

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

Atherectomy Devices

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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.

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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/1.73m²) 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.

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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

revascularization (TVR/TLR) (1.8% vs. 0.6%, $p=0.3584$) and cardiac death (0% vs. 0.7%, $p=0.9976$).

Conclusion: This sub-analysis of the ORBIT II study demonstrates that males and females treated with orbital atherectomy for severely calcified coronary arteries (generally regarded as high-risk revascularization) demonstrate similar 30-day outcomes. In the context of the larger study, one can presume that the novel coronary Orbital Atherectomy System is a safe and effective adjunctive therapy for severely calcified coronary lesions in both men and women.

Bifurcation

CRT-131

Feasibility of the Use of the Tryton™ Dedicated Bifurcation Stent via the Transradial Route - A Single Centre Experience

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Background: The use of the Transradial access (TR) for the treatment of Coronary Bifurcation Lesions (CBL) with Percutaneous Coronary Intervention (PCI) can be limited where a two stent strategy is required as larger sheath and guide catheters are required to facilitate stent delivery. With the development of newer dedicated bifurcation stents, there is an increasing trend of these stents to be adopted in PCI centres to treat CBLs. We report our experience of the use of the Tryton™ dedicated side branch bifurcation stent at our default TR centre where 90% of all PCI are carried out via the TR.

Methods: This was a prospective study of all patients who were found suitable to undergo PCI to CBLs using the Tryton stent between September 2009 and June 2013. Data on patient demographics and procedure characteristics was collected from the local hospital database.

Results: 36 patients (Male 69.4%, age 68.1 years) underwent PCI using the 19mm long Tryton™ bifurcation stent. Most of the CBLs treated were located in the LAD/Branch (52.8%), followed by the Circumflex/Branch (27.8%), Left main stem/Branch (13.9%), RCA/Branch (2.7%) and LIMA graft (2.7%). Tryton™ stents dimensions (Side branch/Main branch diameters) deployed were (2.5/2.5mm - 11.1%; 2.5/3.0mm - 25%; 2.5/3.5mm - 47.2%; 3.0/3.5mm - 8.3% and 3.5/4.0mm - 8.3%). 91.6% of cases were carried out via 6F guide catheters with the remaining cases carried out via the 7F. Mean contrast volume, radiation dose and fluoroscopy times were 306 mls, 98.8 Gy/cm² and 28.2 minutes respectively. 94.4% of all cases were successfully carried out via the TR route with remaining cases switching to the transfemoral route to successfully complete the procedure.

Conclusions: When treating CBLs, a wide range of Tryton™ dedicated side branch stents can be safely and effectively deployed via the TR route using 6F/7F Guide catheter systems. This can avoid the use of the transfemoral route and its associated potential vascular complications.

CABG

CRT-132

Under-Utilization of Statins and Aspirin Following Coronary Artery Bypass Graft Surgery

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Background: Coronary artery bypass graft (CABG) surgery is commonly performed to treat ischemic heart disease, but long term benefits are limited by patency of saphenous vein grafts. Both statin medications and aspirin hold class I indications for all post-CABG patients and should be continued indefinitely unless contraindication exists. Unfortunately, there is limited data regarding long-term usage of these medications. We assessed utilization rates among post-CABG patients without documented contraindication.

Methods: A retrospective analysis of post-CABG patients presenting to the Thomas Jefferson University cardiac catheterization laboratory for a catheterization procedure at least 3 years after surgery was performed. Inpatient and outpatient records were reviewed to assess prescribing patterns of these medications, as well as other pertinent clinical and laboratory data.

Results: The study population consisted of 381 consecutive patients who presented on average 11 ± 6 years from the time of CABG. Mean age of our study population was 69 ± 11 years with 78% male. The most common indications for catheterization were unstable angina (36%), non-STEMI (22%), and an abnormal stress test (15%). Only 67% of patients were being prescribed a statin, while 75% were prescribed aspirin. Only 52% were prescribed both at the time of catheterization. Three percent had a documented intolerance to statin therapy. Patients prescribed a statin had a significantly lower mean LDL (87 vs. 106 [$p<0.01$]) and total cholesterol values (151 vs. 162 [$p<0.01$]). Thirty five percent of patients had LDL ≥ 100 . Only 43% of saphenous vein grafts among the patients not on statin medications remained patent an average of 11 years post-CABG surgery.

Conclusions: Long-term statin and aspirin use following CABG surgery remains suboptimal despite clear guideline recommendations and clinical trial evidence of their effectiveness. Coordinated efforts are needed to improve long-term medication usage in this subset of high risk patients.

Cardiovascular Pharmacology

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Omeprazole Use is Associated with Increased Cardiovascular Complications in Asian Patients on Aspirin and Clopidogrel After Percutaneous Coronary Intervention

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Background: Dual anti-platelet therapy (DAPT) with Aspirin and a Thienopyridine-derivative P2Y₁₂ Inhibitor (commonly Clopidogrel) is mandatory after Percutaneous Coronary Intervention (PCI). H₂ receptor antagonists (H₂RA) or Proton Pump Inhibitors (PPI) are prescribed to reduce gastrointestinal bleeding risk.