



Safety and effectiveness of percutaneous coronary intervention using rotational atherectomy and new-generation drug-eluting stents for calcified coronary artery lesions in patients with chronic kidney disease

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ABSTRACT

Aim: Coronary artery calcification is an important factor influencing revascularisation outcomes in patients with chronic kidney disease (CKD). Lesion preparation using rotational atherectomy (RA) may help adequately modify calcified plaques and facilitate the achievement of optimal clinical outcomes in these patients. In this study, we assessed the safety and effectiveness of percutaneous coronary intervention (PCI) using RA followed by new-generation drug-eluting stent (DES) implantation in patients with CKD and calcified coronary artery disease (CAD).

Methods and results: From November 2014 to October 2019, a total of 203 patients with calcified CAD who underwent RA followed by second- or third-generation DES implantation at our centre were included in the study. Mild, moderate, and severe CKD was present in 38%, 55.5%, and 6.5% of the patients, respectively. Diffused coronary calcifications were present in 85%. Procedural success was 97.5% with minimal periprocedural complications. In-stent restenosis occurred in one patient (0.5%); major adverse cardiovascular and cerebrovascular events were reported in 22 patients (10.8%); cardiac death occurred in eight patients during follow-up.

Conclusion: Percutaneous coronary intervention using RA followed by second- or third-generation DES implantation is feasible and safe with high procedural success and low in-stent restenosis in CKD patients with calcified coronary lesions.

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1. Introduction

Chronic kidney disease (CKD) is a major global public health concern, and its association with cardiovascular disease (CVD) is well established. Most traditional cardiovascular risk factors, such as diabetes and hypertension, also confer a high risk in CKD patients.^{1–3} Along with these conventional CVD risk factors, CKD-specific risk factors, such as low body mass index (BMI), reduced estimated glomerular filtration rate (eGFR), coronary artery calcification, anaemia, and proteinuria contribute to poor cardiovascular

prognosis in these patients.^{2–5} In two distinct large meta-analyses, low eGFR and high albuminuria were found to be significant predictors of cardiovascular mortality even after adjusting for traditional CVD risk factors.^{5,6} Therefore, the prevalence of any CVD event in CKD patients may be twofold higher than in patients without CKD.⁷ Further, the risk of progression of atherosclerotic CVD and CVD-associated mortality may also show a linear increase with a decrease in kidney function.^{7–9} Given these findings, most experts consider CKD as coronary artery disease risk equivalent.^{10,11}

The increased risk and severity of CVD in patients with CKD is possibly due to the high prevalence of traditional and nontraditional CVD risk factors and raised oxidative stress and chronic inflammation. Patients with CKD are at an increased risk of vascular calcification due to the upregulation of calcification inhibitors (fetuin-A and matrix Gla protein) and downregulation of promoters

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(hyperphosphataemia).^{12,13} The deposition of calcified plaques in both the intimal and medial layers of vessels has been reported in patients with CKD and coronary artery disease (CAD).¹⁴ Chronic kidney disease is also associated with increased activity of the renin–angiotensin system and increased sympathetic nerve activity, resulting in impaired endothelial function¹² and subsequent promotion of the rapid progression and diffusion of calcified lesions.¹⁵ Findings from the Chronic Renal Insufficiency Cohort (CRIC) study revealed that coronary artery calcification is significantly associated with subsequent risk of CVD, acute myocardial infarction (AMI), heart failure, and all-cause mortality among dialysis-naïve patients with CKD.¹⁶ A similar association has also been reported in patients with end-stage renal disease (ESRD).¹⁷

The aforementioned multifactorial and complex pathophysiological processes specific to CKD make the treatment of CAD and acute coronary syndrome (ACS) in CKD patients difficult and challenging. Evidence suggests that early revascularisation after ACS may have better survival benefits over conservative management in CKD patients.^{18,19} However, the short- and long-term clinical outcomes of revascularisation are dependent on the treatment approach (coronary artery bypass graft [CABG] or percutaneous coronary intervention [PCI]) and severity of CKD. While the risk of acute kidney injury (AKI), stroke, and death are higher with CABG vs. PCI in the short term among nondialysis CKD patients, the incidence of repeat revascularisation and myocardial infarction (MI) is higher with PCI vs. CABG, with both approaches possessing a similar risk of major adverse cardiovascular or cerebrovascular events (MACCE) and mortality in the long term. In dialysis patients, the risk of death and stroke has been reported to be higher with CABG vs. PCI in the short term, with high rates of repeat vascularisation, MI, and mortality being associated with PCI vs. CABG in the long term.^{11,20–23} The presence of diabetes and extensive CAD has also been found to influence revascularisation outcomes, with significantly worse long-term outcomes noted with PCI vs. CABG in these patients.²¹ Therefore, experts suggest the use of a patient-centric revascularisation strategy, considering factors such as the extent of CAD, risk of AKI, and stage/risk of progression of CKD.¹¹

Revascularisation with PCI in patients with CKD and CAD may be optimised using drug-eluting stents (DESs) to improve treatment outcomes. Several meta-analyses comparing DESs with bare-metal stents in these patients have associated the usage of DESs with a significant reduction in the incidence of major adverse cardiovascular events (MACE), MI, target lesion revascularisation (TLR), target vessel revascularisation (TVR), and all-cause mortality.^{24,25} Kim et al reported that CKD may not influence the risk of device-related events, including stent thrombosis and TLR, in patients with diabetes and ACS in the DES era.²⁶ The use of second-generation DESs appears to have better clinical outcomes compared to the use of older-generation DESs in patients with mild-to-moderate CKD.²⁷ The use of imaging may be another factor influencing the clinical outcomes of PCI in these patients. Several studies have reported high procedural success and better clinical outcomes with intravascular ultrasound (IVUS)-guided PCI in patients with CKD.^{28,29} Appropriate lesion preparation is another key factor influencing PCI outcomes in CKD patients, given the high severity of calcified CAD in these patients.³⁰ The guidelines recommend rotational atherectomy (RA) as a lesion preparation strategy for heavily calcified lesions that might not be adequately traversed or dilated before stent implantation.³¹

In the setting of CKD, only a few studies have examined the safety and effectiveness of PCI using RA in CKD patients in the DES era.³² Therefore, the current study was carried out to evaluate the safety and effectiveness of PCI using RA followed by DES implantation in patients with CKD and moderate-to-severe calcified CAD.

2. Methods

2.1. Study design and population

This was a retrospective, single-centre study. Data on demographic, clinical, procedural, and follow-up outcomes were obtained from the medical records of all consecutive CKD patients with CAD who underwent PCI using RA followed by DES implantation from November 2014 to October 2019 at our centre. The study was approved by the institutional review board. Informed consent could not be obtained from the patients, given the retrospective nature of the study.

2.2. Procedure overview

Most rotablation procedures were performed by the femoral route using a 7Fr guide catheter. Rota floppy wire was used in most cases. Workhorse wire was exchanged for a rota floppy wire with the help of a microcatheter. With plaque modification as the main objective, rather than aggressive debulking, a 1.25-mm or 1.5-mm burr was used individually or sequentially. The average rotational speed was around 160,000 rpm for most procedures. However, in some procedures, the rotablation speed was increased up to 200,000 rpm. Since most patients had long diffuse calcified lesions, the average run time was around 20 s and several procedures required multiple runs. During the procedure, in-centre–developed rota solution consisting of 1 ampoule of adrenaline, 3000 units of heparin, 500 mcg of glyceryl trinitrate, 500 mcg of adenosine, and 1000 mL of saline was used.

Left ventricular assist device was not used in any patient. Rota solution containing adrenaline may have prevented any sudden drop in blood pressure in all patients. A temporary pacemaker was used initially, for the first few cases, especially for procedures involving the right coronary artery (RCA).

Predilatation and lesion preparation with multiple non-complaint (NC) balloons were done in all cases after rotablation. Second- or third-generation DES were deployed only after lesion preparation. Further, we performed postdilatation to optimise results. Intravascular ultrasound was used when required. The activated clotting time was set and maintained at around 250–300 s and echocardiogram checked immediately postprocedure.

2.3. Definitions and endpoints

The primary endpoints were in-stent restenosis and MACCE during follow-up. In-stent restenosis was defined angiographically as >50% diameter stenosis in the stented segment. Major adverse cardiovascular and cerebrovascular events were defined as the composite of all-cause death, stroke, MI, and clinical-driven TLR. Secondary endpoints included procedural success, in-hospital death, death during follow-up, and the individual components of MACCE. Angiographic success was defined as the achievement of a residual stenosis diameter of less than 20% in the presence of TIMI 3 flow. Procedural success was defined as achieving angiographic success without in-hospital MACE, including all-cause death, MI, and repeat revascularisation. Follow-up of patients was done telephonically. Target lesion revascularisation was defined as repeat revascularisation for restenosis >50% in the target segment.

2.4. Statistical analysis

No formal sample size calculation was performed for this study, as it was an observational, single-arm study. Categorical variables have been presented as numbers and percentages and continuous data as mean and standard deviation.

3. Results

3.1. Baseline patient characteristics

A total of 203 CKD patients who underwent PCI using RA for lesion preparation during the study period were included in this study. Table 1 shows the baseline demographic and clinical characteristics of the patients. The mean age of the patients was 63.94 ± 8.79 years, and 73.4% were men. About 30% of patients were aged 70 years and above 45% were aged 60–69 years. Seventy-three percent (73%) of patients were diagnosed with chronic stable angina and 27% with ACS. While 38% of patients presented with mild CKD, 55.5% and 6.5% of patients presented with moderate and severe CKD, respectively. Overall, 90.6% were hypertensive, 65.5% had diabetes mellitus, and 57% had dyslipidaemia. More than half of the patients had mild-to-moderate left ventricular dysfunction. Fifty-one percent (51%) of the patients were smokers. A family history of ischaemic heart disease was noted in 88 cases, and 91 cases had a history of prior angina. Seventy-three patients (36%) had left main involvement. Fifty-three patients (26%) had a history of the previous revascularisation by either PCI or CABG.

3.2. Lesion and procedural characteristics

The PCI procedure was carried out through the femoral route in 191 cases and the radial approach followed in 12 cases. Diffuse coronary calcification was documented in 85% of cases and short heavy calcification in 15% of cases. The mean lesion length for diffused calcified lesions was 42.38 ± 17.67 mm. All were type C lesions. Single-vessel disease was seen in 60 cases, double-vessel disease in 77 cases, and triple-vessel disease in 66 cases. While 116 cases had bifurcation lesions, 46 cases had ostial lesions and 28

Table 1
Baseline characteristics of study patients.

Baseline characteristics	Results (n = 203) ^a
Demographics	
Mean age (mean ± SD) (years)	63.94 ± 8.79
Male, n (%)	149 (73.4)
Female, n (%)	54 (26.6)
BMI (mean ± SD) (kg/m ²)	25.68 ± 3.42
Clinical presentation	
Chronic stable angina	149 (73)
Acute coronary syndrome	54 (27)
Comorbidities and risk factors	
Hypertension	184 (90.6)
Diabetes mellitus	133 (65.5)
Dyslipidaemia	116 (57)
Smokeless tobacco user/smoker	104 (51.2)
History of prior angina	91 (44.8)
History of prior MI	32 (15.8)
Previous CABG	20 (10)
Previous PCI	33 (16)
Family history of IHD	88 (43.3)
Left ventricular dysfunction	
Mild	85 (42)
Moderate	23 (11)
Severe	2 (1)
No LVD	93 (46)
Stages of CKD	
Mild	77 (38)
Moderate	113 (55.5)
Severe	13 (6.5)

BMI: Body mass index; CABG: Coronary artery bypass graft; CKD: Chronic kidney disease; LVD: Left ventricular dysfunction; IHD: Ischaemic heart disease; MI: Myocardial infarction; PCI: Percutaneous coronary intervention; SD: Standard deviation.

^a All data are presented as n (%) unless otherwise specified.

cases had chronic total occlusions. A total of 108 cases (53.2%) had a lesion in the left anterior descending coronary artery, 55 (27%) in the RCA, 27 (13.3%) in the isolated left main coronary artery, and 13 (6.4%) in the left circumflex coronary artery. Burrs of approximately 1.25 mm were used in 55 (27%), 1.5 mm in 81 (40%), and 1.75 mm in 3 (1.5%) cases. Both 1.25- and 1.5-mm burrs were used in 63 cases and 1.5- and 1.75-mm burrs in one case. The mean burr size was 1.36 ± 0.12 mm. In 201 patients, 416 stents were used; on an average, two stents were used per patient (Table 2).

3.3. Procedural and clinical outcomes

Procedural success was achieved in 198 cases (97.5%). Thrombolysis in Myocardial Infarction (TIMI) 3 blood flow after the procedure was seen in all cases. Stent deployment failed in one case, and side branch loss occurred in two cases. There was no death or acute closure of blood vessels during the procedure. Emergency CABG was done in one patient. After the PCI procedure and during hospital stay, left ventricular failure, stent thrombosis, and death occurred in three patients each; haematoma in five patients; cardiac arrest in four patients; and ventricular fibrillation and complete heart block in one patient each (Table 3). The mean follow-up duration was 24.11 ± 18.05 months. During follow-up, symptom-driven coronary angiogram (CAG) check was done in 36 patients (17.7%). Out of these, 35 had patent stents. In-stent restenosis occurred in one patient (0.5%); it was treated with revascularisation with PCI. There were six re-admissions, and MACCE were seen in 22

Table 2
Lesion and procedure characteristics.

Angiographic and procedural variables	Results (patients, n = 203 ^a)
Number of vessels involved	
Single	60 (29.5)
Double	77 (38)
Triple	66 (32.5)
Target vessel	
LMCA	27 (13.3)
LAD	108 (53.2)
LcX	13 (6.4)
RCA	55 (27)
Lesion characteristics	
Calcified lesions	
Diffuse	172 (85.3)
Short heavily calcified	31 (14.8)
Bifurcations	116 (57.1)
Ostial lesions	46 (22.6)
CTO	28 (14)
Mean lesion length ± SD (mm)	42.38 ± 17.67
Procedural characteristics	
Number of burrs ± SD	1.32 ± 0.47
Mean burr size ± SD (mm)	1.36 ± 0.12
ROTA in proximal vessel	153 (75.3)
ROTA in ostial	30 (14.8)
ROTA in mid vessel	11 (5.4)
ROTA in distal vessel	3 (1.4)
Predilatation	200 (98.5)
Postdilatation	200 (98.5)
Maximum balloon inflation (mean ± SD) (atm)	23.70 ± 2.14
Number of stents	
Single stent	52 (25.9)
Double stent	89 (44.2)
Triple stent	54 (26.9)
Quadruple stent	6 (3)
Stent dimensions	
Mean stent diameter ± SD (mm)	3.1 ± 0.5
Mean stent length ± SD (mm)	29.9 ± 8.3

CTO: Chronic total occlusion; DES: Drug-eluting stent; LAD: Left anterior descending artery; LMCA: Left main coronary artery; LcX: Left circumflex artery; SD: Standard deviation; RCA: Right coronary artery; ROTA: Rotational atherectomy.

^a All data are presented as n (%) unless otherwise specified.

Table 3
In-hospital complications after index intervention.

In-hospital complications	Results (n = 203) ^a
Arrhythmia	30 (14.78)
Cardiogenic shock	5 (2.46)
Cardiac arrest	4 (1.97)
Myocardial infarction	3 (1.48)
Left ventricular failure	3 (1.48)
Complete heart block	1 (0.49)
Shock	1 (0.49)
Haematoma	5 (2.46)
Blood loss	4 (1.97)
Stroke	1 (0.49)
Stent thrombosis	3 (1.38)
Death	3 (1.48)

^a All data are presented as n (%) unless otherwise specified.

patients (10.8%) during follow-up. In total, 18 deaths occurred during follow-up: eight related to cardiac and 10 related to noncardiac causes.

4. Discussion

Patients with both CKD and CAD are considered a complex subset. As seen in this study, these patients tend to have severe multivessel CAD, often along with heavily calcified vessels and diffuse lesions. These patients are often deemed as poor candidates for CABG due to poor renal function. Further, in many instances these patients tend to have severe anginal symptoms, that are often poorly controlled even with maximum antianginal therapy. The presence of left main coronary artery disease can further complicate the situation. Rotablation followed by implantation of second- or third-generation DES may offer a viable treatment option for this category of patients who have been refused CABG due to their multiple comorbidities.

This retrospective, observational, single-centre study highlighted the feasibility of such a treatment option for this high-risk subset of CKD patients. The study shows that RA is a safe and effective lesion preparation technique for the optimisation of PCI outcomes in the DES era.

An early invasive approach is recommended in patients with stage 2/3 CKD and ACS by the American College of Cardiology/American Heart Association (AHA) Task Force guidelines. However, the benefits are uncertain in patients with stage ≥ 4 CKD.³³ In these patients, revascularisation options should be based on patient symptoms and preferences and careful assessment of risks vs. benefits.¹¹ Percutaneous coronary treatments have evolved significantly over the years. Currently, with newer-generation DES, there has been a considerably reduced risk of restenosis. The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) recommend DES over bare-metal stent (BMS) if PCI is used as the revascularisation strategy.³⁴

The other advancement in PCI procedures, in addition to DES, is the use of several atherosclerotic plaque modifications techniques before stent implantation in more complex lesions usually seen in CKD patients. The 2011 AHA guidelines suggest that RA is a reasonable plaque modification technique for fibrotic or heavily calcified lesions that cannot be crossed by a balloon catheter or adequately dilated before stent implantation.³¹ The recent North American Expert Review of Rotational Atherectomy also noted that RA can facilitate optimal PCI for calcified coronary lesions with a high degree of efficacy and safety.³⁵ Further, planned atherectomy is associated with reduced procedural time, less use of contrast, and reduced rates of complications in calcified lesions.³⁶

In the current study, coronary calcification was severe enough to be visible angiographically in all cases. Diffuse and superficial calcification of the coronary arteries (length: >22 mm) were noted in 171 patients with superficial and focal calcification in 31 patients. Due to heavy calcification, IVUS was carried out only in 55 patients. Optical coherence tomography was not used due to presence of CKD. In addition to moderate-to-severe CKD (62%), the other high-risk variables in our patient population were mean age of 64 years, 91% with hypertension, 65% with diabetes, and 70.5% with multiple-vessel disease. About 16% of the patients had undergone PCI previously, 10% had undergone CABG previously, 14% had CTO, and 36% had left main coronary artery lesions. Despite the high-risk population and high lesion complexity, RA followed by DES was associated with a very high procedural success rate (97.5%) and minimal periprocedural complications in this study; no dissections or perforations were observed, and all patients had TIMI 3 blood flow after the index intervention. These outcomes coincide with the technical success rate (98%) achieved with PCI using RA in dialysis patients conducted by Aoki et al in the pre-DES era. Most baseline and lesion characteristics in the study by Aoki et al are also similar to those in our study.³⁷ In another retrospective analysis of haemodialysis patients with calcified coronary lesions, only one procedural failure was reported with percutaneous transluminal coronary rotational atherectomy (PTCRA)-guided DES implantation.³⁰

The rate of in-stent restenosis was very low in the current study with the use of new-generation DES preceded by effective rotablation. All lesions were properly prepared using adequately sized NC balloons; cutting balloons were not used in any of these cases. One case of restenosis was reported that had subsequently undergone repeat revascularisation with PCI. Major adverse cardiovascular and cerebrovascular events were seen in 22 patients (10.8%) during follow-up. In a retrospective analysis conducted among haemodialysis patients with calcified lesions treated with DES implantation using PTCRA, 17.4% had restenosis and 11.5% TLR within a year. Cardiac death occurred in 3.8% of patients, with one death occurring during the procedure.³⁰ In our study, while cardiac death occurred in 3.9% of patients, there were no deaths during the procedure. In a retrospective study by Tamekiyo et al, which had a CKD distribution similar to our study, the incidence of binary restenosis per lesion was 40.8% for the ROTA-BMS group and 24.5% for the ROTA-sirolimus-eluting stent (SES) group ($p = 0.062$). At two years post-index PCI, the use of SES after ROTA was associated with a lower crude incidence of MACE as compared to the use of BMS after ROTA (30.1% vs. 43.1%, $p = 0.024$). The difference in MACE in this study was attributed to the more significant reduction in TLR rates with SES compared to BMS ($p < 0.0001$).³⁸ Further, Aoki et al, who used PCI with RA to treat dialysis patients with CAD in the pre-DES era, reported 45% repeat revascularisation with PTCRA over a mean follow-up period of 21 ± 14 months. In-hospital and follow-up death occurred in 1.5% and 27% of cases, respectively.³⁷ The favourable clinical outcomes in our study may have been due to superior optimisation of the PCI procedure. Pre- and postdilatation were performed in nearly 99% of lesions.

Other atherosclerotic plaque modification techniques used in calcified lesions include orbital atherectomy and laser atherectomy. Lee et al determined clinical outcomes in patients with CKD using orbital atherectomy for severe coronary artery calcification before stent implantation. The procedural success rate was 87%, which is slightly lower than that reported in our study. Also, the one-year MACE (19.4%) and cardiac death (4.3%) in this study are comparable to those noted in our study.³⁹

The major limitations of this study are its single-center retrospective design, our results may not be precise because of population bias.

5. Conclusion

Rotational atherectomy followed by new-generation DES implantation was found to be safe and effective in CKD patients with calcified CAD in our routine clinical setting. This strategy was associated with a high procedural success and low rates of in-stent restenosis at follow-up. Future long-term prospective randomised controlled studies are needed to further establish the efficacy and safety of this PCI technique for the treatment of calcified CAD lesions in CKD patients.

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Declaration of competing interest

The authors have no conflicts of interest to declaration.

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