatelet agents, including prasugrel and ticagrelor. Use has extended in clinical practice to elective PCI. The impact of the new agents on complications of RA is unknown and merits study.

The persistence of angiographic and clinical complications of RA underscores the potential for further progress in technology and technique. New devices are in development, including a novel RA device to reduce microcavitation (84) and an orbital atherectomy system for use with coronary lesions. Distinct from RA, orbital atherectomy works on the principle of elliptical burr movement, with variation in effective burr size based on rotational speed. An orbital atherectomy system has shown promise in preliminary studies (85). Use of bivalirudin as the anticoagulant of choice may further reduce bleeding complications of RA, although further data are needed to establish this benefit in the RA setting and to confirm equivalent efficacy for prevention of slow-flow/no-reflow (33).

Finally, global declines in volume of coronary revascularization, in particular PCI for stable ischemic heart disease (86), will further reduce the already uncommon use of RA. This will have important implications for efficacy and safety of RA, a technically demanding procedure reliant on operator experience. We believe the solution to this problem will be to maintain referral centers of excellence for PCI of complex lesions, including RA.

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Key Words: calcified lesions ■ complications ■ drug-eluting stents ■ rotational atherectomy.