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Safety and Clinical Performance of the Drug Eluting Osirio Stent in the Treatment of Subjects With Single De Novo Coronary Artery Lesions-I (BIOFLOW-II)

Stephan Windeker1, Bernhard Witzenbichler1, Karl Stangl2, Ton Slaghboom3, Franz-Josef Neumann4, Thierry Lefevre5, Rafael Ruiz-Salmeron6, Manel Sabate7, Gregorio Piot8, Gert Richard9, Bula Merkely4, Sophie Piot2, Johannigil10, Henrik Schneider11, Paul Barragán12, Stéphane Cook13, Paul Erne14, Ron Waksman15, Michael Haude16,17

1Bern University Hospital, Bern, Switzerland, 2Charité Campus Benjamin Franklin, Berlin, Germany, 3Charité - Campus Mitte, Berlin, Germany, 4Onze Lieve Vrouwe Gasthuis, Amsterdam, Netherlands, 5Universitäts-Herzzentrum Freiburg - Bad Krozingen, Bad Krozingen, Germany, 6ICFIS, Massy, France, 7Hospital Universitario Virgen de la Macarena, Sevilla, Spain, 8University of Barcelona, Barcelona, Spain, 9University of Montpellier, montpellier cedes 5, France, 10Segeberger Kliniken, Bad Segeberg, Germany, 11Semmelweis University Heart Center, Budapest, Hungary, 12Hospital Puerta de Hierro, Madrid, Spain, 13Klinikum Nürnberg Süd, Nurnberg, Germany, 14Universitätsklinikum Rostock, 18057, Germany, 15Polyclinique «Les Fleuves», Ollioles, France, 16Hospital and University Fribourg, Switzerland, 17Fribourg, Switzerland, 18Lazernier Kantonsospital, Lacerne, Switzerland, 19MedStar Health Research Institute, Washington, DC, 20Städtische Kliniken Neuss, Lakskrankenhaus GmbH, Neuss, Germany

Background: The current study compared the novel Biotronik Osirio stent, eluting sirolimus from a biodegradable polymer PLLA, applied on a thin-strut (60 μm) Silicon-Carbide coated Cobalt-Chromium stent with the Abbott Xience PrimeTM stent. The primary endpoint was non-inferiority for in-stent Late Lumen Loss (LLL) at 9 months in de novo coronary artery lesions.

Methods: We performed a prospective, multicenter, randomized controlled study (RCT) in 452 subjects (63.4±10.0 yrs) with symptomatic coronary artery disease due to de novo stenotic lesions in native coronary arteries with a RVD ≥ 2.25 mm, ≤ 4.0 mm and a lesion length ≤ 26 mm. Subjects were randomly assigned 2:1 to receive the Osirio SES or the Xience PrimeTM EES. The primary endpoint of the study is in-stent LLL assessed at 9 months and analyzed according to the intention-to-treat principle. All subjects were enrolled between July 5, 2011- March 23, 2012 and were invited to undergo repeat angiography at 9 months. Clinical follow up visits are performed at 1, 6, 12 and annually for up to 5 years after the procedure. All angiographic images were analyzed by (R. Waksman, Medstar, Washington DC, USA). All clinical events were adjudicated by 3 independent cardiologists (MD:s). Clinicaltrials.gov no. NCT01336888

Results: Both study groups showed comparable populations in terms of demographics, current risk factors, clinical history and lesion/vessel characteristics. The in-stent late lumen loss at 9-months was 0.10 ± 0.32 mm for the Osirio compared to 0.11 ± 0.29 mm for the Xience with a p-value of 0.9849. The non-inferiority hypothesis was thereby confirmed with p-value<0.0001. The clinical endpoint of Target Lesion Failure (TLF) at 9 months was 4.8% for the Osirio compared to 5.3% for the Xience with a p-value of 0.9894. Conclusion: In this RCT the Osirio SES with a biodegradable polymer was non-inferior to the Xience PrimeTM EES with a durable polymer for the primary angiographic endpoint of in-stent late loss at 9 months. Clinical event rates were low and comparable with both Osirio and Xience PrimeTM through 9 months. Results of the clinical event rates at 12 month are now being analyzed and will be presented at the meeting for the first time.

TCT-174

Clinical Outcomes after PCI Treatment of Very Long Coronary Lesions with the XIENCE V Evolutive Eluting Stent (EES): Pooled Analysis from the SPIRIT and XIENCE V USA Prospective Multi-Center Trials

James Hermiller Jr.1

1St Vincent Heart Center of Indiana, Indianapolis, USA

Background: Very long (≥ 35 mm) coronary lesions are more complex than shorter lesions. Single-stent treatment of very long coronary lesions is limited by maximum stent length, and since stents in the everolimus-eluting cobalt-chromium XIENCE family of coronary stents with lengths ≥ 35 mm have only recently become available, a predetermined planned overlap strategy from six prospective multi-center trials: SPIRIT II, SPIRIT III, SPIRIT IV, SPIRIT V, SPIRIT Small Vessel, and XIENCE V USA. Analyses were performed on subjects with lesions ≥ 24 to < 35 mm in length and ≥ 35 mm in length. Clinical outcomes evaluated at 1 year included TLF and MACE, all death, cardiac death, all MI, target vessel MI, ID/CI-TLR, and definite and definite/probable stent thrombosis. All endpoint events were adjudicated by independent clinical evaluation committees. Results: There were 482 patients with 500 lesions ≥ 24 to < 35 mm in length, and 323 patients with 328 lesions ≥ 35 mm in length. The Table shows that 1-year outcomes were not significantly different in very long lesions compared to those > 24 to < 35 mm.

Conclusions: Despite inherent increased complexity of very long coronary lesions, XIENCE V PCI treatment resulted in similar clinical outcomes at 1 year for very long (≥ 35 mm) coronary lesions as for shorter (> 24 to < 35 mm) lesions. Based on these clinical data, XIENCE V PCI treatment of lesions ≥ 35 mm appears as effective and safe as PCI for shorter lesions.

Table. XIENCE V Planned Overlay for Very Long Coronary Lesions (Pooled SIL, SII, SIV, Small Vessel, XV USA)

<table>
<thead>
<tr>
<th>Per Lesion Analysis (baseline)</th>
<th>24 to &lt; 35 mm</th>
<th>35 mm or greater</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Lesion Length (mm)</td>
<td>28.07 ± 2.44 (500)</td>
<td>47.06 ± 13.69 (328)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Mean Total Stent Length (mm)</td>
<td>41.0 ± 9.0 (500)</td>
<td>56.1 ± 17.6 (328)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Per Subject Analysis (1-year)

Hierarchical Subject Counts

| TLF   | 10.1% (47/466) | 9.0% (29/311) | 0.7102 |
| MACE  | 10.1% (47/466) | 9.3% (29/311) | 0.8056 |

Non-Hierarchical Subject Counts

| All Death | 2.8% (13/466) | 4.2% (13/311) | 0.3132 |
| Cardiac Death | 2.1% (10/466) | 2.3% (7/311) | 1.0000 |
| All MI | 3.9% (16/466) | 4.8% (15/311) | 0.5869 |
| Target Vessel MI | 3.6% (17/466) | 4.5% (14/311) | 0.5780 |
| ID/CI-TLR | 5.6% (26/466) | 5.1% (16/311) | 0.8721 |

ARC Stent Thrombosis

| Definite | 0.7% (3/454) | 1.0% (3/307) | 0.6898 |
| Definite/Probable | 1.5% (7/454) | 1.6% (5/307) | 1.0000 |

TLF – cardiac death, target vessel MI, ID/CI-TLR, MACE – cardiac death, all MI, ID/CI-TLR

P-values for per lesion analyses are from Fisher's exact test. All p-values displayed are two-tailed and not from pre-specified hypothesis testing and are displayed for information only.

Denominators for per subject analyses (except for Arc Stent Thrombosis) exclude subjects who are truly loss-to-follow-up, defined as subjects who are lost to follow-up through given timepoint without any DMX event (all death, all MI, all revascularization).

ARC stent thrombosis denominators exclude subjects who were early terminated and did not have definite or probable ARC stent thrombosis.

WHO-based protocol definitions were used for MI except for SPIRIT for which ARC MI definitions were used.

For per lesion analysis, only lesions with planned overlapping stents were included.

TCT-175

Does Diabetes Mellitus Impact Long-Term Clinical Outcomes After Percutaneous Coronary Saphenous Vein Graft Interventions In The Drug-Eluting Stent Era?

lakshmana Pendyala1, Salem Badr1, Israel Barbash1, Hiroromo Kitabata2, Joshua P. Loi3, Sat'ar Minha4, Aljazzar Omar2, Hideaki Ona1, Augusto Picardh1, Lowell F. Saltier1, William O. Siddhath1, Rebecca Torgerson1, Ron Waksman1,2

1Washington Hospital Center, Washington, DC, 2Medstar Washington Hospital Center, Washington, DC, 3Charité - Campus Mitte, Berlin, Germany, 4Onze Lieve Vrouwe Gasthuis, Amsterdam, Netherlands, 5Medstar Washington Hospital Center, Washington, DC, Medstar Washington Hospital Center, Washington, DC, Medstar Washington Hospital Center, Washington, DC, Medstar Washington Hospital Center, Washington, DC, Medstar Washington Hospital Center, Washington, DC, 6Washington hospital center, Washington, United States, 7Washington hospital center, Washington, DC, 8Washington Hospital center, Washington, DC, 9MedStar Health Research Institute, Washington, DC

Background: Patients with diabetes mellitus were shown to have less favorable outcomes after saphenous vein graft (SVG) intervention with bare metal stents while its impact with drug-eluting stents (DES) is not clearly defined. We aimed to compare clinical outcomes in diabetic patients who underwent SVG percutaneous coronary interventions (PCI) with the use of DES.

Methods: From our PCI registry we retrospectively analyzed 477 consecutive patients with prior CABG who underwent SVG PCI with the implantation of DES stratified by presence or absence of diabetes. The primary end point was 1-year major cardiac event

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Conclusions: Unlike the results seen in de novo lesions, when DES are utilized in PCI of SVG lesions, the presence of diabetes is no longer a discriminator of the short- and long-term outcomes.

TCT-176

High variability of systolic blood pressure predicts long-term adverse outcomes after drug-eluting stent implantation

A-e Young Her1, Soe Hee Ahn1, Jong Min Kim1, Yong Hoon Kim1, Jun Ho Lee1, Eun-Sook Shin1
1Kangwon National University, Chuncheon, Kangsondo, 2Ulsan University Hospital, Ulsan, Kyongbukkangnamdo, 3Kangwon National University School of Medicine, Chuncheon, Kangwon Province

Background: A few data were available regarding the association between percutaneous coronary intervention (PCI) with drug-eluting stent (DES) and blood pressure (BP) variability for long-term clinical outcomes.

Methods: Total 994 consecutive patients undergoing PCI with DES from March 2003 to August 2007 were enrolled. We measured patients' BP in a routine ward environment just before transferring to the cath lab and in the cath lab before arterial puncture (ward-to-cath lab BP) and assessed the differences of systolic and diastolic BP, and heart rate. The subjects were divided into 2 groups according to the differences of ward-to-cath lab systolic BP: high variability group (n=383) as the absolute difference > 20mmHg and low variability group (n=424) as the absolute difference ≤ 20mmHg. The primary outcome of interest was the composite of death, myocardial infarction (MI), or stroke.

Results: In 807 patients (522 males, 60±10 years), the mean differences of systolic and diastolic BP, and heart rate were 26.5±18.9 and 11.8±10.2 mmHg and 10.1±8.9 beats/min, respectively. During follow-up of 1878±864 days, composite rate of death, MI, or stroke was higher in the high variability group than the low variability group (10.2% vs. 6.4%; adjusted hazard ratio, 1.96; 95% confidence interval, 1.14-3.38; Cox p=0.016). The rates of death or MI (7.8% vs. 5.2%, p=0.09) and stroke (2.3% vs. 1.2%, p=0.17) were also numerically higher in the high variability group, which did not reach statistical significance. However, there were no significant differences in clinical outcomes for the ward-to-cath lab variability of diastolic BP and heart rate.

Conclusions: This result suggests the variability of ward-to-cath lab systolic BP may contribute to the elevated adverse cardiovascular risk in patients undergoing PCI with DES.

TCT-177

Three-Year Results of the PLATINUM Small Vessel and Long Lesion Trials Evaluating the Platinum Chromium Everolimus-Eluting Stent in De Novo Coronary Artery Lesions

Paul Teirstein1, Gregg Stone2, Ian T. Meredith3, Robert L. Feldman4, Abram C. Robinowitz5, Tommy C. Lee6, Dean Kerreukes7, Didier Carrié8, Dominic J. Alloccio9, Keith D. Dawkins10
1N/A, La Jolla, California, 2Columbia University Medical Center and the Cardiovascular Research Foundation, New York, United States, 3Monash University, Melbourne, Australia, 4MediQuest Research Group Inc. at Munroe Regional Medical Center, Ocala, FL, 5TexSan Heart Hospital, San Antonio, TX, 6Bakersfield Memorial Hospital, Bakersfield, CA, 7The Christ Hospital Heart & Vascular Center, Cincinnati, United States, 8Hôpital Rangueil, Toulouse, France, 9Boston Scientific Corporation, Maple Grove, MN, 10Boston Scientific Corporation, Marlborough, MA

Background: The thin-strut, everolimus-eluting, platinum chromium PROMUS Element stent (Boston Scientific, Natick MA) has shown favorable outcomes at 1 and 2 years post-implantation in the treatment of de novo lesions in small vessels (<2.25mm to <2.5mm in baseline diameter) and long lesions (>24 to ≤34mm in length), but longer-term follow-up has not been previously reported.

Methods: PLATINUM SV and LL are prospective, single-arm, multinational studies that enrolled patients with angiographic or documented silent ischemia and one de novo native coronary artery target lesion. PLATINUM SV enrolled 94 subjects with baseline vessel diameter >2.25mm to <2.50mm and lesion length ≤28 mm, and PLATINUM LL enrolled 102 patients with a target lesion >24 to ≤34mm long with reference diameter ≥2.50 to ≤4.25mm.

Results: Patients were predominantly male (SV: 72.3%, LL: 62.7%) and approximately one third had diabetes (SV: 42.6%, LL: 30.0%). The mean baseline vessel diameter in SV was 2.04±0.26 mm, and mean lesion length in LL was 24.38±8.21 mm. The primary endpoint, 1-year target lesion failure defined as cardiac death, myocardial infarction related to the target vessel, or ischemia-driven target lesion revascularization, was 2.4% for SV and 3.2% for LL, significantly less than the prespecified performance goals of 21.1% for SV and 19.4% for LL (P<0.001 for each). At 3 years, outcomes for 84 evaluable patients in the SV trial were 4 (6.6%) TLVs, 2 (2.4%) TLRs, 2 (2.3%) cardiac deaths, 1 (1.1%) non-cardiac deaths, and 1 (1.2%) MI, with no ARC definite/probable ST events. Through 2-year follow-up in 95/100 patients in LL, there were 8 (8.8%) TLVs, 5 (5.2%) TLRs, 3 (3.6%) cardiac deaths, 1 (1.0%) non-cardiac death, and no MIs or ARC definite/probable ST. Three-year results for LL will be available at the time of the meeting.

Conclusions: The PROMUS Element stent has demonstrated low target lesion failure and revascularization rates, and acceptable safety outcomes with longer-term follow-up in patients with small vessels and long lesions. The three-year results from these studies will be available for presentation for the first time at TCT 2013.