original article

Impact of diabetes mellitus on periprocedural and 18-month clinical outcomes in Korean patients requiring rotational atherectomy: results from the ROCK Registry

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Citation: Lee SN, Moon D, Her SH, Jang WY, Moon KW, Yoo KD, et al. Impact of diabetes mellitus on periprocedural and 18-month clinical outcomes in Korean patients requiring rotational atherectomy: results from the ROCK Registry. Ann Saudi Med 2022; 42(5): 291-298. DOI: 10.5144/0256-4947.2022.291

Received: December 29, 2021

Accepted: May 30, 2022

Published: October 6, 2022

Funding: None.

BACKGROUND: Diabetes mellitus (diabetes) increases the risk of severe coronary artery calcification, which increases the complexity of percutaneous coronary intervention requiring rotational atherectomy (RA) by interfering with lesion preparation, and limiting final stent expansion.

OBJECTIVE: Investigate 30-day and 18-month clinical outcomes in patients with and without diabetes treated with percutaneous coronary intervention requiring RA.

DESIGN: Medical record review

SETTING: Multicenter registry in South Korea

PATIENTS AND METHODS: The ROtational atherectomy in Calcified lesions in Korea (ROCK) registry was a large, retrospective, multicenter study to assess RA treatment of severe coronary artery calcification.

MAIN OUTCOME MEASURES: The primary endpoint was target-vessel failure including cardiac death, target-vessel myocardial infarction, and target-vessel revascularization.

SAMPLE SIZE: 540 patients followed for a median of 16.1 months.

RESULTS: Of the 540 patients, 305 had diabetes (56.5%). The diabetes group had a significantly higher frequency of multivessel disease; comorbidities such as hypertension, dyslipidemia, and chronic kidney disease; and lower ejection fraction of the left ventricle compared to the non-diabetes group (n=235). There were no significant differences in procedure success and complications observed between the two groups. Target vessel failure at 30 days between the diabetes and non-diabetes groups was not statistically significant in a multivariate Cox regression analysis (1.6% vs. 2.6%, adjusted hazard ratio [HR] 0.595, 95% confidence interval [CI] 0.154-2.300, *P*=.451). During an 18-month follow-up, the risk of target vessel failure was higher (12.5% vs. 8.9%) but the difference was not statistically significant (adjusted HR 1.393, 95% CI 0.782-2.482, *P*=.260).

CONCLUSIONS: Patients with diabetes have a risk of complications comparable to patients without diabetes, and 30-day and 18-month

clinical outcomes are similar in severe coronary artery calcification requiring RA, despite having more comorbidities.

LIMITATIONS: Retrospective design. Sample size not based on power calculation.

CONFLICT OF INTEREST: None.

In 2019, at least 463 million people worldwide had diabetes mellitus, an increase from an estimated 382 million people in 2013.[1,2] The incidence rate of diabetes is expected to gradually increase due to lifestyle changes and a "Western-style" diet. Cardiovascular disease is a serious complication associated with diabetes.[3] It is well known that diabetes is closely related to poor prognosis in coronary artery disease (CAD) patients with percutaneous coronary intervention (PCI). In diabetic patients, despite the use of drug-eluting stents, there is more plaque burden and neointimal hyperplasia, resulting in increased in-stent restenosis.[1,4-6]

Severe coronary artery calcification (CAC) accounts for approximately 6-20% of all PCI.[7,8] The presence of severe CAC was related to worse clinical outcomes, including death, repeat revascularization, and myocardial infarction (MI).[7] In particular, diabetes increases the risk of severe CAC, which increases overall procedural complexity by making lesion preparation difficult, complicating device delivery, and limiting final stent expansion.[9] In the PCI era, the burden of CAC is on the rise with an aging society. As one of the solutions, rotational atherectomy (RA) ablates severe calcified plaques leading to better lesion preparation, and better stent expansion.[10]

Previous studies have reported the impact of diabetes on clinical outcomes in patients with severe CAC.[11-13] However, clinical outcomes including angiographic complication in patients with diabetes with CAD requiring RA based on multicenter registry are unknown. Therefore, the objective of the present study was to compare the 30-day and 18-month clinical outcomes in patients with and without diabetes treated with PCI requiring RA.

PATIENTS AND METHODS

This large, retrospective, multicenter study to assess RA treatment of severe CAC involved patients enrolled in the The ROtational atherectomy in Calcified lesions in Korea (ROCK) Registry.[14] The study population included patients entered into the registry from nine tertiary care centers in Korea between January 2010 and October 2019 who underwent PCI using RA. The study population included patients with heavily calcified lesions and significant stenosis (stenosis ≥70% of reference diameter) identified in each institutional database. There were no special exclusion criteria. The patients were classified into a diabetes group (n=305, 56.5%) and a non-diabetes group (n=235, 43.5%). Diabetes was defined as a fasting glucose level ≥126 mg/dL, glycated hemoglobin ≥6.5%, current use of antidiabetic medications, or a self-reported physician diagnosis of diabetes. Data were collected from each institution using standardized forms to document baseline characteristics and follow-up data. Follow-up data were obtained from medical records and patient interviews.

The treatment strategy, including burr sizing during the procedure was at the physician's discretion with careful consideration of clinical risk factors, anatomical complexity, and patient conditions. The description of the rest of the procedure was detailed in a previous paper.[15] All patients provided written informed consent and this study was approved by the Institutional Review Board at each participating hospital

The primary outcome was target-vessel failure (TVF), a composite of cardiac death, target-vessel myocardial infarction (MI), and target-vessel revascularization (TVR). Secondary endpoints were all-cause death, cardiac death, MI, target-vessel MI, TVR, stent thrombosis (ST), stroke, and any bleeding.

Target-vessel MI was apparently spontaneous MI due to the target vessel. Spontaneous MI was defined as an increase in creatine kinase-myocardial band (CK-MB) or troponin above the upper limit of the normal range with ischemic symptoms during post-discharge follow-up. Peri-procedural MI was defined as peak elevations of the CK-MB at least 10-fold above the upper reference limit within 48 hours post-procedure. Chronic kidney disease (CKD) was defined as estimated glomerular filtration rate <60 mL/min/1.73m^2, as calculated according to the Modification of Renal Diet equation. The remaining definitions of variables were described in detail in a previous paper.[15]

Continuous variables were compared using the *t* test and expressed as median and interquartile range or mean and standard deviation. Categorical variables were compared using the chi-square or Fisher's exact

test and presented as number and percentage. Cox proportional hazard models were performed to analyze the impact of diabetes on clinical outcomes. Multivariate Cox regression analyses were conducted with significant variables identified on univariate Cox regression analyses (*P*<.1). The hazard ratio (HR) and 95% confidence interval (CI) were calculated. Clinical outcomes were determined using the Kaplan-Meier method and compared using the log-rank test. A *P* value <.05 was considered statistically significant. The sample size for a one-sided alpha of 0.05, and a power of 80% was calculated as 1543 patients with the HR margin of TVR of 1.343 in the present study. All statistical analyses were conducted using Statistical Analysis Software (SAS, version 9.2, SAS Institute, Cary, NC, USA).

RESULTS

This study included 540 eligible patients, 305 with diabetes and 235 without diabetes (**Table 1**). Comorbidities, including hypertension, dyslipidemia and CKD were more common in patients with diabetes. The diabetes group had lower levels of hemoglobin, total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. The ejection fraction of the left ventricle was significantly lower in the diabetes group. The prevalence of multivessel disease was significantly higher in the diabetes group (**Table 2**). There were no significant differences in procedure success and periprocedural complications between the groups (**Table 3**).

TVF at 30 days and 18 months were not different between the diabetes and non-diabetes groups (1.6 vs. 2.6% at 30 -days, *P*= .545, 12.5 vs. 8.9% at 18 -months, *P*=.193) (**Table 4**). The primary endpoints occurred more often in patients with diabetes compared to patients without diabetes, and had no statistical significance. The incidence rates of cardiac death, target -vessel MI, and TVR at 30 days and 18 months in the diabetes group were comparable with those of patients without diabetes. Diabetes was not significantly related to clinical outcomes at 30 days and 18 months in crude and multivariate adjusted models. Compared with patients without diabetes, there was no difference in the incidence of 18-month TVF in patients with diabetes duration <10-year (unadjusted HR: 1.375, 95% CI: .727-2.602, *P*=.328; adjusted HR: 1.378, 95% CI: .655-2.900, *P*=.398) and diabetes duration ≥10-year (unadjusted HR: 1.729, 95% CI: 1.000-2.990, *P*=.050; adjusted HR: 1.346, 95% CI: .670-2.705, *P*=.403). There was no difference in the incidence of 18-month TVF in patients with diabetes treated with oral hypoglycemic agents (unadjusted HR: 1.092, 95% CI: .663-1.798, *P*=.730; adjusted HR: .925, 95% CI: .513-1.667, *P*=.795) and patients with diabetes treated with insulin (unadjusted HR: 1.573, 95% CI: .818-3.028, *P*=.175; adjusted HR: 2.752, 95% CI: .793-7.748, *P*=.195) compared with patients without diabetes.

DISCUSSION

The principal findings in the present study are that diabetic patients requiring RA had more comorbidities and adverse events compared to those without diabetes. The incidence of hypertension,

Table 1. Baseline characteristics of the study population (n=540).

	Diabetes (n=305)	No diabetes (n=235)	*P* value
Age (years)	72 (13)	74 (14)	.394
Male sex	173 (56.7)	150 (63.8)	.095
Body mass index (kg/m^2)	24.1 (4.2)	23.5 (5.6)	.753
Smoking	55 (18.0)	48 (20.4)	.483
Risk factors			
Hypertension	245 (80.3)	170 (72.3)	**.029**
Dyslipidemia	147 (48.2)	88 (37.5)	**.013**
Family history of coronary artery disease	8 (2.6)	3 (1.3)	.363
Chronic kidney disease	72 (23.6)	24 (10.2)	**<.001**
Previous coronary artery bypass graft	15 (4.9)	9 (3.8)	.543
Previous myocardial infarction	36 (11.8)	30 (12.8)	.735
Stroke	46 (15.1)	29 (12.3)	.361
Heart failure	47 (15.4)	30 (12.8)	.384
Atrial fibrillation	27 (8.9)	22 (9.4)	.838
Clinical presentation			
Stable angina	93 (30.5)	81 (34.5)	
Unstable angina	97 (31.8)	78 (33.2)	
Non-ST-elevation myocardial infarction	82 (26.9)	52 (22.1)	.106
ST-elevation myocardial infarction	7 (2.3)	12 (5.1)	
Silent ischemia	26 (8.5)	12 (5.1)	

Table 1 (cont.). Baseline characteristics of the study population (n=540).

	Diabetes (n=305)	No diabetes (n=235)	*P* value
Clinical diagnosis			
Acute myocardial infarction	89 (29.2)	64 (27.2)	.619
Nonacute myocardial infarction	216 (70.8)	171 (72.8)	
Left ventricular ejection fraction	51.6 (13.4)	54.8 (13.1)	**.007**
Treatment			
Non-vitamin K antagonist oral anticoagulant	10 (3.3)	6 (2.6)	.622
Dual antiplatelet therapy	292 (95.7)	227 (96.6)	.609
Aspirin	299 (98.0)	230 (97.9)	>.999
P2Y12 inhibitor	298 (97.7)	232 (98.7)	.525
Beta blocker	213 (69.8)	167 (71.1)	.757
Renin angiotensin system blocker	189 (62.0)	152 (64.7)	.517
Statin	284 (93.1)	218 (92.8)	.875
Laboratory findings			
Hemoglobin (g/dL)	11.9 (1.9)	12.9 (2.9)	**<.001**
Platelet ($\times 10^9$/L)	215.0 (68.8)	224.6 (73.6)	.121
Glycated hemoglobin (%)	7.3 (1.6)	5.8 (0.5)	**<.001**
High-sensitivity C-reactive protein (mg/dL)	3.6 (11.9)	2.2 (5.4)	.219
Total cholesterol (mg/dL)	136.8 (34.7)	152.5 (41.8)	**<.001**
Low density lipoprotein cholesterol (mg/dL)	79.9 (41.7)	90.9 (35.5)	**.003**
High density lipoprotein cholesterol (mg/dL)	44.2 (13.4)	48.5 (15.5)	**.001**
Triglyceride (mg/dL)	121.2 (73.3)	117.7 (75.2)	.619

Data are expressed as median (interquartile range) for age and body mass index, and mean (standard deviation) or number (%).

dyslipidemia, CKD, non-ST segment elevation MI, silent ischemia, and multivessel disease was higher in patients with diabetes compared with patients without diabetes. Patients without diabetes also had lower ejection fraction of the left ventricle than patients without diabetes. Second, there were no significant differences in procedure success and periprocedural complications between the two groups. Third, 30-day and 18-month clinical outcomes of patients with diabetes were comparable with those without diabetes. To our knowledge, this study is the first to compare the 30-day and 18-month clinical outcomes including angiographic complications in patients with and without diabetes treated with PCI requiring RA in a multicenter registry.

Patients with diabetes have the following characteristic coronary artery disease (CAD) patterns: smaller vessels, multivessel involvement, higher incidence of left main disease, poor collateral vessel development, and CAC.[9,16-19] These factors lead to a poor prognosis in diabetic CAD patients. Despite recent therapeutic advances, such as novel antiplatelet agents and drug-eluting stents, clinical outcomes in patients with diabetes after PCI remain significantly worse than in patients without diabetes. The mechanisms responsible for these differences include a prothrombotic state, increased platelet activation, inflammation, endothelial dysfunction, and other comorbidities.[20,21] According to the results of our study, the proportions of adverse events, such as non-ST segment elevation MI, silent ischemia, and multivessel disease were higher in patients with diabetes than in patients without diabetes.

Severe CAC presents several important technical issues for interventionalists. Severe CAC can increase the risk of major adverse cardiac events including restenosis and stent thrombosis as a result of incomplete preparation of the calcified stenotic lesion and insufficient acute luminal diameter gains.[22] In addition, non-expandable lesions might need to be inflated with a high-pressure balloon, which increases the risk of damage and rupture of the coronary arteries. Therefore, CAC was related to poor prognosis in CAD patients who underwent revascularization.[23] In the future, severe CAC is expected to increase due to the increased prevalence of diabetes, CKD, and elderly patients. RA could be a solution to overcome balloon non-dilatable lesions; however, it increases the risk of procedural complications. RA can increase the minimal lumen diameter after PCI and reduce residual plaque, creating a risk of stent thrombosis and restenosis.[24] Besides RA, other calcium plaque disruptive techniques include

orbital atherectomy and intravascular lithotripsy.[25]

Previous studies have investigated the impact of diabetes on clinical outcomes in patients with severe CAC.[11-13] Two of these studies showed clinical results of orbital atherectomy in diabetes and non-diabetes groups.[11,13] Lee et al reported that the rates of adverse clinical outcomes in patients with diabetes who underwent orbital atherectomy were similar to those in patients without diabetes at 30-day and 1-year follow-up. These results were similar to those of our study. However, they did not evaluate the angiographic complications between patients with and without diabetes.[11] Whitbeck et al investigated acute clinical outcomes after coronary orbital atherectomy in patients with and without diabetes. However, the study was single-center and had limited sample size. They showed no difference in angiographic complications and acute adverse events between groups, but the overall incidence of events was smaller than in our study.[13] There is only one study about the clinical outcomes of patients with diabetes with severe CAC requiring RA compared to patients without diabetes.[12] Januszek et al reported no significant differences in angiographic success and periprocedural complications between patients with and without diabetes. The authors also reported the clinical outcomes in those who did not undergo RA; however, they did not present long-term clinical outcomes. Our study analyzed the angiographic success and periprocedural complications as well as 30-day and 18-month clinical outcomes in patients with and without diabetes who underwent RA.

A limitation of the study is that the sample size was insufficient for a properly powered study and we cannot rule out the possibility of a type 2 statistical error resulting in non-significant differences between patients with and without diabetes. According to a sample size calculation based on the primary endpoint (TVR), 1543 patients would be required for an adequately powered study, but only 540 patients were enrolled in this study. Compared to previous studies comparing the results of atherectomy between patients with and without diabetes, the number of patients was greater than that of all but one other study.[11-13] Larger, fully powered studies are needed prospective studies are needed. A favorable feature of the study is that it was multicenter, but there was no standardized protocol for the use of RA, which was conducted at the discretion of the physician. Although the rate of diabetes in our data was higher than in previous studies, data from a recent Japanese registry reported that diabetes was 57% to 60% in RA patients.[26-29] Also, RA was performed on relatively simple lesions in only 3 patients.In addition,

Table 2. Baseline angiographic and procedural characteristics (n=540).

	Diabetes (n=305)	No diabetes (n=235)	*P* value
Lesion classification			
A	3 (0.9)	0	
B1	19 (5.7)	11 (4.4)	.379
B2	26 (7.8)	23 (9.2)	
C	284 (85.5)	217 (86.5)	
Multivessel disease	251 (82.3)	173 (73.6)	**.015**
Approach			
Trans-radial	132 (43.3)	116 (49.4)	.160
Trans-femoral	173 (56.7)	119 (50.6)	
Preprocedural lesion length (mm)	32.9 (14.5)	30.9 (15.5)	.694
Preprocedural proximal reference diameter (mm)	2.5 (0.4)	2.8 (1.2)	.318
Preprocedural distal reference diameter (mm)	2.2 (0.7)	1.9 (0.8)	.255
Preprocedural minimum lumen diameter (mm)	0.9 (0.3)	0.8 (0.5)	.365
Preprocedural stenosis (%)	83.1 (11.9)	89.8 (15.8)	.486
Stent type			
Balloon angioplasty	11 (3.3)	6 (2.4)	
Drug eluting balloon	11 (3.3)	5 (2.0)	
1st generation drug eluting stent	0 (0.0)	1 (0.4)	.440
2nd generation drug eluting stent	310 (93.4)	239 (95.2)	
Mean stent diameter (mm)	3.0 (0.4)	3.0 (0.4)	.619
Total number of stents	2.3 (1.2)	2.3 (1.1)	.759
Total stent length (mm)	67.5 (36.1)	65.6 (31.7)	.560
Final balloon diameters (mm)	2.3 (0.5)	2.4 (0.6)	.113
Final balloon atmosphere (atm)	15.6 (4.1)	15.6 (4.3)	.895
Final size of burr (mm)	1.5 (0.2)	1.5 (0.2)	.772
Initial size of burr (mm)	1.4 (0.2)	1.4 (0.2)	.843
Intravascular ultrasound	135 (44.3)	114 (48.5)	.326

Data are expressed as mean (standard deviation) or number (%).

Table 3. Complications (n=540).

	Diabetes (n=305)	No diabetes (n=235)	*P* value
Procedure success	296 (97.1)	224 (95.3)	.291
Complication			
Dissection type			
A	1 (0.3)	0 (0.0)	
B	10 (3.3)	2 (0.9)	
C	5 (1.6)	8 (3.4)	.301
D	10 (3.3)	6 (2.6)	
F	1 (0.3)	0 (0.0)	
Perforation	4 (1.3)	6 (2.6)	.344
Slow flow/No reflow			
Slow flow	8 (2.4)	10 (4.0)	.550
No reflow	5 (1.5)	4 (1.6)	
Temporary pacemaker	11 (3.6)	5 (2.1)	.315
Periprocedural myocardial infarction	20 (6.6)	25 (10.6)	.089
In-hospital bleeding	16 (5.3)	11 (4.7)	.765

Data are expressed as number (%).

the follow-up period was relatively short to generalize any clinical outcomes. Despite these limitations, the present results emphasize the impact of diabetes on the clinical outcomes including angiographic complication in patients with CAD requiring RA based on data from a multicenter registry.

In conclusion, patients with diabetes have 30-day and 18-month clinical outcomes comparable to patients without diabetes who have severe calcified coronary lesions requiring RA despite having more comorbidities and adverse factors. RA represents a safe and effective procedure for patients with diabetes with severe calcified coronary lesions. Further long-term prospective research is needed to determine the proper revascularization treatment for patients with diabetes with severe calcified coronary lesions.

Table 4. 30-day and 18-month clinical events by multivariate Cox hazard regression model.

	Diabetes (n=305)	No diabetes (n=235)	*P* value	Univariate hazard ratio (95% CI)	*P* value	Multivariate hazard ratio (95% CI)	*P* value
30 days							
Target vessel failure	5 (1.6)	6 (2.6)	.545	0.636 (0.194-2.084)	.455	0.595 (0.154-2.300)	.451
All cause death	7 (2.3)	4 (1.7)	.763	1.346 (0.394-4.597)	.636	1.502 (0.370-6.094)	.569
Cardiac death	5 (1.6)	3 (1.3)	.999	1.276 (0.305-5.338)	.739	1.108 (0.209-5.882)	.904
Myocardial infarction	1 (0.3)	2 (0.9)	.583	0.385 (0.035-4.242)	.435	0.272 (0.002-32.999)	.595
Target vessel myocardial infarction	0 (0.0)	2 (0.9)	.189	-	-	-	-
Target vessel revascularization	0 (0.0)	2 (0.9)	.189	-	-	-	-
Stent thrombosis	0 (0.0)	3 (1.3)	.082	-	-	-	-
Stroke	2 (0.7)	0 (0.0)	.507	-	-	-	-
Any bleeding	4 (1.3)	3 (1.3)	.999	1.035 (0.232-4.625)	.964	0.776 (0.133-4.536)	.778
18 months							
Target vessel failure	38 (12.5)	21 (8.9)	.193	1.476 (0.866-2.515)	.152	1.393 (0.782-2.482)	.260
All cause death	16 (5.3)	12 (5.1)	.942	1.061 (0.502-2.243)	.876	1.052 (0.469-2.362)	.902
Cardiac death	12 (3.9)	8 (3.4)	.746	1.192 (0.487-2.916)	.701	1.248 (0.455-3.424)	.668
Myocardial infarction	7 (2.3)	7 (3.0)	.620	0.795 (0.279-2.266)	.668	0.500 (0.139-1.803)	.289
Target vessel myocardial infarction	3 (1.0)	4 (1.7)	.475	0.593 (0.133-2.652)	.494	0.253 (0.030-2.163)	.209
Target vessel revascularization	26 (8.5)	13 (5.5)	.183	1.656 (0.851-3.222)	.138	1.592 (0.770-3.292)	.210
Stent thrombosis	3 (1.0)	1 (0.4)	.636	2.392 (0.249-22.998)	.450	3.694 (0.186-73.473)	.392
Stroke	3 (1.0)	4 (1.7)	.475	0.606 (0.136-2.710)	.513	0.415 (0.077-2.226)	.305
Any bleeding	12 (3.9)	9 (3.8)	.950	1.070 (0.451-2.540)	.877	0.968 (0.368-2.549)	.948

Multivariate analysis adjusted by age, sex, smoking, hypertension, dyslipidemia, chronic kidney disease, stroke, clinical diagnosis, multivessel disease, left ventricle ejection fraction, hemoglobin, total cholesterol, low density lipoprotein cholesterol, and high density lipoprotein cholesterol.

REFERENCES

1. Elflein J. Diabetics worldwide 2019 and 2045 2019 [cited 2021 6th, June]. Available from: https://www.statista.com/statistics/271442/number-of-diabetics-worldwide/.
2. Shi Y, Hu FB. The global implications of diabetes and cancer. Lancet. 2014;383(9933):1947-8.
3. Libby P, Nathan diabetes, Abraham K, Brunzell JD, Fradkin JE, Haffner SM, et al Report of the National Heart, Lung, and Blood Institute-National Institute of Diabetes and Digestive and Kidney Diseases Working Group on Cardiovascular Complications of Type 1 Diabetes Mellitus. Circulation. 2005;111(25):3489-93.
4. Kuchulakanti PK, Torguson R, Canos D, Rha SW, Chu WW, Clavijo L, et al Impact of treatment of coronary artery disease with sirolimus-eluting stents on outcomes of diabetic and nondiabetic patients. Am J Cardiol. 2005;96(8):1100-6.
5. Hermiller JB, Raizner A, Cannon L, Gurbel PA, Kutcher MA, Wong SC, et al Outcomes with the polymer-based paclitaxel-eluting TAXUS stent in patients with diabetes mellitus: the TAXUS-IV trial J Am Coll Cardiol. 2005;45(8):1172-9.
6. Moussa I, Leon MB, Baim DS, O'Neill WW, Popma JJ, Buchbinder M, et al Impact of sirolimus-eluting stents on outcome in diabetic patients: a SIRIUS (SIRolImUS-coated Bx Velocity balloon-expandable stent in the treatment of patients with de novo coronary artery lesions) substudy. Circulation. 2004;109(19):2273-8.
7. Bourantas CV, Zhang YJ, Garg S, Iqbal J, Valgimigli M, Windecker S, et al Prognostic implications of coronary calcification in patients with obstructive coronary artery disease treated by percutaneous coronary intervention: a patient-level pooled analysis of 7 contemporary stent trials. Heart. 2014;100(15):1158-64.
8. Généreux P, Madhavan MV, Mintz GS, Maehara A, Palmerini T, Lasalle L, et al Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes. Pooled analysis from the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) TRIALS. J Am Coll Cardiol. 2014;63(18):1845-54.
9. Schurgin S, Rich S, Mazzone T. Increased prevalence of significant coronary artery calcification in patients with diabetes. Diabetes Care. 2001;24(2):335-8.
10. Tomey MI, Kini AS, Sharma SK. Current status of rotational atherectomy. JACC Cardiovasc Interv. 2014;7(4):345-53.
11. Lee MS, Martinsen BJ, Lee AC, Behrens AN, Shlofmitz RA, Kim CY, et al Impact of diabetes mellitus on procedural and one year clinical outcomes following treatment of severely calcified coronary lesions with the orbital atherectomy system: A subanalysis of the ORBIT II study. Catheter Cardiovasc Interv. 2018;91(6):1018-25.
12. Januszek RA, Dziewierz A, Siudak Z, Rakowski T, Legutko J, Rzeszutko Ł, et al Diabetes and periprocedural outcomes in patients treated with rotablation during percutaneous coronary interventions. Cardiol J. 2018;27(2):152-61.
13. Whitbeck MG, Dewar J, Behrens AN, Watkins J, Martinsen BJ. Acute outcomes after coronary orbital atherectomy at a single center without on-site surgical backup: An experience in diabetics versus non-diabetics. Cardiovasc Revasc Med. 2018;19(6s):12-5.
14. Lee K, Jung JH, Lee M, Kim DW, Park MW, Choi IJ, et al Clinical Outcome of Rotational Atherectomy in Calcified Lesions in Korea-ROCK Registry. Medicina (Kaunas). 2021;57(7):694.
15. Lee SN, Her SH, Jang WY, Moon D, Moon KW, Yoo KD, et al Impact of chronic total occlusion lesions on clinical outcomes in patients receiving rotational atherectomy: results from the ROCK registry. Heart Vessels. 2021.
16. Mosseri M, Nahir M, Rozenman Y, Lotan C, Adiabeteson D, Raz I, et al Diffuse narrowing of coronary arteries in diabetic patients: the earliest phase of coronary artery disease. Cardiology. 1998;89(2):103-10.
17. Melidonis A, Dimopoulos V, Lempidakis E, Hatzissavas J, Kouvaras G, Stefanidis A, et al Angiographic study of coronary artery disease in diabetic patients in comparison with nondiabetic patients. Angiology. 1999;50(12):997-1006.
18. Waller BF, Palumbo PJ, Lie JT, Roberts WC. Status of the coronary arteries at necropsy in diabetes mellitus with onset after age 30 years. Analysis of 229 diabetic patients with and without clinical evidence of coronary heart disease and comparison to 183 control subjects. Am J Med. 1980;69(4):498-506.
19. Abaci A, Oğuzhan A, Kahraman S, Eryol NK, Unal S, Arinç H, et al Effect of diabetes mellitus on formation of coronary collateral vessels. Circulation. 1999;99(17):2239-42.
20. Morgan KP, Kapur A, Beatt KJ. Anatomy of coronary disease in diabetic patients: an explanation for poorer outcomes after percutaneous coronary intervention and potential target for intervention. Heart. 2004;90(7):732-8.
21. Prior JO, Quiñones MJ, Hernandez-Pampaloni M, Facta AD, Schindler TH, Sayre JW, et al Coronary circulatory dysfunction in insulin resistance, impaired glucose tolerance, and type 2 diabetes mellitus. Circulation. 2005;111(18):2291-8.
22. Kuntz RE, Safian RD, Carrozza JP, Fishman RF, Mansour M, Baim DS. The importance of acute luminal diameter in determining restenosis after coronary atherectomy or stenting. Circulation. 1992;86(6):1827-35.
23. Vavuranakis M, Toutouzas K, Stefanadis C, Chrisohou C, Markou D, Toutouzas P. Stent deployment in calcified lesions: can we overcome calcific restraint with high-pressure balloon inflations? Catheter Cardiovasc Interv. 2001;52(2):164-72.
24. Whitbourn RJ, Sethi R, Pomerantsev EV, Fitzgerald PJ. High-speed rotational atherectomy and coronary stenting: QCA and QCU analysis. Catheter Cardiovasc Interv. 2003;60(2):167-71.
25. Khandkar C, Patel S, Karimi Galougahi K. Intravascular imaging and novel techniques to disrupt severely calcified lesions. Postepy Kardiol Interwencyjnej. 2021;17(4):337-9.
26. Gorol J, Tajstra M, Hudzik B, Lekston A, Gąsior M. Comparison of outcomes in patients undergoing rotational atherectomy after unsuccessful coronary angioplasty versus elective rotational atherectomy. Postepy Kardiol Interwencyjnej. 2018;14(2):128-34.
27. Beohar N, Kaltenbach LA, Wojdyla D, Pineda AM, Rao SV, Stone GW, et al Trends in Usage and Clinical Outcomes of Coronary Atherectomy: A Report From the National Cardiovascular Data Registry CathPCI Registry. Circ Cardiovasc Interv. 2020;13(2):e008239.
28. Lee MS, Shlofmitz E, Nguyen H, Shlofmitz RA. Outcomes in Diabetic Patients Undergoing Orbital Atherectomy System. J Interv Cardiol. 2016;29(5):491-5.
29. Otsuki H, Jujo K, Tanaka K, Okai I, Nakashima M, Dohi T, et al Sex differences in clinical outcomes after rotational atherectomy of calcified coronary stenoses: from multicenter registry. Am J Cardiovasc Dis. 2021;11(1):12-20.