Conclusion: Despite a greater risk of target vessel revascularization in patients switched from clopidogrel to a Gen 2 APT, there was not an increased risk of stent thrombosis. This data suggests that Gen 2 APT may be employed in higher risk patients but do not increase the risk of stent thrombosis, implying adequate compliance in these high-risk patients.

Variables	Continued Clop (n=5828)	Clop to Gen 2 APT (n=201)	Gen 2 APT to Clop (n=207)	Continued Gen 2 APT (n=653)	p-value
Age	67 ± 12	59 ± 10	62 ± 10	59 ± 10	<0.001
Male	64%	75%	70%	73%	<0.001
African American	37%	27%	30%	30%	<0.001
PCI for AMI	33%	64%	32%	35%	<0.001
IABP	4.4%	7.9%	2.4%	2.8%	0.007
GP IIb/IIIa use	4.8%	11.9%	5.3%	7.2%	<0.001
DES placed	63%	67%	73%	76%	<0.001
Smoking	25%	29%	28%	30%	0.06
Hypertension	88%	78%	80%	79%	<0.001

CORONARY

Atherectomy Devices

CRT-128

Comparing the Procedural and 30-Day Outcomes in Patients with or without a History of Coronary Artery Bypass Graft When Treating De Novo, Severely Calcified Coronary Lesions with Orbital Atherectomy: Results from ORBIT II

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Background: In prior studies, patients with previous coronary artery bypass grafting (CABG) experienced significantly greater incidence of adverse clinical events upon subsequent repeat CABG, percutaneous coronary intervention, or medical treatment, compared to patients with no prior CABG. In this analysis, we evaluate the procedural and 30-day outcomes in patients with and without a history of previous CABG in the ORBIT II Trial.
Methods: The ORBIT II Trial, a prospective, multicenter, non-blinded clinical trial that enrolled 443 consecutive patients, was designed to evaluate the safety and efficacy of the coronary Orbital Atherectomy System to prepare de novo, severely calcified coronary lesions for stent placement. Procedural and 30-day outcomes in patients with history of previous CABG (N=65) and no history of CABG (N=378) were evaluated in this analysis.
Results: Compared to patients without history of previous CABG, patients with history of CABG were more likely to be male (p=0.005) and have a higher prevalence of diabetes mellitus (p=0.025), history of dyslipidemia (p=0.008), hypertension (p=0.028), and myocardial infarction (MI) (p<0.0001). The rate of procedural success (stent delivery with residual stenosis <50% without the occurrence of an in-hospital major adverse cardiac event (MACE)) was similar 83.1% (previous CABG) and 89.9% (without previous CABG) (p=0.132). Statistically similar low rates of severe dissection (7.7% vs. 2.6%: p=0.054), perforation (0% vs. 2.1%: p=0.611), persistent slow flow (0% vs. 1.1%: p=1.0), and abrupt closure (3.1% vs. 1.6%: p=0.333) were observed in the history of CABG and no history of CABG groups, respectively. As estimated by Kaplan Meier at 30-days, patients had similar low rates of MACE (previous CABG: 16.9% vs. without previous CABG: 9.3%, p=0.070).
Conclusion: Preparation of severely calcified coronary lesions with the coronary Orbital Atherectomy System facilitated stent delivery in patients with a history of previous CABG, resulting in low rates of 30-day MACE.

CRT-129

Outcomes in Chronic Kidney Disease Patients Treated for Coronary Arterial Disease Utilizing the Orbital Atherectomy System: An ORBIT II Sub-Analysis

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Background: Cardiovascular disease is common in patients with chronic kidney disease (CKD) and often results in severely calcified lesions that are difficult to cross and treat. As a result, this population may have worse clinical outcomes following percutaneous coronary intervention compared to patients without CKD. Clinical trials typically exclude this patient population.
Methods: ORBIT II patients with severely calcified coronary lesions treated with the coronary Orbital Atherectomy System (OAS) were divided into three groups based on the estimated glomerular filtration rate (eGFR, mL/min/1.73m^2) at baseline: I (CKD Stages 3-5), eGFR<60 (n=115); II (CKD stages 1-2), eGFR 60 to <90 (n=218); and III (normal), eGFR≥90 (n=108).
Results: Patients in groups I and II were older (p<0.0001), and there were more females in these two groups than in group III (p=0.0468). History of previous stroke (p=0.0351) was more prevalent in groups I and II. In addition, the total length of calcium was significantly longer in group II (p=0.0003). Similar successful stent delivery occurred in 97.4%, 97.2% and 99.1% (p=0.7006) of cases with <50% residual stenosis in 99.1%, 98.2% and 99.1% (p=0.8779) of subjects in groups I, II and III, respectively. Statistically similar low rates of severe dissection (1.7%, 5.5%, 0.9%: p=0.0709), perforation (2.6%, 1.8%, 0.9%: p=0.7343), persistent slow flow (0.9%, 1.4%, 0.0%: p=0.8110), and abrupt closure (1.7%, 1.8%, 1.9%: p=1.0000) were observed in groups I, II, and III, respectively. The 30 day Freedom from MACE rates in groups I (87.8%), II (87.1%), and III (96.3%) were similar (p=0.0555).
Conclusion: Severely calcified coronary lesion pre-treatment with the coronary OAS resulted in similar 30 day Freedom from MACE rates and low rates of procedural complications in CKD patients compared with the non-CKD patients despite the older demographic and longer length of calcium in the CKD patients.

CRT-130

Gender Difference on Procedural and 30-day Outcomes in Patients Treated with Orbital Atherectomy for De-Novo, Severely Calcified Coronary Lesions: Results from the ORBIT II Trial

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Background: Previous studies have shown a negative correlation between female gender and adverse events after percutaneous coronary intervention (PCI). In this analysis, we evaluate the procedural and 30-day outcomes of male and female patients in the ORBIT II Trial.
Methods: The ORBIT II Trial, a prospective, multicenter, non-blinded clinical trial that enrolled 443 consecutive patients, was designed to evaluate the safety and efficacy of the coronary Orbital Atherectomy System to prepare de novo, severely calcified coronary lesions for stent placement. Procedural and 30-day outcomes in male patients (N=286) were compared to female patients (N=157). The primary safety endpoint was freedom from major adverse cardiac events (MACE) at 30 days post-procedure. The primary efficacy endpoint was procedural success defined as stent delivery with a residual stenosis of <50% without the occurrence of an in-hospital MACE.
Results: Compared to males, females were older (p=0.0011) and had lower eGFR at baseline (p=0.0024). However males had a higher rate of previous coronary artery bypass graft (p=0.0048). Both males and females met the primary safety endpoint goal of 83% (89.2% [95% CI: 85.5%-92.8%] vs. 90.4% [95% CI: 85.7%-95.2%]) and primary efficacy endpoint of 82% (88.4% [95% CI: 84.1%-91.9%] vs. 89.7% [95% CI: 83.9%-94.0%]). As estimated by Kaplan Meier at 30-days, males and females had similar low rates of MACE (10.8% vs. 9.6%, p=0.6613), myocardial infarction (MI) (10.1% vs. 8.9%, p=0.666), target vessel revascularization/target lesion