

Results: Currently, clinical follow-up was available in 628 patients and angiographic follow-up in 526 patients (608 lesions). The primary endpoints were not statistically different between the 6- and 12-month DAPT groups, including MACE (4.6 vs. 3.4%; $p=0.49$) and stent thrombosis (0.0 vs. 0.3%; $p=0.71$), and MACE (3.4 vs. 4.6%; $p=0.49$) and stent thrombosis (0.3 vs. 0.0%; $p=0.71$), according as type of stents (BES vs. ZES, respectively). The secondary endpoints also were not significantly different between the 6- and 12-month DAPT groups, including target lesion failure (2.0 vs. 1.6%; $p=0.53$), in-segment LL (mm) at 12 months (0.09 ± 0.37 vs. 0.05 ± 0.39 , $p=0.61$). Similar results were shown between stents type. And NIH CSA (mm²) at 6month between BES and ZES were 0.38 ± 0.28 , 0.45 ± 0.32 , respectively ($p=0.41$). **Conclusions:** Six-month DAPT did not increase the risk of MACE, stent thrombosis, target lesion failure, and LL at 12 months after implantation of drug-eluting stents compared with 12-month DAPT. The 2nd generation DES including BES and ZES are comparably efficacious. Our results need to be confirmed in larger trials and further follow up data.

TCT-9

Racial Disparity With On-Treatment Platelet Reactivity In Patients Undergoing Percutaneous Coronary Intervention

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Background: On-treatment platelet reactivity to clopidogrel is variable and in part genetic dependent. In African American (AA) patients, the relation between on-treatment platelet reactivity to clopidogrel and the factors that influence this interaction are unknown. The present study aims to evaluate on-treatment platelet reactivity to clopidogrel in AA patients and its interaction to race and CYP2C19*2 loss of function mutation.

Methods: The study cohort included 289 consecutive patients presenting for percutaneous coronary intervention (PCI) who were entered into a prospective, observational registry. High on-treatment platelet reactivity (HTPR) was defined as P2Y12 reaction units (PRU) ≥ 208 with VerifyNow P2Y12 assay and $>50\%$ by vasodilator-stimulated phosphoprotein phosphorylation assay platelet reactivity index (VASP PRI) measured 6-24 hours post-procedure. CYP2C19*2 (rs4244285) genotype was analyzed by real-time polymerase chain reaction.

Results: The prevalence of HTPR by both PRU (56% vs. 35%, $p=0.003$) and VASP PRI (67% vs. 45%, $p=0.002$) is more common in AA compared to Caucasians, respectively. AA patients had higher on-treatment, mean PRU (207 ± 110 vs. 160 ± 102 , $p=0.002$) and VASP PRI (49 ± 26 vs. 38 ± 26 , $p=0.004$). AA also had a higher prevalence of CYP2C19*2 allele carrier status compared to Caucasians (43% vs. 29%, $p=0.04$). AA race ($p=0.008$) and CYP2C19*2 allele status ($p=0.02$) independently had significant effects on PRU and VASP. Multivariable logistic regression analysis has shown that both CYP2C19*2 allele carrier status and AA race were independent correlates of HTPR for PRU ≥ 208 .

On-treatment Platelet Reactivity and CYP2C19*2 allele Carrier Status by Race

Variable [n (%) or mean \pm SD]	African American	Caucasian	p value
	(n=61)	(n=228)	
VerifyNow aspirin ARU	419 \pm 63	420 \pm 59	0.9
HTPR by ARU \geq 550	6(9.8%)	22(9.9%)	0.99
VerifyNow PRU	207 \pm 110	160 \pm 102	0.002
HTPR by PRU \geq 208	34(56%)	80(35%)	0.003
HTPR by PRU \geq 230	28(46%)	62(27%)	0.005
HTPR by PRU \geq 250	27(44%)	47(21%)	<0.001
VASP PRI	49 \pm 26	38 \pm 26	0.004
HTPR by VASP PRI $>$ 50%	41(67%)	103(45%)	0.002
Carrier of CYP2C19*2 allele (AA/AG)	26(43%)	66(29%)	0.04

HTPR, high on-treatment platelet reactivity; ARU, aspirin reaction units; PRU, P2Y12 reaction units; VASP PRI, vasodilator-stimulated phosphoprotein phosphorylation assay platelet reactivity index

Conclusions: AA patients undergoing PCI not only have a higher prevalence of HTPR to clopidogrel but also have higher CYP2C19*2 allele carrier status compared to Caucasians. Careful selection of antiplatelet agents should be considered in an AA population at higher risk for ischemic complications.

TCT-10

Differences Between US and non-US Cohorts after PCI and Dual Antiplatelet Therapy: Patient Characteristics, Randomization

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Background: Comparative effectiveness studies may seek to enroll geographically diverse populations to enhance generalizability. We compared enrollment, randomization, drug and device utilization between US and non US patients across a large international trial.

Methods: The Dual Antiplatelet Therapy (DAPT) Study is a double-blind randomized trial designed to compare durations of DAPT after PCI with stents with respect to clinical events. Patients were enrolled between August 2009 and July 2011. At 12 months, eligible patients were randomized to receive placebo+aspirin or thienopyridine+aspirin through study endpoint (30 months). We compared patient and procedure characteristics, patterns of stent and medication choice, compliance with antiplatelet therapy, and randomization rates, between patients enrolled in the US and other countries.

Results: The DAPT Study enrolled 26,194 patients treated with drug-eluting (N=23,210) or bare metal (N=2,984) stents, 23,495 in the US (90%) and 2,699 in other countries: UK 629, Poland 388, Germany 372, Romania 312, Hungary 271, New Zealand 239, Australia 197, France 101, Canada 96, and Czech Republic 94. Non-US patients were more likely to be male, current smokers, present with acute coronary syndrome, receive bare metal vs drug-eluting stents, clopidogrel vs prasugrel, and aspirin doses ≤ 100 mg daily (each $p<0.001$). At 12m, non-US patients were more likely to be DAPT compliant (94.7 vs 89.2%, $p<0.001$). Non-US patients were more likely to be randomized (65% vs 43%, $p<0.001$), even after adjusting for baseline characteristics (OR= 2.27; $p<0.001$).

Conclusions: Within the DAPT Study, non-US patients were more likely to be compliant with study procedures, independent of patient characteristics. Regional variation in patient characteristics, compliance, and practice patterns observed in broadly inclusive clinical trials allows for the evaluation of interactions between these factors and treatment effectiveness.

Bare Metal and Drug-Eluting Stents

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