

## Rotational Atherectomy in the Drug-Eluting Stent Era: A Single-Center Experience

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**ABSTRACT: Background.** In heavily calcified lesions, rotational atherectomy (RA) improves procedural success and facilitates stent deployment. Reports on RA in the drug-eluting stent (DES) era are limited. The objective of this study was to determine the presenting characteristics, procedural and in-hospital clinical outcomes of patients who underwent RA at our institution in the DES era. **Methods.** Consecutive cases involving RA between January 1, 2004 and December 31, 2009 at a private, tertiary referral hospital were reviewed retrospectively. **Results.** A total of 158 patients (236 lesions) who underwent RA are described, including 112 patients (158 lesions) with subsequent DES implantation, 19 patients (28 lesions) with bare-metal stent (BMS) implantation, and 27 patients (50 lesions) with no stent. RA was utilized to modify heavily calcified plaque (84%), as bail-out therapy (16%), to preserve the patency of sidebranches (25%) and as debulking therapy for chronic total occlusion (13 lesions) and in-stent restenosis (7 lesions). DES were not placed in 46 patients (23%) due to reference vessel diameter < 2.25 or > 3.75 mm, inability to deliver DES, or desire to avert clopidogrel therapy. Angiographic and procedural success rates were significantly higher in the DES and BMS groups compared with the no stent group (angiographic success: 99.1% for DES versus 95% for BMS versus 63% for no stent;  $p < 0.05$ ; procedural success: 96.4% for DES versus 95% for BMS versus 63% for no stent;  $p < 0.05$ ). **Conclusion.** In the DES era, RA remains utilized primarily to modify heavily calcified plaque. In unadjusted analysis, procedural success appears high with subsequent stent placement (DES or BMS) versus RA alone. However, 1 in 4 are not candidates for stent placement, and the lower procedural success rate in this population should be considered prior to embarking on RA.

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Introduced in the early 1990s, rotational atherectomy (RA) failed to show consistent clinical benefit and resulted in a restenosis rate of 38% at 6 months.<sup>1–4</sup> However, RA has found

a niche in improving procedural success rates in complex, heavily calcified lesions in which balloon angioplasty and stenting alone often result in failure or suboptimal stent expansion.<sup>5,6</sup> In heavily calcified lesions, adjuvant RA prior to bare-metal stent (BMS) deployment improved stent expansion,<sup>7–10</sup> but target lesion revascularization rates remained unacceptably high, ranging from 15–36% at 6–9 months.<sup>10–13</sup> Reports on RA in the drug-eluting stent (DES) era are limited, but indicate significantly improved target lesion revascularization rates in heavily calcified lesions, ranging from 2–10.6% at 6 months to 3 years.<sup>12–16</sup> Reports of RA in the DES era used focused inclusion criteria; that is, RA was indicated only for moderate to severe lesion calcification and all patients received a DES (some reports used a historical control group).<sup>12–17</sup> To our knowledge, no study in the DES era has examined overall use of RA, including patients treated with and without DES implantation and for indications other than severe calcification. Therefore, we sought to analyze patient characteristics, procedural characteristics and in-hospital clinical outcomes of patients who underwent RA between January 1, 2004 and December 31, 2009 to better define the use of RA in the DES era.

### Methods

This was a retrospective analysis at Good Samaritan Hospital, a private, tertiary referral hospital, with approval from the Western Institutional Review Board. The cardiac catheterization database was searched to identify all cases involving RA between January 1, 2004 and December 31, 2009, during which time DES were commonly used. Cases were excluded if the intervention involved the left main coronary artery (reported separately), if the intervention involved the use of brachytherapy, or if the angiographic images could not be obtained. The use of RA and all other clinical decisions were at the discretion of the interventionalist. DES are routinely implanted during coronary interventions unless the clinical situation dictates otherwise (i.e., for lesions < 2.25 mm or > 3.75 mm, for patients with impending surgery or active bleeding, inability to deliver the DES, etc.).

Patient demographics, medical history, procedural characteristics and in-hospital outcomes were recorded through a comprehensive chart review. Procedural and lesion characteristics were further defined using quantitative coronary angiography.

**Definitions.** Patients who presented with a stress test suggesting myocardial ischemia without cardiac symptoms were labeled as having silent ischemia. Lesion calcification was defined prior to contrast injection as: severe if radiopacities were readily

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apparent without cardiac motion; moderate if radiopacities were apparent only with cardiac motion; mild if faint radiopacities were seen only with cardiac motion; and none if no radiopacities were seen.<sup>18</sup> Lesions were classified according to American College of Cardiology/American Heart Association criteria.<sup>18</sup> A lesion was defined as bifurcating if a branch > 1.5 mm with ostial disease originated within the stenosis and the branch was completely surrounded by stenotic portions of the parent vessel.<sup>18</sup> A lesion that originated within 3 mm of the vessel origin was defined as ostial.<sup>18</sup>

Clinical outcomes were determined during the index hospitalization. *Major adverse cardiac events (MACE)* were defined as death, target vessel revascularization, Q-wave myocardial infarction, or non-Q wave myocardial infarction (new creatine kinase elevation above two times the upper limit of normal). *Angiographic success* was defined as < 40% residual stenosis and thrombolysis in myocardial infarction (TIMI) grade 3 flow at the conclusion of the procedure. *Procedural success* was defined as angiographic success in the absence of MACE. *Target vessel revascularization* was defined as repeat percutaneous coronary intervention or coronary artery bypass graft surgery (CABG) to the target vessel.

**Quantitative coronary angiography.** Quantitative coronary angiography was performed using MDQM-QCA (*Medcon Quantitative Measurements-Quantitative Coronary Arteriography; Medcon Limited, Tel Aviv, Israel*) edge-detection software. Measurements were made using the view with the highest degree of stenosis and the least amount of foreshortening. A preintervention angiogram was used to determine lesion length. Reference vessel diameter was determined using a post-intervention image by taking the mean of the angiographically normal-appearing segments proximal and distal to the lesion. If normal-appearing proximal and distal segments were not available (*e.g.*, ostial lesions), then estimates were made using the available segments (*e.g.*, for ostial lesions, the reference vessel diameter was equal to or slightly greater than the normal-appearing distal segment). Minimal luminal diameter (MLD) was determined up to three times: 1) preintervention; 2) post-RA (and balloon angioplasty if balloon angioplasty was done); and 3) post-stenting (if a stent was placed). The percent diameter stenosis at each instance was determined by dividing the MLD at that instance by the reference vessel diameter. Acute gain was defined as post-intervention MLD minus pre-intervention MLD.

**Statistics.** Results are reported as means  $\pm$  standard deviations or percentages of the total. For statistical comparison, cases were stratified into three groups based on stent deployment: DES, BMS, or no stent. Statistical analysis was done using SAS, version 9.1 (*SAS Institute, Inc., Cary, North Carolina*). Statistical significance was considered a *p*-value or *F*-value < 0.05. A one-way ANOVA was used to compare continuous variables. Then, if the overall *F*-value was < 0.05, a *post-hoc* analysis (Tukey's test) was done. Discrete variables from the three groups were compared using Fisher's exact test. If the overall *p*-value was < 0.05, then a pairwise comparison was done. In-hospital

complications were then reanalyzed with the patients restratified based on intention-to-treat so that patients with failed attempts at DES placement were included in the DES group.

## Results

A total of 268 cases involving RA were identified between January 1, 2004 and December 31, 2009. After excluding cases involving an intervention on the left main coronary artery (*n* = 31), brachytherapy (*n* = 10), or in which the angiographic images could not be obtained (*n* = 69), a total of 158 cases (involving 236 lesions) were included. DES were implanted in 112 patients (158 lesions), BMS were placed in 19 patients (28 lesions), and no stent was placed in 27 patients (50 lesions) (Table 1).

The patients were elderly ( $72.3 \pm 11$  years) and comorbidities were common, including hypertension in 89%, diabetes mellitus in 46% and hyperlipidemia in 69% (Table 1). Compared with the DES group, the BMS group had lower ejection fractions (ejection fraction  $\leq 35\%$  was 21% with DES versus 53% with BMS; *p* = 0.0163), and the no stent group had a smaller mean reference vessel diameter ( $2.54 \pm 0.46$  mm versus  $2.22 \pm 0.66$  mm; *p* < 0.0001). Compared with the DES group, the BMS and no stent groups had significantly more diseased vessels (2.0 versus 2.4 versus 2.4 diseased vessels, respectively; *p* = 0.0205). Patients who presented with angina typically received DES, whereas a BMS was slightly more common after a recent myocardial infarction and patients with silent ischemia were more likely not to receive a stent. The other measured baseline characteristics did not differ between the 3 groups.

**Indications for RA.** RA was indicated for plaque modification in the setting of moderate to severe calcification in 84% of lesions, but calcification was not the sole indication for RA in this series (Table 2). In 60 patients (25%), RA was deployed to preserve the patency of a sidebranch. RA was deployed in 13 chronic total occlusions and 7 in-stent restenoses, all of which achieved angiographic and procedural success. In 37 lesions (16%; 34 severe and 2 moderate calcifications), RA was not planned but was utilized as "bail-out" therapy after a prior attempt at PCI had failed or an angioplasty balloon could not be delivered to the lesion (some lesions had multiple indications for RA, so the sum of indications is > 100%).

**DES implantation.** Most patients were treated with a stent (80%), and most stents were DES (71% of all patients). DES were avoided due to clinical factors in 37 patients (23%) for reasons that included a vessel diameter < 2.25 mm or > 3.75 mm, impending surgery and a high risk for bleeding (Table 3). In 9 patients (6%), DES implantation was attempted but failed due to an inability to deliver the stent to the lesion, vessel dissection (BMS used to avoid delayed endothelialization) or vessel perforation (no stent placed to avoid increased bleeding risk with clopidogrel). Thus, DES were successfully implanted in 94% of patients in whom DES placement was attempted despite severe calcification and lesion complexity.

**Procedural and in-hospital outcomes.** Angiographic success and procedural success were achieved significantly more frequently in the DES and BMS groups compared with the no

Table 1. Baseline patient and lesion characteristics.

	Total	DES	BMS	No Stent	p-Value
Number of patients	158	112	19	27	
Number of lesions	236	158	28	50	
Age (years)	72.3 ± 11 (158)	72.9 ± 11 (112)	69.5 ± 12 (19)	71.6 ± 13 (27)	0.4290
Gender, male	68% (107/158)	63% (71/112)	89% (17/19)	70% (19/27)	0.0743
Race					0.0580
Caucasian	37% (58/158)	38% (43/112)	32% (6/19)	33% (9/27)	
Asian	32% (51/158)	35% (39/112)	42% (8/19)	15% (4/27)	
Hispanic	22% (34/158)	19% (21/112)	21% (4/19)	33% (9/27)	
Black	4% (7/158)	2% (2/112)	5% (1/19)	15% (4/27)	
Unknown/other	5% (8/158)	6% (7/112)	0% (0/19)	4% (1/27)	0.4577
Hypertension	89% (141/158)	91% (102/112)	84% (16/19)	85% (23/27)	0.3962
Diabetes mellitus	46% (72/158)	46% (52/112)	32% (6/19)	52% (14/27)	0.6561
Insulin-dependent	19% (30/158)	20% (22/112)	11% (2/19)	22% (6/27)	0.0728
Hyperlipidemia	69% (109/158)	73% (82/112)	47% (9/19)	67% (18/27)	0.3820
Current smoker	18% (28/158)	15% (17/112)	21% (4/19)	26% (7/27)	
Remote PCI	37% (58/158)	37% (41/112)	26% (5/19)	44% (12/27)	0.4759
Remote MI	20% (32/158)	17% (19/112)	37% (7/19)	22% (6/27)	0.1191
Remote CABG	13% (20/158)	11% (12/112)	16% (3/19)	19% (5/27)	0.4094
Creatinine					
Mean ± SD (n) (mg/dl)	1.7 ± 2.1 (157)	1.7 ± 2.1 (112)	2.0 ± 2.0 (19)	1.8 ± 2.1 (26)	0.7514
% (n) ≥ 1.4	25% (39/157)	24% (27/112)	37% (7/19)	19% (5/26)	0.3739
Hemodialysis	12% (19/158)	10% (11/112)	21% (4/19)	15% (4/27)	0.2832
Ejection fraction	47 ± 17% (147)	50 ± 16% (101)	39 ± 18% (19)	45 ± 16% (27)	0.0403*
% (n) ≤ 35%	27% (40/147)	21% (21/101)	53% (10/19)	30% (8/27)	0.0163*
Presentation					0.0034**
Stable angina	32% (50/158)	35% (39/112)	21% (4/19)	26% (7/27)	
Unstable angina	22% (35/158)	28% (31/112)	11% (2/19)	7% (2/27)	
Silent ischemia	22% (35/158)	18% (20/112)	21% (4/19)	41% (11/27)	
Recent MI	21% (33/158)	19% (21/112)	37% (7/19)	19% (5/27)	
Acute MI	1% (2/158)	1% (1/112)	0% (0/19)	4% (1/27)	
Cardiogenic shock	2% (3/158)	0% (0/112)	11% (2/19)	4% (1/27)	
Number of diseased vessels (n)	2.1 ± 0.8 (158)	2.0 ± 0.8 (112)	2.4 ± 0.7 (19)	2.4 ± 0.7 (27)	0.0205**
Left main disease	6% (10/158)	4% (5/112)	5% (1/19)	15% (4/27)	0.1150
Lesion length (mm)	13.6 ± 7.6 (236)	13.7 ± 7.1 (158)	13.8 ± 8.3 (28)	13.2 ± 9.0 (50)	0.9185
RVD (mm)	2.55 ± 0.66 (236)	2.54 ± 0.46 (158)	3.24 ± 1.07 (28)	2.22 ± 0.66 (50)	< 0.0001***
Intervention vessel					
LAD	55% (130/236)	61% (96/158)	46% (13/28)	42% (21/50)	0.0407†
LCx	14% (33/236)	9% (15/158)	4% (1/28)	34% (17/50)	< 0.0001**
RCA	31% (73/236)	30% (47/158)	50% (14/28)	24% (12/50)	0.0546**
Lesion characteristics					
Ostial	28% (66/236)	25% (39/158)	18% (5/28)	44% (22/50)	0.0165†‡
Bifurcation	15% (37/236)	20% (31/158)	7% (2/28)	8% (4/50)	0.0657
Eccentric	32% (76/236)	33% (52/158)	39% (11/28)	26% (13/50)	0.4707
Restenosis	3% (7/236)	4% (6/158)	0% (0/28)	2% (1/50)	0.8543
Chronic total occlusion	6% (13/236)	6% (10/158)	0% (0/28)	6% (3/50)	0.6093
Lesion angulation > 45°	3% (6/236)	3% (5/158)	0% (0/28)	2% (1/50)	1.0
Proximal tortuosity	3% (6/236)	3% (5/158)	4% (1/28)	0% (0/50)	0.4392
Calcification					0.2263
None	9% (22/236)	8% (13/158)	3% (1/28)	16% (8/50)	
Mild	3% (8/236)	5% (8/158)	0% (0/28)	0% (0/50)	
Moderate	8% (20/236)	7% (12/158)	10% (2/28)	12% (6/50)	
Severe	79% (186/236)	79% (125/158)	87% (25/28)	72% (36/50)	
Classification					0.6748
A	2% (4/236)	2% (3/158)	0% (0/28)	2% (1/50)	
B1	5% (12/236)	4% (6/158)	7% (2/28)	8% (4/50)	
B2	63% (148/236)	63% (99/158)	71% (20/28)	58% (29/50)	
C	31% (72/236)	32% (50/158)	21% (6/28)	32% (16/50)	

DES = drug-eluting stent; BMS = bare-metal stent; PCI = percutaneous coronary intervention; MI = myocardial infarction; CABG = coronary artery bypass graft surgery; RCA = right coronary artery; RVD = reference vessel diameter; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery. \*DES versus BMS, p < 0.05; †DES versus no stent, p < 0.05; ‡BMS versus no stent, p < 0.05.

**Table 2.** Indication for and use of rotational atherectomy.

Reason for RA	Total	DES	BMS	No Stent
Outright/planned	84% (199/236)	86% (136/158)	79% (22/28)	82% (41/50)
Moderate or severe calcification	84% (198/236)	84% (133/158)	86% (24/28)	82% (41/50)
Preserve sidebranch patency	25% (60/236)	26% (41/158)	7% (2/28)	30% (15/50)
Chronic total occlusion	2% (4/236)	1% (2/158)	0% (0/28)	4% (2/50)
In-stent restenosis	1% (3/236)	1% (2/158)	0% (0/28)	2% (1/50)
Secondary lesion	3% (7/236)	3% (5/158)	0% (0/28)	4% (2/50)
Bail-out/not planned	16% (37/236)	14% (22/158)	21% (6/28)	18% (9/50)
Prior PCI failed	9% (21/236)	6% (9/158)	21% (6/28)	12% (6/50)
Balloon did not pass	8% (18/236)	8% (13/158)	4% (1/28)	10% (5/50)
Balloon did not expand	4% (10/236)	3% (4/158)	14% (4/28)	4% (2/50)

DES = drug-eluting stent; BMS = bare-metal stent; RA = rotational atherectomy; PCI = percutaneous coronary intervention.

stent group (angiographic success: 99.1% versus 95% versus 63%, respectively;  $p < 0.0001$ ; procedural success: 96.4% versus 95% versus 63%, respectively;  $p < 0.0001$ ) (Table 4). Overall, in these high-risk patients undergoing RA, MACE occurred in 5.7% during the index hospitalization, including death in 3.2% (Table 4). Angiographic success was not achieved in 11 patients, which included 4 deaths and 1 emergency CABG. Compared with the no stent group, the DES group had a significantly lower death rate (11.1% versus 0.9%;  $p = 0.0232$ ) and MACE rate (14.8% versus 3.6%;  $p = 0.0459$ ).

Of the 9 patients in whom attempts to place a DES failed, MACE occurred in 3 patients, including death in 2 patients; therefore, Fisher’s exact test was repeated with these 9 DES failures included in the DES group (they were previously in the BMS and no stent groups according to the treatment they ultimately received). The repeat analysis again showed the DES group to be superior to the no stent group for angiographic and procedural success (angiographic success: 95.9% for DES versus 100% for BMS versus 73.9% for no stent; DES versus no stent  $p < 0.05$

5). Final burr size was  $1.50 \pm 0.22$  mm and was similar among the three groups. The final burr-to-vessel ratio was larger in the no stent group ( $0.71 \pm 0.17$ ) compared to each of the stent groups (DES,  $0.60 \pm 0.11$ ; BMS,  $0.50 \pm 0.09$ ). Balloon angioplasty was utilized less often and with a lower maximum pressure in the no stent group (70%;  $7.0 \pm 4.1$  atm) compared with each of the stent groups (DES, 92% and  $9.9 \pm 4.0$  atm; BMS, 93% and  $11.4 \pm 4.8$  atm). Eighty-four of 186 stented lesions (45%) underwent post-dilation at a mean maximum inflation pressure of  $15.8 \pm 3.9$  atm. Utilization of intravascular ultrasound was low (3.8%) and procedure times were long ( $96 \pm 31$  minutes).

**Quantitative coronary angiography.** Reference vessel diameter differed significantly between each group:  $2.54 \pm 0.46$  mm in the DES group,  $3.24 \pm 1.07$  mm in the BMS group, and  $2.22 \pm 0.66$  mm in the no stent group; Table 5). Similarly, MLD measured initially, after RA, and after stenting differed between groups. Percent diameter stenosis was similar between groups before and after intervention, except that the no stent group reached a smaller percent diameter stenosis after RA and

for each; BMS versus no stent  $p = 0.0645$  for each; data not shown in Table). The in-hospital death and MACE rates were no longer significantly different on repeat analysis (death rate: 2.5% for DES versus 0% for BMS versus 8.7% for no stent;  $p = 0.2129$ ; MACE rate: 5.0% for DES versus 0% for BMS versus 8.7% for no stent;  $p = 0.6940$ ).

**Procedural characteristics.**

Thirty-three percent of patients were treated with multiple burrs (mean,  $1.40 \pm 0.62$  burrs) (Table

**Table 3.** Reasons for not implanting drug-eluting stent.

	By Patient			By Lesion		
	DES (n = 121)	BMS (n = 14)	No Stent (n = 23)	DES (n = 170)	BMS (n = 22)	No Stent (n = 44)
DES implanted	71% (112/158)	0%	0%	67% (158/236)	0%	0%
DES attempted but failed	6% (9/158)	0%	0%	5% (12/236)	0%	0%
Unable to deliver stent*	5			6		
Perforation†	1			1		
Dissection‡	2			2		
Unknown	1			3		
DES not attempted	0%	9% (14/158)	9% (14/158)	0%	9% (22/236)	19% (44/236)
Vessel diameter < 2.25 mm		0	0		0	22
Vessel diameter > 3.75 mm		4	4		9	0
Impending surgery		3	3		3	6
High risk for bleeding		6	6		9	0
Active bleeding		1	1		1	1
Cancer		0	0		0	2
Good angiographic result		0	0		0	2
Vessel size mismatch		0	0		0	1
To avoid jailing a major branch		0	0		0	10

DES = drug-eluting stent; BMS = bare-metal stent. \*2 patients and 2 lesions treated with BMS, the rest with no stent; †treated with no stent; ‡treated with BMS.

**Table 4.** Procedural complications and in-hospital outcomes.

	Total	DES	BMS	No Stent	p-Value
Angiographic success	92.4% (146/158)	99.1% (111/112)	95% (18/19)	63% (17/27)	< 0.0001**
Procedural success	90.5% (143/158)	96.4% (108/112)	95% (18/19)	63% (17/27)	< 0.0001**
MACE	5.7% (9/158)	3.6% (4/112)	5.3% (1/19)	14.8% (4/27)	0.0471†
Death	3.2% (5/158)	0.9% (1/112)	5.3% (1/19)	11.1% (3/27)	0.0246†
CABG	0.6% (1/158)	0.0% (0/112)	0.0% (0/19)	3.7% (1/27)	0.2911
Q-wave MI	0.6% (1/158)	0.9% (1/112)	0.0% (0/19)	0.0% (0/27)	1.0
Non-Q wave MI	1.3% (2/158)	1.8% (2/112)	0.0% (0/19)	0.0% (0/27)	1.0
Procedural complications					
Dissection	4.2% (9/236)	4% (6/158)	7% (2/28)	2% (1/50)	0.4403
Perforation	0.8% (2/236)	0% (0/158)	0% (0/28)	4% (2/50)	0.0578
Sidebranch occlusion	0.4% (1/236)	1% (1/158)	0% (0/28)	0% (0/50)	1.0
Thrombosis	0.0% (0/236)	0% (0/158)	0% (0/28)	0% (0/50)	1.0
Occlusive spasm	2.1% (5/236)	2% (3/158)	0% (0/28)	4% (2/50)	0.6318
No reflow	2.1% (5/236)	2% (3/158)	7% (2/28)	0% (0/50)	0.1725
Hypotension and/or bradycardia	3.0% (7/236)	3% (4/158)	4% (1/28)	4% (2/50)	0.5941

DES = drug-eluting stent; BMS = bare-metal stent; CABG = coronary artery bypass graft surgery; MI = myocardial infarction; MACE = major adverse cardiovascular events. †DES versus no stent,  $p < 0.05$ ; ‡BMS versus no stent,  $p < 0.05$ .

balloon angioplasty compared with each of the stent groups. In these complex, heavily calcified lesions, RA combined with stenting achieved a total acute gain of  $1.58 \pm 0.56$  mm, and reduced an initial percent diameter stenosis of  $68 \pm 14\%$  to  $8 \pm 12\%$ . A small degree of vasoconstriction was frequently observed following RA as suggested by the mean minimal luminal diameter after RA and PTCA ( $1.47 \pm 0.39$  mm) being smaller than the mean burr size ( $1.50 \pm 0.22$  mm).

**Procedural complications.** In this series with 37 bifurcation lesions (15%) and 66 ostial lesions (28%), RA was deployed specifically to preserve sidebranch patency in 60 lesions. Sidebranch patency was preserved in 59 of these 60 lesions (98.3%). Overall, procedural complications included coronary artery dissection in 4.2%, perforation in 0.8%, sidebranch occlusion in 0.4% and acute stent thrombosis in 0% (Table 4). Both perforations were contained (1 small, 1 moderate in size) and treated successfully with prolonged balloon inflations. Six of the 9 vessel dissections were small (type A or B). Three vessel dissections were type E or F and resulted in a Q-wave myocardial infarction, an emergency CABG surgery, and a death. The type F dissection was attributed to the guidewire and 1 of the type E dissections was attributed to balloon angioplasty. Occlusive coronary spasm occurred in 2.1% and marked no reflow was noted in 2.1%. Two cases each of occlusive spasm and no reflow correlated with significant hypotension and/or bradycardia that responded to medical therapy.

## Discussion

This study sought to describe the contemporary use of RA in the DES era. This study confirms that RA is used primarily in complex lesions with moderate to severe calcification where the operators felt balloon angioplasty and stenting alone would not be sufficient. Additionally, this real-world experience reflects the use of RA to preserve the patency of sidebranches in bifurcation and ostial lesions and to debulk large plaque burdens in chronic total occlusions and in-stent restenoses. In the DES era, RA is followed by DES deployment in approximately 3 of 4 patients, whereas 1

in 4 patients are treated with BMS or no stent due to clinical and procedural characteristics, including vessel size. In unadjusted analyses, angiographic and procedural success rates are higher when a stent (either DES or BMS) is placed. However, those in whom no stent was placed faced greater angiographic and procedural failure rates. Anticipated ability to place a stent should be taken into account prior to embarking on RA.

The literature describes the use of RA in heavily calcified lesions to improve procedural success<sup>5,6</sup> and improve stent expansion.<sup>4,7-10</sup> RA enabled DES deployment in nondilatable, calcified lesions.<sup>16,17</sup> In heavily calcified lesions, RA and DES deployment results in target lesion revascularization rates ranging from 2–10.6% at 6 months to 3 years, which is significantly better than RA and BMS.<sup>12-16</sup> Reports on RA and DES focused on calcified lesions.<sup>12-16</sup>

**RA to modify calcified plaque.** RA was employed to modify calcified plaque in 199 lesions (84%) in this series and successfully facilitated DES implantation in 112 of 121 attempts (92.6%). When utilized to facilitate stent implantation in heavily calcified lesions, RA is performed with a relatively small burr-to-vessel ratio (0.5–0.6) because maximizing luminal gain is not necessary.<sup>8,11,13,17</sup> Rather, the objective is to alter the compliance of a calcified lesion in order to optimize stent expansion. In heavily calcified, eccentric lesions, stent expansion is optimized and more symmetric following adjuvant RA to reduce the lesion's rigidity and eccentricity.<sup>9</sup> The benefit of RA cannot be measured by its corresponding acute luminal gain, which was  $0.67 \pm 0.42$  mm in this series. Instead, the impact of RA is reflected in the residual percent stenosis after stenting ( $8 \pm 12\%$  in this series), which would not have been possible without plaque modification from RA. Our operators had a low threshold for using RA to treat heavily calcified lesions. Had RA not been planned, percutaneous intervention by way of stent deployment may have failed in a substantial portion of these calcified lesions, meaning the percentage of "bail-out" procedures would have been higher than reported (37 lesions; 16%). The greatest clinical impact of RA may be enabling percutaneous intervention in lesions that may otherwise require surgical revascularization.

**Table 5.** Procedural characteristics and quantitative coronary angiography.

	Total	DES	BMS	No Stent	p-Value
Burrs					
Number of burrs	1.40 ± 0.62 (236)	1.39 ± 0.60 (158)	1.46 ± 0.69 (28)	1.40 ± 0.64 (50)	0.894
≥ 2 burrs	33% (77/236)	32% (54/170)	32% (7/22)	36% (16/44)	
Final burr size (mm)	1.50 ± 0.22 (236)	1.50 ± 0.22 (158)	1.54 ± 0.23 (28)	1.49 ± 0.21 (50)	0.722
Final burr-to-vessel ratio	0.61 ± 0.14 (236)	0.60 ± 0.11 (158)	0.50 ± 0.09 (28)	0.71 ± 0.17 (50)	< 0.0001**†
Balloon angioplasty	87% (206/236)	92% (145/158)	93% (26/28)	70% (35/50)	< 0.001**
Maximum pressure (atm)	9.6 ± 4.3 (201)	9.9 ± 4.0 (145)	11.4 ± 4.8 (26)	7.0 ± 4.1 (35)	< 0.0001**
Stenting	79% (186/236)				
DES	67% (158/236)	100% (158)			
BMS	12% (28/236)		100% (28)		
No stent	21% (50/236)			100% (50)	
Stent diameter (mm)	2.79 ± 0.5 (186)	2.71 ± 0.3 (158)	3.24 ± 0.9 (28)		< 0.0001*
Stent length (mm)	20.0 ± 6.5 (186)	20.0 ± 6.6 (158)	19.8 ± 6.0 (28)		0.9091
Maximum pressure (atm)	14.5 ± 3.2 (186)	14.3 ± 3.2 (158)	15.7 ± 2.7 (28)		0.0366*
Post-dilation	45% (84/186)	44% (70/158)	50% (14/28)		0.6812
Maximum post-dilation pressure (atm)	15.8 ± 3.9 (84)	15.4 ± 3.8 (70)	18.0 ± 3.2 (14)		0.0204*
IVUS	3.8% (9/236)	5% (8/158)	0% (0/28)	2% (1/50)	0.587
Left ventricular assist device <sup>§</sup>	6.3% (10/158)	4% (4/112)	21% (4/19)	4% (2/50)	0.0140*
Procedural time (min)	96 ± 31 (145)	96 ± 31 (103)	109 ± 37 (17)	88 ± 25 (25)	0.0949
Fluoroscopy time (min)	30 ± 13 (153)	30 ± 12 (109)	33 ± 10 (18)	29 ± 16 (26)	0.4763
Contrast (ml)	212 ± 88 (154)	217 ± 91(110)	237 ± 91 (18)	173 ± 62 (26)	0.0332‡
Length (mm)	13.6 ± 7.6 (236)	13.7 ± 7.1 (158)	13.8 ± 8.3 (28)	13.2 ± 9.0 (50)	0.9185
RVD (mm)	2.55 ± 0.66 (236)	2.54 ± 0.46 (158)	3.24 ± 1.07 (28)	2.22 ± 0.66 (50)	< 0.0001**†
MLD (mm)					
Initially	0.80 ± 0.38 (236)	0.82 ± 0.36 (158)	0.94 ± 0.56 (28)	0.64 ± 0.31 (50)	0.0012**
After RA ± PTCA	1.47 ± 0.39 (236)	1.47 ± 0.35 (158)	1.63 ± 0.57 (28)	1.40 ± 0.39 (50)	0.0444‡
After stent	2.42 ± 0.54 (186)	2.34 ± 0.44 (158)	2.86 ± 0.81 (28)		< 0.0001*
Percent diameter stenosis					
Initially	68 ± 14% (236)	67 ± 14% (158)	71 ± 12% (28)	70 ± 15% (50)	0.1931
After RA ± PTCA	41 ± 13% (236)	42 ± 12% (158)	49 ± 11% (28)	35 ± 15% (50)	< 0.0001**
After stent	8 ± 12% (236)	7 ± 12% (158)	10 ± 11% (28)		0.3002
Acute gain (mm)					
After RA ± PTCA	0.67 ± 0.42 (236)	0.64 ± 0.39 (158)	0.68 ± 0.51 (28)	0.76 ± 0.43 (50)	
After stenting	0.93 ± 0.43 (186)	0.88 ± 0.38 (158)	1.23 ± 0.54 (28)		
Total acute gain	1.41 ± 0.63 (236)	1.52 ± 0.54 (158)	1.92 ± 0.61 (28)	0.76 ± 0.43 (50)	

DES = drug-eluting stent; BMS = bare-metal stent; IVUS = intravascular ultrasound; MLD = minimal luminal diameter; RA = rotational atherectomy; PTCA = percutaneous transluminal coronary angioplasty; reference vessel diameter. \*DES versus BMS,  $p < 0.05$ ; †DES versus no stent,  $p < 0.05$ ; ‡BMS versus no stent,  $p < 0.05$ ; § Tandem Heart (Cardiac Assist Technologies, Inc., Ithaca, New York), 3 intra-aortic balloon pumps.

Of note, a burr-to-vessel ratio < 0.7 reduced the incidence of serious angiographic complications in a randomized study.<sup>19</sup> RA may also improve drug delivery to the subintimal tissue by limiting trauma to the DES coating during deployment in rigid, calcified lesions.<sup>13</sup>

**Indications for RA.** RA was indicated for moderate to severe calcification in 84% of patients in this series. However, in contrast to other reports of RA and DES, this real-world experience also included the use of RA to preserve sidebranch patency in 60 lesions (25%), and to debulk large plaque burdens in 13 chronic total occlusions and 7 in-stent restenoses. Considering the current trend toward the exclusive use of balloon angioplasty and stenting and less use of other modalities in percutaneous coronary interventions, it is important to note these indications for RA in lesion subsets that pose challenges to balloon angioplasty and stenting.

**RA to prevent sidebranch occlusion.** In bifurcation and ostial lesions, RA preserved the patency of sidebranches by debulking large

plaque burdens and limiting the “snow plow” effect whereby balloon or stent expansion shifts plaque from one vessel into another vessel, compromising its patency.<sup>20,21</sup> In this series, RA successfully preserved sidebranch patency in 59 of 60 lesions (98.3%). Often, the parent vessel with a bifurcation lesion was treated with routine DES implantation, whereas the smaller “daughter” branch with ostial disease was treated with provisional stenting. This technique is reflected in the significantly higher portion of ostial lesions in the no stent group and the trend toward increased bifurcation lesions in the DES group (Table 1).

**Drug-eluting stent implantation following RA.** In the DES era, and in this series, DES are routinely implanted during coronary intervention unless the clinical situation dictates otherwise. Indeed, RA was followed by DES implantation in 112 patients (71%) in this series. DES implantation was attempted but failed in an additional 9 patients (6%) due to vessel perforation ( $n = 1$ ), dissection ( $n = 2$ ), or an inability to deliver the stent because of

severe calcification (n = 5). A BMS was planned in 14 patients (9%) and no stent was planned in 23 patients (15%). DES were avoided because of a reference vessel diameter < 2.25 mm or > 3.75 mm (DES are not produced this large), or to avert the need for clopidogrel therapy in patients with impending surgery or at high risk for bleeding.

**Angiographic success and in-hospital outcomes.** In accordance with the literature, angiographic success (defined as < 40% residual stenosis and TIMI 3 flow) and procedural success rates were higher in patients treated with DES or BMS compared with no stent. Without stent implantation, luminal gain was less and the intervention was less likely to achieve < 40% residual stenosis.

Initial analysis suggested that in-hospital death and MACE rates were improved in patients treated with a DES compared with no stent. However, the differences were due to the inclusion of DES failures in the BMS and no stent groups and the difference was no longer significant when patients were restratified based on intention-to-treat (DES failures included in the DES group). Despite a high-risk patient population and complex, heavily calcified lesions, overall angiographic success was high (92.4%) and in-hospital deaths (3.2%) and MACE (5.7%) were low. Each of the 5 patients who died was critically ill prior to the procedure, including 3 in cardiogenic shock, 1 with significant left main, left anterior descending and left circumflex disease in whom repeat CABG was deemed too high-risk, and 1 who presented with syncope and a hip fracture who then underwent carotid endarterectomy complicated by a cerebrovascular accident, aspiration pneumonia and lung collapse. Upon review of these findings, perhaps 1 patient would have benefited from a DES in the ostial left anterior descending coronary artery (no stent was placed to avoid jailing the circumflex artery in the setting of cardiogenic shock). Another patient died after a stent could not be delivered to the lesion, highlighting the severity of atherosclerotic disease in this cohort of patients and perhaps also the importance of further luminal gain achieved by stent implantation irregardless of pretreatment with RA.

**Study limitations.** The treatment of “secondary” lesions impacted these results. RA was indicated for the majority of secondary lesions due to calcification, but the degree of stenosis of many secondary lesions would not have prompted intervention without their proximity to the culprit lesion. Thus, the inclusion of secondary lesions reduced what would have been a higher initial percent diameter stenosis. All 4 class A lesions were secondary lesions.

As all patients received RA, this was not a study of whether RA is superior to other approaches in these patients, but rather a descriptive study of the real-world outcomes in those who receive RA in the current era. Thus, no statements can be made regarding the merits of RA over alternate approaches. It is uncertain whether the results of this retrospective analysis at a single center will translate prospectively to interventional practice in the community. A total of 69 patients were excluded because the angiographic images could not be obtained. Consequently, this relatively small number of patients may not be representative of the larger cohort or of larger patient populations. Differences in outcomes were not adjusted for baseline or angiographic differences. Long-term follow up was not

investigated, where DES are expected to demonstrate benefit over BMS and over RA alone.

## Conclusion

In the DES era, it appears that RA is used primarily in patients with moderate to severe calcification, but other indications were also noted. In the current DES era, approximately 3 of 4 patients treated with RA subsequently received a DES and were met with high angiographic and procedural success; however, DES were avoided or not deliverable in approximately 1 of 4 patients. Importantly, these latter patients had significantly lower angiographic and procedural success rates. Anticipated ability to place a stent (either BMS or DES) should therefore be considered prior to embarking on RA in the current era.

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