Conclusions: SF after BES occurs in 4.1% of lesions and is associated with higher rate of MACE, driven by higher rate of TLR.

TCT-455
Clinical Outcomes in the Percutaneous Coronary Intervention of In-Stent Restenosis with the XIENCE V Everolimus-Eluting Stent
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Background: Though percutaneous coronary intervention with the XIENCE V® everolimus-eluting stent (EES, Abbott Vascular, Santa Clara, CA) for native coronary artery disease has favorable results compared to first generation drug-eluting stents, outcomes with EES for the treatment of in-stent restenosis (ISR) are unknown. The objective of this study is to evaluate the safety and efficacy of XIENCE V for the treatment of ISR.

Methods: XIENCE V USA is a prospective observational multicenter registry evaluating clinical outcomes in patients who received treatment with EES. In this study, we present the 1-year clinical outcomes in patients who received treatment for the release of ISR and non-ISR in this registry. The primary outcome was the composite of target lesion failure (defined as cardiac death, target vessel myocardial infarction, or target lesion revascularization). Secondary outcomes were myocardial infarction, target lesion revascularization, and stent thrombosis.

Results: This registry 383 patients (64±11 years old; 68.4% male) received revascularization for non-ISR lesions. At 1 year, the rate of clinical adverse events (Table) was higher in the ISR group compared to the non-ISR group, however, these differences ceased to exist when case-control matched patients in the non-ISR group were studied.

Conclusions: The treatment of ISR with EES appears to be safe and efficacious at 1-year follow-up. Compared to the non-ISR group, the rate of target lesion failure was much higher indicating a higher risk profile of these patients. However, these differences ceased to exist with case control matched controlling.

Table. Clinical outcomes at 1 year.

<table>
<thead>
<tr>
<th></th>
<th>ISR Group (N=383)</th>
<th>Non-ISR Group (N=4,832)</th>
<th>Case-Matched Non-ISR Group (N=337)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Lesion Failure</td>
<td>12.5%</td>
<td>7.0%</td>
<td>10.0%</td>
</tr>
<tr>
<td>(ARC MI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>7.2%</td>
<td>5.8%</td>
<td>7.1%</td>
</tr>
<tr>
<td>(ARC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion</td>
<td>10.3%</td>
<td>2.9%</td>
<td>6.8%</td>
</tr>
<tr>
<td>Revascularization (ARC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent thrombosis (ARC Defined)</td>
<td>1.7%</td>
<td>0.2%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

TCT-456
The Impact of Atherogenic Neointima on Long-term Clinical Outcomes: An Observational Study from the Optical Coherence Tomography Registry
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Background: Pathological studies have revealed atherosclerotic neointima (AN) after stent implantation. However, the risk factor of neointeralclerosis and its impact on future clinical events remain unclear.

Methods: From the Kobe university OCT database, 137 consecutive patients (253 stents) who underwent OCT examination at >1 year after bare metal or first-generation drug-eluting stent implantation were enrolled. We assessed AN (neointima containing a diffuse border, signal-poor region with invisible struts underneath) by multivariate logistic analysis. LDL cholesterol and hs-CRP were the independent predictors of the presence of AN (OR 1.025 (P=0.011), OR 1.016 (P=0.045), respectively). The rate of MACE were significantly higher in AN than in AN for a average follow-up of 58 months after stenting. After multivariate cox hazard analysis, the presence of AN remained an independent risk factor of MACE (HR 2.345, 95% CI 1.100-5.440, P=0.047).

Conclusions: Increased LDL-cholesterol and hs-CRP level may be risk factors for AN progression in patients treated with coronary stents. In this study, the presence of AN assessed by OCT were independently associated with MACE at >1 year after stent placement, suggesting a need for careful clinical follow-up of patients with AN.

TCT-457
Is There A Difference In The Clinical Presentation Of Patients With In-Stent Restenosis Of First- Versus Second-Generation Drug-Eluting Stents?
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Background: The clinical presentation of bare metal in-stent restenosis (ISR) is reported to be associated with high rates of morbidity, including myocardial infarction (MI). This study aimed to compare the clinical presentation and outcomes between patients treated with 1st- and 2nd-generation drug-eluting stents (DES) and presented with ISR on admission.

Methods: The study identified first episode 1st or 2nd-generation DES ISR patients who underwent re-intervention. The clinical presentation at admission was classified as non acute (asymptomatic or stable angina) or acute (unstable angina, Canadian Cardiovascular Society (CCS) III or IV and MI). We compared the 1st- vs. 2nd-gen DES ISR clinical presentation and the rates of major adverse cardiac events (MACE) as a composite of death, Q-wave MI and target lesion revascularization at 6 months. Results: Overall, 709 patients with 1095 DES ISR lesions (1st-gen DES n=526; 2nd-gen DES n=113) were selected. The mean age was 65 ± 10 years and diabetics comprised 49%. Clinical presentation included asymptomatic/stable angina in 29%, unstable angina in 62% and MI in 8%. Patients with 2nd-generation DES ISR were less likely to present as MI (13% vs. 5%; p<0.05) and with severe symptoms (73% vs. 49%; p=0.01) as compared to 1st-gen DES. The incidence of MACE in the 1st- and 2nd-gen DES at 6 months was 8% and 9%, respectively (p=1.0).

Conclusions: 2nd-generation DES ISR clinical presentation appears to be more benign with less frequency of MI and CCS III or IV symptoms compared to 1st-generation DES. The rates of MACE were similar at 6 months.
Background: The use of DCB in de-novo coronary artery disease is not associated with an increased incidence of late thrombosis in the clinical setting. Unscheduled coronary angiography was performed in over expanded cases (6.8%) within 72 hours after DCB because of recurrent chest pain and showed an excellent short-term result with TIMI III flow and without need for revascularization. 

Conclusions: Incidence of localized haziness after DCB angioplasty in de-novo lesions is comparable to treatment with plain old balloon angioplasty and does not increase the risk of acute coronary thrombosis. 

TCT-459 
Incidence of late thrombosis after paclitaxel-coated balloon angioplasty in de-novo coronary artery disease 
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Background: Clinical studies demonstrated the safety and effectiveness of drug-coated balloon (DCB) in various clinical scenarios and support the use of paclitaxel-elluting balloon for the treatment of in-stent restenosis, of small coronary arteries and bifurcation lesions. We analyzed and compared the safety, focused on the rates of late coronary thrombosis (LT), after DCB in de-novo lesions without additional stenting - the so called "Drug-eluting balloon only" strategy - in four current studies with the outcome in a clinical setting. 

Methods: A retrospective review was done of 191 consecutive patients who underwent percutaneous coronary intervention procedure with the paclitaxel eluting balloon SeQuent Papyrus at a high-volume Heart Center in Potsdam. DCB was used for the treatment of de-novo lesions in 85 patients (male n=61, age 67±10.9 years) in 102 interventions. The primary evaluation was LT. Mean clinical follow-up was 16.3 ± 5.5 months. Duration of dual antiplatelet therapy was 5.4 ± 4.1 months. 

Results: DCB without additional stenting used in different clinical and interventional settings. During follow-up none of the 85 patients (0%) had suffered from late coronary thrombosis in the clinical setting. This is remarkable since DCB were mostly used in complex interventions. Three patients died due to renal failure, one of them after elective cardiac surgery and one patient died due to non-cardiovascular disease. Four DCB trials used the "Drug-elluting balloon only" strategy in de-novo lesions: PEPCAD I SVD, PEPCAD V (side branch), PICCOLETO and DEBUIT. Summarizing the rates of elective cardiac surgery and one patient died due to non-cardiovascular disease. Four patients were revascularized because of vessel underexpansion and 1 patient after in-stent restenosis (ISR). One patient died due to renal failure, one of them after elective cardiac surgery and one patient died due to non-cardiovascular disease. Four patients were revascularized because of vessel underexpansion.