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Original Article

# The use and clinical outcomes of rotablation in challenging cases in the drug-eluting stent era

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**Abstract**

*Background*: Rotational atherectomy (RA) has been advocated in the bare metal stent (BMS) era but is underused now due to technique demands and nonsuperior outcomes. The aim of this study was to evaluate the procedural and clinical outcomes of patients with very complex, severely calcified coronary lesions treated by RA and drug-eluting stents (DESs) in our current percutaneous coronary intervention (PCI) practice in a region where RA use has been limited by lack of insurance reimbursement.

*Methods*: From March 2004 to November 2010, all consecutive patients who required RA treatment for severely calcified *de novo* lesions of native coronary arteries followed by DES implantation were queried from the cath lab database and recruited. Their clinical and angiographic characteristics at the index PCI were analyzed and completed by a thorough review of the medical charts.

*Results*: A total of 67 consecutive patients with 71 very complex, heavily calcified coronary lesions treated with RA plus DES were recruited. Of these patients, 64% presented with acute coronary syndrome, 9.0% with cardiogenic shock, 43.3% with chronic renal failure, and 50.7% with diabetes. Multiple-vessel diseases were found in 92.5% of our patients, and the average coronary artery calcification (CAC) score was $3.6 \pm 1.4$. Of the coronary lesions, 26.7% were either balloon-uncrossable or balloon-undilatable. The angiographic success rate was 100% with one non-Q myocardial infarction. Five patients (7.5%) died in hospital, all initially presenting with extensive myocardial infarction and/or cardiogenic shock. The out-of-hospital major adverse cardiac event was 17.9% at the mean follow-up of 23.2 months (range: 5–86), primarily due to high target-lesion revascularization and target-vessel revascularization rates of 10.4% and 10.4%, respectively. Only one (1.5%) probable subacute stent thrombosis was observed in the follow-up.

*Conclusion*: RA with DES implantation in very complex, heavily calcified coronary lesions can achieve very low complication and low out-of-hospital major adverse cardiac event rates even in high-risk patients despite use limited by lack of insurance reimbursement. The study results convince us to sustain and even broaden the use of this novel, but underused, device in the DES era.



*Keywords:* coronary calcification; drug-eluting stents; rotational atherectomy

## 1. Introduction

Severely calcified coronary lesions, by virtue of their rigidity, often require multiple balloon inflations at high pressures to eliminate the "waist" of the stenoses. Vessels exposed to high inflation pressure had a significantly higher incidence of mural thrombus, dissection, and medial necrosis.[1] It is not unusual that calcified lesions cannot be crossed with even the smallest available balloons. Very tight calcified lesions may also resist dilatation even at the highest possible balloon pressure or may cause rupture of the balloons at low inflation pressure. Furthermore, stent delivery to calcified lesions may be difficult and stent expansion suboptimal due to

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high resistance of the calcified plaques. Rotational atherectomy (RA), with its ability to differentially ablate calcified plaques, is particularly useful in these lesions.[2,3] RA has been advocated in the bare metal stents (BMSs) era. However, in the published literature,[4] it has often been underused due to technical difficulty, cumbersome setup, and nonsuperior outcomes. The ever-growing use of percutaneous coronary interventions (PCIs) in calcified, chronically totally occluded (CTO), complex, bifurcational, and left main lesions in recent years may demand more procedural use of these ablation devices.[5−7] Drug-eluting stents (DESs) have been widely used recently because of their consistent treatment benefits of reducing restenosis and clinical events compared with BMS.[8] DES also provided good follow-up results for a premature coronary artery disease (CAD) group with multiple atherosclerotic risk factors.[9] However, DESs face the same issues as BMSs in calcified and resistant lesions. Up-to-date but limited clinical data are available on the outcomes of RA in challenging heavily calcified coronary lesions in the DES era, especially in the Chinese population.[10] Therefore, it was important to investigate the outcomes of RA plus DES in a region where use of the device was not reimbursed by insurance and frequently taken as the last resort for difficult-to-treat lesions. The aim of this study was to evaluate the procedural and clinical outcomes of patients with very complex, severely calcified coronary lesions treated by RA and DES in our current PCI practice.

## 2. Methods

### 2.1. Patient population

A Windows 2000-based cardiac catheterization report databank has been established at Taichung Veterans General Hospital (TCVGH). It uses the hospital-information-system data stored in the mainframe computer and contains all angiographic reports over the past 15 years. From March 2004 to November 2010, all consecutive patients who required RA treatment for severely calcified *de novo* lesions of native coronary arteries followed immediately by DES implantation were queried from the database for recruitment. All participants with interventions for restenotic lesions were excluded. Patients were also excluded from the study if the RA was followed by BMS placement or balloon angioplasty only. The relevant clinical and angiographic data at the time of index PCI were retrieved from the database and completed by thorough review of the medical chart records. This study protocol was approved by the Institutional Review Board for Human Research and the ethics committee of TCVGH.

### 2.2. Angiographic characterization and measurements

The angiographic measurements were made on a viewing workstation with software for quantitative analysis of angiograms (Medcon/Horizon/TCS, Tel Aviv, Israel). The angiographic characteristics of target coronary lesions in the index coronary angiogram were obtained by reviewing the session cine thoroughly. The CAD vessel numbers were defined as the number of the three major coronary vessels that had a 70% or greater stenotic diameter. Coronary artery calcification (CAC) was defined as readily apparent radio-opacities within the vascular walls on the cine before contrast medium injection. The CAC score in the target lesion was measured by cine-fluoroscopy at the time of diagnostic coronary angiography. The angiographic scoring system was as follows: 0, none; 1, blocky or spotty calcification; 2, linear calcification compromising one side of the arterial lumen; 3, linear calcification found unidirectionally compromising both sides of the arterial lumen; 4, linear calcification found bidirectionally compromising both sides of the arterial lumen; and 5, blanket/circumferential and dense calcification.[11]

All PCIs were performed by experienced, qualified operators using standard practice at our cath lab. Patients were pretreated with aspirin and clopidogrel, or a minimum of 300 mg loading dose of clopidogrel was administered if, in rare cases, patients were not pretreated. Heparin was administered to maintain an activated clotting time (ACT) of $>$ 300 seconds or about 200 seconds if a GP IIb/IIIA inhibitor was used. Rotablation procedures started with a 1.25 or 1.5 mm burr at a speed of 180,000−200,000 rpm and were mostly supplemented by another burr one size bigger. The PCI then proceeded with balloon dilatation and DES implantation to achieve minimal residual stenosis. Dual-antiplatelet therapy with aspirin and clopidogrel (75 mg/day) was continued for at least 12 months after DES implantation.

Angiographic success was defined as achievement of a residual stenosis $<$ 20% in the presence of Grade III thrombolysis in myocardial infarction (TIMI) flow. The procedural success was defined as achieving angiographic success without in-hospital major adverse cardiac events (MACEs), including all-cause death, myocardial infarction (MI), and repeat revascularization. MI was defined according to current guidelines.[12] Target lesion revascularization (TLR) was defined as a repeat revascularization for a restenosis $>$ 50% in the target segment. Target vessel revascularization (TVR) was defined as any repeat revascularization within the treated vessel. Stent thrombosis was classified according to the Academic Research Consortium (ARC) definition.[13]

### 2.3. Statistical analysis

Descriptive analyses were used in this study. Continuous variables were reported as mean $\pm$ standard deviation. Categoric variables are presented as frequencies with percentage.

## 3. Results

During the study period, a total of 126 rotablations (2.4% of all PCIs) were done (Fig. 1). Excluding procedures for native or intrastent restenotic lesions and those not supplemented by DES, a total of 67 patients with 71 severely calcified *de novo* coronary lesions, which were successfully treated with RA plus DES implantation, were recruited into this study and retrospectively analyzed. The baseline clinical characteristics

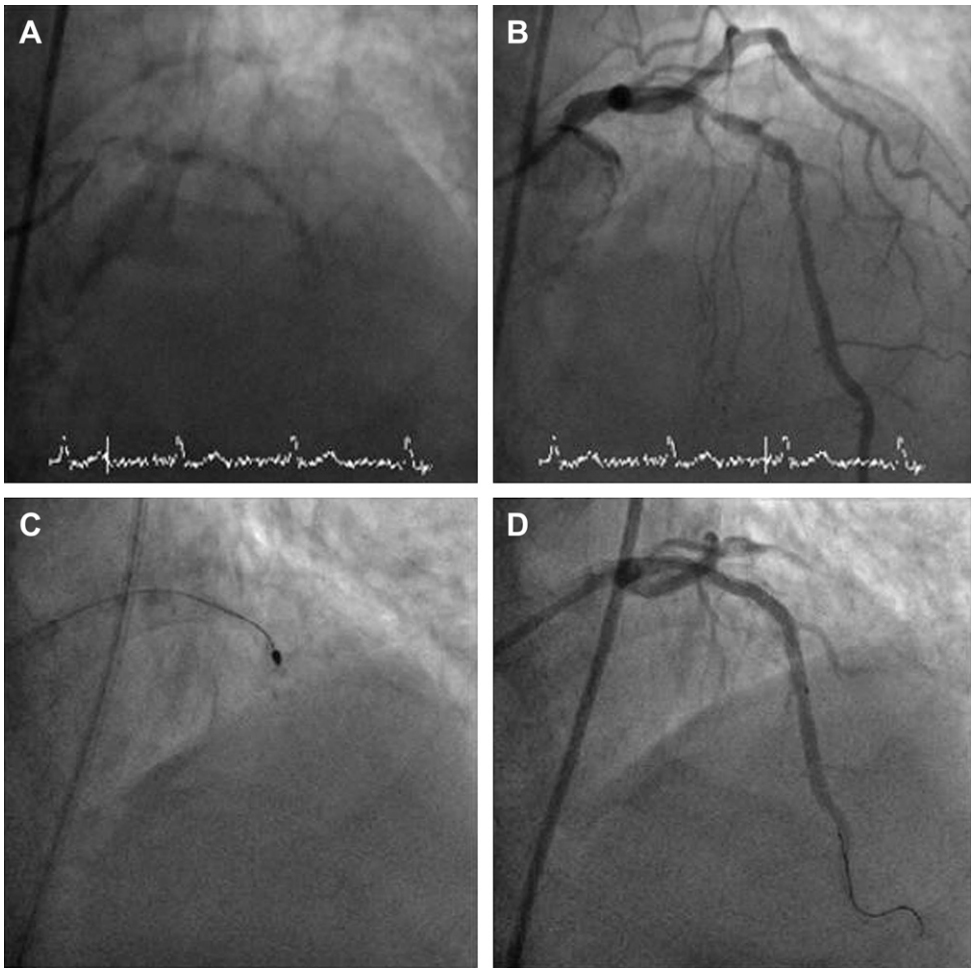


Fig. 1. A typical case of heavily calcified coronary lesions at baseline (A and B) treated with rotablation (C) and post-drug-eluting stent implantation. (D) The presence of circular and diffuse heavy calcification along the treated segment should preclude the proper balloon angioplasty and stent delivery and expansion.

are presented in Table 1. The mean age of successfully treated patients was 73.2 ± 10.3 years. Thirty-four (50.7%) patients had diabetes mellitus and 29 (43.3%) chronic renal failure. Five (7.5%) had prior coronary artery bypass graft surgery (CABG), and 17 (25.4%) had prior myocardial infarction (MI). Twenty-four (35.8%) patients presented with unstable angina, 13 (19.4%) non-ST-elevation MI (NSTEMI) and six (9.0%) ST-elevation MI (STEMI). Additionally, the average serum creatinine was 2.1 ± 2.1 mg/dL.

The angiographic success rate was 100% in these patients in whom the rotablation burr could be delivered to the target lesion and DES implantation completed, complicated by one (1.5%) non-Q MI. There was no other major procedural complication. The overall angiographic and procedural characteristics of our patients are presented in Table 2. Sixty-two (92.5%) of these patients had multiple-vessel diseases. The number of diseased vessels per patient was 2.5 ± 0.6. Most lesions were located at the left anterior descending artery (LAD) or right coronary artery (RCA) (76.0%) and 12 (16.9%) were at the left main coronary artery (LM). There were six (8.5%) chronic total occlusions and 28 (39.4%) bifurcation lesions. Fourteen lesions (19.7%) were balloon-uncrossable and five (7.0%) balloon-undilatable. The average CAC score

Table 1
Baseline clinical characteristics ($n = 67$).

| | |
|---|---|
| Age (y) | 73.2 ± 10.3 |
| Male (*N*), % | 42 (62.7%) |
| Current or ex-smoker (*N*), % | 33 (49.3%) |
| Systemic hypertension (*N*), % | 58 (86.6%) |
| Hypercholesterolemia (*N*), % | 29 (43.3%) |
| Diabetes mellitus (*N*), % | 34 (50.7%) |
| Chronic renal failure (*N*), % | 29 (43.3%) |
| Prior MI (*N*), % | 17 (25.4%) |
| Prior CABG (*N*), % | 5 (7.5%) |
| Clinical presentation (*N*), % | |
| Stable angina | 24 (35.8%) |
| Unstable angina | 24 (35.8%) |
| NSTEMI | 13 (19.4%) |
| STEMI | 6 (9.0%) |
| Cardiogenic shock | 6 (9.0%) |
| LVEF (%) | 42.1 ± 12.2 |
| Total cholesterol (mg/dL) | 162.5 ± 39.2 |
| LDL-cholesterol (mg/dL) | 94.3 ± 34.7 |
| Creatinine (mg/dL) | 2.1 ± 2.1[a] |
| Plasma glucose (mg/dL) | 130.8 ± 51.2 |

Continuous variables are presented as numbers (%) or mean ± SD.
CABG = coronary artery bypass graft surgery; LDL = low-density lipoprotein; MI = myocardial infarction; NSTEMI = non-ST segment elevation MI; STEMI = ST segment elevation MI.
[a] Included six hemodialysis patients.

Table 2
Lesion and procedural characteristics (71 lesions in 67 patients).

| | |
|---|---|
| CAD vessel numbers (*n*), % | |
| Single-vessel disease | 5 (7.5%) |
| DVD | 25 (37.3%) |
| TCD | 37 (55.2%) |
| Number of diseased vessels | 2.5 ± 0.6 |
| Target vessel (*n*), % | |
| Left main | 12 (16.9%) |
| Left anterior descending artery | 40 (56.3%) |
| Left circumflex artery | 5 (7.0%) |
| Right coronary artery | 14 (19.7%) |
| Chronic total occlusion (*n*), % | 6 (8.5%) |
| Bifurcation lesion (*n*), % | 28 (39.4%) |
| Balloon-uncrossable lesion (*n*), % | 14 (19.7%) |
| Balloon-undilatable lesion (*n*), % | 5 (7.0%) |
| CAC score | 3.6 ± 1.4 |
| Reference vessel size (mm) | 2.6 ± 0.6 |
| Lesion length (mm) | 41.3 ± 16.8 |
| Baseline minimal lumen diameter (mm) | 0.7 ± 0.2 |
| Baseline percent diameter stenosis (%) | 75.5 ± 5.8 |
| Number of burrs used per patient (*n*) | 1.6 ± 0.4 |
| Final burr size (mm) | 1.6 ± 0.2 |
| Burr/artery ratio | 0.6 ± 0.1 |
| DES implantation (*n*), % | 71 (100%) |
| Multiple stenting (*n*), % | 41 (57.7%) |
| Mean stent diameter (mm) | 2.8 ± 0.2 |
| Total stent length per lesion (mm) | 46.7 ± 22.7 |
| Total stent length per patient (mm) | 63.6 ± 32.1 |
| Noncompliant balloon post dilatation (*n*), % | 23 (32.4%) |
| Maximum balloon diameter (mm) | 2.9 ± 0.4 |
| Maximum inflation pressure (atm) | 15.3 ± 3.9 |
| Final minimal lumen diameter (mm) | 2.4 ± 0.4 |
| Final percent diameter stenosis (%) | 18.2 ± 5.5 |

Values are presented as numbers (%) or mean ± standard deviation.
CAC = coronary artery calcification; CAD = coronary artery disease; DES = drug-eluting stent; DVD = double vessel disease; TLR = target lesion revascularization; TVR = target vessel revascularization; TVD = triple vessel disease.

Table 3
MACE and stent thrombosis incidence ($n = 67$).

| | |
|---|---|
| In-hospital MACE (*n*), % | 5 (7.5%) |
| Death | 5 (7.5%) |
| Q wave MI | 0 |
| Non-Q wave MI | 1 (1.5%) |
| TLR | 0 |
| TVR | 0 |
| Out-of-hospital MACE (*n*), % | 12 (17.9%) |
| Death | 1 (1.5%) |
| Q wave MI | 0 |
| Non-Q wave MI | 0 |
| TLR | 7 (10.4%) |
| TVR | 7 (10.4%) |
| Stent thrombosis, any (*n*), % | 1 (1.5%) |
| Definite | 0 |
| Probable | 1 (1.5%) |
| Possible | 0 |
| Acute | 0 |
| Subacute | 1 (1.5%) |
| Late | 0 |
| Very late | 0 |

MACE = major adverse cardiac event; MI = myocardial infarction; TLR = target lesion revascularization; TVR = target vessel revascularization.

was 3.6 ± 1.4. The average number of burrs used in each patient was 1.6 ± 0.4. The final burr size was 1.6 ± 0.2 mm and the burr/artery ratio was 0.6 ± 0.1. A Taxus stent (Boston Scientific, Galway, Ireland) was implanted in 24 lesions, Cypher stent (Cordis, Johnson and Johnson Company, Roden, Netherlands) in 15, Endeavor Resolute stent (Medtronic, Galway, Ireland) in 20, Promus stent (Boston Scientific, Galway, Ireland) in nine, and Xience V stent (Abbott, Tipperary, Ireland) in four. Multiple stenting was used in 41 (57.7%) lesions. Among 28 bifurcation lesions, a two-stent strategy was used in 10 lesions. Intravascular ultrasonography (IVUS)-guided procedure was performed in five (7.0%) lesions. The number of stents implanted per lesion was 1.6 ± 0.7, and the total stent length per lesion was 46.7 ± 22.7 mm. Twenty-six patients (38.8%) received additional stents to treat non-rotablated lesions during the index procedure. The total stent length per patient was 63.6 ± 32.1 mm. Five patients (7.5%) underwent intra-aortic balloon pump (IABP)-assisted procedures due to cardiogenic shock or intractable ventricular tachycardia.

The in-hospital and follow-up clinical outcomes are shown in Table 3. The intervention procedure success rate was 92.5% as five patients died during hospitalization, all of them initially presenting as cardiogenic shock complicating extensive myocardial infarction or NSTEMI. The average age for these five patients was 77.6 ± 9.0 years (range: 62−84). Among these five, one had triple-vessel disease (TVD), two TVD with LM bifurcation lesions, one double-vessel disease (DVD) with LM bifurcation lesion, and the other single-vessel disease. Three of them had extensive anterior MI and two others NSTEMI (one following unsuccessful PCI at a local hospital, while the other one received cardiopulmonary resuscitation at the emergency department). One TVD patient received RA plus DES for LM-LAD. One TVD patient received RA plus DES for LM bifurcation lesion and was finished with a culotte stenting technique. One TVD patient received RA plus DES for left circumflex artery (LCX), supplemented with stenting but no RA for two other vessels. The DVD patient received RA plus DES for LCX and DES culotte stenting for LM bifurcation lesion.

Although three NHLBI type B and two type C coronary dissections occurred during procedure, they were successfully treated by stenting and not followed by major adverse cardiac event (MACE). The incidence of out-of-hospital MACE at a mean follow-up of 23.2 months (range, 5−86) was 17.9%. Eighteen patients (26.9%) received clinically driven coronary angiographic follow-up and TLR was needed in seven (10.4%) patients, all for ischemia, and TVR in seven (10.4%) patients. All were successfully reopened by PCI and no CABG was needed. Among patients with angiographic follow-up, no coronary aneurysms were found in the stented segment. Probable stent thrombosis occurred in one patient (1.5%) in the subacute stage with sudden cardiac death 9 days after the procedure in which a Taxus stent was implanted with a total length of 40 mm for the LM-LAD/LM-LCX bifurcation lesion.

## 4. Discussion

Heavily calcified lesions pose great challenges to PCI, even in contemporary practices, despite a lot of helpful techniques and devices. With RA, it is possible to pretreat these lesions, reducing the vessel rigidity and facilitating subsequent interventions.[14] Although excimer laser is a reasonable alternative, it is expensive and not available in most cath labs.[15] Furthermore, excimer laser is useless in extremely calcified lesions.[16] In the BMS era, the combination of RA and BMS was reported to be most likely associated with optimal final lumen dimensions.[17] However, the results of RA plus BMS were not as good as expected.[18] Furthermore, although RA is an effective and less expensive debulking modality and readily available in most cath labs, it is more cumbersome to set up, more difficult to use, especially for distal lesions, and more prone to complications if not adequately prepared or performed.[19,20] Therefore, it has usually been underused, even in the DES era.[21] These limitations were also reflected in our cath labs, in which rotablation was only used in 2.4% of all PCI cases. However, lack of insurance reimbursement for rotablation is probably the major cause of underuse of this device in our country and many others. Underuse, less familiarity with this device and resorting to it only in heavily calcified, complex lesions in high-risk patients may increase the complication rate and decrease the angiographic and clinical outcomes. However, these issues were not seen in our cath lab.

DES effectively reduces restenosis and long-term MACE after PCI; therefore, it prevails in current practice.[22] The angiographic and clinical advantages of DES along with recent advancement in other new concepts and techniques encourage more PCIs for very complex lesions and in high-risk patients.[23] However, the use of DES in heavily calcified lesions poses special challenges: (1) suboptimal deployment of DES may increase the risk of stent thrombosis, (2) rigorous manipulation of a DES may result in disruption of its polymer coating, and (3) stent delivery failure. CAC might cause inadequate diffusion of drug to the vessel wall.[24] CAC in the stent delivery route was reported to be an important determinant of restenosis following sirolimus-eluting stent implantation.[10] These calcifications mandate adequate debulking before standard PCI can be performed. Once the DES is delivered and deployed, good results can be anticipated.[25] Otherwise, DES might fail to prevent restenosis under these circumstances.[26]

The coronary calcification score in the current study was very high. Of our lesions, 26.7% were either balloon-uncrossable or balloon-undilatable. Our patients were all high-risk: 64% of patients presented with acute coronary syndrome, 9.0% with cardiogenic shock, 43.3% with chronic renal failure, and 50.7% with diabetes. The mean left ventricular ejection fraction (LVEF) was 42% and multiple-vessel diseases were found in 92.5% of our patients. The final stent length was 47 ± 23 mm, and the two-stent strategy was used in 36% of true bifurcation lesions in our patients, both demonstrating the complexity of our treated lesions. Despite all these unfavorable factors, the angiographic success rate was 100%, which could be due to more complete lesion modification by using more than one burr per lesion. Although there were five (7.4%) in-hospital deaths, none were procedure-related; all

Table 4
Summary of large-series reports of RA plus DES.

| Author/y | Patient Number (*N*) | Age (y) | Cr/CRF (mg/dL)/(*N*) (%) | ACS (*N*) (%) | Number of diseased Vessels (*N*) | CAC score | Bailout RA (*N*) (%) | Stent length per lesion (mm) | In-hospital deaths/MACE (*N*) (%) | Mean FU | FU MACE/TLR/TVR (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Clavijo LC et al 2006 | 81 | 71.5 ± 9.6 | 1.5 ± 1.8/? | 34 (42%) | 2.2 ± 0.9 | ? | 18 (22%) | 24.4 ± 6.27 | 0 (0%)/1 (1.3%) | 6 mo | 11.0/4.2/?? |
| Furuichi S et al 2009 | 95 | 68 ± 9 | ?/7 (7.4%) | 19 (20%) | 1.6 ± 0.8 | ? | 61 (63.5%) | 48.4 ± 24.9 | 0 (0%)/3 (3.2%) | 17.4 mo | 15.8/9.5/11.6 |
| Tamekiyo H et al 2009 | 79 | 70.6 ± 10.7 | ?/34 (43%)[a] | 25 (32%) | 1.9 ± 0.7 | ?[b] | ? | 36.5 ± 17.2 | 2 (2.5%)/3 (3.8%) | 730 d | 30.1/25.0/?? |
| García de Lara et al 2010 | 50 | 70 ± 1.2 | ?/? | 30 (60%) | 2.4 ± 0.8 | ? | ? | 41 ± 4 | 2 (4%)/2 (4%) | 14 mo | 8.0/6.0/?? |
| Rathore et al 2010 | 391 | 70.8 ± 8.8 | ?/?[c] | 52 (13.3%) | ?? | ?[d] | 27 (6.9%) | 22.4 ± 12.6 | 4 (1%)/10 (2.5%) | 6−9 mo | ?/10.6/? |
| Mezilis N et al 2010 | 150 | 70 ± 8 | ?/? | 14 (8%) | ?? | ? | ? | 38 ± 10 | 0 (0%)/0 (0%) | 3 y | 11.3/2.0/2.0 |
| Benezet J et al 2011 | 102 | 68.8 ± 7.4 | ?/13 (12.7%) | 73 (71.6) | 2.3 ± 0.7 | ? | 21 (19.8%) | 39.3 ± 19.8 | 1 (0.9%)/3 (2.9%) | 15 mo | 12.7/8.8/? |
| Chiang MH et al 2011[e] | 67 | 73.2 ± 10.3 | 2.1 ± 2.1/29 (43%) | 43 (64%) | 2.5 ± 0.6 | 3.6 ± 1.4 | 21 (31%) | 46.7 ± 22.7 | 5 (7.5%)/5 (7.5%)[f] | 23 mo | 17.9/10.4/10.4 |

ACS = acute coronary syndrome; CAC = coronary artery calcification; Cr/CRF = serum creatinine/chronic renal failure; DES = drug-eluting stent; FU = follow-up; MACE = major adverse cardiac event; TLR = target lesion revascularization; RA = rotational atherectomy; TVR = target vessel revascularization.
? data not available in the original article.
[a] A total of 43% were dialysis patients.
[b] A total of 74.2% had severe calcification.
[c] Patients with advanced renal failure on hemodialysis were excluded in this study.
[d] Moderate and severe calcification were 161 (41.2%) and 202 (51.7%), respectively.
[e] Rotablation not reimbursed by insurance.
[f] All deaths were due to cardiogenic shock.

were caused by underlying extensive myocardial infarction/ischemia with cardiogenic shock. The disease severity in these five patients was extremely high, as was the PCI complexity (multi-vessel interventions and two-stent LM bifurcation interventions). However, RA plus DES could be achieved without procedural complications. The follow-up MACE in patients who survived the acute events was 17.9%, most of them due to TLR and TVR. This figure was quite reasonable given a group of patients with very complex, heavily calcified coronary lesions. Our study results were comparable with others in the literature, as summarized in Table 4,[25,27−32] despite the untoward and unfavorable circumstances of using his particular device in this country.

There were some limitations in our study. The sample size in this single-center, observational study was relatively small because of the insurance reimbursement issue in this country. We had to limit RA use to patients with very unfavorable angiographic characteristics, which otherwise would preclude successful PCI treatment without prior mechanical ablation. Furthermore, there was no routine angiographic follow-up of these patients. However, clinically driven follow-up, which was adopted in most DES studies,[22] showed the overall MACE was relatively low and comparable with those of DES treatment in real world practice,[22] especially given the unfavorable background clinical and angiographic settings of our patients.

In conclusion, plaque modification with RA to ensure DES delivery and appropriate stent deployment in very complex, heavily calcified lesions appears to be crucial, clinically rewarding, and could be safely accomplished with very low complication and low out-of-hospital MACE rates even in high-risk patients despite use limited by lack of insurance reimbursement. The high procedural success rate, low TLR and very pleasing cumulative MACE incidence convince us to sustain and even broaden use of this novel but underused device in the DES era.

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