examined at 1 (n=19 devices), 3 (n=21), 6 (n=21), 12 (n=21), 18 (n=19), 24 (n=19), 30 (n=20), 36 (n=20), and 42 mo. (n=21) by light microscopy or scanning electron microscopy (SEM) (110 BVS and 71 XV). In addition, pharmacokinetics and gel permeation chromatography (GPC) analysis were performed at various time points.
Results: Vascular responses to BVS and XV were largely comparable at all time points, with struts being sequestered in neointima. SEM confirmed rapid endothelial coverage by 1 mo. in both BVS and XV implanted arteries. Inflammation was minimal to mild for both devices, though from 12 to 36 mo. mean scores were greater for BVS. Pharmacokinetics revealed a similar drug release profiles for BVS and XV. Consistent with drug elution, fibrin deposition was similar between BVS and XV at 1 mo. and rapidly decreased or was absent beyond 3 mo. Histomorphometry showed positive remodeling in BVS-implanted arteries that started beyond 12 mo. Similarly, histomorphologic changes of BVS dismantling were observed beyond 12 mo., and by 36 mo., resorption sites (pre-existing struts) of BVS were poorly discernible from the surrounding neointima. GPC analysis confirmed that degradation of BVS could be considered complete by 36 mo. Additional histochemical staining demonstrated infiltration of proteoglycans and collagen between acellular homogenous hyaline material in resorption sites of BVS beginning beyond 12 mo. with resorption sites being near completely composed of connective tissue by 42 mo.
Conclusions: BVS demonstrates comparable safety to XV in porcine coronary arteries with positive remodeling, minimal inflammation, and near complete degradation at 36 mo.

TCT-811

Stem Cell Viability Significantly Reduced After Passing Through a Standard Single Lumen Over-the-Wire 0.014" Balloon Angioplasty Catheter

Nabil Dib[1], Robert E. Kohler[3], John P. Abraham[4], Brian D. Plourde[4], Dillon Schwalbach[4], DeAnn Dana[3], Bret J. Baird[3], Todd R. Flower[5], Lester Myers[5], Katherine Hunkler[5]
[1]Mercy Gilbert Medical Centers/Dignity Health, Gilbert, Arizona, [3]Translational Research Institute, Gilbert, AZ, [4]University of St. Thomas, St Paul, MN, [5]Celebration Stem Cell Center, Gilbert, AZ

Background: Intracoronary infusion of stem cells has typically been administered through a standard single lumen, over-the-wire (OTW) 0.014" balloon catheter. These catheters are not optimized for stem cell delivery, can compromise stem cell viability and potential clinical efficacy.
Methods: A Mesenchymal Stem Cell (MSC) solution with cell concentration of 2.5x106/ml was infused through a standard single lumen over-the-wire (OTW) 0.14" balloon catheter during balloon inflation at 6, 8, 10 and 12 atmospheres (atms) at a flow rate of 1ml/min and during balloon inflation at 8 and 12 atms at flow rate of 4ml/min. MSC samples were tested using trypan blue for viability before and after passing through the standard balloon catheter wire lumen.
Results: Physical measurement of the inner lumen demonstrated collapsing of the wire lumen during balloon inflation. Infusing through the catheter at a flow rate of 1ml/minute, cell viability decreased from (97.5% to 91.7%), (95.7% to 94.1%), (94.9% to 86.0%), (97.9% to 76.7%) at 6, 8, 10, and 12 atms respectively. When flow was increased to 4ml/minute, the cell survival decreased from (92.3% to 62.0%) and from (91.3% to 60.8%) at 8 and 12 atms respectively.
Conclusions: A standard single lumen, over-the-wire (OTW) 0.014" angioplasty balloon catheter can decrease stem cell viability and potentially affect the clinical outcome of stem cell therapy.

TCT-812

The Impact of Renal Function on Long-term Mortality in Unprotected Left Main Disease, Milan and New-Tokyo Registry

Kensuke Takagi[1], Chiara Bernelli[2], Mauro Carlino[3], Alaide Chieffo[4], Antonio Colombo[5], Yusuke Fujino[6], Keiko Fukino[6], Cosmo Godino[7], Koji Hozawa[8], Alfonso Ielasi[9], Hisaaki Ishiguro[6], Hiroyoshi Kawamoto[6], Naoyuki Kurita[10], Azeem Latib[2], Takahiro Matsumoto[6], Satoru Mitomo[6], Matteo Montorfano[7], Toru Naganuma[2], Sunao Nakamura[11], Shotaro Nakamura[6], Satoko Tahara[8], Takayuki Warisawa[6], Yusuke Watanabe[6], Hiroto Yabushita[8]
[1]New-Tokyo Hospital, Japan, Matsudo, Japan, [2]San Raffaele Scientific Institute, Milan, Italy, [3]N/A, Milan, Italy, [4]San Raffael Scientific Institute, Milan, Italy, Milan, Italy, [5]EMO GVM Centro Cuore Columbus/San Raffaele Hospital, Milan, Italy, [6]New Tokyo Hospital, Matsudo, Japan, [7]San Raffaele scientific institute, Milano, Milano, [8]New Tokyo Hospital, Matsudo, Chiba, [9]Azienda Ospedaliera Bolognini, Seriate (BG), CA, [10]New-Tokyo Hospital, Matsudo, Chiba, [11]New Tokyo Hospital, Matsudo, Kenya

Background: There is little available data regarding the long term follow-up of patients treated with drug-eluting stent (DES) for Unprotected Left Main (ULM) according to chronic kidney disease determined by estimated GFR (e-GFR).
Methods: All 1032 consecutive patients treated with DES implantation (first and second generation) for ULM stenosis between April 2005 and August 2011 were retrospectively assessed for impact of renal function. Patients were classified into normal renal function (60<; 567 patients), mild (30<60; 367 patients), moderate (15<30; 41 patients) and severe (<15; 57 patients) renal function groups. The end-point of the study was a composite of major adverse cardiovascular events (MACE) defined as all cause death, myocardial infarction (MI) and TLR. Furthermore, the individual components of MACE, cardiac death, definite/probable stent thrombosis (ST), possible ST and TLR for main-branch (TLR-MB) were evaluated.
Results: Patients with a lower e-GFR had more co-morbidities and complex lesions. MACE, all cause death, cardiac death, TLR-MB, MI and definite/probable ST and possible ST were more frequently observed when patients had more compromised renal function (MACE at 5-years 33.1% in overall; 25.9% in normal, 35.0% in mild, 50.7% in moderate and 82.3% in severe, all cause death 17.0%; 10.1%, 18.0%, 42.8% and 68.1%,cardiac death 7.3%; 3.3%. 8.3%, 23.2% and 46.2%, TLR-MB 9.5%; 7.2%, 9.7%, 10.8% and 34.8% and MI 3.4%; 1.3%, 3.7%, 12.6% and 26.1%, definite/probable ST 1.9%; 0.8%, 1.7%, 7.6% and 10.7%, and possible ST 5.2%; 1.9%, 5.7%, 14.6% and 38.5%, respectively). An estimated GFR was strongly associated with all death (adjusted HR 0.979; 95%CI 0.972-0.987, p<0.001), cardiac-death (adjusted HR 0.966; 95%CI 0.941-0.979, p<0.001), definite/probable ST (HR 0.973; 95%CI 0.951-0.996, p=0.024), possible ST (adjusted HR 0.964; 0.950-0.978, p<0.001) and TLR-MB (adjusted HR 0.987; 95%CI 0.977-0.997, p=0.009).
Conclusions: PCI in patients with ULM disease, the severity of CKD as determined by estimated GFR, was associated with an increased risk of clinical events. Some of adverse events may be related to progression of CKD.

TCT-813

A Novel Method for Evaluation of Polymer Absorption from Sirolimus Eluting Stent and its Influence on Biological Effects

Bartłomiej Orlik[1], Piotr P. Buszman[1], Janusz Kasperczyk[2], Adam Janas[1], Michal Jelonek[1], Agata Krauze[1], Stefan Samborski[1], Bogdan Gorycki[3], Wojciech Wojakowski[1], Buszman E. Pawel[4], Krzysztof P. Milewski[1]
[1]American Heart of Poland, Katowice, Poland, [2]Centrum Materiałów Polimerowych i Węglowych w Zabrzu, Zabrze, Śląskie, [3]American Heart of Poland, Bielsko, Poland, [4]American Heart of Poland, Ustroń, Poland

Background: Although many biodegradable polymer based technologies are widely used and tested in the clinical settings, still there is lack of data showing degradation kinetics of a polymer in-vivo. The aim of this preclinical analysis was an evaluation of sirolimus kinetics and biodegradable polymer (BP, poly-lactic acid) absorption from the surface of drug eluting stent using a novel nuclear magnetic resonance (NMR) method.
Methods: In 18 domestic swine 18 BP only coated stents (BPS) and 36 biodegradable polymer sirolimus eluting stents (BP-SES) where implanted with 110% overstretch. The animals were sacrificed at 1, 3, 7, 14, 28 and 56 days follow-up (9 segments per time point). Vessel segments with BPS were harvested to evaluate polymer degradation with a novel NMR method, whereas BP-SES to test sirolimus tissue uptake and retention. In the NMR method a cryoplatform and cryoprobe were used to optimize observation of resonance signals in H-1 NMR spectrum. The lactide molecules as an internal standard were used to confirm quantity of polymers on stent surface. Sirolimus pharmacokinetic analysis was performed with the use of standard liquid chromatography (HPLC) method in order to check its correlation with BP absorption as the polymer degradation and drug release should run almost in parallel during the first four weeks after stent implantation.
Results: The NMR method showed a gradual absorption of the polymer over the six consecutive time points, from 5.48 µg of the polymer on the stent at 1 day follow-up, through 4.33 µg at 3 days, 3.16 µg at 7 days, 2.42 µg at 14 days, 1.92 µg at 28 days to 1.24 µg in the last day of the study. In addition this method showed a good correlation with widely used and standardized HPLC method for sirolimus elution.
Conclusions: The novel NMR method for BP absorption kinetics evaluation is a useful tool which may be widely adopted to test other biodegradable applications. Further, it may substantially improve their safety and efficacy by facilitating programmed polymer and drugs elution. The polymer degradation pattern will be essential in designing a study with the aim to shorten double antiplatelet therapy.

TCT-814

MRI guided implantation of an MR-Enhancing occluder for cardiac septal defects PFO, ASD and VSD in a fresh porcine and Thiel embalmed heart

Erwin Immel[1], Richard Boyd[2], Andreas Melzer[1]
[1]University of Dundee, Dundee, United Kingdom, [2]VueKlar Cardiovascular Ltd, Dundee, United Kingdom

Background: X-Ray with its known disadvantages of iodinated contrast agents, ionizing radiation and lack of soft tissue contrast is currently used for percutaneous closure of PFOs, ASDs and VSDs. Cardiac MRI imaging is compromised by the artifacts of commercial occluders that have been tested. The new MR-Enhancing occluder functions as a local amplifier of the MRI signal and improves imaging and MRI guided closure.
Methods: Resonant occluder manufactured from a Nitinol tube (Ø = 0.2 mm) is designed so that it includes inductivity and capacity necessary for a resonant circuit.