BACKGROUND Covered stents are widely used to address numerous areas of need in peripheral intervention.However, PTFE covered stents have a known relative inflexibility which makes deliverability difficult and associated with a high restenosis rate. In this study we aim to evaluate the performance and vascular response of a new peripheral covered stent in a large animal model as compared to a commercially available PTFE covered stent.

METHODS Six swine were enrolled(45±1 kg). Superficial femoral arteries recieved Solaris (Scitech, Sao Paulo, Brazil) or Fluency (Bard, Tempe, AZ). Stents utilized were 40 mm long for both groups and implanted aiming for a 1.1:1 ratio. Following implantation, animals were recovered and followed for 30 days. At 30 day post-implantation all stents were evaluated under optical coherence tomography (OCT), explanted and subjected to stent integrity analysis and histopathological evaluation.

RESULTS 11 stents were evaluated (Solaris n=6, Fluency n=5). The operator described the Solaris stent as demonstrating a higher navigability when compared to the Fluency stent. The hydrophilic coated delivery system of the Solaris stent allowed a smoother release of the device without any sudden "jump" and greater geographical precision at implantation. At 30 days, OCT revealed a similar stent area for both groups (Solaris 25.8±4.7 vs Fluency 24.7±5mm2). However, Solaris demonstrated a higher lumen area (Solaris 18±4.2mm vs Fluency 13.9±3.4mm2) with a lower neointimal area (Solaris 7.8±1.8 vs Fluency 10.8±2.4mm2) compared to control. This led to a higher percentage stenosis in the control group (Solaris 31.9±7 vs Fluency 44.8±6%). The integrity analysis of the stents via radiographs revealed no fractures in any stent from either group. The results of the histopathological evaluation will be presented in the meeting.

CONCLUSION The Solaris PTFE-covered peripheral stent demonstrated a resistance to fracture with increased flexibility and navigability and better conformability to artery curvature. The release system allowed for an accurate geographical delivery and the components of the device produced a lower OCT morphometrically-assessed neointimal response when compared to the control group.

CATEGORIES ENDOVASCULAR: Peripheral Vascular Disease and Intervention

ACUTE BRS RESULTS

Abstract nos: 128 - 132

TCT-128

Relationship between bioresorbable vascular scaffold technique and acute recoil

Hirofumi Hioki,[1] Salvatore Brugaletta,[2] Luis Ortega-Paz,[3] Kohki Ishida,[4] Ander Regueiro,[1] Xavier Freixa,[5] Victoria Martin Yuste,[6] Monica Masotti,[2] Manel Sabate[7]
[1]Hospital Clinic, Barcelona, Spain; [2]Hospital Clinic Barcelona, Barcelona, Spain; [3]Hospital Clínic of Barcelona, Barcelona, Spain; [4]Kitasato University Hospital, Sagamiharashi, Japan; [5]Hospital Clinic of Barcelona, Toronto, Spain; [6]hospital clinic barcelona, barcelona, Spain; [7]Hospital Clínic; University of Barcelona, Barcelona, Spain

BACKGROUND Proper bioresorbable vascular scaffold (BVS) implantation has shown to reduce device-related events. Whether it could affect acute recoil immediately BRS implantation is unknown. We aimed to analyze relationship between BRS implantation technique and BVS acute recoil.

METHODS In our institution, we identified 158 consecutive patients (mean age 58 years, 79% male, 78% acute coronary syndrome) who received BVS implantation from April 2012 to March 2017. Absolute acute recoil (AAR) was measured by the difference between mean diameter of final balloon (X) and mean lumen diameter of scaffold immediately after balloon deflation (Y). Relative acute recoil (RAR) was defined as (X-Y)/X and expressed as a percentage. The PSP scores, which analyze the goodness of BVS implantation, previously developed in the GHOST registry, were evaluated for each patient included in this study.

RESULTS The AAR and RAR (median [interquartile range]) were 0.12mm [0.04-0.25] and 3.9% [1.4-8.0]. Compared to the patients with PSP-3 lower than median value, patients with PSP-3 higher than median value had a significantly lower AAR (0.09mm vs. 0.15mm, $p < 0.05$) and RAR (2.6% vs. 5.1%, $p < 0.05$). Inversely, PSP-1 and PSP-2 scores were not associated with acute recoil. Within PSP score variables, correct BVS sizing was significantly associated lower degree of AAR and RAR compared to oversizing (0.06mm vs. 0.16mm, $p < 0.05$; 2.0% vs. 5.1%, $p < 0.05$, respectively). Multivariate analysis showed that correct BVS sizing significantly reduce the incidence of AAR (OR, 0.18; 95%CI 0.07-0.47). ST-elevation myocardial infarction (OR, 0.48; 95%CI, 0.21-1.12), pre-dilation (OR, 0.93; 95%CI, 0.35-2.46), post-dilation with NC balloon larger up to 0.5mm (OR, 1.52; 95%CI, 0.70-3.28), and BVS: reference vessel diameter ratio (OR, 0.92; 95%CI, 0.43-1.96) were not associated with AAR.

CONCLUSION Optimized BVS implantation, particularly choosing correct BVS size, could reduce acute recoil. Long-term follow-up is warranted to demonstrate whether AAR is related with clinical outcomes after BVS implantation.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-129

Long-term Follow-up of BRS Implantation for Complex Coronary Lesions: A Multicentre Experience

Damiano Regazzoli,[1] Azeem Latib,[2] Babu Ezhumalai,[3] Akihito Tanaka,[2] Pier Pasquale Leone,[4] Marco Ancona,[5] Antonio Mangieri,[2] Francesco Giannini,[2] Satoru Mitomo,[6] Ashok Seth,[7] Antonio Colombo[8]
[1]San Raffaele Scientific Institute, Milano, Milan, Italy; [2]Interventional Cardiology Institute San Raffaele Hospital, Milan, Milan, Italy; [3]MIOT International, Chennai, Tamil Nadu, India; [4]San Raffaele Hospital, Milan, Milan, Italy; [5]San Raffaele Hospital, Milan, Italy, Milano, Milan, Italy; [6]IRCCS San Raffaele Scientific Institute, Milan, Milan, Italy; [7]Fortis Escorts Heart Institute, New Delhi, Delhi, India; [8]Interventional Cardiology Institute San Raffaele Hospital - Stamford Hospital - Columbia University - Centro Cuore Columbus, Milan, Milan, Italy

BACKGROUND Incidence of late BVS thrombosis is of concern. Clinical experiences have shown that 'dedicated implantation technique' is a key to decrease ST. The aim of this study was to evaluate the use of 'dedicated implantation technique' in the outcome of BRS.

METHODS We retrospectively analyzed consecutive patients that underwent BVS implantation in three high-volume centers before December 2014, in order to have long clinical follow-up. A total of 492 patients were identified for a total of 763 lesions implanted with BRS using a dedicated implantation strategy from the beginning.

RESULTS Mean age was 60±11 (male sex 90%), 35% of patients were diabetics, left ventricular systolic function (54±8%) and renal function (eGFR 90±25 ml/min) were preserved. The coronary anatomy was predominantly complex, with type B2 or C lesions in 75%, CTOs in 5.6%, bifurcations in 31% and severely calcific lesions in 13%. The dedicated implantation technique included good lesion preparation and debulking (when necessary): predilatation was performed in 99% of cases (cutting balloon 3.5%, scoring balloon 8%, rotational atherectomy 5%). OCT and IVUS were used in 15% and 37% of cases, respectively. Mean scaffold length was 31±16 mm, with a 1:1 high-pressure (21±4atm) postdilatation rate of 99.9%. Angiographic success was achieved in 99.9% of cases. All patients were discharged with dual antiplatelet therapy. Median follow-up was 954 (IQR 760-1130) days and was obtained for 98.8% of patients. Definite or probable scaffold thrombosis occurred in 0.6% (3 pts) of patients ay 1 year and remained stable at 2 and 3 year. Rate of target lesion failure (cardiovascular death, target vessel MI, TLR) was 3.8%, 6.1% and 7.1% at 1, 2 and 3 years follow-up respectively. All the patients were in dual antiplatelet therapy at 1 year and 51% of patients did not discontinue DAPT at last contact.

CONCLUSION This large multicenter registry enrolled patients with high prevalence of complex disease and showed good outcomes. The use of a dedicated implantation technique seems to be a mandatory aspect in order to achieve good long term results when implanting BVS. The role of long term DAPT in this setting must be furtherly addressed.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-130

Comparison of Bioresorbable Scaffold Measurements between Intravascular Ultrasound and Quantitative Coronary Angiography in the ABSORB Japan Trial

Kozo Okada,[1] Yasuhiro Honda,[2] Hideki Kitahara,[2] M. Brooke Hollak,[3] Paul G. Yock,[2] Jeffrey J. Popma,[4] Hajime Kusano,[5] Wai-Fung Cheong,[6] Krishna Sudhir,[5] Peter J. Fitzgerald,[2] Takeshi Kimura[7]

[1]Stanford University School of Medicine, Division of Cardiovascular Medicine, Stanford Cardiovascular Institute, Stanford, California, United States; [2]Division of Cardiovascular Medicine, Stanford University School of Medicine, Stanford, California, United States; [3]Stanford University School of Medicine, Division of Cardiovascular Medicine, Stanford, California, United States; [4]Beth Israel Deaconess Medical Center, Boston, Massachusetts, United States; [5]Abbott Vascular, Santa Clara, California, United States; [6]Abbott Vascular, Los Altos, California, United States; [7]Kyoto University Hospital, Kyoto, Japan

BACKGROUND Accurate vessel size assessment is essential for proper device sizing of bioresorbable vascular scaffold (BVS). Theoretical concerns also remain for post-deployment angiographic assessment of BVS, due to possibly different vessel-contour projections between polymeric scaffolds and metallic stents.

METHODS To investigate possible device-specific differences between quantitative coronary angiography (QCA) and IVUS, index measurements at the target and reference segments independently performed at QCA and IVUS core labs were systematically compared in ABSORB Japan IVUS cohort (n=144, 97 Absorb BVS: 47 Xience). Proper device sizing was defined as (nominal device diameter - mean reference lumen diameter) $\leq \pm 0.25$ mm.

RESULTS Compared with IVUS, QCA underestimated reference diameters by up to -0.84 mm (-0.19±0.26 mm, p<0.0001), and 21% of the "properly sized" devices by QCA were considered as "undersized" by IVUS. In addition, 49% of proximal and 30% of distal references had significant (>50%) residual plaque burden. At in-device segments, minimum lumen diameter (MLD) by QCA was also smaller than IVUS-derived MLD (p=0.004) but with no device-specific difference between BVS and Xience (2.9±13.2% vs. 3.2±10.9%, p=0.91). In contrast, when compared with average lumen diameter at minimum lumen area site by IVUS, the difference between the 2 modalities was significantly larger in BVS than Xience (8.9±10.8% vs. 4.7±9.3%, p=0.02), likely attributable to greater lumen eccentricity in BVS.

CONCLUSION Despite the overall underestimation by QCA compared to IVUS, no BVS-specific discrepancy was observed in post-deployment in-device MLD assessment. Further studies are warranted to investigate possible benefits of intravascular imaging guidance to improve long-term outcomes of BVS implantation.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-131

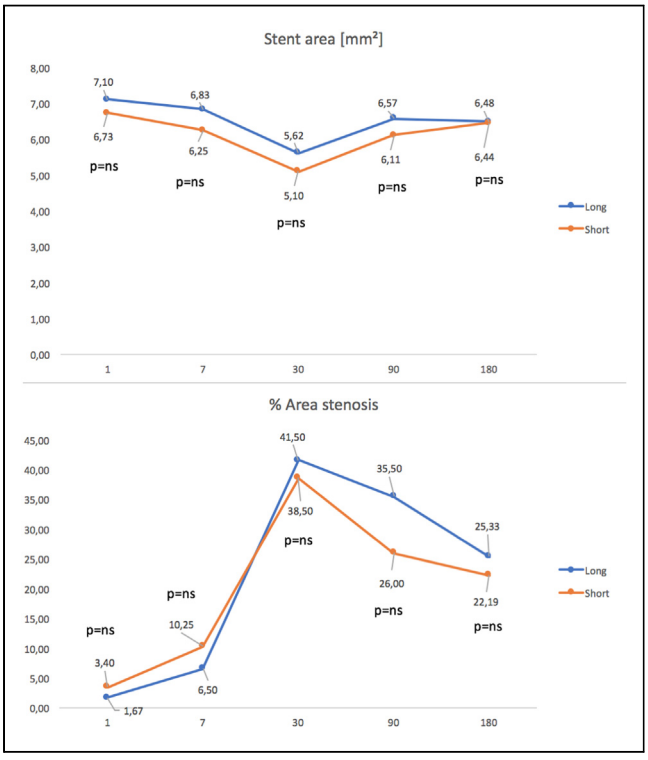
Temporal Vascular Response To Novel, Long, Thin Strut Bioreresorbable Scaffold In The Porcine Coronary Restenosis Model

Piotr Buszman,[1] Mateusz Kachel,[1] Carlos Fernandez,[2] Maciej Pruski, Jr.,[1] Aleksandra Blachut,[3] Adam Janas,[4] Magdalena Michalak,[4] Paweł Buszman,[1] Krzysztof Milewski[1]
[1]Center for Cardiovascular Research and Development, American Heart of Poland, Katowice, Poland; [2]Center for Cardiovascular Research and Development, American Heart of Poland, Katowice, Poland; [3]Center for Cardiovascular Research and Development American Heart of Poland, Katowice, Poland; [4]Center of Cardiovascular Research and Development, American Heart of Poland, Katowice, Poland

BACKGROUND Treatment of long coronary lesions with bioresorbable scaffolds is currently limited to overlapping implantations only due to the lack of long devices. Additionally, vascular response to long versus regular scaffolds is unknown. Therefore, we compare long vs. regular scaffolds with 100 micrometer struts (MeRes100) in the porcine coronary restenosis model.

METHODS In total 35 scaffolds, including 23 regular (3.0 x 16 mm) and 12 long (3.0 x 33 mm) were implanted with 120% overstretch with optical coherence tomography (OCT) guidance in 12 domestic animals for 1, 7, 28, 90 and 180 days. At terminal follow-up, terminal imaging with OCT was performed and long scaffolds evaluated in pathology.

RESULTS Stent areas and the neointimal hyperplasia as expressed as % Area Stenosis were comparable at all time points between long and regular scaffolds (Figure). Healing and endothelialisation were already complete at 28 days in the long scaffold group.



CONCLUSION Implantation of long bioresorbable scaffolds was feasible. At mid-term their integrity remained intact and neointimal response comparable to regular size scaffolds, which is contrary to historical data with metallic stents.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT-132

Strut thickness impact on thrombogenicity in BRS: In-vitro insights

Shengjie Lu,[1] Jaryl Ng,[1] Hui Ying Ang,[1] Valeria Paradies,[2] Philip Wong,[3] Rasha Al-Lamee,[4] Kadem Al-Lamee,[5] Nial Bullett,[6] Naveed Ahmed,[6] Michael Joner,[7] Nicolas Foin[1]
[1]National Heart Centre Singapore, Singapore, Singapore; [2]National Heart Research Institute and National Heart Centre Singapore, Singapore, Singapore; [3]National Heart Center Singapore, Duke NUS Medical School, Singapore, Singapore; [4]Imperial College London, London, United Kingdom; [5]ARTERIUS Limited, Leeds, United Kingdom; [6]Arterius, Leeds, United Kingdom; [7]Deutsches Herzzentrum München, Munich, Germany

BACKGROUND Late stent thrombosis is one of the major complication of percutaneous coronary intervention. It has been suggested that strut thickness of currently available bioresorbable vascular scaffolds (BRS) may impact on thrombogenicity.

METHODS In this study we assessed the thrombus formation of everolimus-eluting Xience stent (81μm), with BVS (157μm) and thin-strut bioresorbable scaffolds (ArterioSorb BRS, 95μm) (3.0mm size, n=3 per group) deployed in an in-vitro coronary model. The samples were perfused with porcine blood at a rate of 200m/min for 4 minutes. Mean thrombus area was evaluated using optical coherence tomography (OCT) and immunofluorescence (IF) and mean fluorescent intensity measured at confocal microscopy.

RESULTS At IF analysis, thin-strut BRS showed a significantly smaller thrombus area as compared to BVS (0.006vs0.035 mm2/mm, p<0.01). No difference was found in terms of thrombus area between thin-strut BRS and Xience (0.006vs0.007 mm2/mm, p=0.98). A similar trend was observed in mean fluorescent intensity and OCT cross-sectional thrombus area. (Fig 1)