Conclusion: The use of drug-eluting stents in patient with DM was safe with low acute complication. Patients treated with BES and EES showed lesser rate of restenosis compared with EES.

TCT-81
One-Year Outcomes in Over 1500 Patients with Diabetes Treated with the Resolute Zotarolimus-Eluting Stent

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Background: The RESOLUTE Clinical Programme comprises 5 trials worldwide evaluating the Resolute zotarolimus-eluting stent (R-ZES), which were prospectively designed with similar methods including: data collection forms, adverse event definitions and adjudication procedures, statistical programming algorithms and data sets to allow pooling. The R-ZES is a contemporary drug-eluting stent composed of a thin-strut cobalt alloy BMS and a proprietary polymer with hydrophilic properties for biocompatibility and hydrophobic properties for uniform prolonged drug release (85% delivered by 60 days; remaining up to 180 days). Extended elution may better balance arterial healing, and any associated sustained proliferative stimuli, in high-risk patients such as those with diabetes mellitus (DM). We will present pooled clinical outcomes at 1 year for patients with DM treated with the R-ZES.

Methods: To date, 5130 patients have been enrolled in 247 centers in 5 R-ZES Trials (Resolute First-In-Man [139], Resolute All Comers [1140], Resolute International [2349], Resolute United States [1402], Resolute Japan [100]). We compared baseline characteristics and clinical outcomes at 1 year for 1555 patients with DM vs those without DM, as well as by insulin requirements.

Results: Of 1555 patients with DM, 455 (29.6%) were insulin treated. At baseline DM patients were older, more were female, with hyperlipidemia, hypertension, previous coronary artery bypass grafting, and moderate/severe calcification. At 1 year, the rates of target lesion failure (cardiac death, target- vessel MI, clinically-driven TLR) were 7.8% for DM vs 6.1% for non-DM (p=0.03), patient-oriented composite (all death, cardiac death, MI, TVR) 13.1% vs 12.1%, p=0.09; target- vessel-related MI (4.7% vs 3.6%, p=0.08); clinically-driven TLR (4.0% vs 2.9%, p=0.06); and ARC definite and probable ST (1.1% vs 0.7%, p=0.17). We will also report outcomes by insulin requirements.

Conclusion: In this large diverse patient cohort with DM, the R-ZES had low event rates despite the high-risk nature of this population.

TCT-82
Impact of Diabetes on Clinical Outcomes after Revascularization with Everolimus- and Sirolimus-Eluting Stents. A Substudy of the SORT OUT IV Trial

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Background: Diabetes is associated with an increased risk of major adverse cardiac events (MACE) following percutaneous coronary intervention. In this substudy of the SORT OUT IV trial, we compared the clinical outcome among patient with and without diabetes mellitus treated with everolimus-eluting (EES) or sirolimus-eluting (SES).

Methods: Of 2,774 patients, 390 (14.1%) patients had diabetes and were treated with EES (n=1,390, diabetes: n=194) or SES (n=1,384, diabetes: n=196). Randomization was stratified by presence/absence of diabetes. The primary endpoint was MACE, defined as a composite of cardiac death, myocardial infarction (MI), definite stent thrombosis or target vessel revascularization within 18 months.

Results: At 18-month, MACE were higher among diabetic patients (diabetic patients: 13.1% vs. non-diabetic patients: 6.4%; Hazard ratio (HR) 95% confidence interval 2.08 (1.51 - 2.86). At 18-month MACE was 10.3% in the EES- and 15.8% in the SES-treated diabetic patients (HR 0.63 95% CI 0.36-1.11) and 6.6% in the EES- and 6.3 in the SES-treated patients without diabetes (HR 1.06 95% CI 0.77-1.46). In diabetic patients cardiac death 3.1% in EES- and 4.6% in SES-treated patients (HR 0.67 95% CI 0.24-1.89), MI 0.5% in EES- and 3.6% in SES-treated patients (HR 0.14 95% CI 0.02-0.16) and clinically driven target lesion revascularization 3.1% in EES- and 7.7% in SES-treated patients (HR 0.40 95% CI 0.15-1.02) did not differ between EES and SES treated patients. Definite stent thrombosis was not seen in diabetic patients treated with EES compared to 4 patients treated with SES.

Conclusion: EES showed a non-significant reduced risk of MAC compared to SES in patients with diabetes mellitus.

TCT-83
Impact Of The Development And Treatment Of Critical Limb Ischemia On Long-Term Cardiac Mortality In Diabetic Patients Treated With Percutaneous Coronary Intervention

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Background: Critical Limb Ischemia (CLI) with or without lower extremity amputation (LEA) is reported as an independent predictor of cardiac mortality in diabetic patients and these deaths are related to the high prevalence of CAD in these subjects. The aim of our study was to investigate the impact on long-term cardiac mortality of the association of CAD with CLI in diabetic patients and the potential effect of coronary and limb revascularization.

Methods: The study was designed as a prospective single centre registry which enrolled and followed for 4 years 764 consecutive diabetic patients undergoing percutaneous coronary intervention (PCI), between July 2002 and May 2007. The development of CLI was diagnosed by a dedicated diabetic foot-clinic specialist. All patients with CLI underwent peripheral revascularization of the culprit limb. Cardiac mortality was the primary endpoint of the study.

Results: Among the 764 PCI patients, 111 (14%) developed CLI during follow-up (PCI+CLI group) and were treated with peripheral intervention in 145 limbs with procedural success in 140 (96%). PCI+CLI patients had lower left ventricle ejection fraction (LVEF) (51±11% vs 53±10%, p=0.008) higher renal failure (25% vs 12%, p=0.005), dialysis (7% vs 3%, p<0.0001) and diabetes duration (13.8 vs 17.7 years, p=0.02) compared to PCI-only patients. Coronary intervention procedural characteristics did not differ among PCI-only and PCI-CLI patients. At 4-year follow up, cardiac mortality occurred in 10(9%) PCI-CLI vs 39(6%) PCI-only patients (p=0.2). Major amputation occurred in 6(5%) patients. Cox regression analysis showed age (OR 1.06, 95%CI 1.02-1.09), dialysis (OR 0.82, 95%CI 0.42-1.83) and LVEF<30% (OR 9.40, 95% CI 4.20-20.61) to be the independent predictors of cardiac mortality which was not influenced by the development of CLI (OR 0.93, 95%CI 0.42-2.06).

Conclusion: In diabetic patients treated with percutaneous coronary revascularization, the development of CLI treated with peripheral intervention, seems not to impact cardiac mortality long terms.

TCT-84
Glycosylated Hemoglobin and Outcomes in Diabetic Patients With Acute Myocardial Infarction After Successful Revascularization

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Background: In acute myocardial infarction (AMI) patients treated with percutaneous coronary intervention (PCI), presence of diabetes mellitus (DM) imparts worse cardiovascular outcomes. In this study, we evaluated the influence of glycemic control on clinical outcomes in DM patients with AMI after successful PCI.

Methods: We examined 231 consecutive DM patients with AMI who underwent successful primary PCI and had evaluation of glycosylated hemoglobin (HbA1c) from 30 days before to 90 days after AMI. Patients were categorized in two groups, controlled DM with HbA1c ≤ 7.0 (n=83, 36%) and uncontrolled DM with HbA1c > 7.0 (n=148, 64%). We assessed 12-month cardiovascular outcomes in study groups.

Results: Uncontrolled diabetics were younger, tended to be less hypertensive, and had higher baseline glomerular filtration rate and final vessel diameter compared to controlled diabetics. Uncontrolled DM patients had similar MACE [composite of all-cause death, myocardial infarction (MI), target vessel revascularization (TVR), and stent thrombosis (ST); 20 vs. 30%, log rank p=0.54, figure], death (8.8 vs. 12%, p=0.40), MI (8.8 vs. 9.6%, p=0.76), TVR (9.5 vs. 8.4%, p=0.95) and ST (3.4 vs. 4.8%, p=0.54) as the controlled diabetics. In Cox regression analysis, after adjustment for baseline differences, glycemic control had no independent influence on study outcomes.

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