TCT-630
Impact of Calcified Plaque on Stent Strut Distribution of Bioresorbable Vascular Scaffolds Versus Metallic Everolimus-eluting Stents: An Optical Coherence Tomography Analysis
Katsumasa Sato1, Azem Latibi2, Vasileios F. Panoulas2, Hiroyoshi Kawamoto3, Tadashi Miyazaki4, Tora Nagamatsu1, Antonio Colombo1
1EMO GVM Centro Cuore Columbus, Milan, Italy

Background: Non-uniform strut distribution (NSD) is an important factor predisposing to intimal hyperplasia through decreased local drug delivery and increased scaffold recoil after BVS implantation. The aim of this study was to evaluate, using optical coherence tomography (OCT), the impact of underlying plaque morphology on strut distribution of bioresorbable vascular scaffolds (BVS 1.1) versus metallic everolimus eluting stents (EES).

Methods: Among 39 patients who underwent elective percutaneous coronary intervention (PCI) (n=20 in BVS group, n=19 in EES group), a total of 1200 post-PCI OCT frames (BVS: 590 frames; EES: 610 frames) were analyzed. NSD was defined as a frame with maximum inter-strut angle ≥ 120°.

Results: The percentage of frames with NSD was significantly higher in the BVS group (26.1% [154/590] vs. 19.0% [116/610], p<0.003). In the EES group the calcium arc in frames with NSD was not significantly different compared to that in frames with uniform strut distribution (USD) (34.6% ± 44.4° vs. 35.6% ± 47.1°, p=0.83). However, in the BVS group the arc of calcium was significantly greater in frames with NSD as compared to those with USD (85.2°±62.6° vs. 21.0°±41.7°, p<0.0001). In multivariable analysis, after adjustment for post-dilatation balloon size and maximum inflation pressure, a calcium arc >75° was identified as an independent predictor of NSD after BVS implantation (odds ratio: 12.1, 95% confidence interval: 7.9-18.8, p<0.001).

Conclusions: The presence of calcified plaque behind BVS struts appears to be an independent predictor for NSD. For calcified lesions, meticulous lesion preparation, including use of dedicated devices, may help prevent NSD after BVS stent implantation.

TCT-631
Clinical Outcome of Patients With Complex Lesion Treated With Bioresorbable Vascular Scaffold; Single Center Experience
Katsumasa Sato1, Azem Latibi2, Vasileios F. Panoulas2, Hiroyoshi Kawamoto3, Tadashi Miyazaki4, Tora Nagamatsu1, Antonio Colombo1
1EMO GVM Centro Cuore Columbus, Milan, Italy

Background: There are limited data regarding clinical outcomes of patients with complex lesions treated with bioresorbable vascular scaffolds (BVS) compared to new generation drug eluting stents (DES).

Methods: We analyzed 1-year clinical outcome data of 432 consecutive patients treated with either new-generation DES or BVS between May 2008 and May 2014. Propensity score (PS) matching was applied prior to comparisons between the two groups. Primary outcome was major adverse cardiac events (MACE) which was defined as all-cause death, follow-up myocardial infarction (MI) and target-vessel revascularization (TVR).

Results: A total of 432 patients were included in this study. After PS matching, 96 patients treated with BVS (BVS group) and 96 patients treated with DES (DES group) were selected. Lesion characteristics were similar between two groups. Over 80% of lesions in both cohorts were ACC/AHA lesion class IIIB. After 1-year follow-up, the percentage of frames with NSD was significantly different compared to that in DES group (100% vs. 72.1%, p<0.01; 100% vs. 86.4%, p<0.01), and maximum inflation pressure after stenting in BVS group was higher than that in DES group (21.1±5.1 atm vs. 18.4±5.1 atm, p<0.01). There was no significant difference in the 1-year cumulative MACE incidence between the BVS and the DES group (10.8% vs. 12.7%, p=0.33). Similarly there was no significant differences in the composite endpoint of all-cause death and MI (3.6% vs. 4.5%, p=0.30), TVR (10.3% vs. 9.6%, p=0.80) or target lesion revascularization (9.2% vs. 5.6%, p=0.51). There was 1 episode of definite stent thrombosis in BVS group and 1 in DES group.

Conclusions: In swine coronary arteries, DM, atherosclerosis and inflammation do not affect BVS degradation or the vascular response to BVS. Both in DM and non-DM, the neointima was equally associated with calcification, lipid accumulation and inhomogeneous collagen deposition indicating early neo-atherosclerosis.

TCT-632
Diabetes and Atherosclerosis Do Not Affect Early Degradation of Bioresorbable Vascular Scaffolds
Mie Kurata1, Nieke S. van Ditzhuijzen1, Dana Sorop1, Richard W. van Duijn1, Ilona Krabbendam-Peters1, Timothy Veldhof1, Patrick W. Serruys1, Felix Zigstraf1, Dirk-Jan Duncker2, Evelyn Regar2, Heleen v Beusekom2
1Department of Cardiology, ThoraxCenter, COEUR, Erasmus MC, Rotterdam, Netherlands

Background: While everolimus-eluting bioresorbable vascular scaffolds (BVS) were studied in healthy swine, effects of inflammation and atherosclerosis on degradation of BVS and vascular behaviour remain to be determined.

Methods: Of 15 farm-bred swine, 8 received streptozotocin to induce diabetes mellitus (DM), then a high cholesterol diet was given to all 15 swine. Nine months later, 32 coronary Absorb BVS (Abbott Vascular, Santa Clara, CA) were implanted under angiographic guidance. Histology, serology and polymer degradation analysis was performed. Results of degradation were compared to controls from normal, non-atherosclerotic swine (n=6/tissue point).

Results: Degradation was similar in diseased and normal healthy swine and was determined only by implanted duration. It was not affected by DM, lipid accumulation in the neointima, or inflammation (Fig). Struts were completely covered at both 3 and 6 months follow-up, irrespective of DM and atherosclerosis. Likewise, DM did not affect histological scores. Importantly, all disease groups showed marked neointimal atherosclerosis, with focal lipid accumulation, irregular collagen distribution and neointimal calcifications. The latter was observed in various patterns, particularly towards the lumen.

Conclusions: In swine coronary arteries, DM, atherosclerosis and inflammation do not affect BVS degradation or the vascular response to BVS. Both in DM and non-DM, the neointima was equally associated with calcification, lipid accumulation and inhomogeneous collagen deposition indicating early neo-atherosclerosis.

TCT-633
Abstract Withdrawn

TCT-634
Is Visual Assessment of Lesion Dimensions Sufficient For Sizing Of Bioresorbable Scaffolds? Insights From The ASSURE Registry
Detlef Mathey1, Christoph Naber2, Thomas Schmitz3, Carsten Schwevenke1, Norbert Frey2, Christian Butter4, Johannes Bruchmann3, Maja Ingwersen3, Anna Drabik1, Sinisa Marcovic1, Jochen Wohrle1
1University Cardiovascular Center Hamburg, Hamburg, Germany, 2Contilia Heart and Vascular Centre, Elisabeth Krankenhuis Essen, Germany, Essen, Germany, 3Contilia Heart and Vascular Centre Essen, Essen, Germany, 4University Medical Center Schleswig-Holstein, Campus Kiel, Kiel, Germany, 5Herzzentrum Brandenburg, Bernau, Germany, 6Klinikum Coburg, Coburg, Germany, 7University Medical Center Hamburg-Eppendorf, Hamburg, Germany, 8University of Ulm, Ulm, Germany

Background: Compared to drug eluting stents, for bioresorbable vascular scaffolds (BVS, Abbott Vascular Inc., Santa Clara, CA) sizing may be more important in terms of malapposition and fracture because of smaller expansion limits. The registry aims

Conclusions: In swine coronary arteries, DM, atherosclerosis and inflammation do not affect BVS degradation or the vascular response to BVS. Both in DM and non-DM, the neointima was equally associated with calcification, lipid accumulation and inhomogeneous collagen deposition indicating early neo-atherosclerosis.
to investigate the safety and efficacy of the BVS in a real world setting, waiving obligatory IVUS or OCT guidance.

Methods: Consecutive patients with ischemic heart disease and de novo native coronary artery lesions were enrolled at 6 German centers in the prospective, observational registry. During the first 6 months of enrollment, only 3.0 x 18 mm BVS were available. From then onwards, 2.5 mm, 3.0 mm, and 3.5 mm BVS of different length were also available. BVS sizing was based on visual estimate of the lesions.

Results: A total of 183 patients were treated with BVS. A complex ACC/AHA lesion morphology of B2 or C was seen in 128 (64.7%) lesions. Compared to QCA, visual estimate overestimated the baseline reference vessel diameter (RVD) by 0.5 ± 0.5 mm and the diameter stenosis (DS) by 13.2 ± 16.5 %. Nevertheless, the final minimal lumen diameter (MLD) closely matched the baseline RVD. Diameter stenosis was 64.6 ± 15.1% at baseline and improved to a residual DS of 16.1 ± 7.7%. Acute gain of MLD was 1.54 ± 0.51 mm. A BVS-RVD mismatch resulted in an optimal MLD but an overexpanded RVD in case of 3.0 BVS for < 2.5 mm vessels, whereas in 3.3 mm vessels final MLD fell below the RVD. Final RVD exceeded the BVS expansion limit in 20 (10.1%) lesions. No peri-procedural dissection was reported from the core laboratory. At 12 months, 1 (0.5%) death due to gastrointestinal bleeding under dual antiplatelet therapy and 3 (1.6%) myocardial infarctions, caused by non-target vessel failure, had occurred. Target lesion revascularization had to be carried out in 5 patients (7.8%).

Conclusions: Visual overestimation of baseline RVD resulted in an optimal final MLD. BVS-RVD mismatch may lead to an inappropriate RVD or MLD. Acute gain and frequency of MACE were in agreement with previous BVS and DES studies.

TCT-635

ACUTE AND MID-TERM CLINICAL OUTCOMES OF THE EVEROLIMUS-ELUTING BIORESORBABLE VASCULAR SCAFFOLDS IN AN ALL-COMER COHORT

Ramaz El Khoury1, Charbel Naim1, Nicolas Noireux1, Andre Kokis2, Francois Gobeil1, Samer Mansour3
1Centre Hospitalier de l’Université de Montreal, Montreal, Canada, 2University of Montreal, Montreal, Quebec, 3University of Montreal, Montreal, Canada

Background: Bioresorbable vascular scaffold (BVS) heralded as the fourth revolution in interventional cardiology. Previous studies demonstrated the safety and efficacy of bioresorbable everolimus-eluting scaffolds in selected group of patients. However, limited data are available on the clinical use and outcomes of BVS in the real life setting.

Methods: Between November 2012 and April 2014, 89 consecutive patients were treated with BVS and enrolled in a prospective single center registry. The indication of BVS was left to the discretion of the operator.

Results: Mean age was 59±11 years old and males in 69%. They had hypertension in 56%, dyslipidemia in 52%, and diabetes in 29%, smokers in 48% and known coronary artery disease in 20%. Clinical presentation was acute coronary syndrome in 70 % of patients. Patients had a single vessel disease in 66% and the left ventricular ejection fraction (LVEF) was 58±18%. One hundred sixteen lesions were treated (30% were type A, 62% type B and 8% type C). Average used BVS/patient was 1.29±0.59. Mean BVS diameter and length were 3.1±0.35mm and 22.5±5.25mm respectively. Procedural success and device success was 100%. The median follow-up was 199 days [29-365]. The in-hospital MACE rate was 5 % (all cause mortality was 1% (probable BVS thrombosis); MI and 22% (1.6%). One hundred sixteen lesions were treated (30% were type A, 62% type B and 8% type C). Average used BVS/patient was 1.29±0.59. Mean BVS diameter and length were 3.1±0.35mm and 22.5±5.25mm respectively. Procedural success and device success was 100%. The median follow-up was 199 days [29-365]. The in-hospital MACE rate was 5 % (all cause mortality was 1% (probable BVS thrombosis); MI and 22% (1.6%). One hundred sixteen lesions were treated (30% were type A, 62% type B and 8% type C). Average used BVS/patient was 1.29±0.59. Mean BVS diameter and length were 3.1±0.35mm and 22.5±5.25mm respectively. Procedural success and device success was 100%.

Conclusions: In this all-comer cohort, BVS was mainly reserved to non-complex cases and had a high acute procedural success with good mid-term clinical outcomes. Ongoing studies with long-term follow-up will confirm the safety and efficacy of BVS in the treatment of more challenging cases.

TCT-636

Use Of Optical Coherence Tomography To Study The Role Of Non-Compliant Balloon Post-Dilation In Optimization Of Bioresorbable Vascular Scaffolds

Jaya Chandrasekhar1, Aun-Yeong Chong1, Michael Froeschl1, Christopher Glover2, Leslie Stephens3, John B. Hernandez3
1Centre Hospitalier de l’Université de Montreal, Montreal, Canada, 2University of Montreal, Montreal, Quebec, 3University of Montreal, Montreal, Canada

Background: The effect of mandatory non-compliant balloon(NCB) post-dilation on bioresorbable vascular scaffolds is not known. We sought to assess the impact of NCB post-dilation on optimizing BVS by using Optical coherence tomography(OCT). We hypothesized that systematic post-dilation to high pressures would significantly improve apposition and reduce malapposition.

Methods: In this ethics approved study we enrolled 18 patients. Per protocol, mandatory pre-dilation was followed by intracoronary glycoprotein and initial OCT assessment. BVS was deployed at ≥14 atm for 30seconds and NCB post-dilation performed at ≥16 atm for a minimum of 30seconds. OCT was repeated after BVS deployment and after NCB post-dilation. All OCT images were analyzed offline. Pre and post NCB post-dilation, the scaffold was analyzed for minimum and mean diameters, and minimum scaffold cross-sectional area. Optimal expansion of BVS was defined as minimum scaffold area of ≥80% of reference vessel area. The length of the scaffold was also assessed for clinically relevant incomplete scaffold apposition (ISA) defined as incomplete contact of BVS struts with vessel wall for a distance of greater than the strut thickness of 0.15mm, over at least 25% of the scaffold circumference, and over a scaffold length of at least 1mm.

Results: 22 lesions in 18 patients were analyzed. Mean patient age was 57.4±10.4 years and 83% were male. The indication was stable angina in 85% cases. Using OCT, the reference vessel diameter at baseline was 2.95mm. The mean BVS diameter used was 2.9mm and the mean diameter of NCB used was 3.5mm. After NCB post-dilation, the minimum scaffold diameter increased by a mean of 0.19mm, the mean scaffold diameter increased by a mean of 0.20mm and optimal expansion increased from 59% to 86.4% of cases (p< 0.0001). After NCB use, clinically relevant ISA decreased from 5 to 3 cases.

Conclusions: Non-compliant balloon post-dilation of BVS significantly increased the minimum and mean scaffold diameter. The rate of optimal scaffold expansion increased by 27%, and the incidence of clinically relevant incomplete scaffold apposition decreased by 40%.

TCT-637

Analysis of Quality of Life Decrements Associated with Changes in Angina Status in the ABSORB II Trial: First Randomized Comparison Between the Absorb and XIENCE Elutriation Stent

Bernard Chevalier1, Patrick W. Serray2, Roseann M. White, Mindy M. Cheng, Leslie Stephens, John B. Hernandez
1ICPS, Massy, France, 2Thoraxcenter, Rotterdam, Netherlands, 3Abbott Vascular, Santa Clara, CA

Background: Patient reported outcomes (PROs) are increasingly recognized as important clinical trial endpoints that provide direct information about health status and help guide clinical and economic decisions. Prior studies have reported quality of life (QoL) decrements attributable to changes in angina status. The objective of this study was to assess the impact of changes in angina status following percutaneous coronary intervention (PCI) on QoL in ABSORB II, a randomized, controlled, multicenter trial that compared the safety and efficacy of the Absorb Bioresorbable Vascular Scaffold (Abbott Vascular, Santa Clara, CA) to the XIENCE™ Everolimus Elution Stenting (Abbott Vascular, Santa Clara, CA).

Methods: In the ABSORB II trial, we obtained disease-specific QoL and general health status information from patients using validated PRO instruments administered pre-intervention, at 6 months, and 1 year post-discharge. We examined the timing of changes in angina status in relation to the assessment date of the EuroQol-5 Dimension Questionnaire (EQ-5D). We compared means and confidence intervals of subjects with changes in angina status within 1 month, 1-3 months, and greater than 3 months prior to assessment. A similar analysis was conducted for the Seattle Angina Questionnaire (SAQ). Multivariate analysis was performed to control for observable patient characteristics that might influence QoL.

Results: The ABSORB II trial enrolled 501 patients at 46 sites in Europe and New Zealand and randomized in a 2:1 ratio to Absorb™ BVS (N = 335) or XIENCE™ (N = 166). We will present results of the univariate and multivariate analyses in the ABSORB II intent-to-treat population.

Conclusions: Research to date indicates that changes in angina status are independently associated with reduced QoL. Results from the ABSORB II trial will provide current evidence of the impact of changes in angina status on QoL, following PCI with Absorb™ and XIENCE™.