

clopidogrel-treated patients undergoing emergent or elective PCI for stable angina or acute coronary syndrome (non-ST-elevation and ST-elevation myocardial infarction, unstable angina). The main outcome measures were cardiovascular (CV) death, definite/probable stent thrombosis (ST), nonfatal myocardial infarction (MI), coronary revascularization (PCI or CABG) and a composite end point of ischemic events. High platelet reactivity (HPR) was defined as PRU (P2Y12 Reaction Unit) value ≥ 240 or 252.

RESULTS In total, 1038 consecutive patients were enrolled (Male 749, 72.7%). Patients with HPR were 487 (46.9%). VerifyNow P2Y12 cartridge was used in 1038 patients. All patients received optimal clopidogrel pretreatment and maintenance therapy. At a 12-month follow-up, we found 85 ischemic events (18 CV deaths [1.7%], 7 nonfatal MIs [0.7%]), 5 stent thrombosis (0.5%) and 47 target-vessel revascularizations (4.5%). The CV rate of patients with HPR (PRU > 240) was significantly higher rate (2.7% vs 1.0% (p = 0.030)) than the patients with normal value. The composite end point event rate of patients with HPR (PRU > 240) was also significantly higher rate (8.07% vs 4.5% (p = 0.020)) than the patients with normal value. In survival analysis, there was no significant difference between patient with HPR (PRU > 240) and normal reactivity. But between patient with HPR (PRU > 252, cutoff value of CILON-T trial) and normal reactivity, the survival rate free from the CV death was significantly lower in patients with high on-treatment platelet reactivity (p = 0.037, Log Rank test).

CONCLUSION HPR tested by VerifyNow predict coronary adverse event in patients after PCI. In Korean, the rate of HPR was higher than western people and we seem to have to raise the optimal cutoff value of PRU to predict future coronary event in Korean.

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Assessment Of Impact Of Chronic Kidney Disease On Platelet Inhibition Among Post Percutaneous Intervention Patients On Antiplatelet Therapy

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BACKGROUND CKD may influence the response to antiplatelet therapy. We, therefore, sought to investigate its effect on platelet inhibition according to its stages.

METHODS We assessed platelet inhibition (PI) among those patients on dual anti-platelet regimen (75 mg of Aspirin and 75 mg of clopidogrel) in various stages of CKD in 922 patients after PCI with stent implantation. Platelet inhibition was tested with platelet aggregometry. Effective PI is defined as > 50% platelet inhibition. CKD was defined as a estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m². eGFR was estimated by MDRD formula. We analyzed PI levels with eGFR values using Pearson correlation test.

RESULTS Total no of cases are 922. Male:female::3:4:1. 606 (66%) were hypertensives, 417 (45%) were diabetics and 224 (24%) were smokers. 548 (59%) pts were presented with ACS and multi vessel angioplasty was done in 214 (23%) patients. Total no of lesions treated were 1225 in 922 pts. Prevalence of patients according to stages of CKD were - Stage 1 - 209(23%); Stage 2 - 415 45%; Stage 3a - 158 (17%); Stage 3b - 104 (11%); Stage 4 - 15 (1.6%); Stage 5 - 19(2%) pts. There was no correlation between estimated GFR and percentage of inhibition of platelets in all pts (Pearson correlation = -0.021; p Value = 0.7) and in different stages CKD pts (Stage 1 - Pearson correlation = -0.039, p value = 0.8, Stage 2 - correlation = -0.008, p = 0.9, Stage 3a correlation = -0.002, p = 0.98, Stage 3b correlation = 0.052, p = 0.8, Stage 4 correlation = 0.9, p = 0.1 and Stage 5 correlation = -0.6, p = 0.3).

CONCLUSION Presence of CKD (including the all stages) does not influence the effectiveness of platelet inhibition with antiplatelet therapy in pts undergoing PCI for obstructive CAD.

ATHERECTOMY DEVICES

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Safety of Rotational Atherectomy in High Risk PCI with Hemodynamic Support

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BACKGROUND Rotational atherectomy (RA) can aid in high risk Percutaneous Coronary Intervention (PCI) with hemodynamic support. There is concern that use of RA could result in increased procedural complications. We report our institution's experience with RA in high risk PCI with hemodynamic support.

METHODS 398 patients underwent high risk PCI with intraaortic balloon pump (IABP) (n=327), Impella (n=57), or Tandem Heart (n=14) between 2008 and July 2014. Patients with ST elevated myocardial infarction were excluded (n=129). Patients who underwent RA (n=34) were compared to those who did not (n=235). Among the 34 patients who underwent RA, Impella use (n=10) versus IABP use (n=23) was compared.

RESULTS Patients in the RA arm were older (71.91±14.47 vs. 64.77±12.63, p=0.003) and less likely in cardiogenic shock (6% vs. 23%, p=0.02). There was no difference in

the number of diseased vessels (RA= 2.86±0.88 vs. no RA =2.68±0.99, p=NS), location of vessels, or number of total occlusions (RA = 32% vs. no RA =32%, p=NS). PCI without stent deployment was less common in the RA arm (15% vs. 37%, p=0.01). There was no difference in stent diameter or length. There was a trend toward more Impella use, but this was not statistically different (RA = 29% vs. no RA =18%, p=NS). There was no difference in morbidity, hospital mortality, recurrent MI, or repeat revascularization. Within the rotational atherectomy group, there was no difference in outcome between IABP or Impella 2.5.

CONCLUSION In our center's experience, use of rotational atherectomy in high risk PCI with hemodynamic support is feasible and not associated with increased morbidity or mortality.

Outcome	No RA n (%)	RA n (%)	p value
Days in intensive care unit	6.79±8.59	5.67±8.26	0.53
Length of hospital stay (d)	12.62±14.74	10.76±10.09	0.35
In-hospital mortality	32(13.62)	2(5.88)	0.28
In-hospital morbidity*	54(22.98)	5(14.71)	0.28
Bleeding complications	16(6.81)	1(3.13)	0.70
Acute renal failure	51(21.70)	6(18.75)	0.62
Stroke	8(3.40)	0(0)	0.60
Ischemic EKG Changes	4(1.70)	0(0)	1.0
Repeat PCI	13(5.53)	4(11.76)	0.24
Recurrent myocardial infarction (3x upper limit of normal Troponin-I)	32(13.62)	7(20.59)	0.37
Recurrent myocardial infarction (5x upper limit of normal Troponin-I)	27(11.49)	4(11.76)	1.0

Outcome	RA +IABP	RA + Impella	p value
Days in intensive care units	4.78±6.62	7.44±11.10	0.44
Length of hospital stay (d)	8.87±8.67	12.50±10.03	0.30
In-hospital mortality	2(8.70)	0(0)	1.0
In-hospital morbidity*	5(21.74)	0(0)	0.29
Bleeding complications	1(4.35)	0(0)	1.0
Acute renal failure	5(21.74)	1(10.0)	0.64
Stroke	0(0)	0(0)	1.0
Ischemic EKG Changes	0(0)	0(0)	1.0
Repeat PCI	4(17.39)	0(0)	0.28
Recurrent myocardial infarction (3x upper limit of normal Troponin-I)	6(26.09)	0(0)	0.12
Recurrent myocardial infarction (5x upper limit of normal Troponin-I)	3(13.04)	0(0)	0.53

*In-hospital morbidity: Patients experience either of the following: Bleeding complications, acute renal failure, Vascular complications, Neurologic Complications, Ischemic Complications (Recurrent Chest pain, Ischemic EKG Changes), instant thrombosis, Arrhythmia Complications, Repeat catheterization, or repeat PCI.

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One-year Safety Outcomes in Diabetic Patients Treated With Orbital Atherectomy For De Novo, Severely Calcified Coronary Lesions: A Sub-analysis Of The ORBIT II Trial

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BACKGROUND Patients with diabetes mellitus (DM) are at increased risk for severe coronary artery calcification. Severely calcified lesions make successful balloon angioplasty and stent delivery more difficult during percutaneous coronary intervention (PCI) and treatment may lead to serious procedural complications. Compared to non-diabetics, diabetics have increased incidence of major adverse cardiac events (MACE) after PCI. In this analysis, we compared 1-year safety outcomes in ORBIT II patients with or without DM treated with the Diamondback 360 Coronary Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc., St. Paul, MN).

METHODS ORBIT II, a prospective, multi-center trial conducted in the US, was designed to evaluate the safety and efficacy of the Diamondback 360 Coronary OAS to prepare *de novo*, severely calcified coronary lesions for stent deployment. Freedom from 1-year MACE (defined as cardiac death, myocardial infarction (MI, CK-MB>3X ULN), and target vessel revascularization (TVR)) was compared in patients with history of DM (DM group, N=160) versus patients without history of DM (no-DM group, N=283).

RESULTS Patients in the DM group were younger (70.3 ± 0.7 vs 72.0 ± 0.6, p=0.02), had higher BMI (31.0 ± 0.5 vs 28.5 ± 0.3, p<0.0001), higher prevalence of hypertension (96.3% vs 89.0%, p=0.01), and higher rate of previous coronary artery bypass graft (20.0% vs 11.7%, p=0.02). As estimated by Kaplan-Meier, at one year both DM and non-DM patients had similar high freedom from MACE (83.5% vs 83.6%,

p=0.98), cardiac death (96.8% vs 97.1%, p=0.84), MI (91.9% vs 89.4%, p=0.40), Q-wave MI (100.0% vs 98.6%, p=1.0), non-Q-wave MI (91.9% vs 90.8%, p=0.70), and TVR (94.1% vs 94.2%, p=0.98).

CONCLUSION Using the OAS as a lesion preparation tool prior to stent deployment in both diabetics and non-diabetics may offer patients with severely calcified coronary lesions a new treatment option, with low rates of MACE at one-year post-procedure.

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Orbital Atherectomy Treatment of Severely Calcified Coronary Lesions in Patients with History of Coronary Artery Bypass Grafting: One Year Safety Outcomes from the ORBIT II Trial

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BACKGROUND History of prior coronary artery bypass grafting (CABG) may be associated with increased incidence of major adverse cardiac events (MACE) in patients undergoing repeat CABG, percutaneous coronary intervention, or medical treatment. In this analysis, one year safety outcomes were evaluated in patients with and without history of CABG treated with orbital atherectomy for *de novo*, severely calcified coronary lesions.

METHODS ORBIT II, a prospective, multicenter, non-blinded trial, enrolled 443 patients with severely calcified coronary lesions. Orbital atherectomy was used to modify lesions for stent placement. One year safety outcomes were compared in patients with and without history of CABG (N=65 and N=378).

RESULTS ORBIT II patients with history of CABG were more likely to be male and have a higher prevalence of diabetes, history of dyslipidemia, hypertension, and myocardial infarction (MI). One year safety outcomes are presented in Table I. The higher rate of in-hospital MACE (16.9% vs. 8.5%, p=0.04) in the prior CABG group was likely driven by the higher rate of non-Q-wave MI (15.4% vs. 7.5%, p=0.05). At one year, however, using multivariate analysis prior CABG was not associated with increased MACE (HR 0.57, p=0.08) after adjusting for baseline and pre-procedural factors.

CONCLUSION Preparation of severely calcified coronary lesions with orbital atherectomy facilitated stent delivery in patients with a history of CABG, resulting in low rates of 1-year MACE, MI, cardiac death, and target vessel revascularization.

Table I. ORBIT II Safety Outcomes Through 1-Year Follow-up

	Prior CABG	No Prior CABG	p-value
1-year			
MACE (%)	26.3	14.7	0.02
Cardiac death (%)	4.7	2.7	0.41
Q-wave MI (%)	1.5	0.8	0.57
Non-Q-wave MI (CK-MB>3XULN) (%)	15.4	7.7	0.05
TVR (%)	8.0	5.5	0.45

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First- Versus Second-generation Drug-eluting Stents Following Rotational Atherectomy in Patients With Heavily Calcified Coronary Lesions

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BACKGROUND Little information is available regarding the comparison between the first- and second-generation drug-eluting stents (DES) following rotational atherectomy (ROTA) for patients with heavily calcified coronary lesions (HCCL).

METHODS Ninety-nine patients with HCCL who underwent RA prior to first-generation DES (n=40, 53 lesions) or second-generation DES (n=59, 63 lesions) implantation were retrospectively analyzed. The primary endpoint was the rate of major adverse cardiac events (MACE).

RESULTS Baseline clinical and procedural characteristics were similar between the two groups, except for more complex type C lesions (81.0% vs. 58.8%, p=0.01) and more proportion of post dilation (52.4% vs. 23.1%, p=0.001) in the second-generation DES group. The procedure success rate was similar in the two groups (95% vs. 100%, p=0.161). Compared with first-generation DES group, there were no differences regarding the occurrence of MACE (11.9% vs. 12.8%, p=1.000), TLR (3.6% vs. 2.7%, p=1.000) and all-cause death (8.5% vs. 10.3%, p=1.000) in the second-generation DES group at 1-year follow-up. No stent thrombosis was found in all patients.

CONCLUSIONS The first- and second-generation DES following ROTA resulted in comparable outcomes in patients with HCCL at 1 year follow-up.

Table I. In-hospital, 6-month and 1-year clinical outcomes

Variable	1-st generation DES (n=40, 53 lesions)	2-nd generation DES (n=59, 63 lesions)	p-value
In-hospital MACE (%)	5.0	0	0.161
6 month follow-up (%)			
MACE	7.5	6.8	1.000
All cause death	5.0	5.1	1.000
Cardiac death	0	5.1	0.274
Q-wave MI	0	0	-
TLR	2.5	1.7	1.000
Stent thrombosis	0	0	-
1 year follow-up (%)			
MACE	12.8	11.9	1.000
All cause death	10.3	8.5	1.000
Cardiac death	0	8.5	0.153
Q-wave MI	0	0	-
TLR	2.7	3.6	1.000
Stent thrombosis	0	0	-

MACE: Major adverse cardiac events; MI: Myocardial infarction; TLR: Target lesion revascularization

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Clinical Outcomes Comparison Among Different Strategies Of Lesion Preparation For Heavily Calcified Coronary Lesions With Drug-eluting Stents Implantation: Plain Balloon, Cutting Balloon And Rotational Atherectomy

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BACKGROUND This study aimed to compare the outcome following plain old balloon angioplasty (POBA), cutting balloon angioplasty (CBA) and rotational atherectomy (ROTA) in patients with heavily calcified coronary lesions (HCCL).

METHODS Clinical data of the patients with HCCL who underwent POBA (n=220), CBA (n=253), or ROTA (n=264) prior to DES implantation from 2003-2013 were retrospectively analyzed. The occurrence of major adverse cardiac events (MACE), defined as all-cause death, myocardial infarction (MI) or target lesion revascularization (TLR) were compared at one year follow-up.

RESULTS Baseline clinical characteristics were similar among the three groups, except for older patients age, and type C lesions in the ROTA versus the CBA and POBA (71.9±10.4 vs. 68.0±10.8, 68.7±11.8 years, p<0.001), and (61.7% vs. 35.8%, 45.0%, p<0.001) respectively. Angiographic success was achieved in all patients. At one year follow-up, the MACE rate was similar (14.6% in the ROTA group, 12.3% in the POBA group and 8.3% in the CBA group, p=0.204). The occurrence of stent thrombosis was 0.6% in the CBA and 0% in the ROTA and POBA group.

CONCLUSIONS In patients with HCCL, ROTA was frequently used for the treatment of more complex lesions compared with CBA and POBA. The different strategies with ROTA, CBA and POBA prior to DES implantation resulted in the similar long-term outcomes after optimal lesion preparation for patients with HCCL.

Table I. 6-month and 1-year clinical outcomes

Variable	POBA (n=220)	CBA (n=253)	ROTA (n=264)	p value
6 month follow-up (%)				
MACE	9.2	3.9	8.6	0.118
All cause death	6.2	2.2	6.3	0.135
Cardiac death	1.6	1.1	1.8	0.897
Q-wave MI	0	0	0	-
TLR	2.4	2.3	2.4	1.00
Stent thrombosis	0	0.5	0	1.00
1 year follow-up (%)				
MACE	12.3	8.3	14.6	0.204
All cause death	8.2	4.5	9.8	0.178
Cardiac death	2.5	1.3	3.1	0.611
Q-wave MI	0	0.7	0	1.00
TLR	3.5	3.9	5.2	0.765
Stent thrombosis	0	0.6	0	0.629

MACE: Major adverse cardiac events; MI: Myocardial infarction; TLR: Target lesion revascularization