Early Healing After Treatment Of Coronary Lesions By Everolimus, Or Biolimus Eluting Bioresorbable Polymer Stents, One-month Results In The SORT-OUT VIII Optical Coherence Tomography Study

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Conclusions: Improved early healing may reduce the risk of early stent thrombosis in patients treated with drug eluting stents. Incomplete healing is found more frequently after treatment for acute myocardial infarction, in patients with acute stent strut malapposition, and after treatment by specific stent types. Dual antiplatelet therapy is used to balance the risk of incomplete healing but early discontinuation is rather common and hard to predict at the primary intervention. We aim to evaluate and compare early healing of an everolimus-eluting biodegradable polymer stent (Syn- Synory, Biotronik, Germany) with the Xience stent (Abbott Vascular, U.S.A) having potential advantages in early healing with a sirolimus-eluting biodegradable polymer stent (BioMatrix NeoFlex, Biosensors, Switzerland).

Methods: The study is a prospective, randomized dual center trial with one month follow-up (Cohort A) or three months follow-up (Cohort B). Patients are randomized 1:1 to Synergy or Biomatrix NeoFlex, Terumo, Japan.

Results from CENTURY II trial

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Background: PCI with use of DES has been increasingly used in patients with high risk acute coronary syndromes (STEMI/NSTEMI). However, controversies related to their long-term safety in this complex patient population are still present. Therefore safety and efficacy of new, sirolimus-eluting stent coated with bioabsorbable polymer, Ultimaster DES(Terumo Corporation, Tokyo, Japan), in high risk acute coronary syndrome (ACS) patients was assessed.

Methods: In the frame of a single-blind, randomized, multicentre CENTURY II study (NCT01123119), 264 patients (123 CAD patients without AC and assigned randomly to treatment with Ultimaster (126) or Xience (138) DES. Primary endpoint of the study was TLF at 9 months. All data were 100% monitored and adverse events were adjudicated by an independent clinical events committee.

Results: Baseline patient characteristics such as age, gender, presence of diabetes, hypertension, dyslipidemia, family history of CAD, smoking, previous MI and previous PCI were similar in both study arms. Also, there were no differences noted in thrombus presence (10.1% vs 11.8%, p=0.61) or bifurcation lesions (10.2% vs 9.8%, p=0.38). LAD was the most frequent target vessel and radial access was used in >70% of cases, without difference between treatment arms. Clinical outcomes at 4-months are shown in the table below. No significant differences were observed between the two stent arms. There were 2 patients with stent thrombosis in Ultimaster and 1 patient with 3 vessels of stent thrombosis in Xience arm, resulting in low and similar ST rates (1.6% vs 0.7%, p=0.51).

Conclusions: Short term safety and efficacy of new Ultimaster DES was very similar to the Xience DES in patients with high risk ACS. Follow up of patients is ongoing and 1-year data will be available at the time of presentation.
Stents - Drug-eluting: Novel Metallic DES

Washington Convention Center, Lower Level, Hall A
Saturday, September 13, 2014, 5:00 PM–7:00 PM

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TCT-599

Final procedural, 30-day and 6-month angiographic, clinical and OCT outcomes from the DIRECT II Trial using the Svelte Integrated Delivery System with Enzymatic Bioabsorbable Sirolimus Coating

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Background: The Svelte (New Providence, NJ) sirolimus-eluting coronary stent with an integrated balloon delivery system (IDS) consisting of a low-compliant balloon with balloon dural effect, was designed for use with the trans-radial approach (TRI), fixed to a 0.014 integrated wire with shapeable tip. The IDS is low-profile and specifically designed for use with the trans-radial approach (TRI), _sleender_ PCI and direct stenting. The DIRECT I First-In-Man study (n=30) reports 2.7% stent volume obstruction (via IVUS) at 6-months with 0% clinically-driven MACE through 24-months. All events and imaging were reviewed and adjudicated by an independent core lab and DSMB.

Methods: 159 patients with symptomatic ischemic heart disease due to de novo stenotic lesions in arteries with RVD 2.5mm–3.5mm and lesion length < 20 mm were prospectively randomized (2:1 Svelte IDS : Medtronic Resolute Integrity) at 18 centers in 4 centers in 3 European countries. There was no distal embolization in both groups, although there was no statistical difference.

Conclusions: MACE at 12 months will be presented, as well as lumen loss and angiographic results at 6 months, and OCT followup at 6 months.

TCT-600

Distinct Vascular Response between Vulnerable and Stable Coronary Plaques after the Second Generation Drug-eluting Stents Implantation: One-year Angiographic Comparison

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Background: The second generation drug-eluting stents (G2-DES) have been implanted safely at culprit lesions not only of stable angina pectoris but also of acute coronary syndrome. The aim of this study was to angiographically characterize vascular response after implantation of various G2-DES and to compare healing processes between stable and vulnerable plaques.

Methods: 106 Svelte IDS arm, n=57 patients (27 BMS, 30 DES) were enrolled in 4 centers in 3 European countries. There was no distal embolization in both groups. The patients in the DES group, found to be more complex, performed well compared to BMS group, although there was no statistical difference.

Conclusions: TCT-600

Abstract nos: 599-609

Table. Angiographic findings in G2-DES

<table>
<thead>
<tr>
<th>Stable plaque</th>
<th>BES (n=8)</th>
<th>EES (n=11)</th>
<th>E-ZES (n=7)</th>
<th>R-ZES (n=7)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good NSC (%)</td>
<td>16.7</td>
<td>45.5</td>
<td>100.0</td>
<td>28.6</td>
<td>0.01</td>
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<tr>
<td>Prevalence of YP (%)</td>
<td>16.7</td>
<td>18.2</td>
<td>0.0</td>
<td>0.0</td>
<td>0.43</td>
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<table>
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<tr>
<th>Vulnerable plaque</th>
<th>BES (n=8)</th>
<th>EES (n=8)</th>
<th>E-ZES (n=5)</th>
<th>R-ZES (n=11)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good NSC (%)</td>
<td>25.0</td>
<td>12.5</td>
<td>100.0</td>
<td>54.5</td>
<td>0.01</td>
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<tr>
<td>Prevalence of YP (%)</td>
<td>85.7</td>
<td>0.0</td>
<td>0.0</td>
<td>9.1</td>
<td>&lt;0.0001</td>
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</tbody>
</table>

Conclusions: Vulnerable plaques implanted with BES remained yellowish and thrombogenic even at one year after stenting, suggesting the distinct vascular response after BES implantation at vulnerable plaques.

TCT-601

Comparison of sirolimus-eluting stents with biodegradable polymer versus sirolimus-eluting stents with durable polymer assessed by optical coherence tomography: The ALSTER-OCT registry


Background: Nevertheless the promising results of 2nd generation DES, recent findings suggest hypersensitivity reactions caused by the durable polymer coatings leading to chronic inflammation and possibly to late stent strut malapposition. Therefore new DES generations with improved biocompatibility and biodegradable polymers were introduced.

Methods: The registry aims to compare optical coherence tomography (OCT) based stent coverage at three, six and nine-months follow-up after PCI by 3rd generation Orsiro Hybrid sirolimus-eluting stents with biodegradable polymer (O-SES, Bio-Monk) and widely used 2nd generation zotarolimus-eluting stents with durable polymer (ECS, Endeavor ResoluteTM and ResoluteTM IntegrityTM, Medtronic Vascular). A total of 80 patients received implantation of O-SES (n=34) and ZES (n=46). Clinical driven OCT-analysis was performed at three, six or nine-months follow-up.

Conclusions: Vulnerable plaques implanted with BES remained yellowish and thrombogenic even at one year after stenting, suggesting the distinct vascular response after BES implantation at vulnerable plaques.